Biosafety Level 3 Laboratory

Audit Report # 12-19
January 14, 2013

Office of Auditing and Consulting Services

"Committed to Service, Independence and Quality"
January 14, 2013

Dr. Diana Natalicio  
President, University of Texas at El Paso  
Administration Building, Suite 500  
El Paso, Texas 79968

Dear Dr. Natalicio:

The Office of Auditing and Consulting Services has completed a limited-scope audit of the Biosafety Level 3 laboratory. The results of the audit are attached.

We appreciate the cooperation and assistance provided by the Environmental Health and Safety, Biological Sciences, Veterinary Services, and Facilities Services during our audit.

Sincerely,

[Signature]

William A. Peters, CPA, CIA  
Director
Report Distribution:

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EXECUTIVE SUMMARY

The Office of Auditing and Consulting Services has completed a limited-scope audit of the Biosafety Level 3 (BSL-3) laboratory. The audit scope was limited to the functions and operations of the BSL-3 laboratory during the 2011-2012 fiscal year. The primary objective of this audit was to review and document the current status of the BSL-3 laboratory and whether it is maintained in compliance with federal regulations and institutional policies.

Our audit results indicated that the BSL-3 laboratory certifications, training, access controls and operations are appropriately documented and functioning in compliance with federal regulations and institutional policies.
BACKGROUND

The University of Texas at El Paso (UTEP) Bioscience Research Building houses a Biosafety Level 3 (BSL-3), laboratory which officially opened on August 31, 2010. The laboratory occupies approximately 3,000 square feet, divided into two independently operating East and West suites. The East suite has two rooms for testing, an animal room and procedure room. The West suite has two sub-laboratories and a procedure room for infectious disease studies. The BSL-3 laboratory is intended to provide a safe working environment for research activities on infectious diseases.

In order to operate, the BSL-3 laboratory is required to be certified in accordance with Center for Disease Control/National Institutes of Health (CDC/NIH) Biosafety in Microbiological and Biomedical Laboratories Guidelines and the NIH BSL-3 Certification Checklist. Yearly certifications are required. The initial certification for the lab was completed in August 2010 and two subsequent have been completed.

AUDIT OBJECTIVES

The primary objective of this audit was to review and document the current status of the BSL-3 laboratory and whether it is maintained in compliance with federal regulations and institutional policies. The focal points of this audit were to determine whether:

A. the lab has completed the prescribed certification procedures,

B. the faculty and staff have the appropriate training to use the facility,

C. the facility is properly secured and available only to authorized personnel, and

D. any issues have affected the operation of the laboratory.

SCOPE AND METHODOLOGY

The audit scope was limited to the functions and operations of the BSL-3 laboratory during the 2011-2012 fiscal year.

Audit methodology included reviewing federal regulations and institutional policies, interviewing personnel, testing training records for use of the facility, and reviewing physical and online access.
AUDIT RESULTS

A. BSL 3 Laboratory Certification
National Institutes of Health (NIH) requirements for BSL-3 laboratories state that they should be certified prior to opening and annually thereafter, or “after a program change, renovation or replacement of critical HVAC/exhaust system components that may affect the operating environment of the laboratory.”

At the time of our review, the UTEP certification documents met NIH certification requirements. In addition, the consultants performed the annual certification during the course of the audit. The laboratories are certified through August 2013.

B. Training of Staff, Faculty and Research Assistants
The UTEP Biological Safety Manual and Standard Operating Procedures for the BSL-3 lab states that “all users will receive training and demonstrate proficiency in microbiological and biosafety practices prior to being allowed access to the BSL-3 and Animal Biosafety Level 3 (ABSL-3) laboratories.” For researchers, research assistants and staff overseeing the labs, 40 hours of training is required for individuals without work experience in BSL-3 labs. For individuals with prior BSL-3 experience, 20 hours is required.

We tested the current trainees from November 2011 through July 2012, and confirmed that the individuals had completed the training as documented by Environmental Health and Safety (EH&S) personnel.

During the course of the testing, EH&S revised its tracking method by creating an individual record for each trainee rather than keeping a combined log. As a result, the training progress of each individual can easily be reviewed.

C. Facility Security
Due to the high risk nature of the research activities in the BSL-3 laboratories, limiting lab access to the facility is a priority. We reviewed access reports for the labs and the online remote access system to determine whether personnel admitted access had the required training and applicable job classifications to warrant access. All were appropriate. During the course of the review, we learned that the online remote access is only monitored by Facilities Services. Utilizing UTEP’s IT Security personnel in a system advisory role would provide valuable expertise in dealing with access risk.

We also reviewed visitor entry permits to confirm that visitors, including UTEP maintenance personnel were accompanied by authorized BSL-3 personnel and completed the required documentation. No exceptions were noted.
D. Operation Issues
Prior to the start of the audit, an incident occurred in the East BSL-3 laboratory during a training session. An obstruction blocking one of the air intakes for the lab caused a negative air pressure change. Both East and West suites were closed until the staff could determine that the equipment was operating properly. The incident was investigated to identify the root causes of the incident and to determine what action should be taken prior to re-opening the labs. EH&S suggested that outside consultants be hired to review the issues and determine the appropriate course of action. The labs’ original design engineer provided the consultation. In addition, Facilities Services brought in a vendor, currently used to maintain the valves and controls for the BSL-3 labs, to provide an additional independent evaluation of the system. Facilities Services completed the recommended alterations and the lab was reopened in August 2012.

We reviewed the internally generated incident reports as well as the consultants’ reports and interviewed key personnel. Based on discussions with all of the parties involved in maintaining and running the BSL 3 labs, appropriate procedures are being followed to minimize the risks associated with the operations of the labs. In addition, consultants will be utilized for specialized expertise as needed.

CONCLUSION

Based on the results of audit procedures performed, we conclude that the BSL-3 laboratory is operating effectively and is in compliance with federal and institutional guidelines. We commend them for their efforts.

We also wish to thank the Environmental Health and Safety, Biological Sciences, Veterinary Services, and Facilities Services departments for their assistance and cooperation provided throughout our audit.