A. PURPOSE:

Quality Action Requests (QAR) are used to evaluate an incident, nonconforming work, or departures from the policies and procedures specified in the Quality Manual and/or the SOP's or other circumstance which may have a negative or detrimental impact on the quality of the forensic work performed in the laboratory. Quality Action Reports may be created in one of three categories; Corrective Action, Preventive Actions or Incident Reports. Corrective Actions are used to investigate identified issues with the quality system. Preventative Actions are used to improve the quality system. Incident Reports are used to document occurrences that have been identified through the quality system, which don't rise to the level of a CAR (Corrective Action) but should be documented and monitored.

B. RESPONSIBILITY:

Director: is responsible for supporting the use of Quality Action Requests, and to review QARs as part of the annual Management System Review.

Deputy Director (DD): is responsible for working with the Assistant Director, Unit Supervisor/Lead and Quality Managers, reviewing and possibly developing the remediation plan for Corrective Actions. Additionally the Deputy Director is responsible to review the Preventive Actions and Incident Reports within their section.

Assistant Director (AD): is responsible for working with the Deputy Director, Unit Supervisor/Lead and Quality Managers, reviewing and possibly developing the remediation plan for Corrective Actions. Additionally the Assistant Director is responsible to review the Preventive Actions and Incident Reports within their Section.

Laboratory Administrative Manager (LAM): is responsible for working with the unit Supervisor/Lead and Quality Section, reviewing and possibly developing the remediation plan for Corrective Actions. Additionally the LAM is responsible to review the Preventive Actions and Incident Reports within their section.

Quality Section (QS): is responsible for keeping the Director informed of issues requiring Corrective Action. The section will regularly update the Director of the implementation of QARs and the status of remediation for Corrective Actions. The Quality Section is also responsible for maintaining all QAR, to ensure that remediation is carried through, and to demonstrate that the identified issues of all Corrective Actions have been corrected. QAR forms will be maintained for a period of 2 ASCLD/LAB audit cycles (8 years). Electronic QARs will enable the Quality Section to maintain the Qualtrax workflow files in lieu of the paper versions (i.e. retired forms GL-9.1 and GL-9.2). These are annotated in Qualtrax as workflows 'QAR – Corrective Action', 'QAR –Preventative Action Report', and 'QAR – Incident Report'.

Quality Manager (QM): is responsible for reviewing all QARs to ensure that underlying issues have been adequately addressed and that there are no related, unrecognized issues. Additionally, the QM and/or the FB/DNA QM will work with Deputy Directors, Assistant Directors, the LAM, the DNA TL, and/or Unit Supervisors/Leads as needed in documenting corrective actions, performing root cause analyses and in determining appropriate remediation for QARs.

FB/DNA Quality Assurance Manager (FB/DNA QM): is responsible for working with Deputy Directors, Assistant Directors, the LAM, and/or Unit/Section Supervisors/Leads, DNA TL and/or the QM, as needed, in documenting corrective actions, performing root cause analyses and determining appropriate remediation for QARs. The FB/DNA QM is generally responsible for the initiation and follow-up of QARs related to the FB and DNA units.

All (Division of Scientific Services) DSS Employees (however titled): are responsible for bringing potential issues/problems to their direct Supervisor/Lead.

Unit Supervisors/Leads: are responsible for notifying the Quality Section and their Assistant Director or Deputy Director or the LAM (depending on chain of command) when a potential QAR is discovered. Section Supervisors/Leads will work with their Deputy Director and the Quality Section to document potential problems through QARs as appropriate. (Note that in DNA, if the Technical Leader is not the Supervisor/Lead, the TL will also be informed by the Supervisor/Lead).

C. PROCEDURE:

When an item/issue is identified as requiring a QAR, the individual identifying the issue will notify their Supervisor/Lead. The Supervisor/Lead is required to notify the Quality Section and the appropriate Assistant Director or Deputy Director or the Laboratory Administrative Manager of the potential QAR. The Quality Section will have final decision as to whether an issue is documented as a Corrective Action, Preventive Action, Incident Report or if a simple notation is appropriate (i.e. such as in a maintenance log, or case file). The Quality Section will work directly with the DNA Technical Leader in determining how to categorize technical DNA issues. The Corrective Action may be documented using the appropriate Qualtrax workflow:

QAR-Corrective Action (used for non-technical testing Sections/Units or if multiple Sections are involved in one issue)

QAR-DNA Corrective Action

QAR-Identification Section Corrective Action

QAR-Chemistry/TOX/CS Corrective Action

Incident Reports and Preventative Actions are documented in Qualtrax Workflows titled:

QAR- Incident Report and QAR Preventative Action Report

All employees have the option of bringing quality related Management System issues directly to their Supervisor/Lead, their Assistant Director, Deputy Director, the Laboratory Administrative Manager, the Quality Section or also can complete the Internal Complaint/Issues form (GL-10.3).

In general, the DSS will make every effort to complete the remediation(s) associated with any Corrective Action within 45 days of initiating the CAR. For Incident reports and Preventative actions, the Division will attempt to complete the remediation (if applicable) within 60 days. However, it is understood that outside influences may delay a remediation (i.e. the purchasing of specific equipment, specialized training requirements etc.).

A QAR-Corrective Action workflow (all specific types) will be initiated in Qualtrax when any of the following is true:

- An incident of non-conforming work that effects the validity of case results is identified
- A departure from policies and procedures, that was not a planned event, and which was of a magnitude such that case analysis may be impacted
- A departure from policies and procedures, that was not a planned event, and which was of a magnitude such that procedure integrity/validity was impacted.
- Discrepancies identified in proficiency test results where the provider's grade is unacceptable (or equivalent). Discrepancies in proficiency test results where the provider's grade was acceptable however the results or process of obtaining the results did not meet the requirements of the DSS.

  Note: All discrepancies identified by the ASCLD/LAB Proficiency Review Committee will be investigated using one of the available Qualtrax QAR-Corrective Action workflows depending on the affected discipline.

  - All discrepancies in proficiency test findings will be reviewed to determine the source of the discrepancy. The nature of the error will dictate the level of the remediation (e.g. error verses improperly performed procedure).
  - When a proficiency test discrepancy is identified the issue will be reviewed to determine if case work could have also been affected.

Instances which may require a Corrective Action include (but are not limited to):

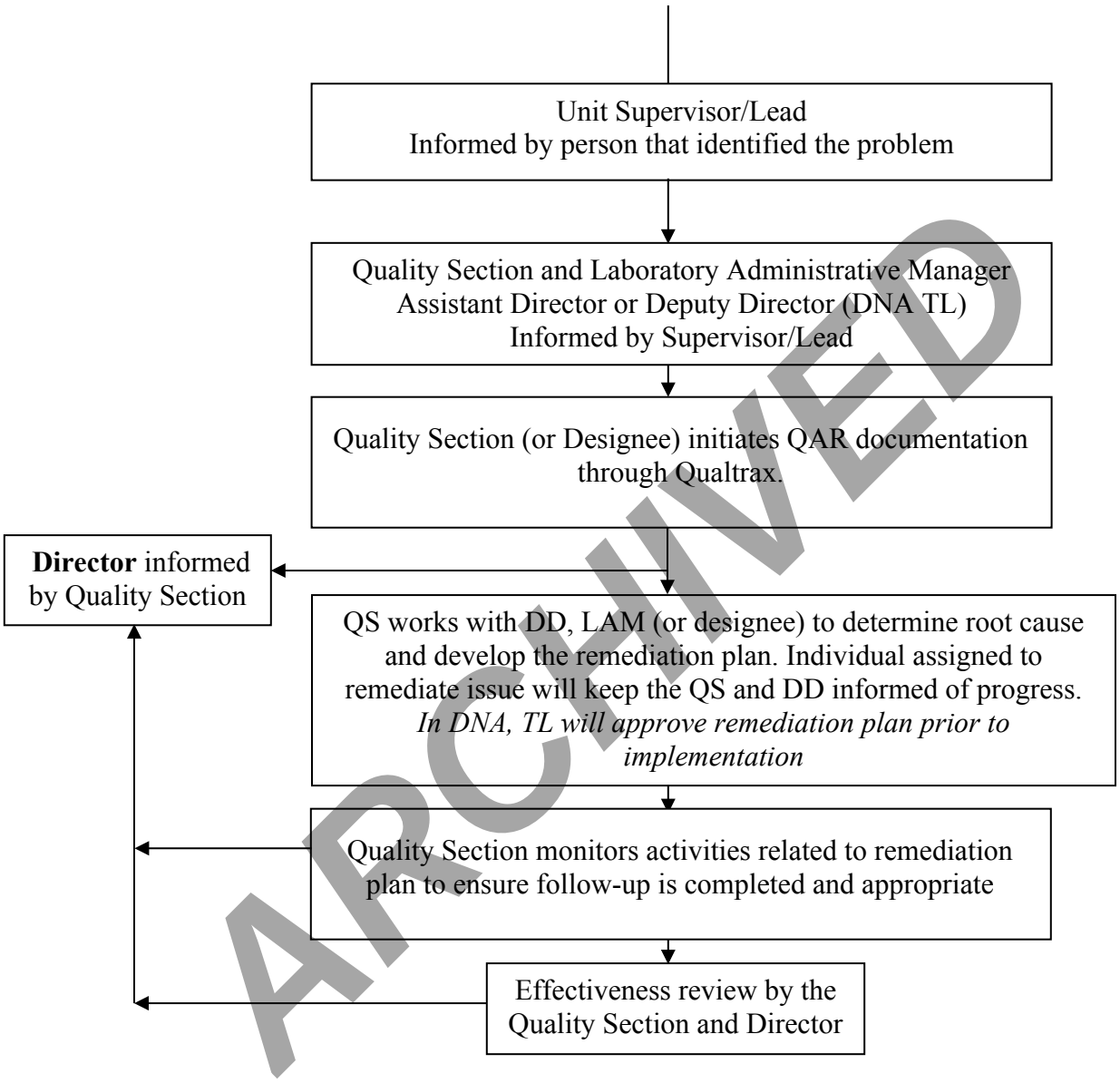
- The need to revise reports based on errors in original reports (such instances do not include supplemental reports or revised reports that are due to errors from information supplied by the submitting agency (e.g. incorrect source names or agency case numbers).
- Instances wherein customer complaints have identified flaws in to the quality system.

- Improper handling/storage of case materials.
- Issues discovered during the annual audit or management system review that affect quality.

Note: Within the DNA section, incidences of contamination will be documented by the FB/DNA QM using a Qualtrax workflow (DNA Contamination Tracking). This will be used to identify trends. In most cases an incident of contamination will not require a Corrective Action. However if trends are noted, a Corrective Action or Incident Report may be initiated based on these events.

I. General Flow to be followed for QARs

Quality Issue Identified
-this can be initiated by anyone in the DSS



II. Completing QAR-Corrective Action Workflows:

Qualtrax QAR-Corrective Action Workflow (CAR) (all types as specified above):

The CAR Qualtrax workflow directs the user during the various steps of documentation. The elements of the CAR are as listed below. More details can be found in the Qualtrax workflow steps. The Quality Section (or a designee) will initiate the workflow in Qualtrax. Depending on the Section, and specific Corrective Action workflow used, elements may be slightly different from the below general format.

1. Notice of Incident:
    i. Date of Occurrence: Date that incident occurred.
    ii. Discipline Affected
    iii. Personnel Involved
    iv. Description of Incident
    v. Effect of Discrepancy
    vi. Standard Violation

The individual initiating the investigation (if applicable), the unit Supervisor/Lead, Assistant Director, Deputy Director (or TL in DNA) or Laboratory Administrative Manager, Quality Section Representative and the Director will be included to review the workflow through Qualtrax. In the Qualtrax workflow, the acknowledgement and/or approval will be done electronically.

The description of the event may be completed by the person discovering the issue of concern, but is typically written by a representative of the Quality Section. The investigation should include a thorough description of the event and the effect or the potential effect of the discrepancy/event on the laboratory. Once the scope of the investigation is identified, appropriate personnel will be assigned by the Deputy Director, Laboratory Administrative Manager, Quality Section or their designee. When appropriate the investigation will include a review to determine if any cases were affected.

2. CAR Designation: unique identification used for tracking the QAR. This will be a unit identifier followed by the date. In instances where multiple CARs are assigned on the same date to the same section, an alpha designator will be added. Example: TX092217-A TX092217-B

3. Incident Write-up

    i. CAR Level: Level 1 CARs will have a direct impact on casework produced in the laboratory.
    ii. Investigation of Incident: Further details on investigation of incident
    iii. Personnel to Review and Acknowledge: Notification sent to personnel that a CAR has been started (for example: Technical Leader in DNA)
    iv. Incident Write up external files: place to upload any external files (if applicable)
    v. Quality Section person for review

4. Review/Acknowledgement: Section of workflow where selected personnel can document that they were notified a CAR was opened. (example: TL in DNA, Deputy Director, Assistant Director)

5. Quality Review: Section of workflow where Quality section has documented acknowledgement of CAR being opened.

6. Director Notification: Section of workflow where Director documents notification.

7. Root Cause Investigation and Remediation Plan Write-up: Define the root cause, the remediation plan, who is to approve the remediation plan, and the date remediation is due.

    i. The root cause analysis allows determination of the underlying reason for the QAR. While root cause analysis may be difficult to establish and define, it is an important part of the QAR process. By determination of the root cause, an appropriate plan of action can be established to remedy the underlying circumstances.

    ii. Since each event will vary, it is important to understand that there may be multiple possible root causes to any Corrective Action event that may need to be investigated. When possible, testing or other appropriate actions will take place to confirm or rule out a possible root cause.

    iii. Intermediate steps may need to be performed to identify the root cause of the issue. This may include re-analysis of test materials, re-validation of reagents, or other such actions.

    iv. The remediation plan consists of the 'Intermediate Steps Taken/Intermediate Plan' and the 'Permanent Changes'. For Corrective Actions generated in the DNA section, which are technical in nature, the remediation plan must be pre-approved by the unit TL prior to implementation. In the Qualtrax workflow, the acknowledgement and/or approval for the plan will be documented electronically; this may be by the Director, DD, LAM, DNA TL or a member of the QS depending on the QAR.

    v. The remediation plan are actions taken which, when implemented, would resolve the event, action or discrepancy which caused the CA.

    vi. An intermediate/remedial plan of action will be decided on and implemented in order to minimize any further departures from the policies and procedures specified in the Quality Manual and/or the SOP's. The intermediate steps may be used to help determine the root cause(s) of the issue(s). The decision on an intermediate/remedial plan and the oversight of it will be the responsibility of the Quality Section with the Laboratory Administrative Manager or Deputy Director (the TL in DNA) or the personnel assigned to the task(s).

    vii. Any individual assigned a task associated with a Corrective Action is responsible to perform the task and provide the related documentation to their Supervisor/Lead or their Deputy Director or LAM as appropriate.

8. Approval of Remediation Plan: This is where the approval of the remediation plan is documented. For example, per the DNA QAS, the DNA TL needs to document approval of the remediation plan prior to it being implemented. This is the location to find this documentation.

9. Remediation and Permanent Changes:

    i. Remediation steps taken

    ii. Permanent Changes made

        1. Following implementation of the intermediate/remedial plan of action, permanent changes will be decided upon in order to correct the incident of nonconforming work. Approval of these changes will be the responsibility of the Laboratory Administrative Manager or Section Deputy Director (the TL in the DNA section), in concert with the Quality Section. In the Qualtrax workflow, the acknowledgement and/or approval will be done electronically.
        2. Changes developed based on the findings of the CAR will be appropriately documented. Appropriate documentation may include changes to SOPs. When changes to SOPs are required, SOP GL-19 Document Control will be followed.
        3. Appropriate documentation will vary depending on the nature and degree of the CAR.

    iii. Supporting Documentation (external and internal files uploaded here)

10. Evidence of Effectiveness: Documents support that the remediation was effective. Any files supporting this can be uploaded and stored at this step.

    i. Implementation of any permanent changes may be monitored for a predetermined period of time by the Quality Section to ensure that compliance with the Quality Manual and/or the SOPs involved in the QAR are satisfied. The need to monitor changes will depend on the nature of the implemented change.

        a. Corrective Actions including effectiveness of the remediation are reviewed during Quality Section Meetings with the Director, Laboratory Administrative Manager, and Deputy Directors. Meeting agendas/notes will serve as documentation of this review.

    ii. Corrective Actions from an internal or external DNA QAS audit will be submitted to the DNA technical leader for review to ensure that the findings were appropriately addressed. In the Qualtrax workflow, the acknowledgement and/or approval will be done electronically.

11. Direct Final Review: Director final review documented here

i. Prior to closing a CAR the Director will review the CAR and document this review in Qualtrax.

ii. Once the CAR is reviewed by, and is found to be satisfactory by, the Director, it is sent to a member of the QS to close.

12. Quality To Close: CAR completed

III. Qualtrax 'QAR-Preventative Action Report' or 'QAR- Incident Report' workflow:

The QAR Preventative Action or QAR Incident Report workflow in Qualtrax directs the user during the various steps of documentation. The elements of the QAR are as listed below.

The Quality Section (or designee) will initiate the workflow in Qualtrax.

This process is used to document events that either are used to improve the quality system or that do not rise to the level of a Corrective Action. Examples of such issues may include contamination issues caught during the analysts normal review process, instrumental problems that are beyond issues from normal use. This cannot be used for any events that affect the integrity of evidence or case results.

Anyone can identify a situation for a Preventative Action or Incident Report. The initial reporting process is similar to a CAR. The person identifying an issue informs their Supervisor/Lead, the Supervisor/Lead informs their Deputy Director or Laboratory Administrative Manager and the Quality Section. The QM or FB/DNA QM will work with the unit to document the issue appropriately. The QM or FB/DNA QM will inform the Director of these issues during Quality Section meetings as necessary.

1. The Quality Section will determine if the issue is a Preventive Action or an Incident Report.
2. The QAR number will be assigned by the Quality Section; the format will be I- unit identifier and Date or P-unit identified and Date. (Example I-GL020513, P-DNA020513).
3. Pick in the section(s) affected.
4. Description of Event: Describe the event including important details such as how it was discovered, what was the affect, or why it was problematic.
    a. Examples:

        During an audit, the QS determined that the use of a control tracking chart would be useful to identify trends in a calibration. The institution of the control chart would be a Preventive Action to improve the quality control measures for a procedure.

    b. A new lot of solvent was discovered to contain unexpected compounds:

This may be handled as an incident report. It would be important to include the lot number of the solvent and the compounds there were found. This would help determine if the contaminant could affect other sections. Also it will help track if multiple sections are having similar issues with the same lot, indicating that the manufacturer may need to be contacted.

5. The person writing the report will add the date and their initials in Qualtrax. The workflow will then be assigned to flow to the Supervisor(s)/Lead(s) Assistant Directors and Deputy Director(s) or LAM of the affected section(s). In the Qualtrax workflow, the acknowledgement and/or approval will be done electronically.
6. A Quality Section representative will complete the 'Review by Quality Section' portion of the workflow.
    a. Determine if there are related instances that might raise the issue from a Preventative Action or Incident Report to a Corrective Action. If there are related instances then reference the related QAR numbers.
    b. If a Corrective Action is initiated due to identifying a trend, reference the numbers of the QARs in each CAR workflow.
        i. If an incident report initiates a Corrective Action, the Qualtrax CAR workflow will automatically be launched. At that point, the Incident report will be closed and the CAR workflow continues.
    c. The QS reviews Preventative actions and Incident reports during QS meetings with the Director, Laboratory Administrative Manager, Assistant Directors and Deputy Directors. Meeting agendas/notes will serve as documentation of this review.
7. A Qualtrax workflow is available for instances that do not rise to a QAR; but are tracked to ensure there are no repeating trends that would then require a QAR. This workflow is titled "Quality Tracking-one-off instances". Examples of what would be tracked in this workflow would be random unexplained events or similar issues discovered as part of normal quality review procedures and normal day to day activities (i.e. minor (non-impacting to evidence) discrepancy of what was submitted by the submitting agency, or an interior door not closing properly within the laboratory, other issues with the building such as leaks). This cannot be used for any events that affect the integrity of evidence or case results.