

# Institutional Biosafety Committee

## AUDIT PROCEDURES

APPROVED SEPTEMBER 2022

### Authority

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

### Introduction

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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 implementing an effective biosafety program. The Biosafety Officer (BSO) and supporting staff conduct 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

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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 within one calendar year 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.)

### BSL-1 & BSL-2 Audits of IBC Registered Labs

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BSL-1 and BSL-2 audits are conducted within one calendar year from the most recent annual update or a 3-year renewal. Audits are pre-scheduled, and checklists are distributed. Audits are collaborative and allow for the auditor to gain an understanding of the biosafety requirements specific to the lab being audited; therefore, the PI or 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**

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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 an understanding of the biosafety requirements specific to the lab being audited; therefore, the PI or 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**

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Laboratories that engage exclusively in clinical diagnostic procedures (except for UT Student Health) are also audited on an annual basis. Audits are pre-scheduled, and checklists are distributed. Audits are collaborative and allow for the auditor to gain an understanding of the biosafety requirements specific to the lab being audited; therefore, the PI/lab manager or 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**

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Teaching labs using biohazards will be audited annually based on criteria established for instructional laboratory safety (see EHS LS-006, Instructional Laboratory Safety Program). Audits are pre-scheduled, and checklists are distributed. Audits are collaborative and allow for the auditor to gain an understanding of the biosafety requirements specific to the lab being audited; therefore, the teaching lab supervisor or 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. 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**

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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. The audit is a time for the auditor to gain an understanding of the biosafety requirements specific to the issued permit and the lab being audited; therefore, the permittee (PI) or designee must be available during the audit to participate in the conversation. The designee must be knowledgeable about permit-related 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**

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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 be 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 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**

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

- 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.

