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May 28, 2015

Dr. David Daniel, President,
Ms. Lisa Choate, Chair of the Institutional Audit Committee:

We have completed an audit of Lab Safety as part of our fiscal year 2014 Audit Plan, and the report is attached for your review. The audit was conducted in accordance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*. The objectives of the audit were to provide assurance that the Lab Safety compliance program is operating effectively and that UT Dallas is in compliance with certain Lab Safety regulations.

Overall, we found that improvements are needed to ensure that the Lab Safety compliance program is operating effectively and that UT Dallas is in compliance with Lab Safety regulations. The attached report details recommendations to improve lab inspections, staffing, safety, and policies and procedures.

Management has reviewed the recommendations and has provided responses and anticipated implementation dates. 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. We appreciate the courtesies and considerations extended to us during our engagement. Please let me know if you have any questions or comments regarding this audit.

Toni Stephens
Institutional Chief Audit Executive

UT Dallas Responsible Parties:
Dr. James Wright, Assistant VP for Environmental Health and Safety
Rafael Martin, Associate VP for Research

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Executive Summary

Lab Safety, Report No. 1516

Audit Objective and Scope: To provide assurance that the Lab Safety compliance program is operating effectively and that UT Dallas is in compliance with certain Lab Safety regulations.

The following is a summary of the audit recommendations by priority and risk type. See Appendix A for additional details.

High (0)	High/Medium (3)	Medium(1)	Low(0)

Recommendation	Priority and Risk Type	Estimated Implementation Date
(1) *Improve the Inspection Process for Labs*	**Life Safety**	June 30, 2015
(2) *Enhance Safety Compliance within Labs*	**Life Safety**	December 1, 2015
(3) *Designate and Define Responsibilities*	**Management Oversight**	June 30, 2015
(4) *Update Policies and Procedures*	**Management Oversight**	November 1, 2015

Responsible Vice Presidents: Dr. Calvin Jamison, VP Administration; Dr. Bruce Gnade, VP Research

Responsible Parties: Dr. James Wright, AVP Environmental Health & Safety; Rafael Martin, AVP Research

Staff Assigned to Audit: Project Leader: Polly Atchison, CPA, CIA, Audit Manager; Staff: Ashley Mathew, Staff Auditor; Student Interns: Sarah Carraher and Deborah Farrell

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Background

The risk management plan for lab safety at UT Dallas designates the Office of Environmental Health and Safety (EH&S), reporting to the Vice President for Administration, as the responsible office at UT Dallas to ensure compliance with lab safety regulations. Currently, lab safety is managed in EH&S by a Safety Technician. In addition, responsibilities for lab safety were recently added in the Research Compliance Office that reports under the Office of the Vice President for Research.

UT Dallas currently has about 215 lab spaces on campus and uses the BioRAFT system to register labs, register and assign staff to labs, deliver training to all registered lab personnel and communicate results of lab inspections with the Principal Investigators (PIs). EH&S and the Office of Research also use this system to monitor training and the issues noted in inspections. Lab safety guidelines and assistance for the campus are located at http://www.utdallas.edu/ehs/labsafety/.

Numerous federal and state regulations exist governing lab safety. Noncompliance with federal and state regulations could result not only in loss of funding and substantial fines to the University, but also injuries, illness, or death to members of the campus community. Lab safety is considered a high-risk area under the UT Dallas institutional compliance program, and a risk management plan was put in place to minimize risks and ensure compliance with federal and state regulations.

UTS 174, *Environmental Health and Safety,* outlines responsibilities and procedures for environmental health and safety programs, including lab safety, throughout the UT System. Each institution is responsible for providing resources sufficient to managing the risks. OSHA laws and regulations outline the responsibilities and standards for hazard communication, chemical hygiene in laboratories, regular inspections of laboratories and safety standards in the workplace. Also, EPA regulations give guidance for the containment, storage and disposal of the hazardous waste generated by the UT Dallas labs.

UT Dallas also has nine lab safety related manuals (Biological Safety, Blood borne Pathogens, Controlled Items, Controlled Substances, Lab Safety Inspections, Lab Space Review, Laser Safety, Radiation Safety, Lab Close Out / Relocation Guidelines) on their website. These manuals provide direction to both the EH&S inspectors and the lab personnel.

Audit Objective

To provide assurance that the Lab Safety compliance program is operating effectively and that UT Dallas is in compliance with certain Lab Safety regulations.

Scope and Methodology

The scope of this audit was fiscal years 2013 and 2014, and our fieldwork concluded on August 20, 2014. To satisfy our objectives, we performed the following:

- Gained an understanding of lab safety operations on campus.
- Reviewed applicable federal, state, and university policies and procedures regarding Lab Safety.
- Reviewed the University's Lab Safety Risk Management Plan.
- Determined if UT Dallas was in compliance with UT System requirements, UT Dallas policies and procedures, and other regulations regarding lab inspections, training, and safety.
- Ensured that lab access was restricted to authorized personnel and properly secured.
- Determined if the hazardous inventory management process was adequate to ensure compliance with applicable safety regulations.
- Determined if training was being conducted and that records were properly maintained to evidence compliance.
- Determined if lab inspections were being conducted and follow ups were performed.

Where applicable, we conducted our examination in accordance with the guidelines set forth in The Institute of Internal Auditor's *International Standards for the Professional Practice of Internal Auditing*. The *Standards* set criteria for internal audit departments in the areas of independence, professional proficiency, scope and performance or audit work, and management of the internal auditing department.

Audit Results and Management's Responses

Controls
Our audit work indicated that the following controls currently exist:

- A Risk Management Plan for lab safety has been documented and contains monitoring, training, and reporting procedures designed to reduce instances of noncompliance.

Audit Recommendations

Although the above controls are in place, opportunities exist to improve compliance with regulations and the effectiveness over lab safety operations.

Priority Findings – UT System

A UT System priority finding is defined by the UT System Audit Office as: "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"[1]

We have **no UT System Priority Findings** resulting from this audit.

Reportable Audit Recommendations

See Appendix A[1] for the Priority Findings and Risk Matrix defining the various risk factors and risk levels for each audit recommendation.

(1) *Improve the Inspection Process for Labs*
Risk Factor: Life Safety; **Risk Rating: High/Medium**★

Lab inspections are conducted annually, or as requested, using a checklist, following the OSHA Lab Standard (29 CFR 1910.1450). OSHA requires "regular inspections of the laboratories, preparations rooms, and chemical storage rooms" and requires "detailed laboratory inspection reports to administration." A lab safety program "should include an appropriate combination of routine inspections, self-audits, program audits, peer inspections, EHS inspections, and inspections by external entities." Without regular inspections and follow-ups to ensure corrective action is taken, issues could linger and unsafe conditions go undetected. This could lead to an incident and cause the university to be potentially fined or even lose research grants and impact the overall reputation of UT Dallas.

We reviewed the lab inspection and follow-up process and noted the following opportunities to improve the inspection process:

- There is no formal annual risk assessment process in place for lab inspections. The annual inspection plan is designed to require that all low risk labs are inspected at least once per year, medium risk labs are inspected twice per year and high risk labs are inspected quarterly. Due to staffing pressures, risks were not being evaluated for each lab, and the listing of principal investigators was not being verified. Instead, lab inspections were being done as staffing permitted.

- Staffing does not appear to be adequate to ensure inspections can be sufficiently performed. Using the formula developed by UT Houston that is considered a best practice, the model suggests 6.5 personnel should be dedicated to the Lab Safety Program at UT Dallas. Currently, UT Dallas has

[1] Appendix A defines the priority and risk ranking used for all internal audit recommendations.

four employees dedicated to lab safety, and an Environmental Manager position was open at the time of our audit.

- Inspectors do not verify the existence of lab inventory listings or the lab's inventory process when conducting inspections.

- In comparing the list of PIs in BioRAFT against the list of PIs the EH&S lab safety inspector uses for inspection planning, the names did not match on both lists. In addition, the lists contained employees that no longer worked at the University. This results from EH&S not being involved in the closeout process with Human Resources when a PI terminates employment. There is a policy available on the EH&S website, but it is not always followed. The link for the "Check Sheet for Vacating Room" is not active and the checklist for terminating PIs is not available online.

- We reviewed all available Chemical Inventory Verification Surveys and Controlled Substances Inspection Reports. At the time of our audit, there were six Chemical Inventory and three Controlled Substances Inspection reports. There were no reports for FY13. Lab inspectors were not verifying lab inventory lists (chemical, biological or radioactive material) for existence, sufficiency or validity during normal inspections. Lab Inspectors should perform spot checks of inventory and, if applicable, controlled substances during every lab inspection. If there are any issues, it should be noted in the BioRAFT lab inspection report. During normally scheduled inspections, the inspector should verify the inventory process for that lab and review a copy of the inventory listing so EH&S could maintain an accurate updated inventory for the University's labs.

- Lab inspection reports are designed to give the PI meaningful feedback on their lab and if there are issues, the notes should be detailed enough to help the PI resolve the issue. We reviewed all lab inspection reports within BioRAFT and noted the following.

  We found that when lab inspections are performed, a rating system is used and some inspections have comments as to issues noted. However, the rating system is not currently defined but instead consists of a one through five star rating, with five being the highest level to achieve. The rating system used seems inconsistent, and rankings do not seem consistent in terms of the nature or number of violations. For example:
  - o We reviewed all lab inspection reports within BioRAFT and noted that 49% of the reports contained no issues or corrective actions, but they were rated less than a five. Two were given a five star rating but had delinquencies noted.
  - o In the reports with issues noted, 34% had no notes or pictures to explain the specifics or nature of the violation observed by the lab inspector.

- Five percent (5%) of the reports had details regarding a violation; however, the issue was never categorized within BioRAFT.

Also, inspectors are not reviewing lab specific training logs and do not adequately note training deficiencies found in BioRAFT or in lab specific training logs for the inspected lab. Fifty percent (50%) of the lab inspections we reviewed did not note the delinquent BioRAFT training for members of the inspected lab.

- Using the BioRAFT rosters and inspection schedule, approximately 70% of the labs were being inspected at the time of our audit. Also, follow-ups were not being conducted on all inspected labs that had issues.

Recommendation: The inspection process should be reviewed and improvements should be made to ensure all labs receive a regular inspection. The process should be based on an appropriate risk assessment, and adequate staffing should be in place. Inspections should have clearly defined and complete written procedures, the listing of labs and PIs should be accurate and up-to-date, and subsequent follow-up of all issues noted should be performed.

Management's Response:
The following operations were established after completion of this audit (August 20, 2014), thus are not included in this report.

To strengthen Environmental Health & Safety functions, the Office of Research of Compliance (ORC) established Laboratory Safety operations with the objective to provide a direct lab safety presence to the Natural Science and Engineering Research Laboratory (NSERL) and the upcoming Bioengineering and Science Building (BSB). The increased oversight over research operations included the appointment of additional staff, which included an Assistant Director, a Lab Safety Manager, and two Safety Support Specialists positions. Kathy White accepted the Lab Safety Manager position and acts as the senior technical safety officer for NSERL. The Safety Specialist positions were established to be the primary in-lab support personnel to the research laboratories. The Safety Specialists are also responsible for inspections of NSERL laboratories. The expansion of ORC laboratory support is discussed in further detail in the Management Response to the third item of this Audit.

Currently, ORC is conducting risk level assessments of NSERL laboratories, including detailed Laboratory Hazard Assessments (LHAT) completed by each Principal Investigator. This data will provide the foundation for identifying the appropriate inspection schedule and risk procedures of the Safety Specialists. Data will be stored and accessible in the BioRAFT lab management system within the next 60 days. As a long term solution for LHAT's, UTD participated in a user consortium with BioRAFT in the fall of 2014, which included participation by other university BioRAFT customers. The goal of the consortium was to develop an enhanced the LHAT module on the BioRAFT platform to systematically create and organize lab risk based on in-lab hazards on a per lab basis. This module is intended to become the standard for lab

hazard assessment and lab risk identification and is scheduled for release in summer 2015 (date TBA). All campus labs will be required to have a current LHAT in the BioRAFT system, updated at least annually or if there is a significant change in risk. The BioRAFT system will ensure systematic and timely updates of lab hazards, which will be accessible for audit and monitoring.

The following outlines ORC's and EH&S's strategy to address deficiencies in laboratory inspections noted in this audit:

- *All labs will have regular inspections based on assessed risk; inspection records including dates, findings, and follow-up actions will be documented and available in the BioRAFT system.*
- *Safety Specialists will have direct lab assignments and will be responsible for the timely completion of inspections and follow-up for their assigned labs. The proposed staffing level increase will support these objectives. The Lab Safety Manager will monitor the completion of these tasks.*
- *All labs will receive at least one formal annual inspection and up to quarterly inspections for higher risk labs.*
- *The current inspection process and documentation process will be documented and published.*
- *Safety Specialists will complete inspection training and inspections will be documented in BioRAFT.*
- *Follow-up will be tracked in BioRAFT and monitored by the Lab Safety Manager.*
- *The Office of Research Compliance will work with the Office of Administration to develop a process for identifying new laboratories on campus.*

As a note, BioRAFT was purchased and implemented for, among many things, the ability to unify and automate critical lab safety information to establish efficiency within the program and to better support our research community. BioRAFT has the ability to allow lab safety staff to document and track all activities related to lab safety. This system will serve as the system of record for all ongoing activities and will be accessible for inspection and audit reporting as necessary.

Estimated Date of Implementation: *Baseline audit schedule and assignment for campus by 4/1/15 (to be addressed in the Management Response to the third item)*

Person Responsible for Implementation: *Rafael Martin, Associate Vice President for Research*

(2) ***Enhance Safety Compliance within Labs***
Risk Factor: Life Safety; **Risk Rating:** High/Medium★

We reviewed the hazardous inventory management process and safety compliance process for labs and found the following:

- EH&S does not have a current and accurate listing of chemical inventories or hazards in UT Dallas Labs. At the time of our audit, EH&S had chemical inventory lists for only 25% of the PIs. No process exists for updating or maintaining the chemical inventory lists.

- The last Hazard Communication Survey was sent out in FY12, and only about 39% of the PIs responded. No survey has been conducted since.

- The US Department of Transportation (DOT) hazardous material transport regulations (49 CFR) requires training of all hazmat employees, and refreshers are required every three years. The International Air Transport Association (IATA) requires those that ship hazardous materials by air to complete training every two years. At the time of our audit, the receiving department had not scheduled training for all of its employees. Without proper DOT and IATA training, employees handling hazardous materials are noncompliant. This could lead to injury or accidents due to inadequate training. Also, it could leave the University without a certified employee to handle hazardous waste shipping.

- During a visit to one of the larger labs, we noticed that a majority of the researchers did not wear full protective gear and often were missing lab coats or safety glasses.

- Internal Audit conducted an anonymous survey of research lab personnel and noted opportunities to improve communication and compliance with safety issues. The results of the survey were shared with EH&S and the Office of Research Compliance to ensure that the concerns of research lab personnel were addressed.

Without appropriate safety measures in place over chemical inventories, training, and communication regarding safety, the University is at risk of injuries, death, fines, and loss of research funding.

Recommendation: The hazardous inventory management process should be improved by ensuring inventories are continuously updated in a timely manner. The safety compliance process for labs should be improved to ensure adequate training and communication.

Management's Response:
UT Dallas has purchased Chemtracker chemical inventory management software development and supported by Stanford University (http://chemtracker.stanford.edu/). Chemtracker is a robust chemical management software and chemical barcoding system that will assist in tracking and maintaining hazardous materials across campus. Full implementation of Chemtracker will require appx. 120 – 180 days and require additional temporary staff for initial barcoding and documenting of current campus inventories. This software will assist ORC lab safety support staff to track and enforce the timely completion of chemical inventories. Because the Chemtracker system includes barcoding features, chemicals can be assessed on a more real-time basis and help to mitigate some risks or uncertainties inherent in once-a-year inventories. ORC will pilot Chemtracker in NSERL in partnership with EH&S and central receiving to establish best practices in preparation for extension of the system campus-wide by 12/1/15.

To address immediate deficiencies in hazard assessment, a campus-wide chemical inventory update request is scheduled to be disseminated to all campus labs within the next 7 – 10 days. The data returned from campus labs will be formatted for upload in Chemtracker and provide the baseline inventories. The Lab Hazard Assessment discussed above will include a response from ORC regarding the appropriate PPE for hazards in the labs. Research Safety Specialists and Environmental Health and Safety staff will assist in the identification of and compliance with the appropriate PPE for each lab. Additional training materials will be provided to lab personnel within the next 60 days.

Estimated Date of Implementation: *Campus implementation of chemical management systems by 12/1/15*

Person Responsible for Implementation: *Rafael Martin, Associate Vice President for Research*

(3) ***Designate and Define Responsibilities***
Risk Factor: Management Oversight; **Risk Rating:** High/Medium★

Because Lab Safety is designated as a high-risk area at UT Dallas, a Risk Management Plan has been developed. The plan documents the risks and regulations associated with lab safety and detail the monitoring, training, and reporting processes in place to minimize the risks. The responsible person listed on the plan is the Director of Emergency Management within EH&S; however, the monitoring and training procedures outlined in the plan document both EH&S and Research Compliance staff performing duties related to lab safety.

At UT Dallas, two offices handle lab safety, and this may cause confusion to the campus researchers as well as potential duplication of efforts and safety issues that may not be addressed:

- The Office of Research Compliance recently added staff to help ensure the University's compliance with lab safety regulations. The Assistant Director of Research Compliance manages the Lab Safety Manager and two safety specialists who conduct inspections and provide training to researchers. Their website at http://www.utdallas.edu/research/orc/lab_safety_training/ provides information and training for researchers.

- EH&S has one Lab Safety Technician that conducts inspections and is currently in the process of hiring a Director of EH&S who will be responsible for: "*…supporting the implementation of the UT Dallas Laboratory Safety Programs. This position will perform duties in Laboratory Safety in a multi-disciplinary Environmental Health and Safety (EHS) environment with strong emphasis on research laboratory safety (biological and chemical safety, occupational safety & health, industrial hygiene and radiation protection).*" Their website also provides information on lab safety at http://www.utdallas.edu/ehs/labsafety/.

Recommendation: We recommend that Research Compliance and EH&S work together to designates and define responsibilities for lab safety to avoid duplication of efforts on campus. Once defined, the risk management plan as well as the university websites should be revised.

Management's Response: *The Vice Presidents for Administration and Research are working together to find the most appropriate, efficient, and effective way to provide oversight over this process that addresses responsibility and accountability.*

Estimated Date of Implementation: *June 30, 2015*

Person Responsible for Implementation: *Dr. Calvin Jamison, VP for Administration; Dr. Bruce Gnade, VP for Research*

(4) ***Update Policies and Procedures***
Risk Factor: Management Oversight; **Risk Rating:** Medium ★

EH&S has not updated or reviewed the lab safety manuals since 2007. Only the Radiation Safety Manual has been recently updated. EH&S has not implemented the peer review recommendation from 2009 that lab safety manuals should include the responsibilities of EH&S, Office of Research, Facilities or Lab personnel. The Waste Disposal manual was last reviewed in 2006.

Without documented policies and procedures, employees are unaware of their responsibilities, and the possibility of inefficiencies and noncompliance with policies are increased.

Recommendation: EH&S should update their procedures and ensure that periodic updates are scheduled in the future.

Management's Response: *Lab Safety staff reviewed and updated 16 of 19 Lab Safety related manuals. This includes listing responsibilities of faculty, support staff and students as well as the date of each plan. The Office of Research Compliance and Environmental Health & Safety will conduct a comprehensive review of policies and procedures and develop the appropriate materials for the campus safety program.*

Estimated Date of Implementation: *To be completed by 11/1/15.*

Person Responsible for Implementation: *Rafael Martin, Associate Vice President for Research, Dr. James Wright, Assistant VP Environmental Health & Safety*

Status of Prior Audit Recommendations

The following is the status of implementation of the recommendations resulting from Internal Audit Report No. R1206, *Lab Safety*, dated January 4, 2012.

Recommendation	Implemented?
Improve Monitoring over the Purchasing of Hazardous and Other Regulated Materials	EH&S and Procurement are working through SciQuest to have these hazardous compounds flagged for approval or at least notify EH&S when purchased.
Update and Implement Controls on the Risk Assessment and Monitoring Plan (RAMP)	Remains in process. See recommendations (1) and (2) above.
Implement Peer Review and Prior Audit Recommendations	Most have been implemented, but see recommendations (1), (2), and (3) above. A new peer review is being considered that will address the issues.
Improve Inspection Monitoring Process	Partially implemented. See recommendation (1) above.
Improve Monitoring over Training	Partially implemented. See recommendation (1) above.

Conclusion

Based on the audit work performed, we conclude that improvements are needed to ensure that the Lab Safety compliance program is operating effectively and that UT Dallas is in compliance with Lab Safety regulations.

We appreciate the courtesy and cooperation received from the management and staff in both Environmental Health & Safety and Research as part of this audit.

Appendix: Priority Findings and Risk Matrix

Definition of Risks

Risk Level	Definition
High	High probability of occurrence that would significantly impact UT System and/or UT Dallas. Reported to UT System Audit, Compliance, and Management Review Committee (ACMRC). Priority findings reported to the ACMRC are defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"
High/Medium	Risks are considered to be substantially undesirable and pose a moderate to significant level of exposure to UT Dallas operations. Without appropriate controls, the risk will happen on a consistent basis.
Medium	The risks are considered to be undesirable and could moderately expose UT Dallas. Without appropriate controls, the risk will occur some of the time.
Low	Low probability of various risk factors occurring. Even with no controls, the exposure to UT Dallas will be minimal.

Risk Factors

- Reputation - damage to the image of UT Dallas and/or UT System
- Information Security - integrity, confidentiality and availability of information
- Compliance – compliance with external legal or regulatory requirements
- Accomplishment of Management's Objectives – goals being met, projects being successful
- Effectiveness and Efficiency – objectives at risk and/or resources being wasted
- Capital Impact - loss or impairment of the use of assets
- Life Safety – including loss of life, injury, toxics/infectious disease
- Management Oversight
- Operational Alignment – management's alignment of people, process and technology to efficiently accomplish organization objectives
- Designed Controls – adequacy of controls within critical operations
- Payments/Expenditures – including fines and legal costs
- Lost Revenue – actual and/or opportunities