SAN DIEGO: AUDIT & MANAGEMENT ADVISORY SERVICES
0919

July 16, 2013

GARRY MAC PHERSON
Director
Environment, Health & Safety
0920

Subject: ***Laboratory Safety – Phase II***
Audit & Management Advisory Services Project 2013-57

The final audit report for Laboratory Safety – Phase II, Audit Report 2013-57, is attached. We would like to thank all members of the department for their cooperation and assistance during the audit.

Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the corrective actions. At that time, we may need to perform additional audit procedures to validate that actions have been taken prior to closing the audit findings.

UC wide 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. We also request that draft reports not be photocopied or otherwise redistributed.

David Meier
Assistant Vice Chancellor
Audit & Management Advisory Services

Attachment

cc: D. Larson
G. Matthews
L. Scott
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UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

Laboratory Safety – Phase II
July 2013

Performed By:

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Approved By:

David Meier, Assistant Vice Chancellor

Project Number: 2013-57

Laboratory Safety – Phase II
Audit & Management Advisory Services Project 2013-57

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Laboratory Safety – Phase II
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I. Background

Audit & Management Advisory Services (AMAS) completed a review Laboratory Safety – Phase II. This report summarizes the results of our review.

Academic research and teaching laboratories are complex work environments. A wide variety of potential hazards exist, resulting directly from the research conducted in the laboratories 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. Environment, Health & Safety (EH&S) coordinates authorizations for biological materials, controlled substances, lasers, and radioactive materials. UCSD EH&S active authorizations involved 733 PIs and 799 Area Service Coordinators (ASC) as of March 2013.

PI, laboratory research and support personnel, UCSD safety committees, Facilities Design & Construction, Facilities Management, and 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.

Monitoring of laboratory safety activities by EH&S is performed through:

- Biohazard, chemical hazard, controlled substance, laser, and radioisotope use authorization approval requirements;
- EH&S laboratory audits, follow up communications, 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.

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 department of Chemistry and Biochemistry.

II. Audit Objective, Scope, and Procedures

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 our objective:

- Reviewed recent and prior laboratory audit scores to evaluate UCSD laboratory safety audit follow up processes;
- Evaluated laboratory audit scheduling and performance to laboratory classification audit frequency schedules;
- Conducted surveys of safety committee members, PIs, and ASCs regarding UCSD's laboratory safety environment (**Attachments 3, 4, and 5**);
- Interviewed EH&S staff and management;
- Observed two laboratory safety audits;
- Tested a sample of 25 ASC payroll titles and employee payroll information; and
- Evaluated the laboratory safety organizational structure of UCSD compared to other academic institutions.

AMAS did not evaluate UCSD compliance with the settlement agreement in the performance of this review or evaluate clinical laboratory safety.

III. Conclusion

We concluded that EH&S laboratory audit processes could be improved to provide increased assurance that the PIs and ASCs are effectively implementing required safety procedures and ensuring a safe working environment. Opportunities for improvement include standardization of audit scheduling and follow up processes; validation of follow

up actions in a timely manner; and additional oversight to ensure that the laboratory assignments, frequency criteria, and follow up validation are achieved in accordance with departmental goals. Ultimately, however, the effectiveness of UCSD's safety programs and procedures in campus research laboratories is primarily dependent on the individual PI and ASC associated with each laboratory.

Based on overall survey results, we noted that UCSD committee members, PIs, and ASCs expressed confidence in the UCSD laboratory safety and monitoring environment. Of the survey respondents, 100% of committee members, 98% of PIs, and 96% of ASC provided a positive response that UCSD promotes a culture of safety within research and teaching laboratories. The campus has implemented additional measures to mitigate the risk of potential occurrences at UCSD and to evaluate and improve its laboratory safety practices. In addition, under the terms of the UC settlement agreement additional laboratory safety enhancements have been implemented within the department of Chemistry and Biochemistry.

IV. Observations and Management Corrective Actions

A. Laboratory Audit Program Process Improvements

AMAS identified additional improvements to increase the effectiveness of the Program.

The performance of laboratory safety audits by EH&S Research Assistance Program (RAP) Specialists (Specialist) and PI implementation of corrective actions for violations identified are a key control to ensure PI accountability of laboratory safety to UCSD and the UC Regents. As part of the *California Code of Regulations, Title 8, §3203, Injury an Illness Prevention Program*, every employer should establish, implement, and maintain an effective Injury and Illness Prevention Program (Program). The Program should include procedures for correcting unsafe or unhealthy conditions, work practices and work procedures in a timely manner based on the severity of the hazard.

The EH&S RAP team provides auditing services and laboratory safety and compliance support to researchers. Currently, the RAP team is composed of five Specialists who each have an expected target of completing approximately 20 laboratory safety audits per month. Specialist assignments are based on research facilities to increase relationships with laboratory representatives and to develop an understanding of the unique needs of each research facility.

Audit Frequency

Specialists interviewed during our review stated that each laboratory should undergo a safety audit two times per year. However, several Specialists also articulated an audit frequency schedule based on a laboratory classification system. The laboratory classification frequency schedule is presented in the table below.

Laboratory Class	Class Criteria	Class Audit Frequency
A	Laboratory contains radiation, is BSL 2+, has high hazard chemical use, or has a previous audit score of >20[1].	6 month audits
B	Laboratory is active with chemical use, biohazards, or laser use, but does not meet the criteria for an "A" laboratory.	12 month audits[2]
C	Laboratory is a low hazard location with compressed gases only or very few low hazard chemicals.	18 month audits[2]
D	Laboratory is a very low hazard, small laboratory or containing compressed gas cylinders.	24 month audits

Specialists have developed their own individual processes for identifying and scheduling audits to be conducted.

We compared laboratory audit scheduling and performance to laboratory classification audit frequency schedules and determined that individualized scheduling processes and inconsistent Specialist understanding of audit frequency schedules did not ensure that laboratory audits were conducted in accordance with the laboratory classification frequency policy. Also, the RAP website did not refer to the laboratory classification frequency, but a semi-annual audit frequency. Since the audit classification frequency schedule is based on safety risk, adherence to the schedule is necessary to provide evidence of the effectiveness of the Program and to provide assurance that the Program is meeting its objective. Standardization of RAP scheduling processes; RAP re-education and application of audit classification and frequency criteria; and modification of the audit frequency data on the RAP website should improve compliance with the Program classification schedules.

[1] The laboratory safety audit scoring system assigns 1, 4, or 16 points to violations, depending on severity. Points double for repeat violations. The audit scoring goal for all laboratories is zero points.
[2] If the laboratory has an audit score of 30 or greater, the audit frequency is adjusted to 6 month audits.

Follow Up Validation

Violations are items identified during a laboratory safety audit that are either of a recurring nature of non-compliance or are identified as an elevated risk of injury. PI written responses are requested for all violations and each Specialist has their own individual process to ensure that the follow up response is received. Validation of corrective actions is conducted by Specialists when they perform the next scheduled audit. In comparing audit scores from one audit to the next, we determined that audit scores did not consistently decrease in subsequent audits. This could be due to unresolved recurring violations. Individualized follow up processes, validation through subsequent scheduled audits, and reliance on PI violation responses did not provide timely assurance of corrective action implementation.

Timely validation of the implementation of corrective actions is necessary to ensure the ongoing safety of UCSD laboratories and to meet Program requirements. In a Citation and Notification of Penalty issued to a UC department in February 2010, the State of California Division of Occupational Safety and Health (OSHA) proposed an assessed penalty because the employer did not follow-up to ensure that corrective action was implemented in a timely manner. OSHA noted that the UC Program required correction of hazardous conditions within time frames up to 30 days; however, conditions remained uncorrected for six months or longer even though they had been recorded as corrected when the work order or request for action was initially issued. Establishing RAP follow up validation activities and standardizing follow up processes should assist in ensuring that the UCSD Program is timely and effective.

Program Oversight

EH&S management performs oversight of the Program in a number of ways, including the monitoring of laboratory safety trends semiannually for reporting to Deans and Department Chairs. In addition, queries are generated on an ad hoc basis to evaluate the effectiveness of audit scheduling conducted by Specialists. However, primary responsibility to ensure that the audits and follow up are conducted in accordance with departmental performance goals resides with the Specialists. Additional oversight by EH&S management to ensure that audits and follow up activities are conducted in accordance with departmental goals should improve the overall effectiveness of the Program.

Based on Specialist understanding that each area audit should be conducted two times per year, the current Specialist laboratory assignments, and the expected goal of 20 audits per month, we determined that the Specialists would not achieve departmental performance goals. However, improved compliance with the

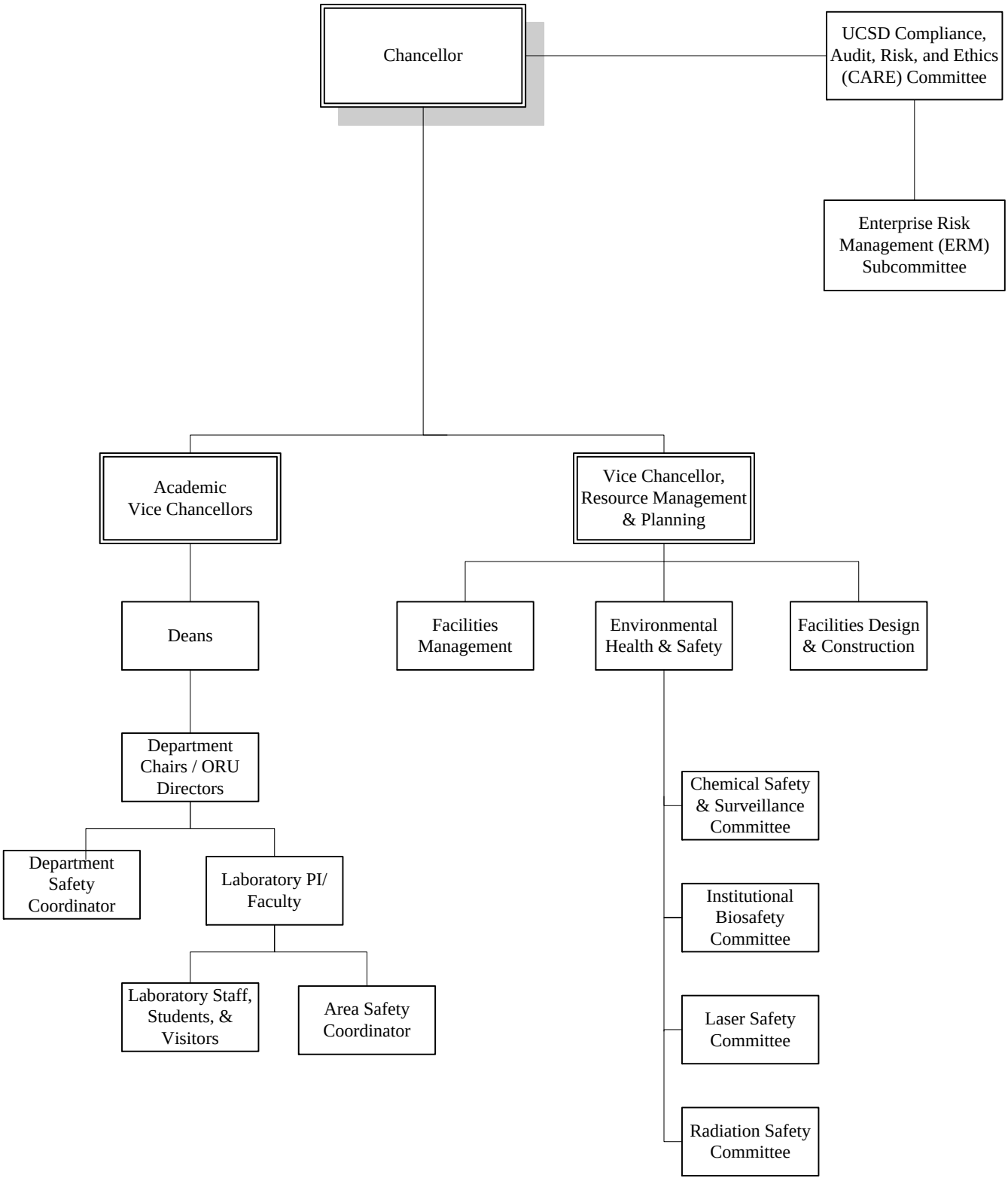
laboratory classification audit frequency schedule as described above may assist the Specialist achievement of this performance goal. Additional EH&S oversight of Specialist assignments and the application of classification audit frequency schedules could have identified these inconsistencies.

Management Corrective Actions:

EH&S management will:

- Standardize RAP audit scheduling and follow up processes;
- Provide re-education regarding the laboratory classification and audit frequency criteria in conjunction with the revised scheduling processes to ensure the consistent application of this criteria in the performance of laboratory audits;
- Update the RAP website for current laboratory classification and audit frequency criteria;
- Validate follow up actions for audits within a timely manner to ensure safety within the laboratories;
- Evaluate individual RAP audit assignments and laboratory audit schedules to ensure that audit assignments can be achieved in accordance with departmental goals and identify additional support if necessary; and
- Provide additional oversight to ensure that the audit scheduling and follow up actions are conducted in accordance with departmental goals.

Laboratory Safety – Phase II
Audit & Management Advisory Services Project 2013-57
UCSD Laboratory Safety Structure – Attachment 1



Compiled by AMAS

Laboratory Safety - Phase II
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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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Results of Committee Laboratory Safety Survey – Attachment 3

1. Select your committee		
CHEMICAL SAFETY AND SURVEILLANCE COMMITTEE	3	23%
INSTITUTIONAL BIOSAFETY COMMITTEE	4	31%
LASER SAFETY COMMITTEE	3	23%
RADIATION SAFETY COMMITTEE	3	23%
Total	13	100%

2. Select your type of appointment		
Faculty	9	69%
Staff	1	8%
Academic	1	8%
Community Representative	2	15%
Total	13	100%

3. Select the name of your Area/Department/Division/Program/Center		
BIOLOGY	1	8%
CHEMISTRY & BIOCHEMISTRY	1	8%
ENVIRONMENT, HEALTH & SAFETY	1	8%
MEDICINE	1	8%
NEUROSCIENCES	1	8%
OPTHALMOLOGY	1	8%
PATHOLOGY	1	8%
PHYSICS	2	15%
RADIOLOGY – SCHOOL OF MEDICINE	2	15%
COMMUNITY REPRESENTATIVE	2	15%
Total	13	100%

4. Laboratory Safety Environment

	Strongly Agree	Agree	Somewhat Agree	Somewhat Disagree	Disagree	Strongly Disagree	Does Not Apply	Don't Know
UCSD promotes a culture of safety within research and teaching laboratories.	7 54%	6 46%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%
UCSD laboratory practices are conducted in a safe and responsible manner to ensure the safety of students, academic appointees, staff, visitors, and surrounding committees.	4 31%	9 69%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%

	Strongly Agree	Agree	Somewhat Agree	Somewhat Disagree	Disagree	Strongly Disagree	Does Not Apply	Don't Know
The Principal Investigator (PI) has primary responsibility for safety within the laboratories.	10	3	0	0	0	0	0	0
	77%	23%	0%	0%	0%	0%	0%	0%
UCSD laboratories have the resources needed to ensure safety within the laboratory.	6	2	3	1	1	0	0	0
	46%	15%	23%	8%	8%	0%	0%	0%

5. Laboratory Safety Oversight

	Strongly Agree	Agree	Somewhat Agree	Somewhat Disagree	Disagree	Strongly Disagree	Does Not Apply	Don't Know
My committee monitors academic institution safety trends and evaluates UCDS policies based on those trends.	6	6	0	0	0	0	1	0
	46%	46%	0%	0%	0%	0%	8%	0%
My UCSD safety committee adequately performs all activities required to meet the committee charge.	8	3	2	0	0	0	0	0
	62%	23%	15%	0%	0%	0%	0%	0%
My committee reviews injury reports submitted by PIs.	7	5	1	0	0	0	0	0
	54%	38%	8%	0%	0%	0%	0%	0%
My committee reviews injury reports generated by EH&S on laboratory inspection results	7	4	1	0	0	0	0	0
	62%	31%	8%	0%	0%	0%	0%	0%
My committee prepares reports that are disseminated to UCSD management on a routine basis.	3	5	2	0	0	0	1	2
	23%	38%	15%	0%	0%	0%	8%	15%
My committee has the resources it needs to provide adequate oversight of laboratory safety.	6	3	2	2	0	0	0	0
	46%	23%	15%	15%	0%	0%	0%	0%

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Results of PI Laboratory Safety Survey – Attachment 4

1. Select the name of your Area/Department/Division/Program/Center		
CLIMATE, ATMOSPHERIC SCIENCE, AND PHYSICAL OCEANOGRAPHY	1	2%
CHEMISTRY & BIOCHEMISTRY	13	26%
GEOSCIENCES RESEARCH DIVISION	3	6%
INSTITUTE OF GEOPHYSICS AND PLANETARY PHYSICS	2	4%
MEDICINE	26	52%
OPTHALMOLOGY	2	4%
PHYSICS	3	6%
Total	50	100%

2. I am the PI for _____ laboratories.		
0	1	2%
1 – 4	48	96%
5 – 9	0	0%
10 or more	1	2%
Total	50	100%

3. My highest Biosafety Level (BSL) laboratory is a BSL _____ laboratory.		
1	4	8%
2	30	60%
2+	0	0%
3	0	0%
I don't know	5	10%
Does not apply	11	22%
Total	50	100%

4. The number of combined members for my UCSD laboratories is _____.		
0	1	2%
1 – 5	22	44%
6 – 10	20	40%
11 – 14	3	6%
15 +	4	8%
Total	50	100%

5. Laboratory Safety Environment								
	Strongly Agree	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Strongly Disagree**	**Does Not Apply**	**Don't Know**
UCSD promotes a culture of safety within research and teaching laboratories.	31 62%	16 32%	2 4%	1 2%	0 0%	0 0%	0 0%	0 0%
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 committees.	37 74%	10 20%	2 4%	0 0%	0 0%	0 0%	1 2%	0 0%
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 committees.	20 40%	18 36%	7 14%	0 0%	1 2%	0 0%	0 0%	4 8%
The Principal Investigator (PI) has primary responsibility for safety within the laboratories.	26 52%	16 32%	6 12%	1 2%	1 2%	0 0%	0 0%	0 0%
UCSD laboratories have the resources needed to ensure safety within the laboratories.	20 40%	14 28%	7 14%	5 10%	2 4%	2 4%	0 0%	0 0%

6. Operational Environment								
	Strongly Agree	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Strongly Disagree**	**Does Not Apply**	**Don't Know**
I understand the reporting requirements for all recordable occupational injury or illnesses as required by UCSD policy *PPM 516-18, Injury and Illness Investigations*, and 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.	13 26%	28 56%	6 12%	1 2%	2 4%	0 0%	0 0%	0 0%

Laboratory Safety – Phase II
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Results of ASC Laboratory Safety Survey – Attachment 5

1. Select the name of your Area/Department/Division/Program/Center		
CLIMATE, ATMOSPHERIC SCIENCE, AND PHYSICAL OCEANOGRAPHY	3	4%
CHEMISTRY & BIOCHEMISTRY	22	26%
GEOSCIENCES RESEARCH DIVISION	9	11%
INSTITUTE OF GEOPHYSICS AND PLANETARY PHYSICS	4	5%
MEDICINE	38	45%
OPTHALMOLOGY	5	6%
PHYSICS	4	5%
Total	85	100%

2. I am the ASC for _____ laboratories.		
0	4	5%
1 – 4	77	91%
5 – 9	1	1%
10 or more	3	4%
Total	85	100%

3. My highest Biosafety Level (BSL) laboratory is a BSL _____ laboratory.		
1	4	5%
2	43	51%
2+	0	0%
3	3	4%
I don't know	2	2%
Does not apply	33	39%
Total	85	100%

4. Select your appointment type.		
Faculty	5	6%
Staff	64	75%
Student	15	18%
Declined Response	1	1%
Total	85	100%

5. The number of combined members for my UCSD laboratories is _____.		
0	1	1%
1 – 5	35	41%
6 – 10	24	28%
11 – 14	15	18%
15 +	10	12%
Total	85	100%

6. Laboratory Safety Environment								
	Strongly Agree	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Strongly Disagree**	**Does Not Apply**	**Don't Know**
UCSD promotes a culture of safety within research and teaching laboratories.	37 44%	35 41%	9 11%	1 1%	2 2%	1 1%	0 0%	0 0%
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 committees.	33 39%	47 55%	3 4%	1 1%	1 1%	0 0%	0 0%	0 0%
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 committees.	20 24%	39 46%	12 14%	1 1%	1 1%	0 0%	0 0%	11 13%
The Principal Investigator (PI) has primary responsibility for safety within the laboratories.	31 37%	39 46%	11 13%	0 0%	2 2%	1 1%	0 0%	0 0%
UCSD laboratories have the resources needed to ensure safety within the laboratories.	25 29%	41 48%	15 18%	2 2%	1 1%	0 0%	0 0%	1 1%

6. Operational Environment								
	Strongly Agree	**Agree**	**Somewhat Agree**	**Somewhat Disagree**	**Disagree**	**Strongly Disagree**	**Does Not Apply**	**Don't Know**
I have the authority needed in the area to address matters of safety.	29 34%	36 42%	12 14%	2 2%	5 6%	0 0%	1 1%	0 0%
I understand the reporting requirements for all recordable occupational injury or illnesses as required by UCSD policy *PPM 516-18, Injury and Illness Investigations*, and 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.	20 24%	37 44%	15 18%	1 1%	2 2%	0 0%	3 4%	7 8%