

Appalachian State University Research Protections and Institutional Biosafety Council Standard Operating Procedures		
SOP #4 Revision # 1	TITLE: Inspections	Date Effective: Revision Date: 8/23/16
Approved By: IBC Chair	Signature <i>Jennifer P. Cecile</i>	Date: 9/12/16
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PURPOSE

To describe the policies and procedures for facilities inspections by the Institutional Biosafety Council.

GENERAL DESCRIPTION

The Appalachian Institutional Biosafety Council must ensure a safe environment for users, staff, and guests in University facilities. This SOP outlines the guidance and references for the inspection of University-owned facilities carried out by the Institutional Biosafety Council. Inspected locations include specialty rooms, and laboratories. This includes locations both on the Appalachian State main campus and may include other locations where activities occur on behalf of the University or by and agent of the University.

RESPONSIBILITY

Unless otherwise excepted by the provisions hereof, the IBC is responsible for conducting inspections where any rDNA research occurs in University facilities as well as other locations whenever projects involve University funding, faculty scholarship or staff/student/agent effort as part of University activities. The provisions of this document shall be interpreted and applied in conformity with Federal, State, and UNC System Policies and Procedures.

PROCEDURES

1. When inspections are performed
2. Conducting inspections
3. Inspection criteria

WHEN INSPECTIONS ARE PERFORMED

Before the approval of protocol with transgenic organisms, or BL2 factors, the location where the protocol will occur will be inspected by the IBC. After approval of these protocols, the IBC must conduct inspections of all laboratories used at least once every three year.

Category	Initial Inspection Required
Registration with IBC (IIIE)	No
Exempt, no transgenic organism	No
Exempt, with transgenic plants or animals	Yes
Non-exempt, BL1, no transgenic organism	No
Non-exempt, BL1, with transgenic organism	Yes
BL2 (exempt or transgenic organism status irrelevant)	Yes

CONDUCTING INPSECTIONS

1. When inspections are required, the IBC Administrator will work with the PI to come up with a times the PI is available to assist and explain during the inspection.
2. As part of the IBC inspections, all members will be invited to visit and review each location.
 - a. Attendance of the University Chemical Hygiene Officer and the Chair are required.
3. Inspection checklists are used to ensure that the conditions are acceptable for research and safe for all personnel conducting the research. The checklists used will correspond to the biosafety

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level of the work and the presence of transgenic organisms. These checklists can be found on the IBC AsU Learn education page or by emailing IBC@appstate.edu.

4. After the inspection, checklists are compiled and the administrator will email the PI a list of deficiencies. The PI should then resolve the deficiencies and notify the administrator. The administrator can be notified by:

- Email
 - May include relevant photos of deficiency resolution, if necessary or requested
- Phone call
- In person visit

No additional re-inspection is needed unless specifically requested by a member of the IBC.

INSPECTION CRITERIA

1. IBC members inspect: locations serving as housing for transgenic organisms and support areas; locations where recombinant nucleic acids are stored, or manipulated.
2. Categories of Inspection include:
 - a. Sanitation
 - b. Sharps
 - c. Waste disposal
 - d. Safety of equipment
 - e. Environmental control and containment
 - f. Occupational health and safety concerns
 - g. Staff training
 - h. Knowledge of applicable rules, regulations, and security
3. Inspection violations are identified as unsatisfactory.
 - a. Unsatisfactory areas are noted in the inspection report and the deficiency list sent to the PI.
 - b. For each identified unsatisfactory, a reasonable and specific plan and schedule for correcting the unsatisfactory is discussed and recorded.
 - c. The responsible individual identified in the deficiency list may negotiate with the IBC to develop a reasonable deadline to correct unsatisfactory items.

RESOURCES

- Biosafety Guidance
- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)
- CDC and HHS Select Agents and Toxins List
- The CDC Publication: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition
- Guidelines for Biosafety Laboratory Competency