	Intermountain Forensics	SOP #	ADM-109
		Revision #	01
Forensic DNA Technical Leader Approval		Issue Date	
		6/3/20	

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.

2. Summary

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

3. Procedure

Quality Work

1. All staff have the responsibility and authority to report any processing, personnel or standard operating procedures (SOPs) that do not conform to the laboratory's SOPs and/or do not meet the level of "quality work" (quality issue)
    a. When a quality issue (QI) is recognized, the Laboratory Director (LD), DNA Technical Leader (DNA TL), Forensic DNA Supervisor, Sr. Forensic DNA Analyst or Laboratory Manager (LM) should be notified
    b. The DNA TL has the ultimate authority for an assessment and remediation of the quality issue

2. When nonconforming work is identified, the DNA TL is responsible for the following, as necessary:
    a. management of QI testing
    b. halting or repeating of the testing
    c. sequestering, rewording, reworking or allowing release of reports
    d. initiating an amended report (if the non-quality work occurred on a case that had already been issued)
    e. risk assessment of the QI

3. An immediate remediation plan should be taken in the short-term to correct the quality issue
    a. This plan should be approved by the DNA TL (at minimum) verbally and followed up with documentation

4. If severity is minimal, remediation can be completed with case documentation
    a. Documentation should focus on being transparent to client and may require direct contact (phone call, e-mail etc.)
    b. This documentation will be retained within the case file or stored within the electronic case folder indefinitely

5. If severity is systemic or the risk of re-occurrence is high, a Corrective Action Report (CAR) should be initiated

Risk Levels

6. Risk Factors to assess the severity of the QI
    a. Low severity
        i. The QI can be remediated with documentation, rework and/or an amendment to the report or casefile
        ii. The QI is the result of a single error and is not systemic to the process
    b. Moderate severity
        i. The QI cannot be remediated with documentation, rework and/or an amendment to the report or casefile
        ii. The QI is the result of a single error and is not systemic to the process
        iii. The QI has caused the result to be reported as inconclusive
        iv. Client contact (phone or e-mail) is required to discuss remediation
        v. A CAR (level 1) may be initiated if deemed necessary by the DNA TL
    c. High severity
        i. The QI can be remediated with documentation, rework and/or an amendment to the report or casefile
        ii. The QI is systemic within the process, standard operating procedures and/or the incorrect or insufficient training of staff member(s)
        iii. A CAR (level 1) must be initiated
    d. Extreme severity

i. The QI cannot be remediated with documentation, rework and/or an amendment to the report or casefile
ii. The QI is systemic within the process, standard operating procedures and/or the incorrect or insufficient training of staff member(s)
iii. The QI has caused the result to be reported as inconclusive
iv. A corrective action report (level 2) must be initiated
v. Client contact (phone or e-mail) is required to discuss remediation
vi. The DNA TL will determine if it is necessary to suspend technical processing
vii. Any accrediting body will be notified

Corrective Action Report

7. Corrective action reports (CAR) are opportunities to improve the overall quality system as a result of an observation, audit/assessment (including the DNA TL annual review), quality issue or other suggestion by staff or external sources

8. The initiation, management and finalization of CAR is of the authority of the DNA TL

9. The CAR# should be logged using the Corrective Action Report / Preventative Action Report Log to monitor status and progress

10. A summary form and electronic folder devoted to the CAR# should be utilized to document the CAR investigation, actions and results and finalization

11. The process of the Corrective Action Report is as follows:
    a. Investigate
    b. Determine root cause(s)
    c. Make urgent action(s) plan
    d. Implement urgent action(s)
    e. Make enduring action(s) plan
    f. Implement enduring action
    g. Assess Effectiveness

12. A documented **investigation** to gather information, data and documents should occur and these should be housed within an electronic folder devoted to the CAR
    a. May involve interviews with staff, re-examination of evidence, review of casefile, report, SOPs etc.

13. A team will be gathered with appropriate staff (including, at minimum, the DNA Technical Leader) and will be assigned to address the CAR

14. **Root cause**(s) will be identified
    a. Where possible root cause analysis techniques can be used help identify the source of the QI

15. Create and implement an **urgent** action plan
    a. The urgent action plan is a short-term remediation to the QI
    b. This ensures quick action to temporarily address the QI
        i. May include an e-mail, documented staff briefing, SOP change or other process change that can easily be implemented, documented and communicated to staff
    c. Urgent action may be all that is needed to ensure QI is no longer relevant or risk is mitigated, thus no enduring action plan is required
        i. Determined by the DNA TL

16. Create and implement an **enduring** action plan
    a. The enduring action plan is a long-term permanent remediation to the QI
        i. May include re-training, validations, new methods, new SOPs etc.

17. Assess Effectiveness
    a. At a time frame specified within the CAR, the team will reconvene to assess the results of the urgent and enduring actions
    b. If determined effective the CAR can be finalized and closed

18. The DNA TL will initial/date each process within the CAR and sign/date to signify final approval of the completed CAR.

Preventative Action Report

19. Preventative action reports (PAR) are **preventive** opportunities to improve the overall quality system as a result of an observation, audit/assessment (including the DNA TL annual review) suggestions, a possible quality issue or other suggestion by staff or external sources

20. The initiation, management and finalization of PAR is of the authority of the DNA TL

21. The PAR# should be logged using the Preventative Action Report / Preventative Action Report Log to monitor status and progress

22. A summary form and electronic folder devote to the PAR# should be utilized to document the PAR investigation, actions and results and finalization

23. The process of the Preventative Action Report is as follows:
    a. Investigate
    b. Determine root cause(s)
    c. Make urgent action(s) plan
    d. Implement urgent action(s)
    e. Make enduring action(s) plan
    f. Implement enduring action
    g. Assess effectiveness

24. A documented **investigation** to gather information, data and documents should occur and these should be housed within an electronic folder devoted to the PAR
    a. May involve interviews with staff, re-examination of evidence, review of casefile, report, SOPs etc.

25. A team will be gathered with appropriate staff (including, at minimum, the DNA Technical Leader) will be assigned to address the PAR

26. **Root cause**(s) will be identified
    a. Where possible root cause analysis techniques can be used help identify the source of the potential QI

27. Create and implement an **urgent** action plan
    a. The urgent action plan is a short-term remediation to the potential QI
    b. This ensures quick action to temporarily address the potential QI
        i. May include an e-mail, documented staff briefing, SOP change or other process change that can easily be implemented, documented and communicated to staff
    c. Urgent action may be all that is needed to ensure potential QI is no longer relevant or risk is mitigated, thus no enduring action plan is required
        i. Determined by the DNA TL

28. Create and implement an **enduring** action plan
    a. The enduring action plan is a long-term permanent remediation to the potential QI
        i. May include re-training, validations, new methods, new SOPs etc.

29. Assess Effectiveness
    a. At a time frame specified within the PAR, the team will reconvene to assess the results of the urgent and enduring actions
    b. If determined effective the PAR can be finalized and closed

30. The DNA TL will initial/date each process within the PAR and sign/date to signify final approval of the completed PAR.

4. References

N/A

5. Definitions

Quality Issue: (QI) work that does not conform to the standard operating procedures and policies of the laboratory and/or a process, standard operating procedure or staff member that is deficient enough in quality that it brings question to the reliability or unbiased nature of our laboratory's result.