Maine State Police Crime Laboratory

Audits and Quality System Reviews

1. Scope

This document outlines the laboratory policies on performing internal audits and the review of the management system. The role of these audits and management system reviews are to continually improve the effectiveness of the management system and to ensure that the laboratory is in compliance with laboratory policies and procedures as well as accrediting body standards.

2. Laboratory Audits

2.1 The Quality Manager and / or a laboratory internal auditor will perform annual audits of the laboratory spaces and functions. These audits may consist of one laboratory-wide audit or smaller targeted audits. Whether via one large audit or smaller targeted audits, all elements of the management system will be audited at least annually. These audits are separate from the DNA Quality Assurance Standards audits.

2.2 Internal auditors will be members of the laboratory supervisory staff.

2.2.1 To perform independent internal audits, an individual must attend a auditing training course and/or monitor one system-wide audit or five targeted audits.

2.2.2 Individuals who have successfully completed an Assessor or Internal Auditor Training Course will be certified to perform independent internal audits.

2.3 The Quality Manager will complete the Audit Schedule (QA-F016) and will disseminate the schedule to supervisors and laboratory staff at the beginning of each year. If adjustments need to be made to the schedule, the Quality Manager will notify the affected parties as soon as practicable.

2.4 In the event a non-conformance or other quality concern arises which indicates substantial non-compliance with laboratory policies or accreditation standards, the Quality Manager may schedule an audit of the relevant section(s).

2.5 Additional audits may also be scheduled as deemed necessary by the Quality Manager and / or Laboratory Director.

2.6 Internal audits shall include direct observation of a sampling of testing within each discipline.

2.7 The Quality Manager will issue an audit report to the supervisor of the section being audited. The audit report will identify any findings. Opportunities for improvement and preventive actions may also be identified in the audit report. The audit report will document whether the management system conforms to the most recent version of the ISO and ANAB requirements, in addition to the laboratory's own requirements.

2.8 If during the course of an audit possible non-conformances or other quality concerns are identified, the Quality Manager or internal auditor will complete the Quality Assurance Report.

2.9 The Quality Manager will be responsible for ensuring that any items identified in the audit are addressed in a timely manner.

2.10 The Quality Manager will be responsible for completing the conformance checklist to ANAB.

3. Management System Review

3.1 The Quality Manager and the Laboratory Director will annually assess the management system of the laboratory and report the assessment to the Laboratory Supervisors.

3.2 The assessment will include:

- general overview of the management system
- outline of findings reported in the conformance checklist and/or surveillance visit
- summary of internal audits
- summary of corrective actions
- summary of preventive actions
- summary of assessments by external bodies when applicable
- proficiency testing inconsistencies
- summary of laboratory cases received, laboratory case report output and backlogs and if relevant, a summary of changes in the type of work being received by the laboratory
- how each section attained the goals set forth for the year
- goals for the upcoming year; recommendations for improvement
- laboratory complaints where applicable
- feedback from the customer survey

- items from laboratory staff interviews where relevant
- summary of staff trainings for the current year
- other relevant information related to the management system
- a review of the suitability of laboratory policies and procedures
- reports from supervisors as to the status of the section, to include progress on meeting the annuals goals of the laboratory

3.3 The Management System Review will be disseminated to all laboratory staff for review.

3.4 Any significant findings in the management review will be documented in a Quality Assurance Report.