

3.15. Laboratory Inspections and Corrective Action Procedures

Laboratory inspections are conducted to ensure that laboratories utilizing biological materials meet specific requirements and follow certain safety guidelines. Inspections are intended to promote a safe laboratory working environment and to ensure compliance with the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#), the [Biosafety in Microbiological and Biomedical Laboratories, 5th ed.](#), the IU Biosafety Manual, and the [OSHA Bloodborne Pathogens Standard](#). Interactive inspections are conducted where the inspector makes observations as well as speaks with a laboratory designee to answer and discuss specific laboratory procedures and safety practices.

3.15.1. Annual Inspections

Annual Biological Safety Inspections are conducted for all laboratories utilizing biological materials for teaching or research purposes at BL1 or higher. Annual inspections are PI specific, thus more than one inspection may be conducted per room for shared spaces. Upon inspection of the laboratory, deficiencies will be documented and an inspection report sent to the PI. The inspection report will contain a description of the individual deficiencies as well as recommended or required corrective actions.

It is expected that all deficiencies be addressed and corrected as soon as possible. PIs will be given 2-3 weeks from the receipt of their inspection report to begin corrective action. A written verification of complete or partial correction is required. Corrective action can be emailed to the general IUEHS Biosafety email address for your respective campus or a hard copy can be sent via campus mail to IUEHS Biosafety or your respective campus. IUEHS Biosafety for your respective campus is available to provide advice on how to address the deficiencies.

If sufficient progress has not been documented, a follow up inspection can be conducted 2-3 weeks after the inspection report is sent to verify progress. Follow-up inspections at the regional campuses are the responsibility of the IUEHS representatives for the respective campus.

Imminent danger or egregious violations are cause to terminate laboratory operations immediately.

3.15.2. Corrective Action Procedures

3.15.2.1. Level 1

Failure to take sufficient corrective action by the end of the initial 2-3 week corrective action period or the severity of remaining violations will determine if the process proceeds to Level 1. If very little or no progress has been made a Level 1 response will be necessary and a re-inspection of the laboratory will be conducted if necessary. IUEHS Biosafety will send copies of the Level 1 re-inspection report to the PI.

IUEHS Biosafety will discuss the Level 1 re-inspection with the PI to agree upon corrective actions. The PI will be given an additional ten (10) business days to correct all violations. Written verification of corrected deficiencies must be submitted to IUEHS Biosafety

within that time period. A follow-up inspection will be conducted to verify that all corrections have been made unless written verification is deemed sufficient.

3.15.2.2. Level 2

If written verification has not been submitted within the additional ten (10) day time period, a re-inspection and follow up inspection will be conducted by IUEHS Biosafety or other personnel if necessary. The IUEHS Biological Safety Manager for the respective campus will send a letter and copies of inspections and any PI, lab manager, or lab supervisor responses to the PI, the IBC, and the Department Chair or Director. The letter will give the PI an additional five (5) business days to correct remaining violations and submit written verification.

Mandatory retraining of laboratory personnel will be considered if the violations reveal a lack of understanding or deliberate avoidance of biological safety guidelines.

3.15.2.3. Level 3

If written verification of completed corrective actions has not been submitted to IUEHS Biosafety by the end of the process through Level 2 (a total of 25-30 business days), IUEHS Biosafety will send a letter of non-compliance to the PI, the IBC, the Department Chair or Director, and the administrative head of the college, school, or unit. A re-inspection and follow-up inspection will be conducted as necessary.

Failure of the PI to submit verification of corrections will impact their ability to obtain approvals for permits and grant certifications requiring validation of compliance with applicable state and federal regulations. If the laboratory involves work with non-exempt recombinant or synthetic nucleic acid molecules an incident report of non-compliance will be sent to the NIH.

Extensions to provide corrective action may be requested in writing at any stage of this process from IUEHS Biosafety staff.

3.15.2.4. Level 4

If the steps taken in the previous action levels have not resulted in the submission of a written verification of completed corrective actions to IUEHS Biosafety within the established timeline then the laboratory will be deemed noncompliant. The chief academic officer of the campus where the laboratory is located and the University Director of Environmental Health and Safety will be notified of the noncompliant laboratory and punitive action will be requested which may include prohibiting employee access to the laboratory until corrective action has been taken. The IBC may terminate approved protocols and place a hold on funding until appropriate action is taken. If the action taken by the chief academic officer does not result in compliance by the noncompliant laboratory then the Executive Vice President for University

Academic Affairs will be requested to take punitive action to ensure compliance.

3.15.3. IBC Approval Inspections

Protocol specific laboratory inspections will be conducted prior to protocol approval for protocols utilizing material that fall under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, all protocols and research that have been otherwise required to be reviewed and approved by the IBC. Upon inspection of the laboratory any deficiencies must be corrected or addressed before approval of the proposed IBC protocol. Deficiencies will be documented and an inspection report sent to the PI. IUEHS Biosafety for your respective campus would be available to provide advice to the PI to address and correct any deficiencies in a timely manner for approval. An annual inspection may be accepted in place of a separate IBC inspection as deemed appropriate by IUEHS Biosafety for your respective campus.