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 actions, preventive actions and 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 by the quality system, where the occurrence does require documentation, but does not require a full corrective action investigation.

B. **RESPONSIBILITY**:

Director: is responsible to support the use of Quality Action Requests, additionally they are responsible to review QARs as part of the annual Management System Review.

Deputy Director: is responsible to work with the section Supervisor 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 sections.

Quality Section: is responsible to keep 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 to maintain all QAR forms and to assure that remediation is carried through and demonstrates that it has corrected the identified issue of all Corrective Actions. QAR forms will be maintained for a period of 2 ASCLD/LAB audit cycles (10 years).

Quality Manager (QM): is responsible to review all QARs to assure that the underlying issue has been adequately addressed and that there are no related, but unrecognized issues. Additionally the QM and/or the AQM will work with Deputy Directors, the DNA TL, and/or Section Supervisors as needed in documenting corrective actions, performing root cause analysis and determining appropriate remediation for QARs.

Assistant Quality Manager (AQM): is responsible to work with Section Supervisors and/or the QM as needed in documenting corrective actions, performing root cause analysis and determining appropriate remediation for QARs.

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

Section Supervisors/Leads: are responsible to involve the Quality Section and Deputy Director when a potential QAR is discovered. Section Supervisors will work with the Deputy Director and Quality Section to document these potential problems through QARs as appropriate. (Note that in DNA if the Technical Leader is not the Supervisor 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. The Supervisor is required to notify the Quality Section and the Deputy Director of potential QARs. 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 such as in a maintenance log is appropriate. Note that the Quality Section will work directly with the DNA Technical Leader in determining how to categorize technical DNA issues. The Corrective Action is documented using form GL-9.1, Incident Reports and Preventive Actions are documented using form GL-9.2. The completed form and related documentation will be maintained by the Quality Section.

All employees have the option of bringing Quality related Management System issues directly to their Supervisor or the Quality Section or to complete the Internal Complaint/Issues form (GL-10.4).

In general the Division 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. 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 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 is not a planned event, that is of a magnitude such that case analysis may be impacted
- A departure from policies and procedures, that is not a planned event, that is of a magnitude such that procedure integrity/validity is impacted.
- Discrepancies identified in proficiency results where the provider grade is unacceptable (or equivalent). Discrepancies in proficiency test results where the provider grade is acceptable however the results or process of obtaining the results do not meet the requirements of this Laboratory.

Note: All discrepancies identified by the ASCLD/LAB Proficiency Review Committee will be investigated using a Corrective Action Form GL-9.1.

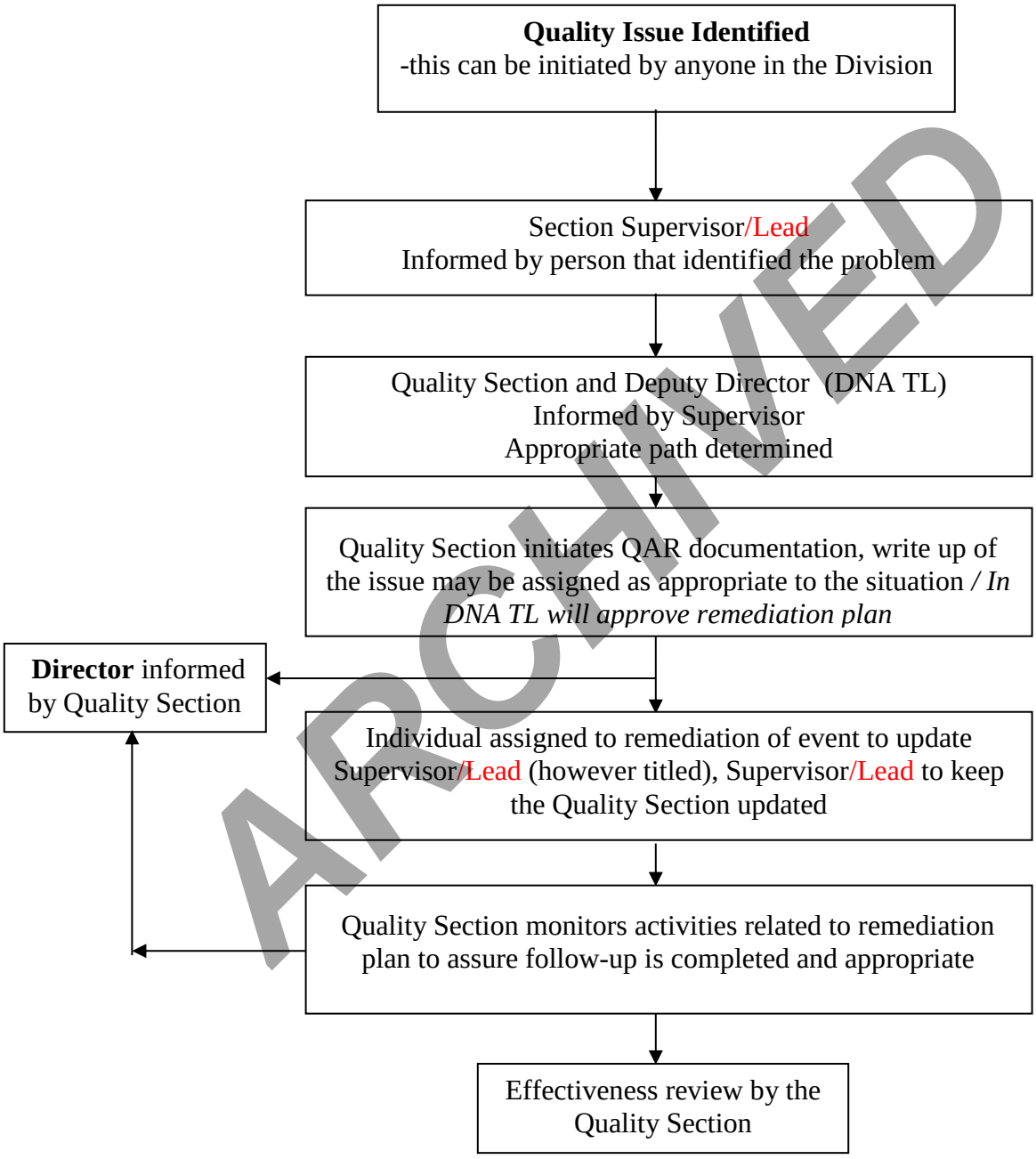
- All discrepancies in proficiency findings will be reviewed to determine the source of the discrepancy, the nature of the error will dictate the level of the remediation typographical error verses improperly performed procedure.
- When a discrepancy is identified the issue will be reviewed to determine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

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

- The need to revise reports based on incorrect original reports (this does not include supplemental reports, or revised reports that stem from errors on information supplied by the submitting agency such as incorrect source names or agency case numbers)
- Issues identified through customer complaints that identify a flaw 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 Quality Section 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:

Note that as Qualtrax software is developed with a workflow for QARs the QAR process will flow through Qualtrax. QAR forms may not be used however, the basic components of the forms will be addressed.

Corrective Action Form:

1. Header:
    i. QAR Number: an unique identification used for tracking the QAR. This will be a section 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 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, the section Supervisor, Deputy Director (or TL in DNA), Quality Section Representative and Deputy Director will initial and date the form as the investigation is initiated. The Director will be informed and will initial in this section appropriate section.

3. Description of Event/Investigation/Effect of the Discrepancy:
    i. Generally completed by the person discovering the issue of concern, but may be performed by supervisory/management personnel. 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 or their designee. The investigation should include a review to determine if any cases were affected.

4. Root Cause(s)
    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. 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.
    iii. 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 the testing or other appropriate actions will take place to confirm or rule out a possible root cause.
5. Remediation Plan: consists of the 'Intermediate Steps Taken/Intermediate Plan' and the 'Permanent Changes'. For CARs generated in the DNA section, that are technical in nature, the remediation plan must be pre-approved by the section TL prior to implementation.
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 a intermediate/remedial plan and the oversight of it will be the responsibility of the Quality Section with the 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.
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 or departure from the policies and procedures specified in the Quality Manual and/or the SOP's. Approval of these changes will be the responsibility of the Deputy Director (the TL in the DNA section), in concert with the Quality Section.

ii. 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.

1. Appropriate documentation will vary depending on the nature and degree of the CAR. At minimum a file will be maintained by the Quality Section documenting the CAR 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 assure that compliance with the Quality Manual and/or the SOP's 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 and Deputy Directors; meeting agendas/notes will act to document this review.

i. 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.

Preventive Action/Incident Report Form:

This form is used to document events that although important 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 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 initiate a Preventative Action or Incident Report form. The initial reporting process is similar a CAR, the person identifying an issue informs their Supervisor/Lead, the Supervisor/Lead informs the Deputy Director and Quality Section. The QM or AQM will work with the section to document the issue appropriately. The QM or AQM will inform the Director of these issues during Quality Sections meetings if necessary.

1. The Quality Section will determine if the issue is a Preventive Action or Incident Report.
2. The QAR number will be assigned by the Quality Section, this 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. This institution of the control chart would be a preventive action to improve the quality control measures for a procedure.

    b. In Arson, a new lot of solvent discovered to contain unexpected compounds:

        It would be important to include the lot number of the solvent and the compounds found. This will help determine if the contaminant will affect other sections. Also it will help track if multiple sections are having similar issues with the same lot, indicating 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).
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 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 CAR form.
    c. The QS reviews Preventative actions and Incident reports during QS meetings with the Director and Deputy Directors; meeting agendas/notes will act to document this review.