

COMS Inspection Policy

I. Purpose

The purpose of this policy is to standardize the information provided by all BSOs to the Office of Biological Safety and COMS committee members on the laboratory inspection data.

II. Applicability

All laboratories that have a registered COMS application must have a current laboratory inspection date and be in compliance with findings that resulted from their laboratory inspection.

III. Definitions

IV. Implementation procedures

A. Oversight

Section IV-B-2-b-(1) of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) states that the Institutional Biosafety Committee (known here as the Committee on Microbiological Safety (COMS)) is responsible for the assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant (DNA) research. In order to fulfill these COMS requires:

- Institutional Biosafety Officers (BSOs) submit on an annual basis a Standard Operating Procedure (SOP) including, but not limited to, inspection checklists, methods to address noncompliance,
- BSOs submit on a monthly basis, completed inspection dates
- BSOs should submit any significant or chronic biological safety issues that were identified.

A. Review:

Documents and inspection results submitted by BSOs to fulfill the requirements above will be reviewed by the Associate Director of Microbiological Safety. If necessary, the

Associate Director may raise specific documents or inspection results to the attention of COMS Chair and/or COMS.

B. Frequency

The NIH Guidelines require that BSOs (or alternate personnel trained by the BSOs) conduct periodic laboratory inspections to ensure that laboratory standards are rigorously followed. COMS requires that inspections of all laboratories with active COMS registrations be conducted once per calendar year for Biosafety Level 2 (BL2) and Biosafety Level 3 (BL3). COMS requires Biosafety Level 1 (BL1) laboratories be inspected at least once per every other calendar year.

(i)

C. Reporting

Significant and/or chronic problems, biosafety violations, violations of the NIH Guidelines, or research-related accidents identified during laboratory inspections or otherwise must be reported to COMS as soon as the BSO is aware. The COMS Incident Reporting Policy should also be reviewed to determine if reporting to governmental agencies is required.

V. **Policy Authority**

VI. **Related Policies**

COMS Incident Reporting Policy

VII. References