	Q.P.005.03		
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CONTROL INFORMATION	
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Contents:

1.0 – Purpose

To establish a procedure and to assign responsibilities for identification, documentation and disposition of non-conforming work.

2.0 – Responsibilities

Evolution ensures that the authority and responsibility for controlling non conformances are delegated to the appropriate management authorities. These authorities are authorised to halt any analytical testing or procedures related to the non conformance and to invalidate test results that are affected. The responsible personnel authorised to resume work after a non conformance is identified in the laboratory's' corrective action procedure.

3.0 – Procedure

1. Non conformances can occur at various places within the quality system and technical operations, examples include customer complaints, unacceptable quality control samples, instrument problems, environmental problems that affect results, purchased materials for laboratory use, staff observations, management reviews and audits,

2. Identified non conformances with any procedure, quality control parameter or customer requirements are documented on the laboratory's corrective action process. This process involves the evaluation of the impact on quality and operations,

3. When a non conformance is detected, laboratory data is held and not released until the problem is resolved and verified by the laboratory management in accordance with the corrective action process. Resumption of work is performed after the corrective action has been taken and approved,

4. Non releasable data is not approved by management until product disposition has been made and documented. Dispositions or actions taken on a non conforming work product are:

    a) **Rework**. Action taken on non conforming product so that it will fulfil the specified requirements,
    b) **Redone**. Action taken to re-collect sample or re-analyse sample to bring the product into conformance,
    c) **Use as is.** Approving the use of non conforming product without rework or redoing, a disclaimer is made that the product was accepted and the quality requirements that the product did not meet are specified,
    d) **Unable to use.** Action taken is unable to resolve problem. The receiver is notified that the data cannot be reported.

5. Reworked or redone products are reviewed to verify that they comply with specifications,

6. When necessary, the customer is notified of the non-conformance and specification may be changed depending on the usage of the data, e.g. information purposes only,

7. If properly executed, quality control parameters can monitor the various aspects of data quality on a routine basis. In instances where performance fall outside acceptable limits, the data produced can be questions and, after investigation, a determination made as to its validity. The laboratory's internal quality control program is the principal recourse available for ensuring that only a quality product is released. Quality control parameters and quality assurance elements are defined in the laboratory's quality control program. These identified quality objectives are the critical elements that would cause a non conforming product if not met.

8. Records shall be retained.

4.0 – <u>Revision History</u>

Revision	Date	Changes Made
01	21st May 2011	First issue.
02	11th December 2013	Header and footer updated, sections 5 and 6 deleted as contained no information.
03	06/01/2018	Section 3.0 Point 8 added.

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