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 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 unit Supervisor/Lead and Quality Section, 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.

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 assure that remediation is carried through, and to demonstrate that the identified issue 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. 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 assure 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, 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 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 Deputy Director 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).

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 Deputy Director 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 form GL-9.1, Incident Reports and Preventive Actions may be documented using form GL-9.2. The completed form (electronic or paper) and related documentation will be maintained by the Quality Section. In transitioning to electronic QARs, a Qualtrax workflow may be used in place of forms GL-9.1 and GL-9.2.

All employees have the option of bringing quality related Management System issues directly to their Supervisor/Lead, Deputy Director, the Quality Section or 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 form GL-9.1 will be completed, or the Qualtrax equivalent workflow will be initiated, 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 QAR-Corrective Action Form GL-9.1 or the equivalent Qualtrax workflow.

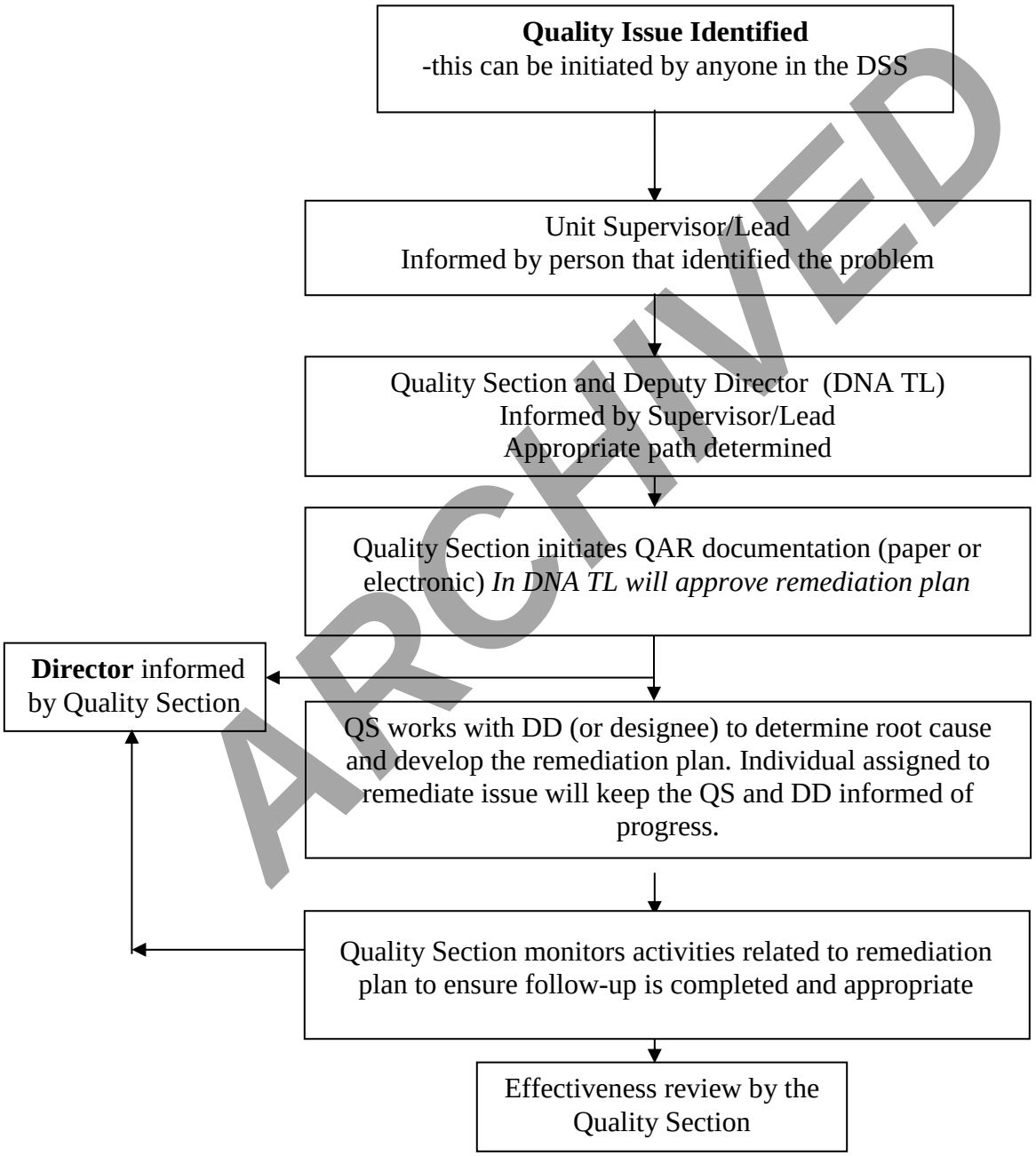
  - All discrepancies in proficiency test findings will be reviewed to determine the source of the discrepancy. The nature of the error will dictate the level of the remediation (e.g. error verses improperly performed procedure).
  - When a proficiency test discrepancy is identified the issue will be reviewed 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 spreadsheet. This spreadsheet 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.

General Flow to be followed for QARs



Completing QAR Forms:

The preferred method to document QARs is through the designated Qualtrax workflow. If a paper form is used to initiate a QAR this will be entered into Qualtrax for completion by the QS.

Corrective Action Form/Qualtrax QAR-Corrective Action Workflow (CA):

The CA Qualtrax workflow directs the user during the various steps of documentation. The elements of the CA form, as listed below, will be captured but the workflow varies in arrangement from the printed GL-9.1 form. The Quality Section will initiate the workflow in Qualtrax.

1. Header:
    i. QAR Number: an unique identification used for tracking the QAR. This will be a unit identifier followed by the date. In instances where multiple Corrective Actions are assigned on the same date to the same section an alpha designator will be added.

       Examples: TX09221 –A, TX092211-B

    ii. Date Initiated: date the CAR was started (not the date of the incident)

    iii. Element Affected: this is the section or standard of a specific document that the incident would fall under.

       Example - Element Affected: 4.2.2.1 ASCLD/LAB Supplemental 2011

    iv. Corrective Action: Indicated whenever a policy or procedure does not achieve its stated goal or whenever an incident occurs that is outside a standard procedure or expected result. Check the appropriate level, note that all Level 1 Corrective Actions must be reported to ASCLD/LAB though the Quality Section.
        1. Level 1 – a non-conformity where the work product or the evidence integrity are directly impacted.
        2. Level 2 – a non-conformity where the work product or evidence integrity are not directly impacted.
2. Initiated by:
    i. The individual initiating the investigation (if applicable), the unit Supervisor/Lead, Deputy Director (or TL in DNA) or Laboratory Administrative Manager, and Quality Section Representative will initial and date the form as the investigation is initiated. The Director will be informed and will initial in the appropriate section. In the Qualtrax workflow, the acknowledgement and/or approval will be done electronically.

3. Description of Event/Investigation/Effect of the Discrepancy:
    i. 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. The investigation should include a review to determine if any cases were affected.

4. Root Cause(s)/Plan:
    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.
5. Remediation Plan
    i. The remediation plan consists of the 'Intermediate Steps Taken/Intermediate Plan' and the 'Permanent Changes'. For Corrective Actions generated in the DNA section, that are technical in nature, the remediation plan must be pre-approved by the section TL prior to implementation. In the Qualtrax workflow, the acknowledgement and/or approval for the plan will be documented electronically.
    ii. The remediation plan are actions taken which, when implemented, would resolve the event, action or discrepancy which caused the CA.
6. Intermediate Steps Taken/Intermediate Plan:
    i. 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).

ii. 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.

7. Permanent Changes

i. 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.

ii. Changes developed based on the findings of the CA 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.

1. Appropriate documentation will vary depending on the nature and degree of the CA. At minimum a file will be maintained by the Quality Section documenting the CA process for the event.

8. Evidence of Effectiveness

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.

Preventive Action/Incident Report Form or 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 form, as listed below, will be captured but the workflow varies in arrangement from the printed GL-9.2 form. The Quality Section 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, random unexplained events or similar issues discovered as part of normal quality review procedures. This form 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 CA. 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-Date or P-Date, with a section identifier. (Example I-GL020513, P-DNA020513).
3. Fill 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 sign and date the form, this will then be signed by the Supervisor(s)/Lead(s) and Deputy Director(s) 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 form.
    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 on each CA form.
        i. If an incident report initiates a Corrective Action, the Qualtrax CA workflow will automatically be launched. At that point the Incident report will be closed and the CA workflow continues.
    c. The QS reviews Preventative actions and Incident reports during QS meetings with the Director, Laboratory Administrative Manager and Deputy Directors. Meeting agendas/notes will serve as documentation of this review.