SECTION S13 – NON-CONFORMITY & CORRECTIVE ACTION PROCEDURES

OBJECTIVE

To ensure that quality nonconformities are recorded and actions taken to control, correct and prevent future recurrences.

RESPONSIBILITIES

QE Manager	-	Overall responsibility and authority for the establishment, implementation and maintenance of the Nonconformities and Corrective Action Procedures.
All other staff	-	Follow this procedure upon detection of non-conformities
		Implement necessary action to achieve resolution

PROCEDURES

1. Non-Conformity Identification

Non-conformities may be identified by any staff internally during their course of work or from external interested parties. These may be received in different ways such as verbally (in-person, through the phone) or in a written form.

Details of the non-conformities shall be taken down and passed on to the QE Manager or Director-in-Charge who shall identify the responsible person.

The responsible person shall review the nature of the non-conformity and take actions together with relevant staff to ensure its control and correction & deal with the consequences.

2. Evaluation of the Non-Conformity

The QE Manager or Director-in-Charge shall together with relevant staff evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by:

(a) reviewing the non-conformity;

(b) determining the causes of the non-conformity;

(c) determining if similar non-conformities exist, or could potentially occur;

3. Implement Corrective Actions

The QE Manager or Director-in-Charge shall together with relevant staff shall implement any corrective action needed. Any corrective action taken to eliminate the cause of non-conformity shall be appropriate to the magnitude of the problem whilst also in proportion to the risk presented by the non-conformity.

4. Reviewing Effectiveness

The QE Manager or Director-in-Charge will perform independent verification of the actions taken to ensure the actions are effective in resolving the root cause(s). This verification should examine evidence and take into consideration the following:

- Has the corrective action plan removed the root cause(s)?
- Does the corrective action appear to eliminate the original issue reported?
- Were any related documents updated, as needed?
- Was training conducted, if required?
- Does the corrective action require an update to the internal audit schedule?
- Were all interested parties properly notified of the actions taken?

5. Changes to the QEMS

The QE Manager or Director-in-Charge together with the process owner shall make changes to the QEMS if necessary.

REFERENCE

Form S13.A - Non-Conformity & Corrective Action Report