PREVENTIVE ACTION		
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Preventive Action

GUIDING PRINCIPLES AND SCOPE

Preventive action is a pro-active process to identify opportunities for improvement and potential sources of non-conformities rather than a re-active process to the identification of problems or complaints. Aside from the review of the operational procedures, preventive action may involve analysis of data including trend and risk analyses and proficiency test results.

This document describes the Department's procedure to identify potential preventive actions, either technical or concerning the Management System, and the steps to be taken to deal with the issues identified.

PROCEDURE

1. Any staff member that becomes aware of potential sources of non-conformities in laboratory operations informs their immediate supervisor and/or Assistant Director as soon as practicable.
   a. Immediate supervisors notify their Assistant Director if the AD was not part of the initial notification. The initial process to communicate potential preventive actions up the chain-of-command ensures that any follow-up action is implemented sooner, rather than later.

2. The immediate supervisor and/or Assistant Director investigates the potential problem and conducts a preliminary review of the root cause(s) of any potential non-conformity to determine if action is necessary. The appropriate Technical Leader (if the potential problem is a technical problem), the Quality Assurance Manager, and/or other supervisors/managers may be consulted for assistance.
   a. If the investigating supervisor/manager does not agree that a potential problem exists, no further action is necessary.

3. If the investigating supervisor/manager agrees that a potential problem exists, and if a root cause of the potential non-conformity is determined, the immediate supervisor and/or Assistant Director develops a plan of action to deal with the issue. This may include a change in technical procedures and/or the initiation of new guiding principles. The plan of action shall include the initiation of controls to ensure that the preventive actions are effective. A description of the potential problem, root cause, and plan of action is documented on a **Preventive Action Form** and submitted to the Quality Assurance Manager. If the preventive action is of a technical nature, the Quality Assurance Manager will forward the form to the appropriate Technical Leader for review.

4. If the preventive action is of a technical nature, the appropriate Technical Leader either approves the plan or decides on an alternate arrangement.

   If the preventive action concerns a potential non-conformity in the Management System, the Director or his/her designee either approves the plan or decides on an alternate arrangement.

5. The Preventive Action Form and any associated documentation (such as Manual Change Forms, copies of emails, etc.) are filed with the Quality Assurance Unit.

6. The Quality Assurance Manager reviews the Preventive Action Form within six months to determine if the preventive action plan that was put into place has been effective.
   a. The Quality Assurance Manager records their evaluation of effectiveness on the Preventive Action form, e.g., a notation that none of the anticipated non-conformities had occurred.
   b. If the action plan is determined to have been effective, the preventive action is considered to be complete.
   c. If the action plan is determined not to have been effective, the Quality Manager will determine whether the changes made as a result of the action plan need to be discontinued or revised