

## POLICY ON LABORATORY INSPECTIONS

**Date:** August 25, 2014

**Supersedes:** Policy on Safety Inspections 11/12/02

### I. PURPOSE

New York Medical College (NYMC) is committed to protecting the environment and maintaining a safe and healthy workplace in accordance with all applicable federal, state and local regulations. As one means of accomplishing this, the Department of Environmental Health & Safety (EH&S) performs comprehensive inspections of all academic and research laboratories a minimum of once per calendar year. Additionally, EH&S may choose to conduct additional "focused" inspections based on compliance patterns observed from comprehensive inspections and/or the need for additional data. Laboratories with specialized hazards and/or those that are subject to specific regulatory requirements may receive additional specialized inspections in order to ensure compliance with all applicable regulations, policies and procedures.

### II. POLICY

This policy establishes procedures for conducting laboratory inspections in order to periodically identify, document and appropriately resolve deficiencies in compliance with federal, state and local regulations, as well as with NYMC policies and procedures.

### III. SCOPE

This policy applies to all faculty, staff, students, contractors, and licensees who are responsible for and/or work within NYMC laboratories, laboratory support spaces and/or "core facilities."

### IV. DEFINITIONS

**Authorized User ("AU"):** is an individual approved by both NYMC and the NYSDOH for the possession and use of radioisotopes, and to supervise use by radiation workers under his/her supervision.

**Laboratory:** As used in this policy, "laboratory" refers to any part of a building used or intended to be used by NYMC for research or other scientific activities which may be hazardous. This includes teaching laboratories, shared support and/or "core" facilities, and research laboratories.

**OSHA Laboratory Standard** (CFR 1910.1450): Federal regulation requiring all employers to develop and enforce appropriate safety procedures and policies for laboratory personnel.

**Principal Investigator (PI)**: The senior individual with supervisory responsibility for a laboratory.

## V. PROCEDURES

A. **Laboratory Registrations.** Principal Investigators (PIs) are required to submit all requested information regarding their laboratory activities/operations semiannually. The laboratory registration process assists EH&S in tracking hazards and increasing compliance with environmental and safety regulations and policies. Laboratory registrations must be submitted electronically; EH&S sends each PI an email containing the link to the registration document, which must be completed within ten business days of receipt.

### B. Types of Laboratory Inspections

1. **Comprehensive Laboratory Inspections.** A comprehensive safety inspection of all laboratory spaces at NYMC is conducted twice per calendar year by EH&S. This inspection utilizes a standard template; the items assessed during the inspection include (but are not limited to) training compliance, chemical hygiene, biosafety, the availability and use of personal protective equipment, engineering controls, and life safety.
2. **Focused Laboratory Inspections.** EH&S periodically conducts “focused laboratory inspections,” which are targeted inspections of a single compliance topic (e.g. biosafety, regulated medical waste, chemical hygiene, etc.). Topics for focused laboratory inspection may be selected because of widespread non-compliance within a specific program or compliance category, due to a need for benchmarking data, and/or in order to build a wider understanding of specific areas of compliance.
3. **Audits of Areas Posted for Use of Radioactive Materials (RAM).** All laboratories actively permitted for the use of radioactive material are audited by EH&S on a quarterly basis. A written report summarizing all deficiencies is sent to the Authorized User (AU) and his or her departmental Chairperson; copies are also distributed to the Radiation Safety Officer, the Director of Environmental Health & Safety, the Radiation Safety Committee, and the Associate Vice President, Human Resources. The failure to implement corrective actions for all of the deficiencies outlined in the audit report may result in the loss of the AU’s permit for the possession and use of radioactive materials.

4. **Biosafety Level 3 Suite Inspections.** NYMC's Biosafety Level 3 (BSL-3) suite is inspected by the Select Agent Program's Responsible Official (or Alternate Responsible Official) once per calendar year, in accordance with federal regulations. Inspection reports are distributed to the Program Director, the Institutional Biosafety Committee, and the Associate Vice President, Human Resources. The Responsible Official is responsible for ensuring that all the necessary corrective actions are implemented for all deficiencies reported. Inspection reports must be made available for the Centers for Disease Control (CDC) upon request.
- C. **Inspection Documentation.** All inspection reports summarize all areas of non-compliance found at the time of inspection and recommend the appropriate corrective action(s). Although different types of inspections have different inspection report distribution requirements, for each types of inspection, the PI and departmental Chairperson receive a copy of the inspection report within ten business days of the inspection being conducted. Additionally, the PI receives a customized copy of the "Response to Inspection" form.
  - D. **Documentation of Corrective Actions.** All areas of non-compliance addressed in an inspection report must be corrected within ten business days of receiving the report. The PI must document all corrective actions on the "Response to Inspection" form that is distributed with all inspection reports. While the PI may designate a responsible party to address open items and to submit the inspection response form, this individual must have the ability to commit the necessary resources to correcting all the deficiencies specified in the inspection report. If deficiencies cannot be corrected within the required timeframe, the PI (or his/her designee) must detail a corrective action plan on the "Response to Inspection" form, including detail on how the necessary corrections will be implemented and the estimated date of completion. Any inspection finding posing imminent danger (likely to cause a serious hazard, injury, disability or death) must be corrected immediately; if they are not, EH&S may close the laboratory until the hazard(s) has been sufficiently abated.
  - E. **Inspection Closeout Process.** Once the PI has documented all areas of non-compliance from his or her inspection report as "closed," a re-inspection will be scheduled. If all issues have been resolved to the satisfaction of EH&S, the inspection will be noted as satisfactorily closed and the PI will receive written notification of such.
  - F. **Non-Compliance With Inspection Process.** If a PI does not comply with the inspection process outlined in this policy, s/he and the departmental Chairperson will receive a written warning. Subsequent non-compliance will result in a formal written report to senior management and may result in disciplinary action.

**VI. EFFECTIVE DATE**

This policy shall be effective as of the date signed.

**VII. POLICY RESPONSIBILITIES**

**A. Department of Environmental Health & Safety**

1. Conducts periodic laboratory inspections and makes determinations as to the severity of any areas of non-compliance;
2. Produces a report outlining all areas of non-compliance and that recommends the appropriate corrective actions for correcting such;
3. May order the immediate shutdown of a laboratory for safety or environmental deficiencies that pose an immediate danger to life, health and/or the environment;
4. In the case of the shutdown of a laboratory, determines when laboratory activities may safely resume.

**B. Principal Investigators**

1. Provides oversight for laboratory activities;
2. Ensures that all personnel in his/her laboratory are properly trained;
3. Works with EH&S to acceptably resolve all cited deficiencies within the appropriate length of time;
4. Reports any unsafe conditions or inadequate facilities to EH&S.

**C. Departmental Chairpersons**

1. Reviews departmental laboratory inspection reports;
2. Maintains compliance with all applicable regulatory standards within his/her department.

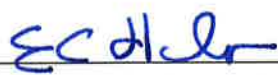
**VIII. POLICY MANAGEMENT**


Responsible Executive: Senior Vice President and Chief Financial Officer

Responsible Officer: Director, Environmental Health & Safety

Responsible Department: Environmental Health & Safety

**APPROVED:**

  
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Edward C. Halperin, M.D., M.A.  
Chancellor for Health Affairs and  
Chief Executive Officer

  
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Date