Institutional Biosafety Committee

AUDIT PROCEDURES
APPROVED MAY 2019

Authority

Authority for the Institutional Biosafety Committee (IBC) and its scope, purview, policies, and procedure is described in the IBC Charter & Bylaws document.

Introduction

To protect the campus community, the IBC is tasked with evaluating research, teaching and diagnostic testing involving biological hazards and monitoring safety and compliance. Biosafety audits represent one of the most important elements in this task and in the implementation of an effective biosafety program. The Biosafety Officer and supporting staff (hereafter, BSO) conducts audits on behalf of the IBC to assess biological hazards and associated safety procedures; laboratory infrastructure, including any supporting facilities (e.g. laboratory animal facilities, greenhouses, insectaries, etc.); safety and containment equipment; and any relevant documentation (e.g. IBC registrations, regulatory permits, training records, etc.). The protocols that guide each type of biosafety audit are detailed below:

Initial Visit

The submission of a request for an initial IBC registration will trigger an initial audit by the BSO. This audit is a contingency for IBC approval. Initial visits are designed to review the proposed biological hazards and associated procedures, any specific risks or concerns, and the requirements for the operating biosafety level. Required signage and labeling, as well as instructions related to record keeping and training, will be provided. Follow-up meetings to clarify and assist with establishing the appropriate containment and administrative procedures will be scheduled as needed as per the initial discussions. A follow up audit will be conducted 6 months after IBC registration approval. (Note: although teaching and diagnostic labs are not tied to a formal IBC registration process, a similar approach will be taken for new labs at the discretion of the BSO.)

Self-Assessments

A self-assessment is required for each annual update of the IBC registration. A self-assessment is a list of questions addressing procedures, practices, and equipment that impact the overall level of biological safety in the lab. The questions are answered by the Principle Investigator (PI) or the individual completing the annual update on behalf of the PI. The BSO will follow up on any identified/declared deficiencies or concerns accordingly.
BSL-1 & BSL-2 Audits of IBC Registered Labs

BSL-1 and BSL-2 audits are conducted 6 months from the most recent annual update or 3-year renewal. Audits are pre-scheduled and checklists are distributed for each containment level. Audits are collaborative and allow for the auditor to gain understanding of the biosafety requirements specific to the lab being audited; therefore, the PI or his/her designee must be available during the audit to participate in the conversation. The designee must be knowledgeable about laboratory operations and must be an employee of the University of Tennessee. Unannounced and/or for-cause audits may take place if there is concern about imminent danger or if the lab is involved in an escalation event. Audit reports are prepared and issued to the PI, audit contacts, and other relevant personnel within five business days.

BSL-3 Audits of IBC Registered Labs

BSL-3 audits are conducted semiannually. Audits are pre-scheduled and a BSL-3 checklist is distributed in advance. Audits are collaborative and allow for the auditor to gain understanding of the biosafety requirements specific to the lab being audited; therefore, the PI or his/her designee must be available during the audit to participate in the conversation. The designee must be knowledgeable about laboratory operations and must be an employee of the University of Tennessee. Unannounced and/or for-cause audits may take place if there is concern about imminent danger or if the lab is involved in an escalation event. Audit reports are prepared and issued to the PI, audit contacts, and other relevant personnel within five business days.

Facility and mechanical performance verification is conducted at least annually (usually during a pre-scheduled laboratory closure). Any identified deficiencies in facility structure or performance will be communicated to the PI, preventative maintenance and/or engineering contractors, IBC, and Designated Official within two business days. Repairs must be completed and verified prior to resuming BSL-3 procedures.

Diagnostic Lab Audits

Laboratories that engage exclusively in clinical diagnostic procedures (with the exception of UT Student Health) are also audited on an annual basis. Audits are pre-scheduled and checklists are distributed for each containment level. Audits are collaborative and allow for the auditor to gain understanding of the biosafety requirements specific to the lab being audited; therefore, the PI/lab manager or his/her designee must be available during the audit to participate in the conversation. The designee must be knowledgeable about laboratory operations and must be an employee of the University of Tennessee. The audits follow the same procedure as BSL-1 and BSL-2 audits. Unannounced and/or for-cause audits may take place if there is concern about imminent danger or if the lab is involved in an escalation event. Audit reports are prepared and issued to the PI/lab manager, audit contacts, and other relevant personnel within five business days. (Note: IBC registrations are not required for diagnostic labs unless additional procedures meeting IBC registration criteria are conducted.)
Teaching Lab Audits

Teaching labs that meet the criteria outlined in the **Biosafety Framework for Teaching Labs** will be audited annually based on the American Society for Microbiology (ASM) guidelines for teaching labs. Audits are pre-scheduled and checklists are distributed for each containment level. Audits are collaborative and allow for the auditor to gain understanding of the biosafety requirements specific to the lab being audited; therefore, the teaching lab supervisor or his/her designee must be available during the audit to participate in the conversation. The designee must be knowledgeable about teaching lab operations and must be an employee of the University of Tennessee. The framework applies to teaching labs, practical exercises, or other experiential learning where there is a high likelihood of exposure to biological hazards, and which are conducted at UTK campuses (or satellites). Audit reports are prepared and issued to the teaching lab supervisor, audit contacts, and other relevant personnel within five business days. (Note: IBC registrations are not required for teaching labs unless additional procedures meeting IBC registration criteria are conducted.)

**CDC/USDA Permit Audits**

Laboratories that operate under the authority of a federally issued permit (e.g. CDC or USDA APHIS) with conditions that warrant physical oversight will also be audited on an annual basis. Audits are pre-scheduled and checklists are distributed for each containment level. The audit is a time for the auditor to gain understanding of the biosafety requirements specific to the issued permit and the lab being audited; therefore, the permittee (PI) or his/her designee must be available during the audit to participate in the conversation. The designee must be knowledgeable about laboratory operations and must be an employee of the University of Tennessee. Unannounced and/or for-cause audits may take place if there is concern about imminent danger or if the lab is involved in an escalation event. Audit reports are prepared and issued to the permittee (PI), audit contacts, and other relevant personnel within five business days. (Note: IBC registrations are not required for processes covered under a federal permit unless additional procedures meeting IBC registration criteria are conducted.)

**Supporting Facilities Audits**

Supporting facilities include, but are not limited to: equipment rooms/core facilities; laboratory animal facilities; large animal facilities (barns, stables, stalls, etc.); greenhouses; growth chamber rooms (phytotrons); and insectaries. As applicable, supporting facility audits will performed coincident to and in accordance with the respective procedure(s) outlined above. Facility managers will be invited and encouraged to participate in the audit in addition to the PI/supervisor or his/her designee. Unannounced and/or for-cause audits may take place if there is concern about imminent danger or if the supporting facility is involved in an escalation event. Audit reports are prepared and issued to the PI, audit contacts, facility manager, and other relevant personnel within five business days.
Re-audits

Re-audits may be required in the event of any of the following:

- The score on the audit is less than 85%.
- Action items to mitigate significant risk(s) and/or those identified during previous audits have not been addressed.
- The auditor discerns conditions that must be corrected and re-evaluated in a timely manner.

Refer to the UTK IBC escalation procedure for re-audit information related to escalation events.