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Table of Contents

<table>
<thead>
<tr>
<th>Table of Contents</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. RATIONALE</td>
<td>1</td>
</tr>
<tr>
<td>II. PROCEDURES</td>
<td>1</td>
</tr>
<tr>
<td>III. REVIEW CYCLE</td>
<td>2</td>
</tr>
</tbody>
</table>

I. RATIONALE

Johns Hopkins University is committed to providing a safe laboratory environment for staff and students. The purpose of this document is to specify the progressive response to laboratories and their faculty principal investigator (PI) directors when those laboratories are deemed out of safety compliance after a repeat inspection indicates failure to correct safety violations cited on a previous inspection. The response is based on a series of escalating corrective actions, detailed below. As escalation progresses, more parties are brought into the discussion, in an effort to facilitate progress.

Note: In the event that a laboratory condition poses an extraordinary risk to personnel or property, in the face of gross investigator non-cooperation, or if a given laboratory is a chronic violator, the Chair of the Johns Hopkins Committee on Health, Safety, and Environment may escalate a violation directly to a higher level of corrective action (detailed below), may escalate timescales and deadlines, or invoke additional sanctions as appropriate.

II. PROCEDURES

Initial Routine Laboratory Safety Inspection Action:
The annual laboratory safety inspection results in a letter (usually sent within 24 hours of inspection) from the HSE Research Safety Specialist Team to all affected PIs and their department administrator(s) indicating any safety compliance issues found during the inspection and requesting corrective action. The letter notes that the Research Safety Specialist Team will return in a week to assess implementation of corrective actions, the expectation being that the issues will have been corrected during the week. Of importance, the letter offers a 24-hour grace period to correct issues and, thereby, keep the issues from being formally recorded as deficiencies in safety compliance.

If, during re-inspection, all noted safety issues are found to have been corrected, the lab passes the annual inspection and no escalation is necessary.

If, during re-inspection, all noted safety issues HAVE NOT been corrected, the following series of corrective actions are triggered:

First Corrective Action: Follow-up Letter from the HSE Research Safety Specialist Team
A follow-up letter will be sent to the PI’s department administrator and all affected PIs, requiring the PI to either (ideally) correct the remaining issues within one week or provide a compelling rationale that describes the infeasibility of doing so, and the actual corrective action plan that will be implemented. This corrective action plan must include milestones, and will be considered (if accepted and approved by HSE) as a contract between the PI and HSE. If the corrective action plan proposed by the PI is not accepted and approved by HSE after good-faith efforts to reach a mutually satisfactory agreement, the process will immediately escalate to the second corrective action. Similarly, if ongoing inspections in the context of the plan’s milestones demonstrate lack of adequate progress or achievement of a milestone, the process will escalate to the Second Corrective Action.
Second Corrective Action: Letter from the Chair of the Joint Committee for Health, Safety and Environment
A PI who has not adequately responded to a First Corrective Action will receive a letter from the Chair of the Joint Committee (cc’d to the PI’s department administrator, primary department chair, and relevant vice dean for research) describing the ongoing safety and compliance issues and the lack of corrective action (which by definition constitutes a breach of the contract between the PI and HSE), and requiring a written response from the PI to the Chair of the Joint Committee, the department chair, and the vice dean for research that includes a plan for corrective action, within 24 hours of receipt of the letter (or less where appropriate to the risk posed by the ongoing safety and compliance issues). That plan presumably would bear some relation to the plan generated in the First Corrective Action, with revised milestones. If the corrective action plan proposed by the PI is not accepted and approved by HSE after good-faith efforts to reach a mutually satisfactory agreement, or if the PI does not respond adequately or in a timely fashion, the process will immediately escalate to the Third Corrective Action. Similarly, if ongoing inspections in the context of the plan’s milestones demonstrate lack of adequate progress or achievement of a milestone, the process will escalate immediately to the Third Corrective Action.

Third Corrective Action: Laboratory Closure
A PI who has not adequately responded to a Second Corrective Action will receive a letter from the Chair of the Joint Committee (cc’d to the PI’s department administrator, primary department chair, relevant vice dean for research, and school dean) describing the ongoing safety compliance issues and the ongoing lack of corrective action (which by definition constitutes an ongoing breach of the contract between the PI and HSE), and requiring the PI to immediately terminate operations in the laboratory or laboratories under his or her control that are out of safety compliance, except those operations necessary to protect life, health, and property, until a restart plan addressing all known safety and compliance issues in the lab is approved by the Department of Health, Safety, and Environment. That restart plan will include a set of milestones that address both progress towards completely resolving all safety and compliance issues and a specification of what and when certain laboratory activities may resume. Health, Safety and Environment will work with the PI to assist him or her in expediting the recommissioning process.

The letter shall be delivered by hand to the PI or (in his or her absence) the department administrator, and copies delivered to the department chair, the relevant vice dean for research, and the dean of the PI’s school of primary appointment. The Department of Health, Safety, and Environment shall immediately order the laboratory closed upon delivery of the letter, and shall inspect the laboratory as often as deemed necessary to confirm that the restart plan is being adequately followed.

III. REVIEW CYCLE
Annual

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