Corrective and Preventive Action Reports

1. Purpose

This defines the laboratory policy on using corrective and preventative action to remediate quality issues and prevent them from occurring or reoccurring.

2. Summary

The policy defines what constitutes a nonconformity and when it triggers a response utilizing the corrective action report process or preventative action report process. The risk severity for nonconformities is defined with recommended or required responses. Preventative measures are also defined to circumvent potential quality issues. The Corrective and Preventative Action Report processes are defined and authorization for the Forensic DNA Technical Leader to manage and approve is documented.

3. Procedure

1. All staff have the responsibility and authority to report any situations that do not conform to or meet the expectations of the laboratory's SOPs or the laboratory's adopted accreditation standards.
    a. When a such a situation is recognized, the DNA Technical Leader (DNA TL) must be notified.
    b. A documented investigation and assessment to gather information, data and documents will occur.
    c. The DNA TL has the ultimate authority for an assessment of the reported situation, determination of a nonconformity, and initiating the appropriate process in response to the outcome of the investigation.
        i. Not all reported situations will rise to the level of a nonconformity and may be addressed with preventative action or determined to be immaterial.
        ii. This process may involve interviews with staff, re-examination of evidence, review of case files, and evaluation of past and current revisions SOPs.
        iii. All applicable accreditation standards should be referenced during this process to aid in determining nonconformity with them, as well as with IMF SOPs.
        iv. Documentation of the investigation and assessment will be maintained in the following locations:
            1. Corrective Actions Folder, in a folder titled with the CAR#, if a nonconformity is identified.
                a. Nonconformities will be tracked by entry into the second tab titled "Corrective Action" in the DOC-305 Corrective Action Preventative Action Log. The CAR# format is IMF-## and will be tracked sequentially in the order they are identified.
            2. Preventative Actions Folder, in a folder titled with the PAR#, if an opportunity for improvement is identified.
                a. Opportunities for Improvement will be tracked by entry into the second tab titled "Preventative Action" in the DOC-305 Corrective Action Preventative Action Log. The PAR# format is PA-IMF-## and will be tracked sequentially in the order they are identified.

3. Reported Nonconformities Folder, in a folder titled with the date and general summary of the issue, if the report is determined to be immaterial.
    a. Immaterial reported nonconformities will be tracked by entry into first tab titled "Reported Nonconformities" in the DOC-305 Corrective Action Preventative Action Log

2. An immediate corrective action may be required to address the nonconformity, based on the severity of the situation and the potential impact to casework.
    a. Any immediate corrective action should be approved by the DNA TL prior to implementation.
        i. Based on the immediate nature of the nonconformity, approval of the actions may be verbal, but written documentation of the immediate corrective action plan and approval by the DNA Technical Leader must be completed in the DOC-320 Corrective-Preventative Action Form.

Corrective Action Report Process

1. Corrective action reports (CAR) are performed to correct nonconformities and to improve the management system in an effort to eliminate the cause of the nonconformity, so it will not occur again in the future

2. When nonconforming work is identified, the DNA TL is responsible for initiating the corrective action report process which includes the following, as necessary:
    a. management of cause analysis
    b. halting or repeating of testing
    c. resumption of testing
    d. sequestering, rewording, reworking or allowing release of reports.
    e. initiating an amended report(s), where applicable
    f. risk assessment of the nonconformity

3. Documentation will be maintained in the following manner:
    a. The CAR# and required information will be tracked using the DOC-305 Corrective Action Report / Preventative Action Report Log to monitor status and progress of the CAR
    b. An electronic folder named with the CAR# will be utilized to store documentation.
    c. If the nonconformity is case-related, documentation should focus on being transparent to client and may require notification to the customer.
    d. Documentation should include at a minimum:
        i. DOC-320 Corrective-Preventative Action form
        ii. Cause Analysis documentation, where applicable
        iii. Objective Evidence of completion of planned corrective actions
        iv. DOC-339 Corrective Action Effectiveness Evaluation Form, where applicable
    e. The DNA Technical Leader will document their approval and the progress of the CAR using the initials, date, and signature fields of the DOC-305 Corrective Action Preventative Action Log, DOC-320 Corrective-Preventative Action Form, and the DOC-339 Corrective Action Effectiveness Evaluation Form.

4. The process of the Corrective Action Report is as follows:
    a. Perform an assessment on the impact on current and past casework associated with the nonconformity.

i. If the quality of the work is significantly impacted by the nonconformity the processing, interpretation and/or reporting will be deemed unacceptable, and recall/modification of this previous work affected by this nonconformity will be required.
    1. This impact assessment will be documented and directed by the DNA Technical Leader
    2. Laboratory re-work, reinterpretation and/or issuing of an amended report will be required at the direction of the DNA Technical Leader
    3. The client(s) will be notified of this recall and rework plan.
ii. The DNA Technical Leader has the authority to suspend and resume casework for the laboratory.

b. The Risk Level of the nonconformity should also be assessed and documented using the following scale:
    i. Low severity
        1. The nonconformity **can** be remediated with documentation, rework and/or an amendment to the report or case file.
        2. The nonconformity is the result of a single error and is not systemic to the process.
        3. Documentation of remediation will be stored within the electronic case file indefinitely.
    ii. Moderate severity
        1. The nonconformity **cannot** be remediated with documentation, rework and/or an amendment to the report or case file.
        2. The nonconformity is the result of a single error and is not systemic to the process.
        3. Client contact (phone or e-mail) is required to discuss remediation, where appropriate.
        4. Cause Analysis may be initiated if deemed necessary by the DNA Technical Leader
        5. Documentation of remediation and contact with the customer will be stored within the electronic case file indefinitely.
    iii. High severity
        1. The nonconformity **cannot** be remediated with documentation, rework and/or an amendment to the report or case file.
        2. The nonconformity is systemic within the process, standard operating procedures and/or the incorrect or insufficient training of staff member(s)
        3. Client contact (phone or e-mail) is required to discuss remediation, where appropriate.
        4. Cause Analysis must be completed.
        5. The DNA TL will determine if it is necessary to suspend technical processing.
        6. All appropriate accrediting bodies may be notified, where appropriate.
    iv. Extreme severity
        1. The nonconformity **cannot** be remediated with documentation, rework and/or an amendment to the report or case file.
        2. The nonconformity is systemic within the process, standard operating procedures and/or the incorrect or insufficient training of staff member(s) and involves casework from more than one customer.

3. Contact with all involved customers (phone or e-mail) is required to discuss remediation.
    a. Contact will continue throughout the corrective action report process with all impacted customers.
4. The DNA TL will determine if it is necessary to suspend technical processing.
5. All appropriate accrediting bodies will be notified.

c. Cause Analysis will be completed, according to the assigned severity level.
    i. Documentation to support the identified cause must be maintained in the CAR documentation folder.

b. Document and complete any steps of the immediate corrective action plan, if necessary
    i. The urgent action plan is a short-term remediation to the nonconformity.
    ii. This ensures quick action to temporarily address the nonconformity where casework is at risk.
    iii. The immediate action may be all that is needed to ensure nonconformity is no longer relevant, or risk is mitigated, thus no enduring action plan is required.
        1. Determined by the DNA Technical Leader

c. Make an enduring action plan.
    i. The enduring action plan is a long-term permanent remediation to the nonconformity.
        1. May include re-training, validations, new methods, new SOPs etc.
    ii. The enduring action plan should include the action to be taken, the responsible party for the action, and a reasonable timeframe for completion of the action.
        1. The timeframes may be shifted as required, but there should be an expectation of completion within a reasonable time.

d. Implement the enduring action(s)
    i. Actions will be assigned to appropriate staff members by the DNA Technical Leader.
    ii. Maintain documentation of the completion of the ensuring action(s)
        1. Store the documentation in a folder titled “Objective Evidence” in the CAR folder.

e. Assess Effectiveness of the corrective action
    1. Within a time period specified within the CAR, the results of the urgent and enduring actions will be assessed to ensure they were successful in addressing the cause of the nonconformity and no recurrences of the issue had arisen in the set time period and/or the planned corrective action was implemented as intended.
    2. The review of the effectiveness will be documented on the DOC-339 Corrective Action Effectiveness Evaluation Form
        a. This form will be retained in the corrective action documentation folder.
    3. If determined effective the CAR can be finalized and closed
    4. If the enduring action(s) are found to not be effective, then the process must either return to the determine root cause(s) step, or the make an enduring action plan step.
        a. The step that the process will return to will be determined by the DNA Technical Leader
        b. These steps must be documented on the DOC-339 Corrective Action Effectiveness Evaluation Form
        c. Alternatively, a new corrective action report can be initiated but each file must contain reference to the associated CAR#.

Preventative Action Report Process

1. Preventative action reports (PAR) are preventive opportunities to improve the overall quality system as a result of an observation, audit/assessment suggestions, a situation that has the potential to lead to a nonconformity, identification potential conflicts of interest, or other suggestion by staff or external sources

2. The initiation, management and finalization of PAR is of the responsibility of the DNA Technical Leader

3. The PAR# and required information should be logged using the DOC-305 Corrective Action Report / Preventative Action Report Log to monitor status and progress

4. An electronic folder named with the PAR# should be utilized to maintain documentation of the preventative action report process.
    a. Minimum documentation includes:
        i. A signed copy of DOC-320 Corrective-Preventative Action Form
        ii. Objective Evidence of completion of planned corrective actions
    b. The DNA Technical Leader will document their approval and the progress of the CAR using the initials, date, and signature fields of the DOC-305 Corrective Action Preventative Action Log and the DOC-320 Corrective-Preventative Action Form.

5. The process of the Preventative Action Report is as follows:
    a. Perform a documented investigation to gather information, data and documents to determine a suitable preventative action
        i. This may involve interviews with staff, re-examination of evidence, review of casefile, report, SOPs etc.
    b. Make an enduring action plan.
        i. The enduring action plan is a long-term permanent remediation to the potential nonconformity.
            1. May include re-training, validations, new methods, new SOPs etc.
    a. Implement enduring action(s)
        i. Actions will be assigned to appropriate staff members by the DNA Technical Leader.
        ii. Maintain documentation of the completion of the ensuring action(s)
            1. Store the documentation in a folder titled “Objective Evidence” in the CAR folder.

4. References

N/A

5. Definitions

Nonconformity - Something which has gone wrong or not met the requirements of the quality management systems processes or accreditation standards.