

HMS Primary Responsible Office: COMS Office of Biological Safety (COMS Office)

Approval Body: Committee on Microbiological Safety (COMS)

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COMS Inspection Policy

I. Purpose

The purpose of this policy is to set minimum requirements for inspections of COMS (Committee on Microbiological Safety)-registered research spaces and standardize the reporting of inspection data by Biosafety Officers (BSOs) to the COMS Office and COMS committee members.

II. Applicability

All laboratories that have an approved COMS application must have a current laboratory inspection date and have addressed all findings related to biosafety from their laboratory inspection.

III. Definitions

Annual: Inspections of BL2 laboratories that are conducted within one calendar year of the previous inspection. Unless an extension is granted by the COMS Office, the inspection should be completed within 30 days of the date of the previous years' inspection. COMS will only approve amendments to existing protocols once inspections have been completed.

Biennial: Inspections of BL1 laboratories that are conducted within one calendar year. Unless an extension is granted by the COMS Office, the inspection should be completed within 30 days of the date of the previous years' inspection. COMS will only approve amendments to existing protocols once inspections have been completed.

Significant:

- Incidents result in overt exposures to any materials containing CRM. Unreported incidents/ situations that may lead to exposure.
- Incidents that involve violation of NIH guidelines (ex: Appendix A and Appendix G)
- Work not registered with COMS
- Breach of BL3 containment due to Mechanical system failure or laboratory equipment;

IV. Implementation procedures

Oversight

Section IV-B-2-b-(1) of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid 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, training and expertise of personnel involved in recombinant DNA research. In order to fulfil these, COMS requires the following:

- 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 completed inspection dates as part of each COMS protocol submission. BSOs ensure filing of reports in accordance with the COMS Incident Reporting Policy for any issues identified during inspections.

Review

Documents and significant inspection results submitted by BSOs to fulfill the requirements above will be reviewed by the COMS Office, The Director may raise specific documents or inspection results to the attention of COMS Chair and/or Committee.

Frequency

The NIH Guidelines require that BSOs (or designated inspectors) 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 to be inspected at least once every other calendar year.

Reporting

The BSO and the COMS Office should refer to the COMS Incident Reporting Policy determine if a laboratory inspection finding is reportable to COMS or outside entities.

V. Policy Authority

The COMS Office of Biological Safety of the Harvard Medical School is responsible for supporting the Committee on Microbiological Safety.

VI. Related Policies

COMS Incident Reporting Policy

VII. References

[Lab Safety Assessments & Inspection](#)

[NIH Guidelines](#)

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition](#)