

Biosafety Infractions Policy

Introduction

A biosafety infraction occurs when established biosafety practices and procedures are not being followed as described in internal UVA policy or applicable external regulations. These include research labs, teaching labs, or ancillary group activities (i.e., Facilities Management, Athletics, Medical Center, etc.) as they relate to work with or around biological materials.

Biosafety Infractions

Biosafety policy and procedures are determined by collaboration between the Biosafety Officer (BSO) and the Institutional Biosafety Committee (IBC). Minor biosafety infractions* are identified as a function of routine laboratory inspections and resolved through verbal or written communication between the Principal Investigator (PI) and the Environmental Health and Safety (EHS) Biosafety Group. This process ensures that problems are promptly identified and corrected.

Notification of Infractions

Following an inspection or investigation, Biosafety will send a detailed list of deficiencies and corrective measures to the PI and/or contact person. Infractions are documented in lab inspection reports stored in the EHS database. Incidents or accidents involving biological materials may involve departures from established biosafety practices and are presented to the IBC. Incident reports are kept on file in EHS Biosafety. Incidents involving exposure to recombinant DNA or synthetic nucleic acids require reporting to the NIH Office of Science Policy by the BSO. Additionally, an Observed Infraction Report may be generated which documents the type and frequency of infractions on an annual basis. Follow up communications are regularly performed based upon the severity of the infraction and Lab Inspections are not approved or renewed until all deficiencies are addressed. In situations where satisfactory resolution is not achieved in a timely manner, notifications will be elevated to the Institutional Biosafety Committee (IBC), department chairperson or director.

Reporting infractions and investigations

The Biosafety Officer (BSO) will review and if warranted, investigate reports of infractions. Any employee, student, or associate of UVA reporting a biosafety-related concern will be protected against reprisal. Every effort will be made to protect the individual's confidentiality in accordance with UVA policy.

If an investigation is necessary, the BSO may obtain additional information by direct communication with the Principal Investigator (PI), contact person, co-workers, etc., review of laboratory procedures, IAR registrations, training records, or via other related lab/facility documents. In some cases, an unannounced visit to a laboratory of concern may be prudent.

Reporting mechanisms:

- Any individual who has concerns may contact the Biosafety Officer by email (eep3p@virginia.edu) or phone (2-5005)
- Contact any member of the IBC <http://ehs.virginia.edu/Biosafety-IBC.html>
- Report through the EHS website for accidents or safety concerns: <https://researchcompliance.web.virginia.edu/report/user/concern.cfm> .
- By direct observation from IBC members, Biosafety or other EHS staff during inspections, routine outings, or during incident investigation where additional infractions are observed

IBC Involvement

Infractions of a serious nature**, involving recombinant DNA, or those that are not resolved in a timely manner, are presented to the IBC for discussion. The BSO may consult with the IBC Chair as necessary to determine the seriousness of the infraction. For those deemed serious, or demonstrate a repeat pattern, the BSO will present a summary of the violation and findings at a convened IBC meeting. Infractions which meet the NIH Guidelines reporting requirement may involve significant problems, violations, or any significant research-related accidents, overt exposures and illnesses with respect to recombinant DNA. Those incidents will be reported by the BSO to the Office of Science Policy on a case-by-case basis.

Disciplinary Actions

The BSO or IBC Chair may suspend activities if there is a significant threat to public health or compromise of safety and regulatory compliance. Committee enforcement or disciplinary action may include, but is not limited to: a letter of reprimand from the IBC Chair or BSO, mandatory retraining, a visit by Biosafety or IBC members, or suspension or termination of IBC approval and/or privileges. The IBC will work with EHS Biosafety to bring the registration and all activities into compliance.

Misconduct

Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research are considered research misconduct. Where there is willful or negligent violation of established biosafety practices and procedures, or if a PI continues research activities after notification by the IBC, it may be deemed research misconduct. The Research Integrity Officer will be notified for administrative review and determination of action. Refer to the UVA Policy on Research Misconduct (RES-004 <http://uvapolicy.virginia.edu/policy/RES-004>) for more information.

**Examples of minor infractions include: training not current, current Biosafety e-Manual printed, ownership of biohazardous equipment (i.e., freezers), food and drink violations, eyewash flushing & maintenance.*

*** Examples of serious infractions may include: posing immediate harm to the health or safety of employees, students, the public, or the environment, a serious deviation from IBC policy or IAR specific procedures, or knowingly failing to register a research protocol.*