A. PURPOSE:

Quality Action Request (QAR) is a general term that includes Corrective Actions, Incident Reports and Preventative Actions. QARs are used to monitor errors and events of non-conforming work.

Quality Action Reports may be created in one of three categories; Corrective Actions (CAR), Preventive Actions (PA) or Incident Reports (IR).

Corrective Actions are used to evaluate nonconforming work categorized as an error. This may include departures from the policies and procedures specified in DSS procedures or other circumstance which may have a negative or detrimental impact on the quality of the forensic work performed in the laboratory. All errors as defined below will be documented as a CAR.

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. Some events (as defined below) may be documented as a IR.

B. RESPONSIBILITY:

1. **Managers**: Responsible to provide direction to subordinate staff under their purview as indicated by the organization chart
2. **Supervisors:** Responsible to provide supervision to subordinate staff under their purview as indicated by the organization chart
3. **FSE2:** responsible as a working lead to subordinate staff as indicated on the organizational chart.
4. **FSE1, CCT, FCA and Lab Assistants**: Responsible to adhere to this procedure as it pertains to their Unit.
5. **ECO**: Responsible to adhere to this procedure as it pertains to their Unit.
6. **Support Personnel** (however titled): Responsible to adhere to this procedure as it pertains to their Unit.

C. DEFINITIONS:

1. **Non-Conformity**: work that does not meet that which is expected. This may be an instrument failure, an occasion where a procedure is not followed, a control failure or other similar issue. Non-Conformities or Non-conforming work are categorized as errors or events.
2. **Event**: an occasion that is outside of the expected and is caught during the normal review process.
3. **Error**: an event where a method (or portion of a method) is incorrectly performed, where the occurrence is not identified or corrected during the normal review processes, resulting in a report being released with the incorrect information or where incorrect information is otherwise released.

D. PROCEDURE:

Events may require review by the Unit Supervisor or Lead or the AD/DD depending on the nature of the event. Since events are caught during normal review it may be appropriate to only document the occurrence as part of the case notes, in a reagent or instrument log book or on a case review sheet. The Unit AD or DD may determine that an QAR is appropriate to document an event; this will be determined based on the circumstances of the event.

All non-conformities categorized as errors will be documented as Corrective Actions (see exceptions for amended reports below). Additionally events that may re-occur if not corrected will be documented as Corrective Actions. All corrective action will be documented using the appropriate workflow in the Quality Management Software (QMS).

When a QAR is Required:

1. When an error is identified, the individual identifying the issue will notify their Supervisor or Lead. The Supervisor or Lead will notify the appropriate Assistant Director or Deputy Director. The Manager will notify the Quality Section of the potential QAR. The Unit Supervisor, AD or DD will work to control the issue to ensure the effect is minimized. For the DNA Unit this will include issues for casework or database analysis.
2. The Quality Section with the appropriate Manager will assess the event to determine the extent of the issue. The goal is to ensure that the QAR is appropriate to the effects of the non-conformities identified (i.e. impact on validity of results v. an administrative issue). The Quality Section will have the 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.
3. Risk assessment may be used as a tool in the process of investigating a potential issue or opportunity for improvement. When an event is brought forward, identify if there is a risk associated with the event (is there a non-compliance to a procedure, a failure to a system or other) or if the issue raised identifies a potential improvement to a current system or process. The manner to proceed can vary based on the risk assessment. Risk assessments may be documented through a QAR (CAR, IR or PA) or other based on the nature of the assessment.
4. Quality Action Requests will be documented using the appropriate QMS workflow:
    i. QAR-Corrective Action (used for non-technical testing Sections/Units or if multiple Sections/Units are involved in one issue)
    ii. QAR-DNA Corrective Action
    iii. QAR-Identification Section Corrective Action
    iv. QAR-Chemistry/TOX/CS Corrective Action
    v. QAR- Incident Report

vi. QAR Preventative Action Report

5. In general, the DSS will make every effort to complete the remediation(s) associated with any Corrective Action within 60 working days of initiating the CAR. For Incident reports and Preventative actions, the Division will attempt to complete any actions and documentation within 60 working days. However, it is understood that outside influences or the scope of the issue may delay a remediation (i.e. the purchasing of specific equipment, specialized training requirements etc.).
6. A QAR-Corrective Action workflow (all specific types) will be initiated when any of the following is true:
    i. An incident of non-conforming work, categorized as an error or non-conforming work that could re-occur is identified. These may include:
        i. A departure from policies and procedures, that was not a planned event, and which was of a magnitude such that procedure integrity/validity or case analysis could be impacted.
        ii. An issue that impacts the validity of laboratory results.
        iii. All cases of sample switches.
        iv. Mishandling of case materials which affect the patency of the item(s).
        v. When an amended report is required the QM will review the reason for the amended report to determine if a CAR or IR is needed or if documentation via the amended report workflow is sufficient. Considerations:
            a. The reason for the amendment is based on an error from the submitting agency (such as providing a wrong name spelling, item number or demographic information) – no QAR is required.
            b. The Quality Manager will take into account previous similar events for a Unit, specific analyst or technical reviewer when determining the appropriate level of documentation when the issue is administrative in nature:
                i. Typographical error
                ii. Error in a case demographic (i.e. submitting agency, agency case number, source or suspect name ect.)
                iii. Minor omissions that do not affect the outcome.
            c. QARs will be used for amended reports when:
                i. The edit is due to questions raised by a customer.
                ii. The edit is due to errors in the findings of the report that are non-typographic in nature.

iii. Findings or other needed information was omitted.

ii. 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.

i. 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).

ii. When a proficiency test discrepancy is identified the issue will be reviewed to determine if case work could have also been affected.

iii. An issue identified by an external audit/assessments that is reported as a non-conformity. All non-conformities identified by ANAB or other assessing body will be investigated using one of the available QMS QAR-Corrective Action workflows depending on the affected discipline.

7. Instances which <u>may</u> require a Corrective Action include (but are not limited to):

i. Instances wherein customer complaints have identified flaws in the quality system.

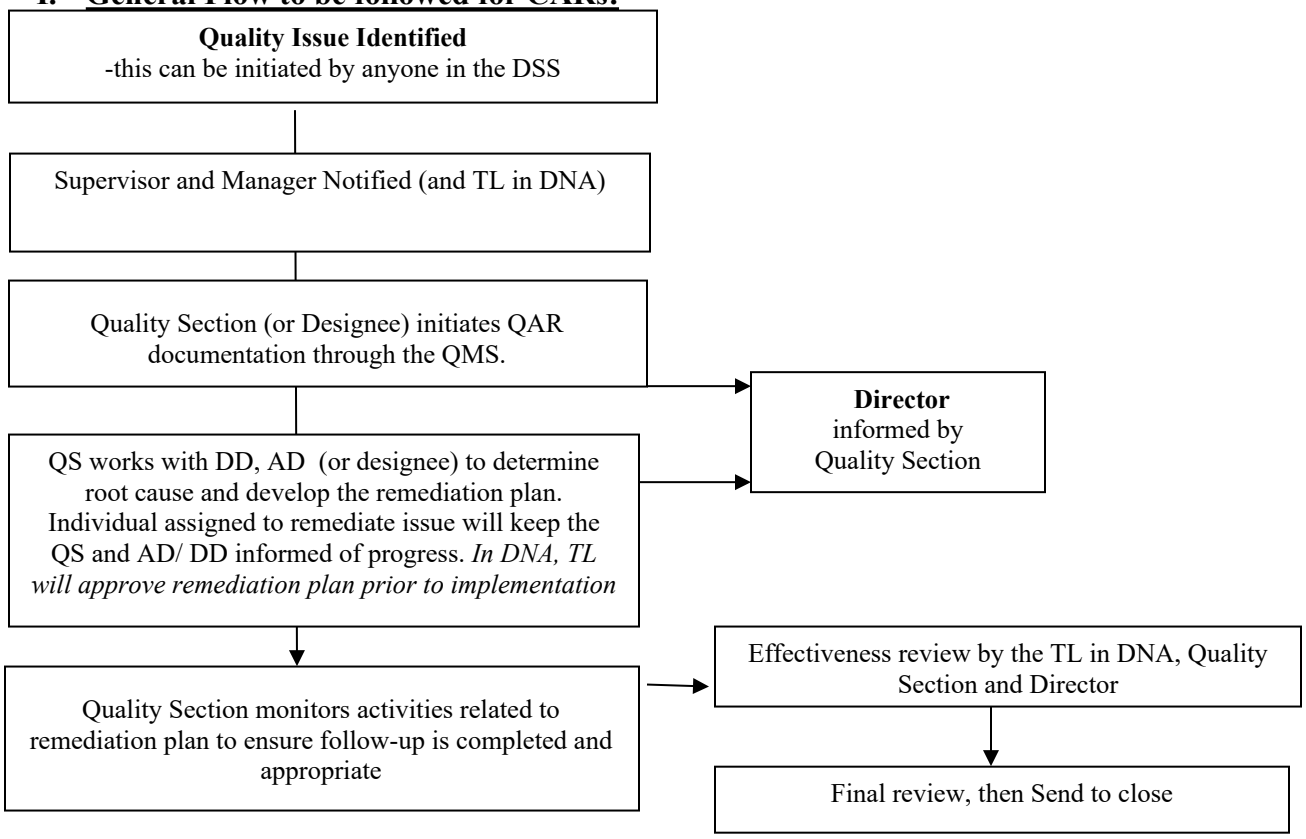
ii. Instances where review of testimony identifies issues in which remediation is required. This may include but not be limited to testifying outside the limits of expertise, not adequately answering questions, or other inappropriate testimony.

iii. Issues discovered during an annual internal audit, DNA internal audit or management system review that affect quality.

a. Note: Within the DNA section, incidences of contamination will be documented through the use of a QMS 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.

iv. Corrective actions may also be used when patterns are identified. This may be through the review of incident reports, QC log books, chain of custody correction or other tracking methods.

I. General Flow to be followed for CARs:



II. Completing QAR-Corrective Action Workflows:

a. Select the appropriate QMS Workflow (CAR)
   i. QAR-Corrective Action (used for non-technical testing Sections/Units or if multiple Sections/Units are involved in one issue)
   ii. QAR-DNA Corrective Action
   iii. QAR-Identification Section Corrective Action
   iv. QAR-Chemistry/TOX/CS Corrective Action

b. The CAR 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 workflow steps. The Quality Section (or a designee) will initiate the workflow. . Depending on the Section, and specific Corrective Action workflow used, elements may be slightly different from the below general format.
   i. Notice of Incident

ii. Date of Occurrence: Date that incident occurred if identifiable.

iii. Discipline(s) Affected

iv. Personnel Involved; in general initials will be used to identify the personnel involved.

v. Description of Incident

vi. Effect of Discrepancy

vii. Standard Violation (if applicable)

c. The individual initiating the investigation (if applicable), the Unit Supervisor or Lead, DNA TL when the issue relates to DNA, Assistant Director, Deputy Director or, Quality Section Representative and the Director will be included to review the workflow t In the workflow, the acknowledgement and/or approval will be done electronically.

i. Those notified will depend on the issue. In general the Section Manager(s), Quality Manager and Director will be involved in all corrective actions.

d. The description of the event may be completed by the person discovering the event or the appropriate Manager, 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 event on the work of the laboratory. Once the scope of the investigation is identified, appropriate personnel will be assigned by the appropriate Manager, Quality Section or their designee. When appropriate the investigation will include a review to determine if any cases were affected.

e. CAR Designation: unique identification used for tracking the QAR; the QMS ID may also be used for this purpose. 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. When multiple Units are involved GL may be used as the letter designation.

f. Incident Write-up:

i. Investigation of Incident: Further details on investigation of incident. In this step information that may be included are:

- What was done to control the incident.
- Identification of any consequences.
- Identification of other related non-conformities.
- Personnel to Review and Acknowledge: Notification sent to personnel that a CAR has been started (for example: Technical Leader in DNA).

- Incident Write Up external files: place to upload any external files (if applicable).
- Quality Section person for review.

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

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

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

j. 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 CAR. While root cause analysis may be difficult to establish and define, it is an important part of the CAR 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 Unit, which are technical in nature, the remediation plan must be pre-approved by the Unit TL prior to implementation. In the workflow, the acknowledgement and/or approval for the plan will be documented electronically; this may be by the Director, DD, AD, 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 need for the Corrective Action.

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, Assistant Director 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, Assistant Director or their Deputy Director as appropriate.

k. Remediation Plan: The issue is evaluated to determine a plan to correct the issue and prevent re-occurrence of the issue. If upon review it is determined that the non-conformity could occur in other units the remediation plan will include steps to prevent this.

l. Remediation Plan Approval: This is where the approval of the remediation plan is documented. This may be by the Supervisor, DNA TL and/or the appropriate Manager. Per the DNA QAS the DNA TL needs to document approval of the remediation plan prior to it being implemented.

i. Remediation and Permanent Changes.

ii. Remediation steps taken; items completed from the remediation plan are documented in this section.

ii. Permanent Changes made:

i. Following implementation of the intermediate/remedial plan of action, permanent changes will be decided upon, if appropriate, in order to correct the incident of nonconforming work.

ii. Approval of these changes will be the responsibility of the Assistant Director or Deputy Director (the TL in the DNA section), in concert with the Quality Section. In the workflow, the acknowledgement and/or approval will be done electronically.

iii. 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.

iv. Appropriate documentation will vary depending on the nature and degree of the CAR.

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

iii. Evidence of Effectiveness: Review for effectiveness is generally performed by the QS. The QM or designee will note in this area how appropriateness was assessed (Case file review, section audit or other as determined by the issue). Documents that support that the remediation was effective may be attached to the CAR.

iv. 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 CAR are satisfied. The need to monitor changes will depend on the nature of the implemented change.

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

v. Corrective Actions related to the DNA Unit including those 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 workflow, the acknowledgement and/or approval will be done electronically.

vi. If necessary the risks and opportunities will be re-evaluated based on the effectiveness of the changes.

vii. Director Final Review: Director final review is documented here.

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

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.

viii. Quality To Close: CAR completed.

III. <u>'QAR-Preventative Action Report' or 'QAR- Incident Report' workflow</u>:

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

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

c. 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 or instrumental problems that are beyond issues from normal use. This <u>cannot</u> be used for any non-conformities that are categorized as errors and have therefor affected the integrity of evidence or case results.

d. 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 event informs their Supervisor or Lead, the Supervisor or Lead informs their Assistant Director or Deputy Director who will inform 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.

i. The Quality Section will determine if the issue is a Preventive Action or an Incident Report.

ii. The QAR number will be assigned by the Quality Section; the format should be I-unit identifier and Date or P-unit identifier and Date. (Example I-GL020513, P-DNA020513).

iii. Pick the section(s) affected.

iv. Description of Event: Describe the event including important details such as how it was discovered, what was the affect, or why it was problematic.

b. 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.

A new lot of solvent, commonly used throughout the DSS 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/Units are having similar issues with the same lot, indicating that the manufacturer may need to be contacted.

2. The person writing the report will add the date and their initials in the QMS. The workflow will then be assigned to flow to the Supervisor(s) or Lead(s), Assistant Directors and Deputy Director(s) of the affected section(s). In the workflow, the acknowledgement and/or approval will be done electronically.

3. 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 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, Assistant Directors and Deputy Directors. Meeting agendas/notes will serve as documentation of this review.

IV: **Records**:

1. The documentation of all QARs will be maintained electronically in the QMS.
2. In the case where a QAR was initiated pre-QMS the Quality Section will maintain the original documents.
3. Documentation of QARs will be maintained for a minimum of 8 years.