Maine State Police Crime Laboratory

Nonconforming Work and Corrective Action

1. Scope

The Maine State Police Crime Laboratory is committed to addressing nonconformance or potential issues through an open and honest assessment. Any identified potential nonconformance shall be documented and investigated. This process can be initiated by any laboratory staff member. Examples of a nonconformance include inaccurate analyses, inaccurate laboratory reports, instruments out of calibration or inoperable, non-fulfillment of an accreditation requirement, non-fulfillment of a laboratory policy, etc. Any personnel matters identified during the course of the investigation will be handled separate from the quality assurance program.

2. Summary of Process

The following is an outline of the process for identifying and correcting nonconforming work. Further details to each step are outlined later in this document. This process is a group process where the team typically consists of the relevant Section Supervisor(s), the Quality Manager, and the Laboratory Director. Other laboratory staff may be asked to participate in the process as situations warrant. For clarity, this summary outlines the individual responsible for each step; however, all team members are involved in the decision-making process.

- A Quality Assurance Report is initiated by any laboratory staff member. The QAR is initiated in Paradigm.
- A QA number is generated by Paradigm.
- The Quality Manager will make an initial assessment and make an initial determination of a course of action. The Quality Manager will assign the relevant Section Supervisor to perform an investigation. If more than one section is involved, the Quality Manager will identify a lead investigator. The Director will also be notified of the quality issue at this point.
- The Quality Manager will set a reasonable timeframe for the completion of each step of the QAR in Paradigm. Supporting records will be attached to the QAR if the timeframe is delayed.
    - Corrections should be completed in 30 days
    - Corrective/Preventive actions should be completed in 90 days
- The Section Supervisor will investigate the issue and make a recommendation to the Quality Manager. If the Quality Manager, Section Supervisor or Laboratory Director have determined that the quality issue is a corrective action, the Section Supervisor will conduct a root cause analysis as part of the investigation.
- The Quality Manager and Director will review the investigation and will make a final determination of a course of action (correction, corrective action, preventive action, etc.).
- If the customer has been impacted or a report needs to be recalled, the customer will be notified, generally with the issuance of an amended report. If necessary, the Director will notify the customer before the amended report is issued.
- Minimally, corrective actions will be initiated if the nonconforming work is significant in nature and is likely to recur; if the laboratory has substantive noncompliance with its own

policies; if an analyst error has occurred in a proficiency test; or if a technical error has occurred and has gone beyond the technical review process.

- The Quality Manager may request that a root cause analysis be performed in instances of nonconforming work where a corrective action is not necessary.
- The Section Supervisor will be responsible for implementing the Corrective Action Plan and for evaluating the effectiveness of the corrective action.
- The Section Supervisor and Quality Manager will approve all Corrective Action Plans.
- The Section Supervisor, Quality Manager, and Director will approve all Corrective Action Implementations and Verifications.

3. Identifying a Nonconformance

3.1 If a laboratory staff member has a quality issue related concern, the staff member shall initiate a Quality Assurance Report in Paradigm. These concerns could be identified as a result of audits, inspections, proficiency tests, casework reviews, department personnel, customer complaints, testimony reviews, daily activity, etc.

3.2 The Quality Assurance Report will be submitted to the Quality Manager.

3.3 A QA number will be assigned for tracking purposes.

3.4 The Quality Manager will perform an initial evaluation of the QAR. The Quality Manager may request a meeting with the Section Supervisor and the Laboratory Director to discuss the potential nonconformance.

3.5 The Quality Manager will assign the relevant Section Supervisor to conduct an investigation. Other staff members may be assigned to assist with the investigation. If more than one section is involved in the potential nonconformance, the Quality Manager will assign one lead investigator. The investigation will include a discussion with any involved examiners.

3.5.1 If the potential issue involves an examiner and a potential error in casework or databasing samples, the examiner will not continue to process similar casework or databasing samples.

3.5.2 If the potential issue involves laboratory equipment, the equipment will not be used.

3.5.3 If the potential issue involves a method or procedure, the method or procedure will not be used.

4. Investigation

4.1 During the course of the investigation, the Section Supervisor, Quality Manager and Director may determine that casework may resume while the investigation continues. The affected staff will be notified.

4.2 Upon completion of the investigation, the Section Supervisor will make a suggestion as to whether the issue is a nonconformance and if so, if the issue is a correction or a corrective action.

4.3 The Quality Manager and Laboratory Director will review the investigation and must approve of the results prior to casework resuming.

4.4 If no nonconformance occurred, then casework will resume.

4.5 If a nonconformance did occur, the following items must be considered:

- Does the nonconformance affect the customer? If so, does the customer need immediate notification? In addition to notification of the law enforcement agencies, the prosecuting attorney may also need to be notified.
- Does the work need to be recalled? The laboratory may issue amended reports in lieu of recalling the original report.
- Does the nonconforming work require a corrective action plan or can it be simply corrected?
- Have any risks or opportunities for improvement been identified?

4.6 The following is a guideline of when the laboratory will implement the corrective action process:

4.6.1 A corrective action is not punitive and is meant to address a failure of the laboratory management system. The final corrective action report will not reference examiner names or laboratory case numbers.

4.6.2 Corrective action is <u>required</u> in any of the following situations:

- when there is a likelihood that the nonconformity will recur;
- significant noncompliance with laboratory policies;
- if an analyst error has occurred in a proficiency test;

- if a technical error has occurred and has gone beyond the technical review process.

NOTE: A single instance of a lapse of laboratory policy may not require a corrective action. For example, if a daily calibration is missed on one occasion AND no casework results were affected, no corrective action would be necessary. However, if the missed calibration affected casework results OR there are repeated instances of a missed calibration, corrective action may be necessary.

4.6.3 When considering if a corrective action is necessary, the severity of the nonconformance will be examined. A corrective action is required if the nonconformance directly affects and has a fundamental impact on the work product of the laboratory or the integrity of the evidence; or there is a concern that if the problem continues for an extended period the work product of the laboratory or integrity of the evidence could be negatively affected.

4.6.4 If the issue does not, to any significant degree, affect the fundamental reliability of the work product of the laboratory or the integrity of the evidence, a corrective action may not be necessary. Examples may include minor analytical discrepancies identified and corrected in technical review; minor, non-disruptive equipment failure; proficiency test inaccuracies that are the result of poorly administered tests; etc.

4.6.5 Repeated instances of a non-significant issue or multiple non-significant issues may rise to the level of corrective action based on the frequency and time span of the issues.

4.6.6 When making a determination if a corrective action is warranted, consideration should be given as to whether or not the testing methods and conclusions are reasonable and within the range of acceptable opinions of peers within the discipline.

4.6.7 Examples of instances where a corrective action may be necessary include but are not limited to:

- A misidentification is made.
- An exclusion is made when the evidence indicates an inclusion.
- A positive identification is not made when it should have been made.

- The results are reported as an inconclusive when the data indicated a more definitive conclusion.
- An error of omission; an analyst fails to observe obvious physical evidence or fails to perform appropriate analysis.
- The information in the case notes does not corroborate the reported conclusions.
- An employee fails to perform needed examinations on a case, fails to track the case and thus does not perform any examination, or fails to transfer evidence to another section.
- An employee uses an unreliable method, a method that has not been properly validated, or an inappropriate method during the examination of evidence
- Equipment is found to be nonfunctional or operating outside of normal parameters and the results of testing conducted with the equipment have been relied upon to draw conclusions.
- A proficiency result is different from the expected result without a reasonable explanation such as an unfair test. Refer to the policy on Proficiency Tests (QA-P007).
- This list is not all-inclusive and cannot account for every situation in which corrective action may be necessary. The corrective action process may be implemented at the discretion of the Section Supervisor, Quality Manager, and Director in accordance with the laboratory's corrective action procedures.

4.7 Instances of nonconforming work that do not rise to the level of corrective action must be corrected, but can be addressed without use of the corrective action procedure.

4.8 Corrections will be documented in the Investigation documentation.

4.9 If casework was suspended and no corrective action is necessary, casework may be resumed upon mutual agreement of the Section Supervisor, Director, and Quality Manager.

5. Corrective Action

5.1 If the investigation determined that a corrective action is necessary, the casework or databasing may continue to be suspended until the completion of the corrective action process.

5.2 A root cause analysis will be conducted as part of the investigation process. The Section Supervisor is responsible for performing the root cause analysis. There are a variety of mechanisms for performing a root cause analysis. The investigator(s) may use whatever tools are available to determine the root of the issue and identify possible solutions. Records of the root cause and root cause analysis will be retained in Paradigm under the Investigation step for each corrective action.

5.3 The Section Supervisor will evaluate the causes and possible solutions identified during the investigation and determine a plan for taking corrective measures. The plan may include the following:

- Rewriting policies, methods, or other documents.
- Retesting or revalidating faulty methods or equipment.
- Retraining the examiner. Retraining may take the form of a formal training program, outside training, verbal communications / conversations, or a combination of these depending on the issue to be addressed.
- Retesting the examiner. The Quality Manager or Director may request that a proficiency test be assigned.

5.4 If the nonconformance directly impacted the quality of casework, the Section Supervisor may review an appropriate amount of similar casework.

5.4.1 If the problem involves an examiner and was identified after the case completed technical review, previous casework will be reviewed. The casework review period typically dates back to the date of the most recent passed proficiency test in the same sub-discipline. However, depending on the issue, volume of cases, and the time span of the proficiency testing period, the review may extend beyond that date or may not extend to that date.

5.4.2 If the problem was identified prior to or during technical review and all of the information necessary for case review is available in the affected case folders, the Section Supervisor may choose one or both of the following:

- The Section Supervisor may review an appropriate amount of similar previous casework.

- The Section Supervisor may review an appropriate amount of similar casework that the examiner completes after completion of any necessary retraining.

- Both of the above may be employed.

5.5 The Section Supervisor will submit a Corrective Action Plan to the Quality Manager for approval. The corrective action plan will include corrective actions, expected completion dates, and individuals responsible for completing the corrective actions, anticipated re-training, casework review, and anticipated re-proficiency testing.

5.6 The Section Supervisor is responsible for updating the Quality Manger and Laboratory Director as the corrective actions progress.

5.7 The Section Supervisor will document the implementation of corrective actions.

5.8 If casework was suspended, casework may be resumed upon mutual agreement of the Section Supervisor, Director and Quality Manager.

5.9 The Section Supervisor will verify the effectiveness of corrective actions; the verification will be documented.

5.10 Upon the verification of effectiveness, the Quality Manager and Laboratory Director will finally approve the corrective actions.

5.11 A Corrective Action Report (QA-F002) can be printed upon request.

5.12 The Section Supervisor will notify the CODIS Administrator of any relevant corrective actions.