

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Preventive Action		
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Preventive Action

1 Guiding Principles and Scope

- 1.1 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.
- 1.2 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.

2 Procedure

- 2.1 Any staff member that becomes aware of potential sources of non-conformities in laboratory operations informs their immediate supervisor, Assistant Director and/or the Quality Assurance Manager as soon as practicable.
- 2.2 The supervisor/manager 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 (if not already part of the preliminary review), and/or other supervisors/managers may be consulted for assistance.
- 2.3 If the investigating supervisor/manager does not agree that a potential problem exists, no further action is necessary.
- 2.4 If the investigating supervisor/manager agrees that a potential problem exists, and if a root cause of the potential non-conformity is determined, the investigating supervisor/manager 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 they are not acting as the investigating 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 (if they are not already part of the investigation and remediation process).

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- 2.5 If the preventive action is of a technical nature, the appropriate Technical Leader either approves the plan or decides on an alternate arrangement (if they are not already part of the investigation and remediation process).
- 2.6 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.
- 2.7 The Preventive Action Form and any associated documentation (such as Manual Change Forms, copies of emails, etc.) are filed with the Quality Assurance Unit.
- 2.8 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.
 - 2.8.1 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.
 - 2.8.2 If the action plan is determined to have been effective, the preventive action is considered to be complete.
 - 2.8.3 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