Lab Safety

Audit Report No. R2405 | *February 1, 2024*

Executive Summary

Audit Objective

To provide assurance that UTD has an effective compliance program over lab safety that ensures compliance with federal and other regulations related to lab safety.

Controls and Strengths

- Specialists rotate labs every two years which encourages a diverse skill set, different perspectives, and helps to avoid burnout.
- Performance Evaluations, a form of inspections, are conducted with two specialists which help reduce bias and increase reliability.
- There is an emphasis on a culture of safety, including good communication within the safety functions.
- ChemTracker and bar coding are used for additional tracking and inventory of chemicals.
- The Atlas ticketing system is used for waste management.
- Automation and strong controls are in place over the Lab Coat Program Management which reduces safety risks.
- A step-by-step guide for BioRaft and other programs are used to help specialists know exactly how to operate programs.
- A flowchart and checklist are used which assists in clarity and standardization of the close out process.

Overall Conclusion

UT Dallas has processes in place to ensure compliance with federal and other regulations over lab safety; however, processes can be improved that will enhance the overall effectiveness of the lab safety compliance program.

Observations by Risk Level

Management has reviewed the observations and has provided responses and anticipated implementation dates. Detailed information is included in the attached report.

Observation	Risk Level	Management's Implementation Date
1. Risk Management Plan and Quarterly Compliance Reporting	**High**	September 1, 2024
2. Appointment of the Institutional Biosafety and Chemical Committee (IBCC)	**Medium**	March 1, 2024
3. Chemical Tracking and Training	**Medium**	September 1, 2024
4. Lab Close Out Process	**Low**	June 1, 2024
5. Policies and Written Procedures	**Low**	May 1, 2024

For details about the audit and methodology, explanation of risk levels, and report distribution, please see Appendices A, B, and C, respectively, in the attached report.

Detailed Audit Results

Observation	Risk Level/Effect	Recommendation[1]
1. ***Risk Management Plan and Quarterly Compliance Reporting***		***High***
Risk management plans (RMP) are designed to document a compliance program's monitoring, training, and reporting procedures that help ensure instances of noncompliance with applicable regulations[2] are minimized. Each quarter, the responsible party submits a report to the Office of Institutional Compliance, Equity, and Title IX Initiatives that documents the results of the monitoring, training, and reporting procedures listed on the RMP. The RMP for Lab Safety falls under the leadership of the Office of Institutional Risk and Safety, led by the Senior Director who is considered the responsible party for the compliance program. In reviewing the lab safety program, we found many strengths; however, the following opportunities exist to strengthen the risk management plan and quarterly compliance reports. • Though the RMP contains strong operating controls, monitoring procedures that would be performed by	As outlined in the risk management plan, an ineffective compliance program could result in the following: "*Risk of injury or illness to campus community members and/or damage to university property due to lack of safety training, inadequate safety or health control measures and protection practices and/or deficiencies in maintenance/operation of campus equipment and/or infrastructure. Failure to address these risks could result in fines and/or loss of funding for non-compliance with Federal and/or State regulations*."	Management should update the risk management plan to include the monitoring procedures, ensure appropriate approvals are documented, and create monitoring, training, and reporting procedures for the Academic Lab Safety Program.

[1] See Appendix B on page 13 for definitions of observation risk rankings. Minimal risk observations were communicated to management separately.
[2] Applicable regulations are included in the Risk Management Plan for Research, Academic, and Campus Safety and include federal, state, and UT System regulations and policies.

Observation	Risk Level/Effect	Recommendation[1]
the responsible party are not documented. Monitoring is the process of checking the progress or quality of something over a period. Currently, the documented monitoring procedures are counts of items performed that are more related to operating controls. • The report is not approved by a Vice President. • For instances of noncompliance, there is no description of what was done to resolve the instance and no status of follow-up. • Instances of noncompliance that are not resolved within 60 days are not tracked or followed up on to ensure appropriate measures were implemented. • There are no repercussions or enforcement measures in place for instances of noncompliance. • The training section of the quarterly compliance report is not filled out, and this area should be used for tracking training and certifications of the safety specialists. • External reviews are not always noted in the report. In October of FY23 there was an external review that was not noted in the quarterly compliance report.		

Observation	Risk Level/Effect	Recommendation[1]
In addition, monitoring for the Academic Safety Program should be created. This program is moving towards a risk mitigation protocol where not all areas are inspected. Instead, the risk mitigation approach will focus on empowerment, outreach, and education. While this approach will be helpful, inspections are an important part of ensuring a safe environment. Some design spaces and electrical/mechanical areas are now bringing in chemicals, and the space is not designed to handle chemicals. When chemicals are added to spaces that are not equipped to handle chemicals, the risk of injury is increased. Also, without proper monitoring or training from the Academic Lab Safety team, there is a higher opportunity for mishandling. Because of this, not all academic safety areas are currently identified. Other areas of concern include education and research dual use area spaces, maker spaces, studio spaces and theater spaces. Due to the nature of these spaces, there is an increased risk for injury and misuse.		

Observation	Risk Level/Effect	Recommendation[1]
Management's Action Plan: OIRSP will update the quarterly reporting to reflect the specific issues and the recommendations for identification, resolution and follow-up. The OIRSP Academic laboratory operations have evolved with the growing needs of academic programs and will continue to evolve, including the addition of new spaces and activities that carry innate hazard and risk, e.g., maker spaces. The laboratory safety RMP will be updated to reflect these changes and will include recommendations related to the research findings. The chemical issues identified above will be included in the response for item #3, *Chemical Tracking and Training.* **Responsible Party Name and Title:** Shane Solis, Sr. Director, Paula Tate, Associate Director **Estimated Date of Implementation:** Academic programs RMP/Q Reports: September 1, 2024		
2. ***Appointment of the IBCC***		***Medium***
The Institutional Biosafety and Chemical Committee (IBCC) does not have the appropriate committee appointments. National Institutes of Health (NIH) guidelines require there to be one plant expert and one animal expert on the committee. Currently, there is only an animal expert on the committee.	Without appropriate members appointed to the IBCC, the committee is not in compliance with NIH guidelines.	Ensure compliance with NIH guidelines by including a plant expert on the IBCC.
Management's Action Plan: After a further review of the NIH guidelines (pp. 30 - 31, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf), the following guidance addresses this topic: ***"Section IV-B-4. Plant, Plant Pathogen, or Plant Pest Containment Expert***		

Observation	Risk Level/Effect	Recommendation[1]
When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with Appendix L, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants, the institution shall appoint at least one individual with expertise in plant, plant pathogen, or plant pest containment principles (who is a member of the Institutional Biosafety Committee). ***Section IV-B-5. Animal Containment Expert*** *When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with Appendix M, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals, the institution shall appoint at least one individual with expertise in animal containment principles (who is a member of the Institutional Biosafety Committee)."* Based on these guidelines, UT Dallas requires animal and plant experts only when experiments requiring IBCC approval are required for experiments using these materials/organisms. The IBCC member assignments regularly include faculty with animal expertise. However, UT Dallas has limited rDNA plant-based research, and thus, there are limited faculty researchers with foci/expertise in rDNA with plants. If IBCC membership expertise is required for these areas, the IBCC will seek internal or external expert(s) in these fields for protocol reviews that require the specific expertise. OIRSO will also make clear to the Committee on Committees that that faculty members with this expertise are specifically sought for IBCC Committee membership. Policy UTDPP1016 (*Biosafety Committee*) will be updated to reflect these guidelines (see #5). **Responsible Party Name and Title:** Shane Solis, Sr. Director, Paula Tate, Associate Director, Stacey Gregersen, Biosafety Officer (BSO) **Estimated Date of Implementation:** March 1, 2024		
3. ***Chemical Tracking and Training***		***Medium***
Across campus there is not a consistent method for chemical tracking, training, and handling. Every building or department has an employee who is charged with the	Without consistent safety measures in place, there is an increased risk of accidents and injuries, legal implications, and reputational damages.	Create consistent safety guidelines and procedures for safety offices across campus and periodically monitor compliance.

Observation	Risk Level/Effect	Recommendation[1]
tracking, training, handling, and monitoring of chemicals within their area. The employees charged with this do not follow the same set policies, standards, or guidance. There is no communication between these parties to understand and know what the other areas are doing.		
Management's Action Plan: Growth on campus continues to expand the physical loci of chemical receipt, use and storage. As recommended, OIRSP will update operational procedures and guidelines, training procedures and monitoring program for handling chemicals, gases and hazardous materials consistently across campus buildings. **Responsible Party Name and Title:** Shane Solis, Sr. Director, Paula Tate, Associate Director **Estimated Date of Implementation:** September 1, 2024		
4. ***Lab Close Out Process***		***Low***
There are good procedures and resources in place for faculty to use when a lab is closed. However, faculty members often leave the university without cleaning their labs and without informing the Office of Institutional Risk and Safety in a timely manner. This leaves the administrative staff, students, and the Office of Institutional Risk and Safety team to clean the space for the next employee to use the lab.	Labs that are not properly cleaned upon closing by the responsible faculty could result not only in inefficiencies but could also result in noncompliant cleaning measures, disposal methods, and injury.	The Office of Institutional Risk and Safety should work with the Provost's Office for notification when faculty members leave the university to ensure timely and safe lab close outs.

Observation	Risk Level/Effect	Recommendation[1]
Management's Action Plan: The timely and proper facilitation and coordination of laboratory closeouts is dependent upon clear and timely communication from the Provost's Office and departing faculty member's department. To address this, OIRSP will coordinate with the Provost Office and the Departments to facilitate the closeout of faculty labs. Once the Provost Office/Department have initiated the process (formal notification has occurred with faculty and to OIRSP), OIRSP will provide a checklist/guidance document to the lab and will support the lab until the time of move out. Once the faculty vacates the space, OIRSP will coordinate the removal of waste, materials and surplus equipment and facilitate decontamination with an external vendor. Once decontamination is completed, the space will be available for occupancy. A formal timeline and guidance document will be delivered to and agreed upon by the Provost's office and the Department. **Responsible Party Name and Title:** Shane Solis, Sr. Director, Paula Tate, Associate Director **Estimated Date of Implementation:** Timeline development finalized with stakeholders: April 1, 2024; Process implemented: June 1, 2024		
5. ***Policies and Written Procedures***		***Low***
The following procedures are not up to date: • UTDPP1016, Biosafety Committee, lists the 2016 version of the NIH guidelines; however, the most current NIH guidelines are from 2019. • UTDPP1042, Management of Controlled Substances, is not in line with current procedures and titles. • The Job Aid for Safey Performance Evaluations (SPE) states, "Conduct physical safety performance evaluation," but does not document how to conduct a SPE. Without details on how to conduct SPEs, a safety specialist may miss instances of noncompliance. Also,	Outdated policies and procedures could result in employees not knowing the proper procedure or protocol which could result in noncompliance, inefficiency, and error.	Update existing policies and procedures develop procedures for reviewing and updating in the future.

Observation	Risk Level/Effect	Recommendation[1]
policies that govern lab safety are not mentioned in the procedures.		

Management's Action Plan:
OIRSP will update these policies and submit them to the HOP. Policies will be reviewed on an annual basis based on the fiscal year schedule (September) or when updates from the governing agencies occur.

OIRSP will develop a detailed job procedure guide for conducting Safey Performance Evaluations (SPEs), including references to applicable policies. Laboratory Safety management will ensure that Safety Specialists who perform SPEs are trained to properly reference and apply the SPE guidance.

Responsible Party Name and Title:
Shane Solis, Sr. Director, Paula Tate, Associate Director, Stacey Gregersen, Biosafety Officer (BSO) - Policies

Estimated Date of Implementation:
Policy updates submitted to HOP: April 1, 2024; SPE Job Guide Completed: May 1, 2024.

Overall Conclusion

UT Dallas has processes in place to ensure compliance with federal and other regulations over lab safety; however, processes can be improved that will enhance the overall effectiveness of the lab safety compliance program.

Appendix A: Information Related to the Audit

Background

Under the direction of the University Chief Compliance Officer and Vice President and Chief of Staff, the Office of Institutional Risk and Safety Programs (OIRSP) is responsible for risk and safety programs that include the safety of university labs. Their program is described at their website at https://risk-safety.utdallas.edu/. The OIRSP oversees the safety of over 200 research labs and countless academic safety areas.

The FY23 Lab Safety Risk Management Plan lists the following risks of noncompliance, and controls to mitigate these risks are included in the plan:

- *Failure to identify unsafe research or academic laboratory conditions and/or failure to adequately identify/secure hazardous material, equipment, and/or controlled substances.*
- *Unauthorized Laboratory Access.*
- *Failure to inform individuals of the hazards in the workplace and/or failure to train individuals to appropriately manage hazards.*
- *Failure to identify new faculty members, laboratories and / or research staff.*
- *Unapproved purchase or shipment of controlled, regulated, or highly hazardous materials.*
- *Failure to identify unsafe occupational exposure to physical conditions and/or failure to adequately assess occupational health exposures.*
- *Recurring/unaddressed hazards – failure to perform post-incident assessment following receipt of occupational injury, occupational illness, or near-miss reports.*

Objective

To provide assurance that UTD has an effective compliance program over lab safety that ensures compliance with federal and other regulations related to lab safety.

Scope

The scope of the audit was fiscal year 2023. Fieldwork began in August 2023, and the audit concluded on November 27, 2023.

Methodology

The audit was conducted in conformance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*. Additionally, we conducted the audit in accordance with generally accepted government auditing standards (GAGAS). Both standards are required by the Texas Internal Auditing Act, and they require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. The Office of Audit and Consulting Services is independent per both standards for internal auditors.

GAGAS also requires that auditors assess internal control when it is significant to the audit objectives. We used the Committee of Sponsoring Organizations of the Treadway Commission (COSO) framework in assessing internal controls[3].

Our audit methodology included interviews, observations of processes, reviews of documentation, and testing. The following table outlines our audit procedures and overall controls assessment for each of the audit area objectives performed.

Audit Area	Methodology	Observations Related to the Audit Area
Lab Safety	• Gained an understanding of the compliance program by reviewing federal, state, and UT System regulations, the related UT Dallas policies, and internal procedures. • Interviewed various responsible parties within the Office of Institutional Risk and Safety Programs.	#2, #3, #4, #5

[3] http://www.coso.org

Audit Area	Methodology	Observations Related to the Audit Area
Risk Management Plan	Reviewed and evaluated the Risk Management Plan to ensure that a plan exists that will ensure compliance with federal and other regulations over lab safety.	#1
Quarterly Compliance Report	Reviewed the quarterly compliance report to ensure the monitoring procedures, training procedures and reporting procedures were performed as outlined in the risk management plan.	#1

Follow-up Procedures

Though management is responsible for implementing the course of action outlined in the response, we will follow up on the status of implementation subsequent to the anticipated implementation dates. Requests for extension to the implementation dates may require approval from the UT Dallas Audit Committee. This process will help enhance accountability and ensure that timely action is taken to address the observations.

Appendix B: Observation Risk Rankings

Audit observations are ranked according to the following definitions, consistent with UT System Audit Office guidance.

Risk Level	Definition
Priority	If not addressed immediately, a priority observation has a significant probability to directly impact the achievement of a strategic or important operational objective of UT Dallas or the UT System as a whole. These observations are reported to and tracked by the UT System Audit, Compliance, and Risk Management Committee (ACRMC).
High	High-risk observations are considered to be substantially undesirable and pose a high probability of adverse effects to UT Dallas either as a whole or to a division/school/department level.
Medium	Medium-risk observations are considered to have a moderate probability of adverse effects to UT Dallas either as a whole or to a division/school/department level.
Low	Low-risk observations are considered to have a low probability of adverse effects to UT Dallas either as a whole or to a division/school/department level.
Minimal	Some recommendations made during an audit are considered of minimal risk, and the observations are verbally shared with management during the audit or at the concluding meeting.

Appendix C: Report Submission and Distribution

We thank the Office of Institutional Risk and Safety Program management and staff for their support, courtesy, and cooperation provided throughout this audit.

Respectfully Submitted,

DocuSigned by:
Toni Stephens
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Toni Stephens, CPA, CIA, CRMA, Chief Audit Executive

Distribution List

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- Mr. Shane Solis, Senior Director, Office of Institutional Risk and Safety Programs
- Ms. Paula Tate, Associate Director
- Ms. Stacey Gregersen, Biosafety Officer (BSO)

Other Interested Parties

Ms. Sanaz Okhovat, Chief Compliance Officer and Associate Vice President for Research and Innovation

External Parties

- The University of Texas System Audit Office
- Legislative Budget Board
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- State Auditor's Office

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