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INTERNAL AUDIT AND ADVISORY SERVICES

Laboratory Safety Follow-Up Audit

Report No. M24A005

Internal Audit and Advisory Services Team:
Randy Schwantes, Internal Audit Director
Eduardo Perez Ruiz, Senior Internal Auditor

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Laboratory Safety Follow-Up Audit

EXECUTIVE SUMMARY

Internal Audit and Advisory Services (Internal Audit) has conducted an audit of UC Merced's Laboratory Safety (lab safety) Program. This audit was performed as part of Internal Audit's responsibility to complete the fiscal year 2024 audit plan at the request of senior leadership. The primary objective of the audit was to evaluate processes and controls in place to facilitate lab safety compliance and governance.

EH&S has faced leadership and staffing challenges, impacting the effective administration of the lab safety program. Acknowledging these challenges, EH&S leadership has been proactive in brainstorming and implementing solutions. In addition, university stakeholders have welcomed EH&S' openness and positively received recent leadership changes. EH&S staff are committed to collaborating with the university community to ensure effective lab safety and support the university's research mission and this has led to recent improvements to improve the effectiveness of the lab safety program.

However, Internal Audit noted instances of control weaknesses that need improvement in order to provide reasonable assurance that risks are being mitigated and objectives are being met. The following observations need improvement to strengthen internal controls and/or effect compliance:

EH&S Bandwidth. Internal Audit recommends EH&S collaborate with UCOP EH&S to leverage systemwide resources (i.e., UCOP EH&S expertise, UCLA Center for Laboratory Safety, Centers of Excellence Program) to conduct a staff and resource assessment and to review the overall EH&S lab safety program's alignment with best practices within the UC. The outcome of the staff and resource assessment should be shared with UC Merced leadership for their consideration and follow up.

Lab Inspections. Internal Audit recommends EH&S reimagine the inspection process and requirements to include: the cadence of EH&S inspections and follow-up on PI self-inspections. In addition, EH&S should consider inspecting labs based on physical location rather than PIs to ensure efficiency of inspections and limiting gaps. UC Merced should also consider having a fulltime embedded RSS specialist on campus.

Policy of Assurance for Laboratory Safety Compliance. Internal Audit recommends EH&S collaborate with ORED, ECP, and school leadership to develop a plan to draft an agreed-upon lab safety policy that will aid the schools in fulfilling the research mission of the university safely.

Lab Deficiency Escalation Process. Internal Audit recommends EH&S collaborate with ECP, ORED, and school leadership to reimagine the unresolved lab deficiency escalation process.

Lab Safety Training Program. Internal Audit recommends EH&S collaborate with Research and Compliance Integrity; and HR to reimagine the lab safety training program.

In addition, Internal Audit recommends HR collaborate with relevant stakeholders to assign specific supervisors in UC Path for all student workers.

Lab Closeout Process. Internal Audit recommends EH&S collaborate with school leadership and ORED to develop a plan to standardize and formalize a lab closeout process.

Hazardous Chemical Waste Labeling. Internal Audit recommends EH&S clearly communicate to PIs the expectations for safe and compliant hazardous waste management practices including hazardous waste management training requirements. In addition, EH&S should consider revamping the waste management training, including its modality.

Field Safety Plans. Internal Audit recommends Risk Services collaborate with ORED, EH&S, and school leadership to reimagine the field research identification process.

Biosafety Level 3 (BSL-3) Lab. Internal Audit recommends that the CFO, COO, VCR, and Provost conduct a cost benefit analysis to determine whether UC Merced should (1) decommission the BSL-3 lab and not invest any further resources in the project, (2) invest sufficient resources in the project to make the BSL-3 lab operational, or (3) invest sufficient resources to operate the current BSL-3 lab as a BSL-2 lab until sufficient resources are available to operate it at the BSL-3 level.

Biological Use Authorizations (BUAs) Escalation Process. Internal Audit recommends EH&S partner with the Institutional Biosafety Committee to develop and implement a BUA escalation process to effect compliance with NIH guidelines.

Chemical Hygiene Plan – Particularly Hazardous Substances (PHS). Internal Audit recommends EH&S revise the CHP to include expanded guidance on the additional provision to ensure safety when working with PHS. EH&S should consider including SOPs as reference.

Annual PI Chemical Inventory Certifications. Internal Audit recommends EH&S reimagine the annual PI chemical inventory certification and annual EH&S chemical inventory reconciliation processes. If the annual EH&S chemical inventory reconciliation process remains a summer project for student-workers, EH&S should consider implementing a follow-up process with PIs to ensure the completion of certification requirements. In the

alternative, EH&S could include annual chemical inventory certification in the lab inspection process.

Controlled Substances (CS) Cabinets. Internal Audit recommends EH&S collaborate with the Department of Animal Research Services to get the CS cabinets replaced. In addition, Internal Audit recommends keeping a key issuance log for the newly installed CS cabinets.

Controlled Substances Chain-of-Custody Documentation. Internal Audit recommends EH&S implement a chain-of-custody form process for controlled substances once the safe is approved by the DEA.

BACKGROUND

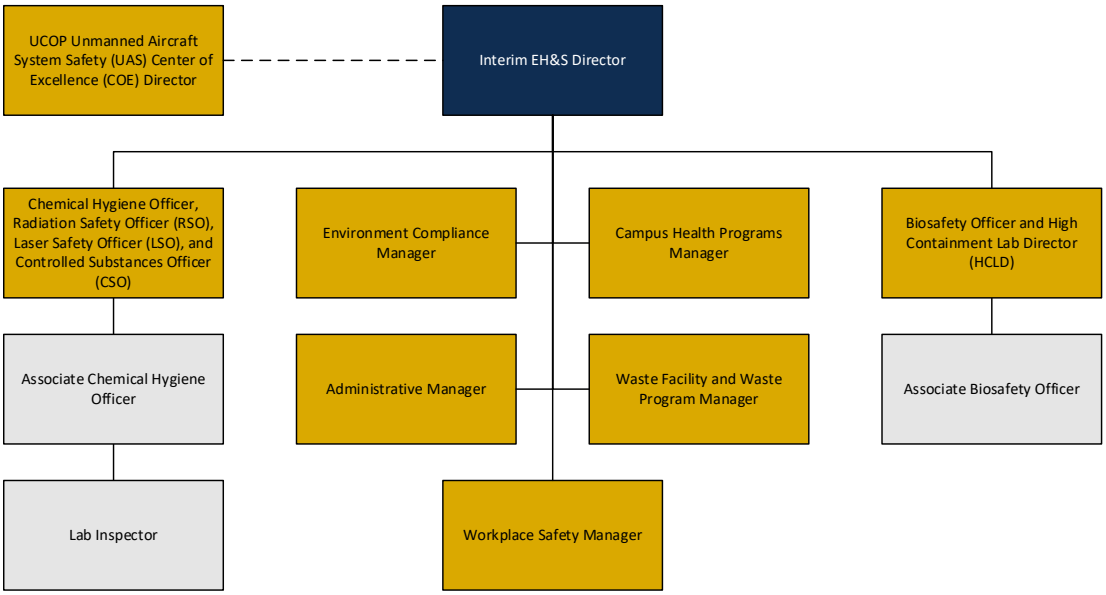
An effective lab safety program is a critical component of the university's research function. The university has an obligation to safeguard the wellbeing of the university community engaging in research activities.

At UC Merced, Environmental Health & Safety (EH&S) is tasked with the administration and oversight of the university's Injury and Illness Prevention Program (IIPP) and the Laboratory Safety Plan (LSP), the two programs governing lab safety.

The mission of EH&S is to support the academic and administrative functions of the university to help ensure a safe and healthful workplace and the environmentally sound management of hazardous materials. This is accomplished through collaborative, team-oriented methods that identify the optimum compliance strategies in harmony with the activities of the university.

As of June 2024, EH&S is currently staffed with 11 FTE. Further, UC Merced houses UCOP's Unmanned Aircraft System Safety (UAS) Center of Excellence, with the director having a dotted line to the EH&S director.

EH&S Organizational Chart



Areas of Responsibility

EH&S works to identify and mitigate risks at UC Merced including the in the following areas:

- Workplace safety
    - Facilities and skilled trades safety, e.g., lockout tagout, hot work, confined space
    - Cal/OSHA compliance
    - Ergonomics
    - Fire safety
    - Injury & illness prevention
    - Heat illness prevention
    - Incident investigation
- Industrial hygiene
    - Respiratory protection
    - Hearing conservation
    - Indoor air quality
    - Personal and environmental exposure assessment
    - Hazardous materials management

- Environmental Programs
    - Air quality & emissions
    - Aboveground storage tanks
    - Hazardous materials storage
    - Hazardous waste management
    - EPA / San Joaquin Valley air district compliance
    - Sewer system management
    - Storm water management
    - Underground storage tanks
    - Food safety
    - Pool safety
    - Water quality
- Research and Lab Safety
    - Biological safety
    - High containment lab (BSL3)
    - Chemical safety
    - Laser safety
    - Controlled substances
    - Lab design review and consultation
    - Field safety
    - Waste disposal
    - Personal protective equipment (PPE)
    - Radiation safety
    - Shipping hazardous materials
    - New lab worker support
    - Principal Investigator support
    - Move out close out

Risk & Safety Solutions (RSS)

RSS is a risk safety solution built to support the UC's risk management needs, which includes lab safety efforts. It is built based on modules that allow for flexibility based on the function's needs. In addition, RSS incorporates analytics into the solution that allows users to analyze data for informed decision-making. The RSS support team strives to

address the unique needs of the UC community through collaborations with the UC's EH&S and research communities.

Injury and Illness Prevention Program (IIPP)
Cal/OSHA (Title 8, section 3203) requires the university to have an Injury and Illness Prevention Program (IIPP). To ensure the safe and safety of university employees. As stated in the UC Merced EH&S website, the IIPP is the "umbrella under which all employee health and safety programs are implemented and provides a framework for identifying and correcting workplace hazards."

Lab Safety Plan (LSP)
The LSP is a comprehensive guide for identifying and controlling potential lab hazards, applicable to all facilities and personnel handling hazardous materials. It covers areas like fire safety, chemical safety, storage, personal protective equipment (PPE), biosafety, and radiation safety. The LSP includes all elements of the Chemical Hygiene Plan as outlined and required by the California Code of Regulation (CCR) Title 8 Section 5191.

UCOP Centers of Excellence (COE) Program
The UCOP COE program was designed to leverage existing expertise across the UC system that can serve the needs of the university community. The COE program identifies individuals or teams across the university that can provide expertise in their respective subject matter areas with little or no direct cost to individual campus EH&S teams.

UCLA's UC Center for Laboratory Safety (UCCLS)
The UCCLS is one of the COEs and "was created to improve laboratory safety by conducting research to provide evidence-based best safety practices on the laboratory."

According to the UCCLS website, the mission of the UCCLS is to:

- Conduct and support research in laboratory and translate it to best practices.
- Communicate and engage with researchers and health & safety professionals on laboratory safety.
- Provide expert advice and consultation regarding laboratory safety.

SCOPE AND OBJECTIVES

This audit was performed as part of Internal Audit's responsibility to complete the fiscal year 2024 audit plan at the request of senior leadership. The primary objective of the audit was to evaluate processes and controls in place to facilitate lab safety compliance and governance.

Additional objectives included:

- Assess the accuracy and completeness of the hazardous chemicals inventory system.
- Assess the frequency and thoroughness of EH&S and self-inspections.
- Verify the implementation and effectiveness of a lab deficiency resolution and escalation process.
- Ensure the administration of the chemical hygiene plan adheres to regulatory guidance.
- Verify that all lab personnel have received appropriate safety training.
- Evaluate the completeness and effectiveness of risk assessments and safety planning for field activities.
- To assess and evaluate the effectiveness of lab safety governance.
- Assess the adequacy of physical access controls to lab facilities.
- Assess the effectiveness of biosafety and radiation safety controls.
- To assess the effectiveness and completeness of the lab closeout process.
- Assess and analyze recurrent findings in past audit reports and evaluate corrective action effectiveness.

Repeat Observations Assessment

During the planning phase of the engagement, the Internal Audit reviewed three prior lab safety audits (conducted in fiscal years 2011, 2015, and 2021). The FY 21 audit report noted that some of the findings in the prior audits were recurring observations that had not been effectively addressed. Internal Audit assessed the three prior audits to identify recurring observations over the course of the three engagements that would inform the development of audit objectives and testing procedures. The evaluation identified the following recurring observations for these three prior audit reports:

- Identified lab deficiencies are not being addressed in a timely manner.
- There is no (effective) escalation process for unresolved lab deficiencies.
- Lab self-inspections are not being conducted and/or documented.
- The university chemical inventory is not kept current and certified.
- EH& does not track all labs on- and off-campus, impacting required annual lab inspection efforts.
- EH&S is unable to validate that all required persons have taken the required lab safety training(s) (an issue in FY11), and not all persons subject to lab safety training requirements have completed the required training(s) (issue noted in FY15 and FY21).

- There are no formalized policies and procedures to identify when research is conducted at off-site locations.

Internal Audit's primary scope included all of the EH&S lab safety controls in place during fiscal year 2023. The audit included interview of personnel, review of policies, observations and tests of current practices and processing techniques, and other auditing procedures considered necessary.

POSITIVE OBSERVATIONS

UC Merced is dedicated to upholding excellence in fulfilling its core objectives of teaching, research, and public service. To fulfill this mission, all university stakeholders are expected to demonstrate a strong commitment to driving positive transformations within the institution. As such, Internal Audit is committed to highlighting practices within the audited areas that facilitate changes both within the audited area and across the university.

During the Laboratory Safety Follow-Up Audit, Internal Audit noted the following positive observations:

- EH&S had previously identified some of the challenges noted in the audit and has been proactive about brainstorming and implementing changes to remediate issues and make processes more efficient.
- EH&S staff have demonstrated a drive to effectively promote lab safety on campus.
- University stakeholders have responded positively to the new leadership changes in EH&S and have welcomed the open approach that EH&S is fostering.
- School leadership have expressed the desire to build closer relationships with EH&S to promote lab safety.
- There is a sense of collaboration across departments and a concerted effort to address chemical Maximum Allowable Quantities (MAQs) on campus.
- EH&S staff have worked diligently to ensure recent regulatory agency visits culminated in positive outcomes.
    - No Cal/OSHA, EPA violations
- EH&S has collaborated with ECP to ensure Laboratory Safety Fundamentals training compliance is over 98%.
- EH&S is leveraging RSS to provide more on-site support for the research community by providing training opportunities and one-on-one consultation.
- EH&S is networking effectively with colleagues at UCOP EH&S and other campuses.

MANAGEMENT ADVICE

While conducting the engagement, Internal Audit identified potential inefficiencies that do not rise to the level of a formal recommendation. These inefficiencies are highlighted in the management advice section, and management is not required to formally report their response to this advice.

ANNUAL REVIEW OF THE CHEMICAL HYGIENE (CHP) PLAN

Background
According to the California Division of Occupational Safety and Health (Cal/OSHA), the university "shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary."

In the 2021 lab safety audit, EH&S management implemented a process by which the Chemical Safety Committee would review and approve the CHP. This process is well designed as it fosters a spirit of buy-in with the safety committee stakeholders making the CHP more effective.

Observation
The CHP was not formally reviewed in 2023. In addition, the Chemical Safety Committee that was charged with the annual review of the CHP was dissolved.

Per discussions with EH&S staff, competing priorities and the dissolution of the safety committee impacted the annual review of the CHP. Internal Audit was unable to discern the reason for the dissolution of the safety committee.

Without an annual review of the CHP, UC Merced is not fully compliant with Cal/OSHA CHP requirements, which could subject the university to increased scrutiny from Cal/OSHA. Furthermore, without an engaged safety committee, the CHP could be faced with resistance to ownership of roles and responsibilities, and negatively impact stakeholder buy-in.

Though the CHP has not been reviewed, Internal Audit notes there have not been substantive changes to both university practices and regulatory guidance that would necessitate significant revisions to the CHP.

Recommendation
Internal Audit recommends EH&S work to reconstitute the Chemical Safety Committee and leverage them in the annual review of the CHP.

RSS INSPECTION DEFICIENCIES CLEAN-UP

Background
Addressing lab deficiencies noted during an inspection is a vital role in the university lab safety program as it allows management to discern and address safety concerns. The success of this process is reliant on clearly defined categorization of the deficiencies and established timeframes for their timely resolution. In addition, robust verification controls ensure the lab deficiencies have been properly addressed.

Furthermore, clean and accurate data within the university's risk management solutions plays a vital role in identifying and mitigating lab risks and cultivating a safe work environment. Finally, by maintaining clean and accurate documentation, the university can effectively document its safety efforts, which can serve as evidence of due diligence in the event of an incident.

Observation
For fiscal years FY 2019 to 2023, RSS showed 2,416 deficiencies with a "not resolved" status and 247 "in progress". This would indicate that the inspected labs had not addressed the deficiencies. In addition, there were 852 deficiencies with a "ready for verification" status, which would indicate that the labs resolved the deficiencies, but they had not been validated by EH&S.

Internal Audit notes this is a symptom of challenges with an ineffective escalation process, see **Observation 4: Lab Deficiency Escalation Process**. The unresolved deficiencies create a narrative of significant issues that do not truly exist. In addition, it may give lab personnel the false impression that clearing deficiencies is not important to EH&S.

Internal Audit notes that many of these deficiencies have been resolved but have not been properly documented in RSS. If a lab undergoes an inspection in FY 2024, any deficiencies noted in inspections conducted between FY 2019 and FY 2023 would be considered resolved if they were not identified during the FY 2024 inspection.

Recommendation
Internal Audit recommends that EH&S work to resolve the deficiencies from prior years in RSS.

LARGE-QUANTITY WASTE GENERATOR CLASSIFICATION

Background
As a large-quantity waste generator, the university would be subject to increased regulatory requirements that include written contingency planning and emergency procedures. The university will also be required to revisit roles and responsibilities to ensure they align with requirements (i.e., the responsible employee for coordinating

emergency response measures having authority to commit resources needed to carry out the contingency plan). In addition, the university would be subject to reporting requirements, which currently as a small-quantity waste generator, the university is not required to do. Lastly, the university will be required to revise waste management training program to align with regulatory guidance.

Observation
Currently, UC Merced is categorized as a small-quantity waste generator; however, with the increase in operations of the university, it is close to being considered a large-quantity waste generator.

Recommendation
Internal Audit recommends EH&S collaborate with Risk Services, ORED, and school leadership to develop a plan to address the increased compliance requirements associated with the transition from a small-quantity to a large-quantity waste generator.

CAL FIRE MARSHAL – TEMPORARY CERTIFICATE OF OCCUPANCY (TCO)

Background
During walkthroughs of the Biomedical Sciences and Physics (BSP) building, Internal Audit was informed of multiple engineering and construction issues that resulted in a Temporary Certificate of Occupancy (TCO) rather than a Certificate of Occupancy, which has significantly inhibited the ability of UC Merced to effectively utilize the space.

Observation
During discussions with EH&S staff and the Lead Designated Campus Fire Marshal about the BSP building, Internal Audit noted that there could be similar issues with other buildings on campus. Given the challenges the university faced when resolving the noted issues, the Lead Designated Campus Fire Marshal suggested that UC Merced act proactively to assess and remediate any similar issues in other buildings on campus.

Internal Audit notes that tremendous work has been put into resolving issues in BSP and this work could act as a blueprint to addressing potential issues in other buildings.

Recommendation
Internal Audit recommends UC Merced follow the advice of the Lead Designated Campus Fire Marshal and take proactive steps to assess and remediate any issues with other campus buildings including the plans for the new Medical Education Building.

OBSERVATIONS

1. EH&S BANDWIDTH

Background
To fulfill its mission of supporting the academic and administrative functions of the university to help ensure a safe and healthful workplace and the environmentally sound management of hazardous materials, the EH&S function must be sufficiently resourced in the following areas:

Budget allocation. Sufficient budgetary resources are allocated to support EH&S initiatives and operational expenses.

Staffing levels. Staffing levels should be determined based on the size and complexity of the institution, as well as the scope of EH&S responsibilities. Staffing may need to be adjusted based on the maturation of the EH&S program as well as the rapid growth in the overall research program of the institution.

Professional development. Funds should be allocated to fund EH&S staff development through conference attendance, workshops, and continuing education courses. This investment keeps staff professionally engaged and informed on evolving regulations, best practices, and emerging technologies.

Equipment and tools. Funds should be provided for the purchase, maintenance, and calibration of necessary equipment and tools used in EH&S activities. This includes personal protective equipment (PPE), sampling and monitoring devices, laboratory instrumentation, and emergency response gear.

Software and technology. Funds should be invested in EH&S management software, database systems and digital tools to streamline processes, manage data effectively and ensure compliance with regulatory reporting requirements. This may involve initial procurement costs as well as ongoing maintenance fees.

Consulting services. Funds should be available for external consulting services or partnerships with EH&S experts, particularly for specialized projects, regulatory compliance audits and in-depth assessments.

Observation
Throughout the engagement, Internal Audit noted certain EH&S functions were not functioning effectively due to insufficient EH&S bandwidth. The functions included:

- Conducting and documenting EH&S annual inspections.
- Following up on deficiencies from lab inspections and clearing resolved issues.
- Following up on lab self-inspections.
- Supporting lab clean-ups for lab spaces left uncleaned by the departing PIs.

- Conducting risk assessments for the labs to ensure high-risk labs are inspected more frequently.
- Updating and revising the Laboratory Safety Plan.
- Ensuring all lab personnel are compliant with training requirements, which includes identification of required training and tracking completion.
- Making full use of the RSS system to streamline processes.
- Providing effective in-person training to PIs and lab personnel.
- Developing dashboards with relevant information/metrics to keep PIs and senior leadership informed of lab safety efforts
- Establishment of an effective Chemical Safety Committee.
- Regularly consulting with the schools to help identify PIs joining and departing the university.
- Ability to operate in the centralized chemical storage and distribution room.
- Effectively managing and overseeing the biosafety, radiation, laser, and controlled substances safety programs.
- Internal business continuity
- Chemical purchase approval.
- Chemical inventory management.
- Compressed gas cylinder delivery.
- Website updates.

With the current staffing and resources, EH&S appears to be reactive, responding to issues as they arise instead of proactively consulting with the schools and lab personnel to anticipate and prevent issues within the labs. EH&S has not been able to focus strategically to develop efficient and effective processes that would benefit themselves and their stakeholders. In addition, other departments within UC Merced have stepped up to lead some areas traditionally lead by EH&S, resulting in EH&S's low visibility into to those processes. As a result, EH&S has not been able to cultivate collaborative relationships with the schools and lab personnel to be perceived as a trusted consultant for health and safety concerns.

When EH&S was established at UC Merced, it was resourced in accordance to the size of the university and the level of research occurring at the time. However, as the research increased, EH&S' capacity did not, which forced EH&S to prioritize on areas that demand immediate attention. See **Appendix A** for an analysis[1] of EH&S staffing and resourcing

[1] The figures used in the analysis were self-reported by EH&S. Internal Audit did not perform any testing procedures to assess the accuracy of the figures.

across UC Campuses. EH&S has been audited multiple times in prior years, producing repeat findings for which EH&S has not been able to implement the agreed-upon management corrective actions.

Adjusting EH&S staffing and resources to match the full scope of their responsibilities and the growing complexity of the institution would enhance EH&S's expertise and bandwidth to function effectively. It would also provide EH&S the support necessary to cultivate collaborative relationships and work towards becoming a trusted advisor to the research community, and ultimately helping them fulfill their mission.

Internal Audit notes that without a proactive, consultative EH&S, the university is exposed to gaps in its lab safety efforts. This could lead to a lack of crucial collaborations between EH&S and lab personnel needed to ensure lab safety. Furthermore, there have been preventable lab incidents in the last three years that likely would have been mitigated had EH&S been able to have a more effective, supportive safety program. The EH&S bandwidth gaps hinder the function from effectively mitigating the inherent risks associated with research, which include life/safety and compliance risks.

Recommendation
Internal Audit recommends EH&S collaborate with UCOP EH&S to leverage systemwide resources (i.e., UCOP EH&S expertise, UCLA Center for Laboratory Safety, Centers of Excellence Program) to conduct a staff and resource assessment and to review the overall EH&S lab safety program's alignment with best practices within the UC. The outcome of the staff and resource assessment should be shared with UC Merced leadership for their consideration and follow up.

Management Corrective Action (MCA)
EH&S retained Mr. Larry Wong, retired UCOP Associate EH&S Director and two-time Interim Director of UCM EH&S to complete a staffing analysis. Mr. Wong started work on July 15, 2024. In addition, EH&S requested support from UCOP EH&S for Marsh Risk & Insurance Services to complete a more formal assessment. The target date for completion is by March 28, 2025.

2. LAB INSPECTIONS

Background
A well-designed lab inspection program begins with a complete inventory of all lab spaces on campus. This inventory creates the baseline for ensuring comprehensive coverage and accurate risk assessments of lab spaces. The risk assessment process plays a vital role in the inspection program by aiding in the categorization of lab spaces based on their inherent risk. This categorization, in turn, could determine the frequency of lab inspections.

Furthermore, a well-designed lab inspection program relies on robust technology and software. This adequate software facilitates proper recordkeeping of inspections and enables EH&S to conduct inspections effectively. Additionally, it ensures and validates that PIs are conducting effective self-inspections.

Observation

During the engagement, Internal Audit became aware of multiple issues with regard to inspections that included but were not limited to:

- The current RSS configuration does not lend itself to ensuring a complete inventory of lab spaces, nor does it identify inspections based on the location of the labs. Currently, RSS is based almost exclusively on PIs and does not efficiently identify the physical lab spaces the PIs occupy. Internal Audit compared the physical location of the labs by PI as noted by Space, Capital Planning and Real Estate (Space Planning) with the list of locations received from EH&S and noted multiple discrepancies. During lab walkthroughs, Internal Audit noted that the Space Planning list appeared to be accurate.
- Internal Audit was unable to ascertain that PI lab self-inspections were done consistently across all labs. Internal Audit noted in FY23 only 32% of PIs had a lab self-inspection documented in RSS.
- EH&S Inspections do not have full coverage and a risk-based model has not been developed. Internal Audit noted for FY23 EH&S inspected 75% of labs as documented in RSS.
- Inspections are selected by PI rather than by physical location, so for shared spaces, the current process omits the formal identification/remediation of issues with other areas in the lab not controlled by the PI being inspected. During the lab walkthroughs, Internal Audit noted that lab spaces were frequently shared by multiple PIs. Since EH&S only inspected the portion of the lab occupied by the PI being inspected, other issues that were noted in the lab were not formally documented or followed up on in RSS.
- EH&S date of inspections in RSS do not accurately reflect the actual date of the inspection. Internal Audit noted EH&S conducts administrative pretesting for the inspection before the actual date of the physical inspection. The date that the inspection is created in RSS has been used as the date of the inspection, which can impact any timelines for deficiency resolutions. RSS does allow EH&S to modify that date to the actual date of the physical inspection.
- Internal Audit notes that there is a benefit to EH&S walking through all lab spaces annually as they can discover PIs working in areas EH&S was not aware of, and looking at unoccupied labs spaces would take minimal time.

There are multiple causes for the various issues with the inspection program. These issues include the configuration of the RSS, which is not currently set up to efficiently identify

labs by their physical location. Moreover, EH&S and other stakeholders have pointed out a lack of adequate capacity within EH&S to carry out annual inspections or the required risk assessments that determine inspection frequency. This extends to the follow-up process with PIs to ensure completion of their annual self-inspections.

Internal Audit notes that EH&S has concerns that inspecting physical lab spaces rather than inspecting by PI would require multiple inspection reports in RSS and that inspecting empty lab spaces would not be a good use of time.

The current inspection process design, as well as capacity issues within EH&S, have resulted in gaps in both PI self-inspections and EH&S inspections. Internal Audit notes in conversations with stakeholders, the reputation of EH&S as a support to PIs has waned in the last few years. Finally, the gaps in inspections could result in a culture of complacency, impacting the enforcement of high standards for lab safety; a culture that could lead to lab accidents and an overall unsafe work environment.

Internal Audit notes that increasing touchpoints with PIs, both in reviewing their self-inspections and conducting formal inspections, would result in greater familiarity with the labs and the work conducted by the PIs. This, in turn, could further EH&S' efforts of fostering stronger relationships between EH&S and the PIs.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Recommendation
Internal Audit recommends EH&S reimagine the inspection process and requirements to include: the cadence of EH&S inspections and follow-up on PI self-inspections. In addition, EH&S should consider inspecting labs based on physical location rather than PIs to ensure efficiency of inspections and limiting gaps. UC Merced should also consider having a fulltime embedded RSS specialist on campus.

Management Corrective Action (MCA)
The UCM EH&S backfilled two jobs in the research safety program in May 2024. The lab inspection program restarted in June 2024. Our strategy is to complete a round of inspections following the established process then initiate a comprehensive review of the inspection process in with a research safety committee. This approach will facilitate continuity of the program while enabling new employees to gain experience and perspective prior to the comprehensive review. We shall develop an implementation plan by March 28, 2025. EH&S has coordinated with RSS to increase on site support. A RSS customer success technician is spending one day on the UCM campus every two weeks since May 2024.

3. POLICY OF ASSURANCE FOR LABORATORY SAFETY COMPLIANCE

Background
Effective policy development requires a methodological approach driven by the university's mission and involves key stakeholders that can effect change within the university. The methodological approach requires the early engagement of key stakeholders being affected by the policy and requires the assessment of needs and intended outcomes. By adopting a collaborative approach to policy development, the policy writers ensure successful buy-in and implementation.

Observation
There were significant foundational deficiencies in the development of the interim Policy of Assurance for Laboratory Safety Compliance (policy) that impacted its successful finalization and implementation. Some of the key deficiencies in the development of the policy included:

- Key stakeholders were not engaged early in the development of the policy.
- Roles and responsibilities were not well defined—they were perceived as misplaced and stringent in faculty comments.
- The interim policy references policies that did not pertain to lab safety.
- Ownership of the policy was vague.
- Reporting to senior leadership on lab safety compliance efforts was not addressed but was an MCA in the 2021 audit report.

EH&S staff indicated that prior management's intent was that the policy would remain interim deliberately to maintain flexibility. They voiced concerns and a level of resistance regarding the initial drafting of the policy in 2018. In 2022, a significant revision of the policy was undertaken and EH&S voiced their concerns once again. It was circulated for public review as well as academic senate review. Despite both public and academic senate feedback expressing concerns about the language in the policy, these comments were deemed immaterial to warrant edits to the policy. Subsequently, the policy was released to the community with minimal communication, particularly to school leadership. Due to the isolated development process and lack of engagement with stakeholders, the policy lacked sufficient support for effective implementation.

A lab safety policy implemented without sufficient buy-in by stakeholders will not be effective in establishing robust working relationships, delineating roles and responsibilities, and enforcing best practices. This could ultimately result in a less safe environment for researchers, staff, and students working in the labs.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Recommendation
Internal Audit recommends EH&S collaborate with ORED, ECP, and school leadership to develop a plan to draft an agreed-upon lab safety policy that will aid the schools in fulfilling the research mission of the university safely.

Management Corrective Action (MCA)
EH&S will work with ORED and school leadership to stand up a research safety committee during the 2024-25 academic year. The committee will include faculty and other key stakeholders and will be co-chaired by EH&S and ORED. We shall develop an implementation plan by March 28, 2025.

4. LAB DEFICIENCY ESCALATION PROCESS

Background
Ensuring timely resolution of lab deficiencies is imperative for safeguarding the safety of the university community utilizing the lab spaces. As such, recurring and unresolved deficiencies must be escalated appropriately to ensure their resolution.

An efficient, formalized escalation process is essential for delineating roles and responsibilities, establishing a clear hierarchy of escalation devoid of conflicts of interest. Additionally, the process must delineate specific timeframes and communication protocols that will ensure the resolution of persisting lab deficiencies.

Observation
EH&S is not effectively following up on unresolved deficiencies. As a result, Internal Audit noted a significant number of unresolved deficiencies and unverified resolutions.

EH&S was required to formalize the Interim Policy of Assurance for Laboratory Safety Compliance, which included an escalation process to address unresolved lab deficiencies. EH&S developed an escalation process; however, it was not properly designed as the policy delineates the escalation responsibilities to the school leadership. The escalation process was structured around a hierarchy that was susceptible to conflicts of interest. Moreover, EH&S' role in the escalation process appears to be insufficient; they will escalate unresolved lab deficiencies to the department chairs, and thereafter, EH&S is no longer involved in the escalation process.

Per discussions with EH&S, ECP, and ORED staff, there were foundational deficiencies in the drafting process of the policy that impacted its appropriate finalization and implementation; the escalation process is one of those foundational deficiencies.

Unresolved lab deficiencies pose safety risks to individuals accessing lab spaces. The level of risk an individual could face is relative to the severity of the unresolved deficiency.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Recommendation
Internal Audit recommends EH&S collaborate with ECP, ORED, and school leadership to reimagine the unresolved lab deficiency escalation process.

Management Corrective Action (MCA)
EH&S will work with ECP, ORED and school leadership to stand up a research safety committee during the 2024-25 academic year. The committee will include faculty and other key stakeholders and will be co-chaired by EH&S and ORED. We shall develop an implementation plan by March 28, 2025. The basic structure of will include a simple process for escalation of lab safety deficiencies starting with the Principal Investigator (PI), as well as clearly defining roles and responsibilities for EH&S and school leadership.

5. LAB SAFETY TRAINING

Background
Lab safety is fundamental to the successful achievement of the university's research mission, and it is therefore reliant on a robust lab safety training program. In addition, an effective training program also aids in safeguarding the safety of all individuals and equipment in the lab spaces. As such, the training program needs to be robust, comprehensive, and flexible. To achieve the goal of a strong lab safety training program, the program requires an effective governance structure; one where roles and responsibilities are clearly defined, and training requirements are identified, assigned, and tracked for completion.

Best practices for training would have supervisors responsible for ensuring their direct reports have taken the required training. In addition, an effective escalation process would be in place to hold supervisors accountable to ensure their units are taking the required training. In a lab environment, PIs would assign their lab members training and be responsible for ensuring it is complete. A third party, such as EH&S or HR, would then conduct checks to ensure all parties are taking the training and that it has not expired.

Observation
Internal Audit sampled 13 labs, and all had instances of lab members not completing the required training for the risks associated with their labs. While the current lab safety plan designates PIs for training assignment and monitoring responsibilities, they lack the authority to assign training to their lab personnel as they are not designated as supervisors in UCPath.

During inspections, when lab members are identified as not completing the required training(s), EH&S staff notes this as a finding which requires remediation from the PI. If the training deficiencies persist, the escalation policy requires the PIs to report lack of compliance to the department chairs; however, this creates conflict of interest since PIs would not be incentivized to escalate instances of noncompliance in their respective areas.

In addition, Internal Audit notes that student-workers including those in labs are not assigned to their specific supervisor so their specific supervisor cannot assign and monitor their required training.

Based on discussions with EH&S and HR staff, it appears roles and responsibilities for the lab safety training program are not well defined. Consequently, it calls into question the ownership of training requirements.

Moreover, training requirements can be dynamic based on the nature of the lab spaces on campus, and this too adds a layer of complexity in the oversight of training requirements since the PIs would be the ones who know with certainty what training needs their lab personnel require.

Lastly, there are challenges with the systems (i.e., UCPath, UCLC, and RSS) used to assign and track lab personnel and training needs. EH&S is currently undertaking efforts to improve the interface between these systems.

An ineffective lab safety training program can expose individuals to unsafe lab conditions, resulting in harm to individuals and equipment. Proper training is often the first line of defense when it comes to remediating incidents and determining causes. In addition, ineffective documentation of training could create litigation exposure for the university in the event of an accident.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Recommendation
Internal Audit recommends EH&S collaborate with Research and Compliance Integrity; and HR to reimagine the lab safety training program.

In addition, Internal Audit recommends HR collaborate with relevant stakeholders to assign specific supervisors in UC Path for all student workers.

Management Corrective Action (MCA)
EH&S worked with Ethics and Compliance to implement an effective compliance monitoring process for Lab Safety Fundamentals. EH&S is investigating the feasibility of scaling up that process to include additional training courses. Additional opportunities EH&S is exploring include review and update of training content available in the UC

Merced UCLC, sourcing net new training content from the Risk & Safety training Center of Excellence at UC Riverside, and partnership with Risk and Safety Solutions (RSS) in development of a training module. EH&S shall develop an implementation plan by December 1, 2024.

EH&S and HR met on July 3, 2024 to discuss how to address the challenges with the systems. HR will develop an implementation plan – contingent with UCOP governance of the systemwide LMS and functionality – for UCLC functional and reporting improvements by February 2025.

To address the recommended action of "reports to" clean-up, HR will work with Business and Financial Services, Academic Personal Office, and EH&S to identify and implement corrective actions and reconciliation of existing data on employee (staff, academic, and student) reporting relationship within UCPath as well as process improvement for collecting, assigning, or modifying the "reports to" relationship and data. Proposed implementation of these actions to be completed by June 2025.

6. LAB CLOSEOUT PROCESS

Background
An effective, well-documented, and standardized lab closeout process is crucial for the safe and efficient closure of research laboratories. Additionally, a well-defined lab closeout process ensures the safety of individuals accessing the lab spaces and safeguards university resources. The lab closeout process should encompass the following key elements:

- Procedures for scheduled, and unscheduled faculty departures.
- Clearly defined roles and responsibilities.
- Notification requirements.
- Defined timelines for completion.
- Comprehensive chemical and equipment inventory.
- Physical lab space inspections and clean-up procedures, including:
    - Final inspections.
    - Equipment and chemical inventory checks.
    - Safe disposal of any remaining hazardous waste.

Observation
There are multiple issues with lab closeouts at UC Merced including:

- EH&S is not consistently being notified timely that labs are closing.

- Responsibility for lab cleanup is not agreed upon between PIs, schools, and EH&S.
- Labs are not consistently being inspected before PIs leave to ensure the lab is ready for another PI to use.
- Insufficient collaboration between EH&S and the schools when PIs leave unexpectedly.

The lab closeout process is largely ad-hoc and highly dependent on communications between the departing faculty, the schools, and EH&S. According to school leadership, the responsibility for vacating lab spaces when a faculty member leaves is not well defined. It is unclear what the school is responsible for, and what should be handled by EH&S—particularly when it comes to handling chemicals.

EH&S does have a published lab closeout process; however, this process appears to not have been well communicated, thus not used by the schools. In addition, the documentation available to the schools (i.e., closeout checklists) include erroneous information.

The schools expressed a need for more collaboration from EH&S, particularly for the disposal of chemicals when PIs leave without cleaning their labs. As noted in Observation 1, EH&S has significant bandwidth issues that have prevented them from being more active in lab closeouts.

The university is exposed to a wide range or safety risks by not having a well-defined, standardized lab closeout process. Some of these risks have already materialized, most recently exemplified in the December 2023 incident where pyrophoric chemicals were left unaccounted for and undisposed of in a glove box, which eventually came into contact with oxygen, creating a combustion reaction. Per discussions with school leadership, this issue was most likely the result of a breakdown in communications and lack of proper chemical inventory. Additionally, school leadership have expressed other instances of vacated lab spaces being left in unsafe conditions, which creates issues when trying to clean out the lab space.

The unsafe conditions of the vacated lab spaces exposes individuals to health and safety risks. It further exposes the university to potential litigation risks in the event of an individual being harmed.

Recommendation
Internal Audit recommends EH&S collaborate with school leadership and ORED to develop a plan to standardize and formalize a lab closeout process.

Management Corrective Action (MCA)
EH&S is currently working with School of Natural Sciences (SNS) leadership on a close out of a departing Chemistry faculty member's lab. EH&S is leveraging the existing resources

and process on our website to facilitate the close out. Our approach will include working with school leadership and faculty to clearly communicate timeline, roles and responsibilities with emphasis on follow through to completion. After completion of the current lab close out EH&S will facilitate a review of the process with SNS leadership and faculty to identify strengths and opportunities of the close out process and customer experience. We shall then work with the research safety committee to develop an implementation plan by March 28, 2025.

7. HAZARDOUS CHEMICAL WASTE LABELING

Background
Proper hazardous chemical waste labeling is crucial to ensure compliance with regulatory guidance and to ensure the safety of individuals handling hazardous chemical waste.

According to the UC Merced Laboratory Safety Plan, “all personnel who are responsible for handling, managing, or disposing hazardous waste must attend training prior to working with these materials.” In addition, “all the chemical constituents in each hazardous waste stream must be accurately identified by laboratory personnel, even those components present at trace levels,” and “hazardous waste labels must be placed on the hazardous waste container upon the start of accumulation.”

The procedures outlined in the Laboratory Safety Plan align with federal guidance on hazardous chemical waste management. According to federal guidance 40 CFR section 262.34(d)(5)(iii), as a Small Quantity Generator, UC Merced “must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies.”

Observation
During the walkthroughs of labs, Internal Audit noted instances of waste not being labeled properly. Furthermore, Internal Audit noted eight of the 13 labs in the sample had instances of noncompliance with hazardous waste management training.

According to EH&S staff, proper waste management training informs lab personnel on proper waste labeling. However, Internal Audit noted hazardous waste management training compliance is not tracked. EH&S is reliant on the PIs as the supervisors of the work environment to identify, assign, and track the need for hazardous waste management training.

By not having proper labeling on hazardous waste, the university is exposed to significant fines in the event of inspections. These fines can have significant impacts on research since the labs being fined would be liable for the fines. More importantly, noncompliance with labeling requirements can expose individuals handling hazardous waste to safety concerns.

Internal Audit was made aware anecdotally of instances of safety concerns when handling improperly labeled chemical waste.

Currently, UC Merced has a hazardous waste management training on UC Learning Center (UCLC) that appears to be robust and covers the labeling requirements thoroughly. The modality of the training will be especially important as the university transitions into a large-quantity waste generator; regulatory guidance becomes more prescriptive for training requirements, including requiring some in-person training.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Recommendation
Internal Audit recommends EH&S clearly communicate to PIs the expectations for safe and compliant hazardous waste management practices including hazardous waste management training requirements. In addition, EH&S should consider revamping the waste management training, including its modality.

Management Corrective Action (MCA)
Communication strategies under consideration include Monday Memo, Departmental Faculty meetings and Faculty Senate. EH&S will work through the research safety committee to develop an implementation plan by March 28, 2025.

8. FIELD SAFETY PLANS

Background
Field safety plans are broadly required based on Cal-OSHAs Injury Illness Prevention Program (IIPP) requires locations to develop field safety plans for field work in remote locations to ensure safe, successful field courses and research trips. The field safety plans should include site information and emergency procedures.

Observation
UC Merced does not have effective controls in place to identify field research. Consequently, the university has instances of field research without the required safety plans.

The responsibility falls on the PIs to identify field research components in their projects. The current process only identifies field research in the proposal stage of a project; no follow-up occurs during the award stage.

Without effective controls, field research could go unidentified, which could hinder the university's field safety efforts. Conversations with ORED staff have already confirmed instances of PIs not disclosing field research components in their projects. The university

would be unable to appropriately respond to emergencies in remote locations if the field safety plan is not properly filed.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Recommendation
Internal Audit recommends Risk Services collaborate with ORED, EH&S, and school leadership to reimagine the field research identification process.

Management Corrective Action (MCA)
EH&S will partner with Risk Services, ORED and school leadership to align on roles and responsibilities for field safety plans. We will also leverage the UCOP Center of Excellence for field safety for support and insight. We shall develop an implementation plan by March 28, 2025.

9. BIOSAFETY LEVEL 3 (BSL-3) LAB

Background
BSL-3 labs are used to study infectious agents or toxins that may be transmitted through the air and cause potentially lethal infections. Researchers perform their experiments in an environment that is specially designed to contain any toxins. These labs are expensive to design and construct due to their specific engineering requirements. They are also expensive to maintain since they have such exacting requirements.

Observation
The UC Merced BSL-3 lab has not been able to operate due to engineering issues with the design and construction of the lab. These issues include the autoclave being installed backwards (designed to keep contaminants out of the lab rather than containing the toxins within the lab), and being unable to maintain acceptable negative air pressure within specific standards. In addition, the lab does not have budget for a lab manager to oversee the operations of the lab, nor an operational budget for the lab to cover common BSL-3 lab expenses.

The air handling and autoclave issues are a result of problems with the design and construction of the building. Currently, UC Merced is working with Plenary, Webcor and Johnson Controls Inc. (JCI) to address these issues. The budget issues are a result of the overall budget issues within the university. This issue has been brought forward to campus leadership; however, competing priorities have not allowed the university to properly resource the BSL-3 lab.

Relationships with researchers who were recruited with the promise of availability of a BSL-3 lab could be hindered due to the current inoperability of the lab. Internal Aduit notes one PI is currently having to outsource their research, which is more expensive than

being able to do the work in a UC Merced lab. Consequently, there is a risk of UC Merced losing faculty who cannot perform their research due to the inoperability of the BSL-3 lab. In addition, there is a risk of the university being unable to recruit faculty for biomedical science and clinical research that is increasingly involving infectious disease research, thus reliant on a BSL-3 lab.

Recommendation
Internal Audit recommends that the CFO, COO, VCR, and Provost conduct a cost benefit analysis to determine whether UC Merced should (1) decommission the BSL-3 lab and not invest any further resources in the project, (2) invest sufficient resources in the project to make the BSL-3 lab operational, or (3) invest sufficient resources to operate the current BSL-3 lab as a BSL-2 lab until sufficient resources are available to operate it at the BSL-3 level.

Management Corrective Action (MCA)
EH&S shared this recommendation with the COO on June 7, 2024 and VCR on June 10, 2024. EH&S emailed the CFO, COO, VCR, and Provost on July 17, 2024. We expect the group to meet and decide how to move forward by March 28, 2025.

10. BIOLOGICAL USE AUTHORIZATIONS ESCALATION PROCESS

Background
Per the Laboratory Safety Plan:

> For research that involves recombinant nucleic acid (unless exempt from NIH Guidelines), microorganisms infectious to humans, animals or plants, or human and non-human primate source materials (tissues, organs, cells, blood or other body fluids); or storage of those biohazardous materials, a Biological Use Authorization (BUA) must be submitted. No work with infectious biological agents or rDNA is permitted on the UC Merced campus without prior approval of a BUA.

Observation
Internal Audit noted five instances of affected research being conducted without an approved, unexpired BUA.

According to EH&S staff, they do not have the administrative capacity needed to have effective oversight of BUAs. UC Merced does not have a tailored BUA escalation process to ensure research is not being done without an approved, unexpired BUA. Additionally, bandwidth constraints have hindered timely BUA renewal reviews, leading to instances of research being done without approved, unexpired BUAs.

Working without approved BUAs is in violation of NIH guidelines, which can lead to significant consequences. Typically, NIH can issue action items with specified timeframes

for such cases; however, they can also potentially revoke NIH funding altogether. The severity of NIH's response to noncompliance is linked to the nature of the research being conducted and the level of risk inherent in that research.

It is worth noting that though EH&S does not have a BUA escalation process to ensure BUAs are active while research is being conducted involving recombinant and/or synthetic nucleic acids and/or risk group 2 agents, EH&S staff is able to control the start of new research and unapproved research through the procurement process, where EH&S has the authority to deny purchase requisitions.

Recommendation
Internal Audit recommends EH&S partner with the Institutional Biosafety Committee to develop and implement a BUA escalation process to effect compliance with NIH guidelines.

Management Corrective Action (MCA)
ORED identified a new chair of the IBC on July 17, 2024. EH&S will ask the IBC to address this topic and develop an implementation plan by March 28, 2025. It is likely that it will mirror the lab deficiency escalation process. We expect the basic structure will include a simple process for escalation of BUA deficiencies starting with the Principal Investigator (PI), as well as clearly defining roles and responsibilities for EH&S and school leadership.

11. CHEMICAL HYGIENE PLAN – PARTICULARLY HAZARDOUS SUBSTANCES (PHS)

Background
Cal/OSHA requires the chemical hygiene plan (CHP) to include elements and the “specific measures” that the university will take to ensure lab employee protection. These elements include:

> provisions for additional employee protection for work with particularly hazardous substances. These include ‘select carcinogens,” reproductive toxins and substances which have a high degree of acute toxicity. Specific considerations shall be given to the following provisions which shall be included where appropriate:
>
> - Establishment of designated areas;
> - Use of containments devices such as fume hoods or glove boxes;
> - Procedures for safe removal of contaminated waste; and
> - Decontamination procedures.

Observation
The CHP section covering PHS does not contain all the required elements prescribed by regulatory guidance. While the CHP list the required provisions, it does not “indicate specific measures that the employer will take to ensure laboratory employee protection.”

Per discussions with EH&S staff, compliance with Cal/OSHA guidance is achieved by bulleting the provisions in the CHP. The language on the additional provisions for PHS is purposely generalized in the bulleted format since this gives the EH&S team flexibility in the enforcement of such provisions, given the variety of ways compliance with these four provisions can be achieved. There is concern that if the guidance is expanded, it might restrict compliance into one narrow focus. However, Internal Audit notes compliance could be achieved by reference to the SOPs of each lab.

This issue could result in users of the CHP potentially not possessing the necessary guidance to ensure safety when working with PHS. This could potentially lead to unsafe working environments, which could result in harm to individuals and equipment.

Recommendation
Internal Audit recommends EH&S revise the CHP to include expanded guidance on the additional provision to ensure safety when working with PHS. EH&S should consider including SOPs as a reference.

Management Corrective Action (MCA)
EH&S will revise the CHP to include expanded guidance on the additional provision to ensure safety when working with PHS by by March 28, 2025. EH&S is currently working to update SOPs for PHS.

12. ANNUAL PI CHEMICAL INVENTORY CERTIFICATIONS

Background
According to the UC Merced Lab Safety Plan:

> Each PI/Laboratory Supervisor is required to maintain a current comprehensive chemical inventory, through the chemical inventory system (UC Chemicals), which lists the hazardous chemicals and compressed gases used and stored in the labs and the quantity of these chemicals. This information is managed and reported to meet obligations under the Emergency Planning and Community Right-to-Know Act (EPCRA) that is managed in California by the Certified Unified Program Agencies (CUPA). This inventory needs to be updated:
>
> 1. At least annually.
> 2. Whenever new chemicals are introduced into the laboratory.
> 3. Whenever a chemical is completely removed from the laboratory.

The annual EH&S chemical inventory reconciliations and PI certification are the mechanisms used to comply with inventory requirements.

Internal Audit notes that this is a repeat finding from the FY 21 Audit.

Observation
Internal Audit noted four instances, out of a sample of 13, where the PI did not certify their chemical inventory.

The annual PI certification is closely tied to the annual EH&S chemical inventory reconciliation process. EH&S instructs the PIs to certify the inventory scans that the EH&S student workers did during the reconciliation process. EH&S staff reach out to the PI to schedule a time for the student worker to scan chemical inventories. Once the inventory is scanned, a report is generated and sent to the PI for certification.

If the PI does not answer to the request for date and time, EH&S will not perform a scan of the inventory and the inventory will be deemed not reconciled or certified. It appears no additional follow-up with the PI is conducted in these cases.

A lack of annual certification requirements could lead to discrepancies in inventory levels. Furthermore, PIs are not being held accountable for maintaining accurate chemical inventories. Hazardous chemicals could go unaccounted for, which could create safety concerns for individuals accessing lab spaces.

Internal Audit notes that the current procurement process for chemicals mitigates some of the stated risks associated with the lack of annual PI certifications. Currently, EH&S labels incoming chemicals and adds them to the inventory. The PIs, on the other hand, are responsible for removing the chemicals from inventory as they are used up. This process would result in instances of chemical overstatements rather than understatements if the PIs are not being proactive with chemical inventory management. However, given the current scrutiny over MAQs, it is inefficient to overstate chemicals.

Recommendation
Internal Audit recommends EH&S reimagine the annual PI chemical inventory certification and annual EH&S chemical inventory reconciliation processes. If the annual EH&S chemical inventory reconciliation process remains a summer project for student-workers, EH&S should consider implementing a follow-up process with PIs to ensure the completion of certification requirements. In the alternative, EH&S could include annual chemical inventory certification in the lab inspection process.

Management Corrective Action (MCA)
EH&S will incorporate annual chemical inventory certification into both the chemical inventory reconciliation process and the lab inspection process. We will formalize by updating the program documents for inventory reconciliation process and the lab inspection process by March 28, 2025.

13. CONTROLLED SUBSTANCES (CS) CABINETS

Background
UC Merced holds a Drug Enforcement (DEA) Administration registration to handle Schedule 2-5 substances that are used in research. As such, the university is subject to regulatory requirements enforced by the DEA. According to federal regulatory guidance 21 CFR section 1301.71(a), "all applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.". In addition, per 21 CFR 1301.75(b), "controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet."

Observation
Key issuance logs were not kept for the CS cabinets. As a result, EH&S was unable to validate the access controls to CS cabinets.

During discussions with EH&S staff, it was noted that the former Department of Animal Research Services (DARS) manager distributed CS cabinet keys to faculty; however, they did not keep proper key logs to document who had what keys. As a result, when EH&S tried reconciling keys to ensure access to CS cabinets was managed, significant discrepancies with key inventory were noted. Consequently, EH&S was unable to ascertain the effectiveness of CS cabinets access and determined that the cabinets had to be replaced since rekeying them would not be feasible.

By not having an accurate inventory of keys to the CS cabinets, the university is exposed to potential unauthorized access of CS. In addition, from a regulatory standpoint, the university could be subject to civil penalties and administrative actions imposed by the DEA, the federal agency governing controlled substances. Administration actions could include suspension and revocation of the university's DEA registration.

EH&S staff identified the issues with the CS cabinets keys before the start of the audit, and as a result of the issue not being remediated, EH&S restricted access to the CS cabinets room to only three individuals: the chemical hygiene officer, Director of Animal Care Operations and a senior technician. This restriction will be lifted when the CS cabinets issues get resolved. Once resolved, access to the CS cabinets room will reflect the authorized access/users listed in the approved Controlled Substances Use Authorizations.

Recommendation
Internal Audit recommends EH&S collaborate with DARS to get the CS cabinets replaced. In addition, Internal Audit recommends keeping a key issuance log for the newly installed CS cabinets.

Management Corrective Action (MCA)
EH&S raised this topic with ORED leadership on March 28, 2024. ORED replaced the CS cabinets in the S&E 1 vivarium in May 2024. EH&S will work with DARS to formalize a process for key control by November 1, 2024.

14. CONTROLLED SUBSTANCES (CS) CHAIN-OF-CUSTODY DOCUMENTATION

Background
UCOP BUS-50: Controlled Substances Policy (BUS-50) requires locations to maintain documentation pertaining to controlled substances, which includes chain-of-custody forms. This requirement aligns with federal regulatory requirements for CS record keeping. According to regulatory guidance 21 CFR section 1304.21(a):

> Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

Observation
EH&S is not maintaining chain-of-custody documentation for the CS that are delivered to campus. Currently, when the controlled substance arrives, the PI is instructed to pick it up; therefore, there is no chain-of-custody process needed since the CS is directed handed off to the recipient.

However, according to EH&S staff, this process is inefficient since PI schedules do not always allow for the pick-up when the delivery occurs. There have been instances where EH&S has had to pick up the CS on behalf of the PI. In these instances, a chain-of-custody form would be required.

According to EH&S staff, they have procured a safe that will act as a holding place for the CS while the PI is able to pick it up. They have installed the safe and relevant security measures, as well as drafted required documentation and written procedures, all they are waiting for is DEA approval of the safe to start using it. Once the safe is approved and in use, EH&S will be able to implement the chain-of-custody process they have already created.

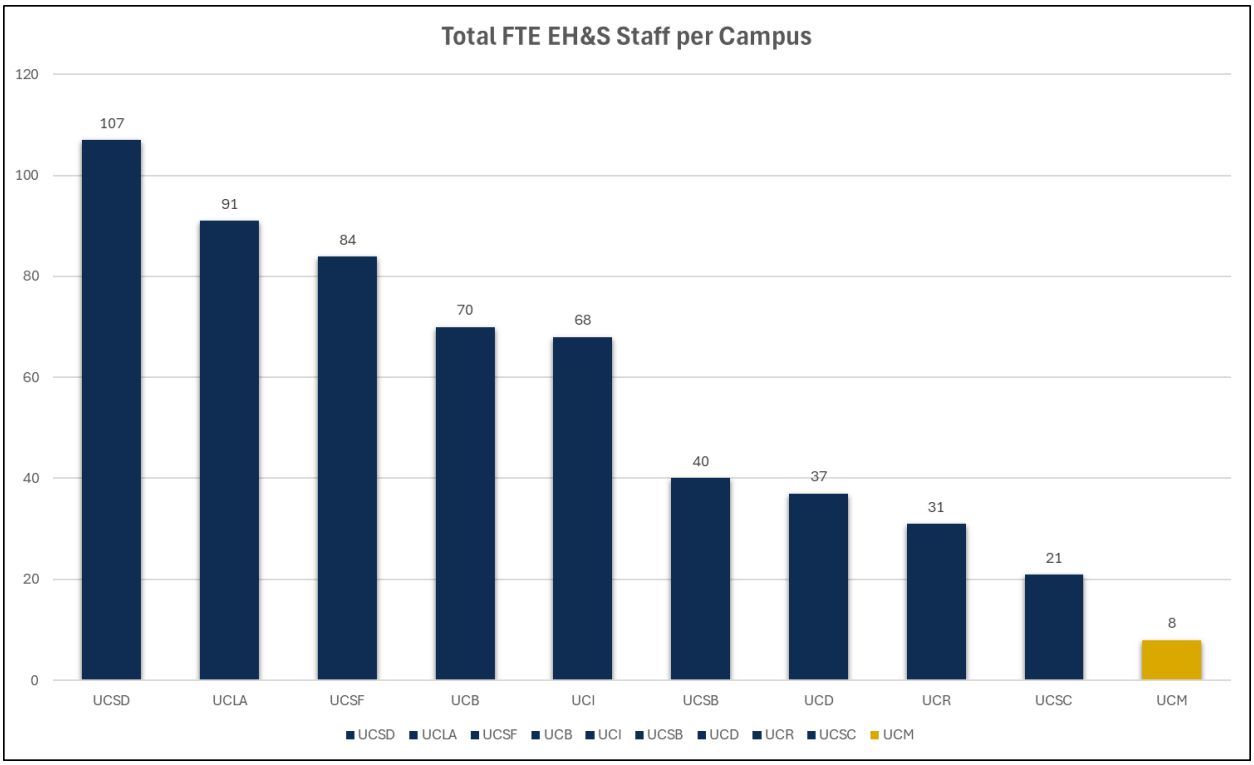
Without a chain-of-custody form, especially as the university's process is changing with the use of the safe as a holding place, the university could be exposed to potential loss or theft of controlled substances, which would expose the university to scrutiny from the DEA. The DEA could ultimately impose civil and administrative penalties that range from fines to suspension and/or revocation of the university's DEA registration.

Recommendation
Internal Audit recommends EH&S implement a chain-of-custody form process for controlled substances once the safe is approved by the DEA.

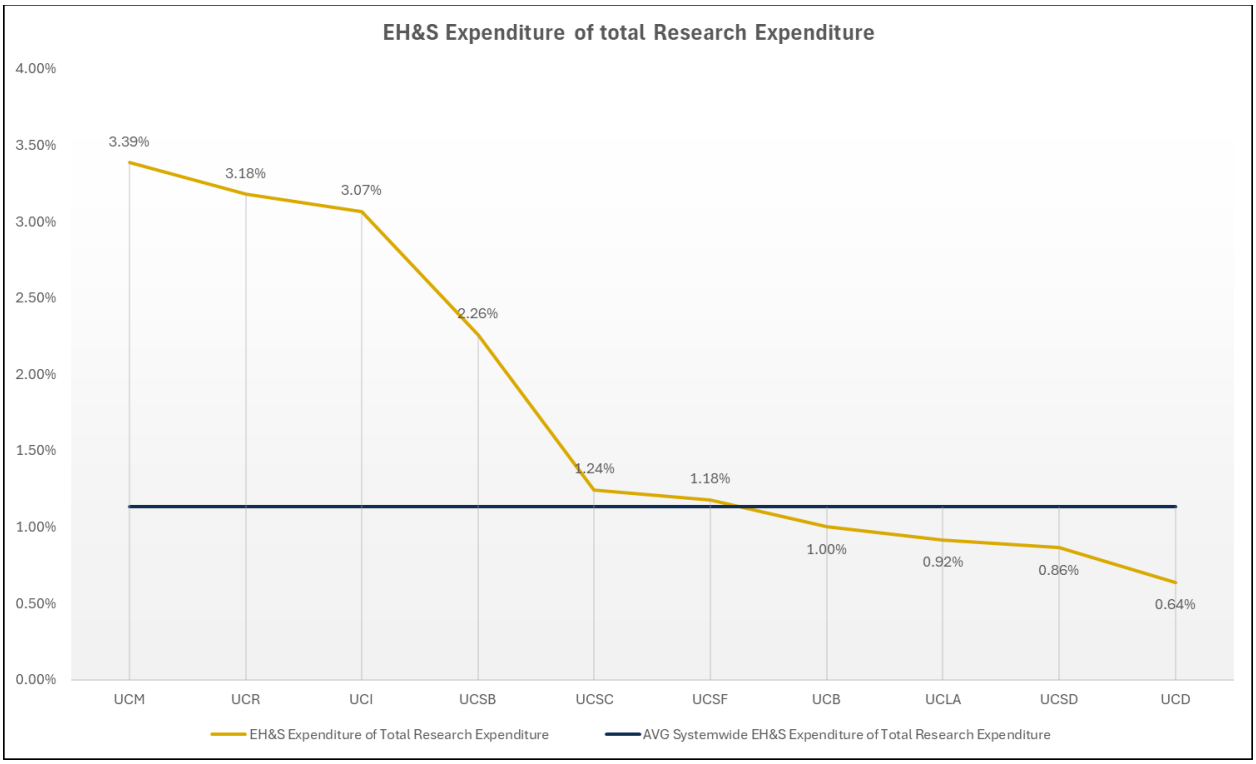
Management Corrective Action (MCA)
The safe was approved by the DEA and a chain-of-custody form process was implemented in May 2024.

APPENDIX A

This appendix illustrates UC Merced EH&S resources compared to a systemwide average. Internal Audit received the data[1] from a shared Excel file with all campuses self-reporting. The graphs analyze UC Merced's capacity in terms of personnel and financial resources to effectively manage the baseline EH&S functions. While the data presented appears to show that UC Merced is in line proportionally with the other UC campuses for resourcing, Internal Audit noted multiple areas within EH&S that were not performing effectively due to a lack of resources. This indicates that there is a baseline of resourcing that an effective EH&S function would need, regardless of size, to effectively manage the safety mission. Discussions with EH&S experts at UCOP bear out this premise.



[1] Internal Audit did not perform any testing procedures to verify the accuracy of the self-reported figures.


EH&S Expenditure of total Research Expenditure
4.00%
3.50%
3.00%
2.50%
2.00%
1.50%
1.00%
0.50%
0.00%
3.39%
3.18%
3.07%
2.26%
1.24%
1.18%
1.00%
0.92%
0.86%
0.64%
UCM
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UCSF
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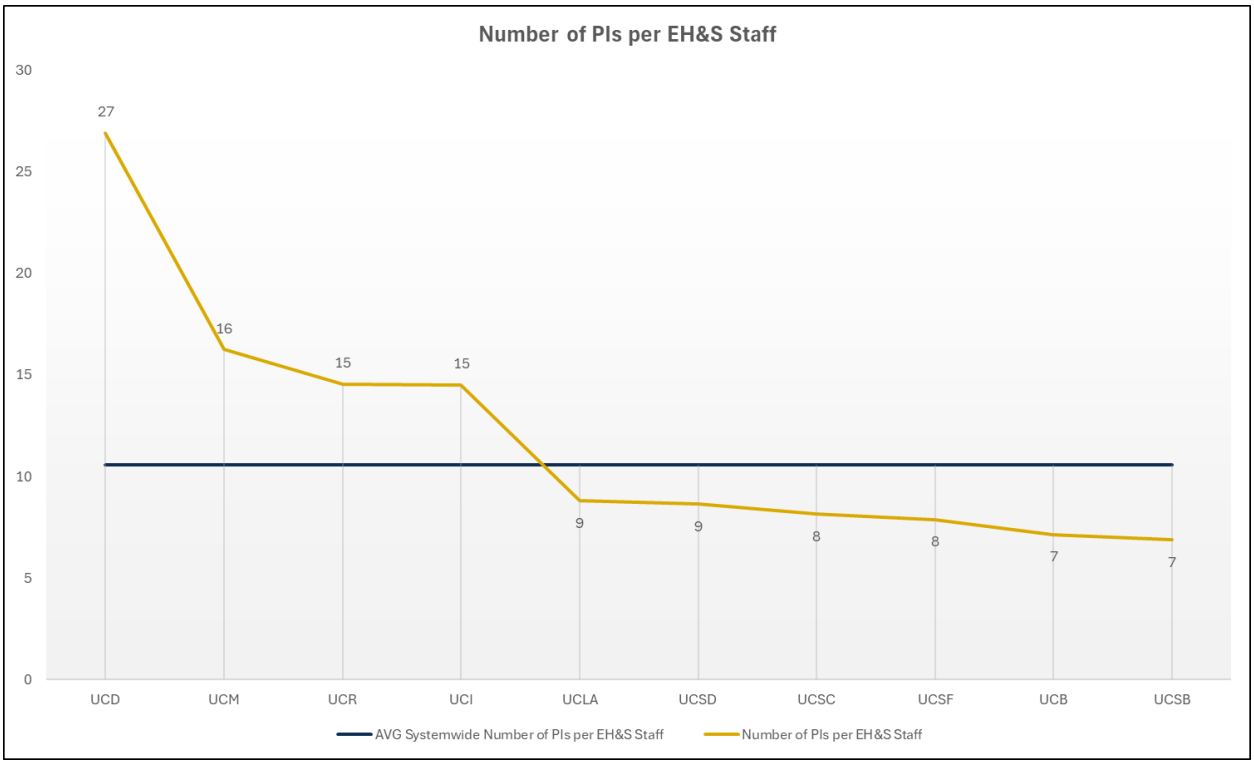
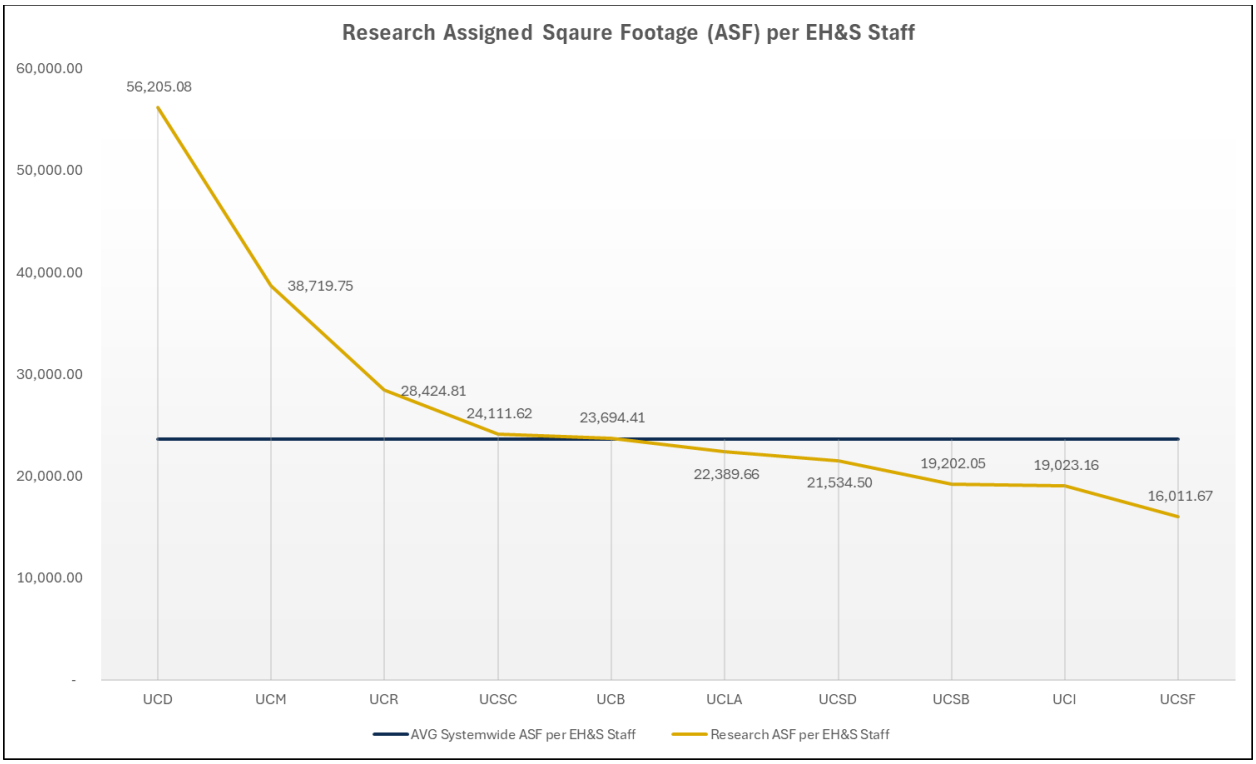
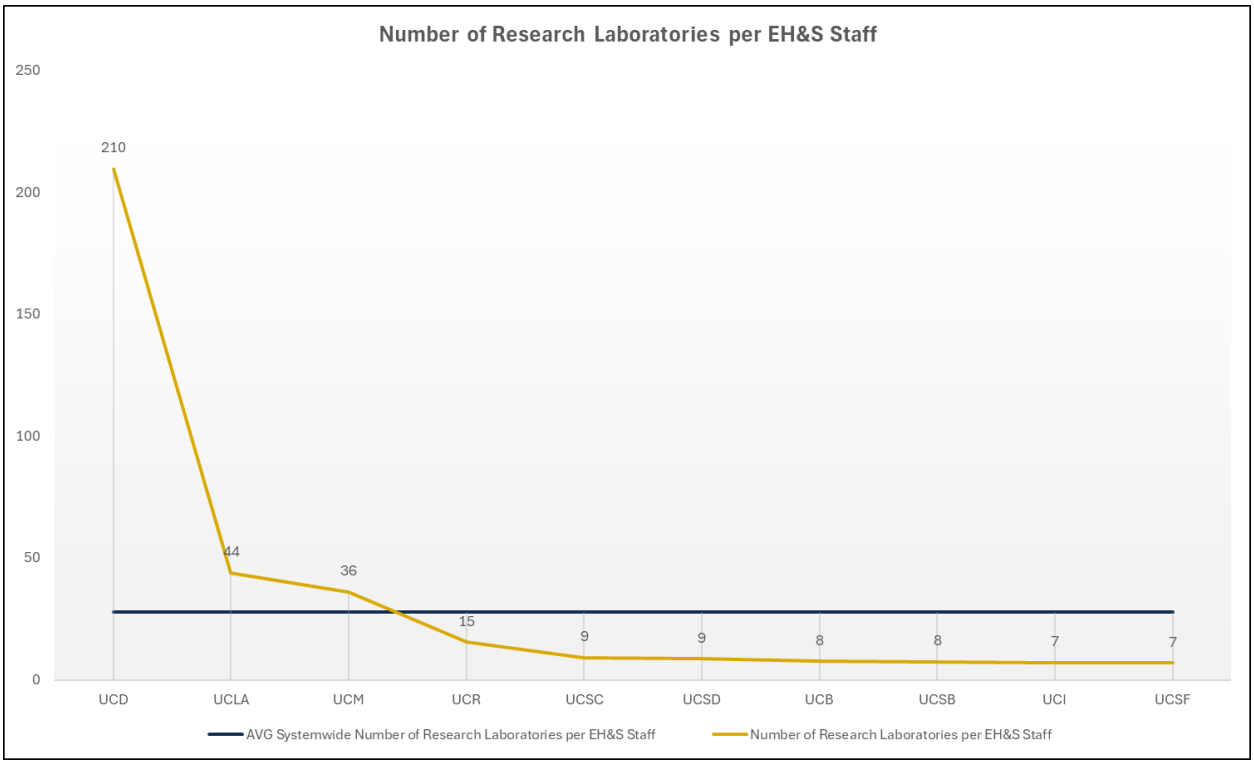
UCLA
UCSD
UCD
EH&S Expenditure of Total Research Expenditure
AVG Systemwide EH&S Expenditure of Total Research Expenditure


Number of PIs per EH&S Staff
30
25
20
15
10
5
0
27
16
15
15
9
9
8
8
7
7
UCD
UCM
UCR
UCI
UCLA
UCSD
UCSC
UCSF
UCB
UCSB
AVG Systemwide Number of PIs per EH&S Staff
Number of PIs per EH&S Staff


Research Assigned Sqaure Footage (ASF) per EH&S Staff
60,000.00
50,000.00
40,000.00
30,000.00
20,000.00
10,000.00
-
56,205.08
38,719.75
28,424.81
24,111.62
23,694.41
22,389.66
21,534.50
19,202.05
19,023.16
16,011.67
UCD
UCM
UCR
UCSC
UCB
UCLA
UCSD
UCSB
UCI
UCSF
AVG Systemwide ASF per EH&S Staff
Research ASF per EH&S Staff


Number of Research Laboratories per EH&S Staff
250
200
150
100
50
0
210
44
36
15
9
9
8
8
7
7
UCD
UCLA
UCM
UCR
UCSC
UCSD
UCB
UCSB
UCI
UCSF
AVG Systemwide Number of Research Laboratories per EH&S Staff
Number of Research Laboratories per EH&S Staff