

January 24, 2013

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Director
Environmental Health & Safety
0920

Subject: *Laboratory Safety – Phase I
Audit & Management Advisory Services Project 2012-09*

Audit & Management Advisory Services (AMAS) has completed a review of Laboratory Safety – Phase I as part of the approved audit plan for Fiscal Year 2011-12. This report summarizes the results of our review.

Background

Academic research and teaching laboratories are complex work environments. A wide variety of potential hazards exist, resulting directly from the work conducted or the tools used to conduct that work.

It is University of California, San Diego (UCSD) policy to provide and maintain a safe environment for its students, academic appointees, staff, visitors, and surrounding communities. Policy requires that all laboratory activities involving chemical, physical, and biological hazards be conducted in a safe and responsible manner. Authorization must be obtained before Principal Investigators (PIs) may begin research using animal subjects, biological materials, controlled substances, human gene transfer clinical trials, human subjects, lasers, radioactive materials, select agents, or stem cells. UCSD had 1,183 active authorizations involving 729 PIs and 760 Area Service Coordinators (ASC) representing 61 areas, departments, divisions, programs, or centers on June 15, 2012.

PI, laboratory research and support personnel, UCSD safety committees, Facilities Design & Construction, Facilities Management, and Environment Health & Safety (EH&S) share responsibility for maintaining laboratory safety standards as depicted in **Attachment 1**. Departments and Organized Research Units (ORUs) are required to delegate at least one Department Safety Coordinator (DSC) to represent department personnel, regardless of the kind of work performed, and to facilitate the communication of safety information and programs from EH&S to the department. In addition, any facility where work with hazardous material occurs must appoint an ASC to conduct employee safety orientations, coordinate safety activities, serve as a safety audit liaison, conduct fire extinguisher inspections, and ensure proper hazardous waste management. Some departments that conduct high risk activities also employ a Department Safety Officer (DSO), a career safety professional.

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Monitoring of laboratory safety activities is performed through:

- Biohazard, chemical hazard, controlled substance, laser, and radioisotope use authorization approval requirements;
- EH&S laboratory inspections, follow up site visits or discussion, and reporting;
- Incident reports and follow up activities;
- EH&S program peer reviews;
- Other federal, state, county or agency audits or inspections; and
- Safety committee activities.

A description of oversight provided by various campus committees related to laboratory safety is provided in **Attachment 2**.

Laboratory incidents may result in injury or death to laboratory and/or personnel; damage to the equipment, laboratory, and/or building; citations and/or fines, lawsuits, criminal charges, and reputation harm. One such incident occurred at a University of California (UC) campus in 2008 and the UC Regents have executed a settlement agreement associated with that incident.

A United States Chemical Safety Board (CSB) video, *Experimenting with Danger*, identifies similarities between three major laboratory accidents in 1997, 2008, and 2010 that caused the death of two researchers and seriously injured another researcher. According to the video, findings related to these incidents included:

- Protective gear was not worn;
- Laboratory safety training was not documented;
- Failure to report a laboratory event that was a seemingly innocuous event; and
- Deficiencies in each layer of safety management within the institution, including insufficient safety accountability and oversight by the PI, the Department, and university administration, and gaps beyond the university.

The video states that Occupational Safety and Health Administration (OSHA) standards were developed to address health hazards of chemicals, but do not adequately address the physical hazards of chemicals.

CSB recommendations related to its investigation into one of these incidents required the institution to:

- Ensure that research-specific hazards are evaluated and then controlled by developing specific written protocols and training;
- Expand existing laboratory safety plans to address physical hazards;
- Ensure that safety personnel report directly to a university official who has the authority to oversee research laboratories and implement safety improvements; and
- Document and communicate all laboratory near-misses and incidents.

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To mitigate the risk of potential occurrences at UCSD, the campus has implemented additional measures to evaluate and improve its laboratory safety practices. In addition, under the terms of the UC settlement agreement additional laboratory safety enhancements are being implemented within the departments of Chemistry and Biochemistry.

The objective of our review was to evaluate the effectiveness of safety programs and procedures in campus research laboratories.

We completed the following audit procedures to achieve the project objective:

- Reviewed the UCSD Biosafety Handbook, UCSD Blink guidance on laboratory safety, and applicable University of California (UC) and UCSD policies and procedures and campus notices;
- Identified all campus departments responsible for some aspect of laboratory safety (**Attachment 1**);
- Reviewed applicable prior audit and peer review reports;
- Reviewed the Environmental Health & Safety (EH&S) organizational chart;
- Analyzed recent laboratory incident media reports;
- Evaluated a July 1, 2011 through April 30, 2012 injury report for laboratory injuries;
- Performed data analysis on active violations as of June 12, 2012;
- Obtained information regarding the EH&S application for laboratory use authorizations, laboratory audits, and reports and information regarding the requirements for a future application;
- Reviewed the Chemical Safety and Surveillance Committee (CSSC), Institutional Biosafety Committee (IBC), Laser Safety Committee (LSC), and Radiation Safety Committee (RSC) charges and minutes;
- Reviewed the charges for the Compliance, Audit Risk and Ethics (CARE) committee and of the newly created Enterprise Risk Management (ERM) subcommittee;
- Summarized laboratory safety oversight committees (**Attachment 2**);
- Analyzed current authorizations as of June 15, 2012;
- Reviewed 2010 EH&S statistics on activities;
- Interviewed EH&S management, Staff Education & Development management, and one DSC; and
- Performed a preliminary risk assessment based on the interviews conducted, UCSD Blink guidance and related policies and procedures to identify areas of UCSD laboratory safety that will be the subject of additional focused testing during Phase II of this review.

Conclusion and Supporting Comments

Based on our preliminary evaluation, we concluded that recent measures implemented to improve laboratory safety should be effective.

EH&S has evaluated the safety program in response to recent academic institution accidents, and is implementing improvements including:

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- Creating safety videos and providing links to other laboratory safety videos on the laboratory safety webpage;
- Evaluating and updating safety policies and procedures related to laboratory safety;
- Obtaining additional funding to implement a Personal Protective Equipment (PPE) initiative, which provides basic PPE and laundering of laboratory coats to all research personnel at no additional cost to the PI or researcher;
- Evaluating the usage of specific hazardous material usage and inventory and eliminating these materials when practical;
- Ensuring that all laboratories using pyrophoric liquids had class D fire extinguishers in the laboratories;
- Classification of laboratories and modifying laboratory inspections to a risk-based process;
- Development of a Chemical Hazard Use Authorization program;
- In coordination with other UC campuses, developing a new EH&S laboratory auditing system;
- Observation of a sample of laboratory inspections by the Research Assistance Program (RAP) Supervisor; and
- Identification of critical laboratory deficiencies and evaluation of the critical deficiency follow up periods.

We noted that EH&S performs risk based laboratory inspections and provides an inspection report to the people directly responsible for the laboratory, and quarterly reports to Vice Chancellors or Deans. However, we determined that further review of the UCSD laboratory safety structure, monitoring, and reporting (e.g., results of laboratory inspections and incidents) would help ensure the effectiveness of the laboratory safety program.

Based on our analysis of the active laboratory violations identified as of June 12, 2012, we determined that 85 percent of the open violations were high hazard (18%) violations or medium hazard (67%) violations. Therefore, we concluded that further review of violations and corresponding follow-up would help ensure that the EH&S follow up process ensures timely closure of identified laboratory safety violations.

The further work noted above is referenced below in next steps, which AMAS plans to complete during Fiscal Year 2012-2013.

Next Steps

We plan to complete a detailed review of the UCSD laboratory safety structure and monitoring, reporting and follow up processes during Phase II of this project. Focused audit testing will include data analysis regarding laboratory inspections; surveys of safety committee members, PIs, and ASCs; evaluation of safety committee meeting minutes and review of laboratory safety reporting; observation of laboratory safety inspections; evaluation of laboratory inspection follow up processes; and evaluation of the UCSD laboratory safety structure.

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The following attachments provide additional information for Phase II of our Laboratory Safety review:

- Laboratory Safety – Phase II Work Plan (**Attachment 3**);
- Laboratory Safety Survey Sample Methodology (**Attachment 4**); and
- Laboratory Safety Surveys (**Attachment 5**).

Audit & Management Advisory Services appreciated the cooperation and assistance provided by EH&S personnel during Phase I of this review.

UC policy requires that all draft audit reports, both printed (copied on tan paper for ease of identification) and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel or destroy them at this time.

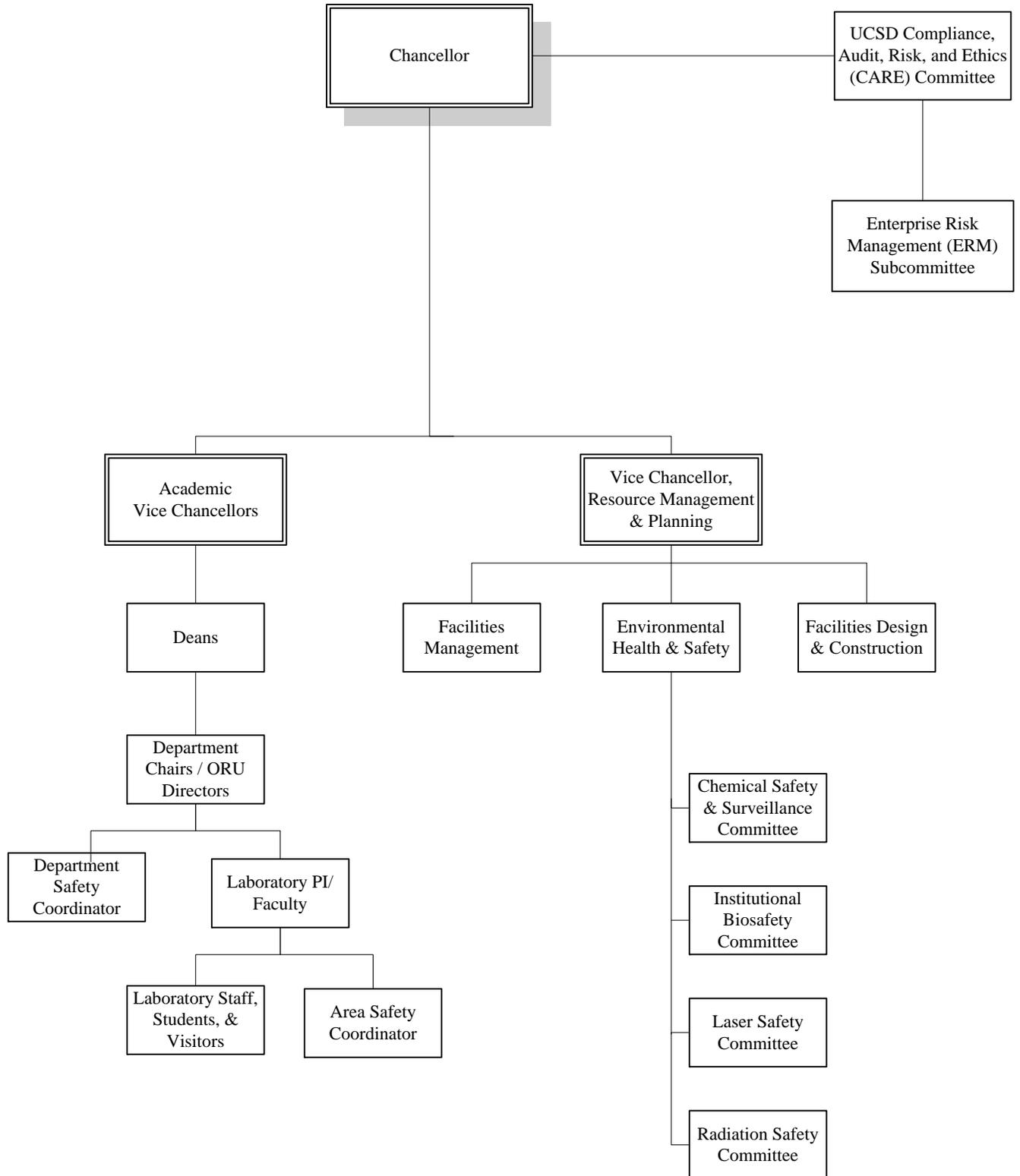
If you have any questions regarding this report, please contact me at (858) 534-1334 or by email at dmeier@ucsd.edu.

David Meier
Assistant Vice Chancellor
Audit & Management Advisory Services

Attachments

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Laboratory Safety – Phase I
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UCSD Laboratory Safety Structure – Attachment 1



Laboratory Safety - Phase I
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UCSD Committees Involving Laboratory Safety - Attachment 2

Committee	Charge	Members	Advisory to
Compliance, Audit Risk and Ethics (CARE) Committee	Provide ongoing oversight of compliance with established policies and procedures in a variety of areas; and make recommendations for improving compliance programs.	Vice Chancellors or their alternates from each area of campus, subject matter experts, and selected ex-officio members, including the Health Sciences Compliance and Privacy Officer, the Assistant Vice Chancellor of Audit & Management Advisory Services, and Campus Counsel.	UCSD Chancellor; the University of California (UC) Systemwide Compliance Risk Council; and the UC Office of Ethics, Compliance, and Audit
Enterprise Risk Management (ERM) Subcommittee	Prepare the annual CARE Compliance Plan (the Plan) and develop and compile appropriate reporting metrics for key risk areas, for the campus and the Office of the President.	Subject matter experts across campus.	CARE
Chemical Safety and Surveillance Committee (CSSC)	Reduce risks associated with hazardous chemicals and establish policies and procedures that meet or exceed applicable norms, monitor new regulations, and implement adopted policies and procedures for hazardous chemicals.	Ex officio and appointed members representing a diversity of disciplines relevant to the work being evaluated, developing technology, chemical health and safety, and engineering.	UCSD Chancellor through the Vice Chancellor - Resource Management & Planning (VC-RM&P)
Institutional Biosafety Committee (IBC)	Establish, monitor, and enforce policies and procedures which meet or exceed applicable norms or regulations for biohazardous materials and/or recombinant DNA.	Ex officio and appointed members from the community and UCSD with ad hoc subject matter experts.	UCSD Chancellor through the VC-RM&P
Laser Safety Committee (LSC)	Advise the University on all matters relating to laser safety, review and approve all proposed uses of laser radiation, and provide advice and guidance in carrying out the UCSD Laser Safety Program.	Ex officio and appointed members representing a diversity of disciplines.	UCSD Chancellor through the VC-RM&P
Radiation Safety Committee (RSC)	Advise the University on all matters relating to radiation safety and recommend policies and procedures to ensure an adequate Radiation Safety Program.	Ex officio and appointed members experienced in the use of radioisotopes and in protection against ionizing radiation, including the Radiation Safety Officer and additional human subjects experts.	UCSD Chancellor through the VC-RM&P

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Laboratory Safety – Phase II Work Plan– Attachment 3

Audit Objective:

To evaluate whether two key components of the UCSD laboratory safety program are operating effectively to ensure the safety of faculty, staff, students, and visitors in campus laboratories.

Two Key Components:

1. UCSD laboratory safety structure, monitoring, and reporting; and
2. EH&S laboratory inspection violation follow up process.

Work Plan:

UCSD Laboratory Safety Structure, Monitoring, and Reporting

1. Obtain and review the activities associated with the charge of safety committees through interviews and review of minutes;
2. Conduct surveys (Attachment 5) of a sample of PIs and ASCs and all voting CSSC, IBC, LSC, and RSC members;
3. Perform analysis of laboratory inspection timeliness;
4. Perform analysis on a sample of laboratory audit scores and/or violations;
5. Observe some EH&S laboratory inspections; and
6. Evaluate whether the UCSD safety structure, monitoring, and reporting appear adequate to effectively ensure the safety of faculty, staff, students, and visitors in campus laboratories.

EH&S Laboratory Inspection Violation Follow Up Process

1. Conduct interviews of EH&S regarding their follow up process;
2. Perform analysis on a sample of laboratory audit scores and/or violations; and
3. Evaluate whether the EH&S laboratory inspection violation follow up processes appear adequate to ensure the safety of faculty, staff, students, and visitors in campus laboratories.

*Laboratory Safety – Phase I
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Laboratory Safety Survey Sample Methodology – Attachment 4*

AMAS will survey current PIs, ASCs, and Safety Committee Members who have active authorizations. AMAS judgmentally selected the PI and ASC areas from large and small areas across scientific disciplines. ASCs selected for survey excluded PIs also serving as the ASC for their laboratories. Committee members selected for survey were all voting members. The survey sample selection is provided in the table below.

PI Area	Approximate Number of Participants
Department of Medicine	100
Department of Chemistry & Biochemistry	54
Department of Physics	22
Geosciences Research Division	19
Institute of Geophysics & Planetary Physics	9
Department of Ophthalmology	8
Climate, Atmospheric Science, & Physical Oceanography Research Division	8
Total PIs	220
ASC Area	Approximate Number of Participants
Department of Medicine	103
Department of Chemistry & Biochemistry	58
Department of Physics	22
Geosciences Research Division	19
Institute of Geophysics & Planetary Physics	12
Department of Ophthalmology	7
Climate, Atmospheric Science, & Physical Oceanography Research Division	8
Total ASCs	229
Committees	Approximate Number of Participants
Chemical Safety & Surveillance Committee	13
Institutional Biosafety Committee	13
Laser Safety Committee	9
Radiation Safety Committee	18
Total Committee Members	53
Survey Set	Coverage Percentage¹
Areas	11%
PIs	30%
ASCs	30%
Voting Safety Committee Members	100%

¹ Population was 61 areas, 729 PIs, 760 ASCs, and 53 Voting Safety Committee Members. Coverage was calculated as Area (7 sample areas / 61 population areas = 11%), PIs (220 sample PIs / 729 population PIs = 30%), ASCs (229 sample ASCs / 760 population ASCs = 30%), Voting Safety Committee Members (53 sample Voting Safety Committee Members / 53 population Voting Safety Committee Members = 100%)

Laboratory Safety – Phase I
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Laboratory Safety Surveys – Attachment 5

Please evaluate each statement as it relates to your recent experience at UCSD.

Strongly
Agree

Strongly
Disagree

Not.
Applic.

Don't
Know

Chemical Safety and Surveillance Committee – Reduce risks associated with hazardous chemicals; and establish policies and procedures that meet or exceed applicable norms; monitor new regulations; and implement adopted policies and procedures for hazardous chemicals.

Institutional Biosafety Committee – Establish, monitor, and enforce policies and procedures which meet or exceed applicable norms or regulations for biohazardous materials and/or recombinant DNA.

Laser Safety Committee – Advise the University on all matters relating to laser safety, review and approval all proposed uses of laser radiation; and provide advice and guidance in carrying out the UCSD Laser Safety Program.

Radiation Safety Committee – Advise the University on all matters relating to radiation safety; and recommend policies and procedures to ensure an adequate Radiation Safety Program.

- | | | | | | | | | | |
|-----|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 7. | My committee reviews injury reports submitted by PIs. | <input type="checkbox"/> |
| 8. | My committee reviews reports generated by EH&S on laboratory inspection results. | <input type="checkbox"/> |
| 9. | My committee prepares reports that are disseminated to UCSD management on a routine basis. | <input type="checkbox"/> |
| 10. | My committee has the resources it needs to provide adequate oversight of laboratory safety. | <input type="checkbox"/> |

Laboratory Safety – Phase I
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Laboratory Safety Surveys – Attachment 5

Please evaluate each statement as it relates to your recent experience at UCSD.

Strongly
Agree

Strongly
Disagree

Not
Applic.

Don't
Know

Operational Environment

11. In your experience, what other controls could the campus implement to ensure safe and responsible laboratory practices are conducted for the safety of students, academic appointees, staff, visitors, and surrounding communities? *(text box field)*

Laboratory Safety – Phase I
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Laboratory Safety Surveys – Attachment 5

Please evaluate each statement as it relates to your recent experience at UCSD.

Strongly
Agree

Strongly
Disagree

Not.
Applic.

Don't
Know

PI SURVEY

Background Information

- a. Select the name of your Area/Department/Division/Program/Center *(to be selected via drop down menu)*
- b. I am the PI for _____ laboratories. *(to be selected via drop down menu)*
- c. My highest Biosafety Level (BSL) laboratory is a BSL _____ laboratory. *(to be selected via drop down menu)*

Laboratory Safety Environment

- | | | | |
|---|---|--------------------------|--------------------------|
| 1. UCSD promotes a culture of safety within research and teaching laboratories. | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. For those laboratories where I am the PI, laboratory practices are conducted in a safe and responsible manner to ensure the safety of students, academic appointees, staff, visitors, and surrounding communities. | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. UCSD laboratory practices for laboratories administered by other PIs are conducted in a safe and responsible manner to ensure the safety of students, academic appointees, staff, visitors, and surrounding communities. | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. The PI has primary responsibility for safety within the laboratories. | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. UCSD laboratories have the resources needed to ensure safety within the laboratories. | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Laboratory Safety – Phase I
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Laboratory Safety Surveys – Attachment 5

Please evaluate each statement as it relates to your recent experience at UCSD.

Strongly
Agree

Strongly
Disagree

Not
Applic.

Don't
Know

Operational Environment

6. You understand the reporting requirements for all recordable occupational injury or illnesses under Title 8 California Code of Regulations Section 342 as required by the UC June 27, 2012 settlement agreement pertaining to the Department of Chemistry & Biochemistry?

7. In your experience, what other controls could the campus implement to ensure safe and responsible laboratory practices are conducted for the safety of students, academic appointees, staff, visitors, and surrounding communities?

(text box field)

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Laboratory Safety Surveys – Attachment 5

Please evaluate each statement as it relates to your recent experience at UCSD.

Strongly Agree		Strongly Disagree		Not Applic.	Don't Know
<input type="checkbox"/>					

ASC SURVEY

Background Information

- a. Select the name of your Area/Department/Division/Program/Center *(to be selected via drop down menu)*
- b. I am the Area Safety Coordinator (ASC) for _____ laboratories. *(to be selected via drop down menu)*
- c. My highest Biosafety Level (BSL) laboratory is a BSL _____ laboratory. *(to be selected via drop down menu)*

Laboratory Safety Environment

- | | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. UCSD promotes a culture of safety within research and teaching laboratories. | <input type="checkbox"/> |
| 2. For those laboratories where I am the ASC, laboratory practices are conducted in a safe and responsible manner to ensure the safety of students, academic appointees, staff, visitors, and surrounding communities. | <input type="checkbox"/> |
| 3. UCSD laboratory practices for laboratories administered by other ASCs are conducted in a safe and responsible manner to ensure the safety of students, academic appointees, staff, visitors, and surrounding communities. | <input type="checkbox"/> |
| 4. The PI has primary responsibility for safety within the laboratories. | <input type="checkbox"/> |
| 5. UCSD laboratories have the resources needed to ensure safety within the laboratories. | <input type="checkbox"/> |

Laboratory Safety – Phase I
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Laboratory Safety Surveys – Attachment 5

Please evaluate each statement as it relates to your recent experience at UCSD.

Strongly
Agree

Strongly
Disagree

Not
Applic.

Don't
Know

Operational Environment

6. You have the authority needed in the area to address matters of safety?

7. You understand the reporting requirements for all recordable occupational injury or illnesses under Title 8 California Code of Regulations Section 342 as required by the UC June 27, 2012 settlement agreement pertaining to the Department of Chemistry & Biochemistry?

8. In your experience, what other controls could the campus implement to ensure safe and responsible laboratory practices are conducted for the safety of students, academic appointees, staff, visitors, and surrounding communities?

(text box field)