1.0 PURPOSE

1.1 The purpose of this procedure is to provide a uniform and consistent method for undertaking corrective (reactive) and preventive (proactive) action to eliminate the causes of actual or potential non–conformances.

2.0 SCOPE

2.1 This procedure is applicable to materials, services or system – related non–conformaces or potential non–conformances observed either during supervision, review or internal audit. It is also applicable to all customer or third party complaints whether written or verbal.

3.0 PROCEDURE

3.1 Identification and Recording

3.1.1 Corrective Action Report shall be a mechanism to:

a. Undertake corrective (reactive) action to eliminate the causes of system non–conformance;

b. Undertake preventive (proactive) action to eliminate potential causes of system non–conformance;

c. Handle customer complaints; and,

d. Suggest improvements to the quality system.

3.1.2 Non–conformances or potential non–conformances or deficiencies which require issuing of CAR may be observed in the quality system in any of the following situations:

a. Non–conformances observed in the products as part of regular supervision, inspection and testing. The disposal or remedial measure for the non–conforming product is addressed in procedure of Control of Non–conforming Products. If the type of

non–conformance is such that corrective or preventive action can be taken, then the corrective and preventive action section of the CAR form shall be completed;

b. Materials, services or system–related non–conformances or improvements observed during reviews of the quality records, processes, CAR's and operations;

c. Non–conformances observed during internal quality audits. It is the responsibility of the Auditor to issue CAR to auditee; and

d. All customer or third party complaints shall be addressed by issuing CAR's. The person responsible for receiving the complaint or QMR shall issue the CAR. The QMR or responsible person shall acknowledge receipt of complaint in writing.

3.1.3 All CAR's raised shall be forwarded to the QMR who shall co – ordinate and ensure that they are investigated and corrective and preventive action are taken. The QMR shall maintain a sequential numbering system and a log for CAR's for effective implementation and follow – up.

3.1.4 It is not the intention to raise CAR for every little deficiency observed in implementation of systems and procedures. CAR's should only be issued for handling major system non–conformances, potential non–conformance or improvements.

3.1.5 Major non–conformances are those related to lack of procedure, system, standard or misuse of the quality standards initially agreed.

3.1.6 Minor non–conformances such as single instances where the agreed requirements are not adhered, genuine mistakes or deficiencies within process limitations shall be fixed on the spot and may be reported as observations as part of that activity report, e.g., audit report observations.

3.2 Review, investigation and implementation:

3.2.1 QMR, auditee or the person responsible for the activity shall review the CAR. They may obtain if required inter–departmental help in proposing and undertaking corrective and preventive actions.

3.2.2 After review and investigation of the observed or potential nonconformance or improvement suggestion or complaint, the reviewer shall propose corrective and preventive action. A copy of the CAR shall be passed to the initiator and QMR.

3.2.3 The proposed actions shall be implemented by the responsible person nominated in CAR. The effects of the corrective and preventive actions shall be monitored by implementing personnel.

3.2.4 In case of customer complaints, the QMR shall reply in writing to the customer the investigation results and corrective and preventive measures taken to eliminate the cause of non–conformance.

3.2.5 Changes in procedures resulting from corrective and preventive actions are implemented and recorded by the QMR.

3.3 Follow – up:

3.3.1 Follow – up monitoring or audits shall be undertaken by QMR or his nominated representative to verify that the corrective and preventive actions are implemented and to ensure that the desired goals are achieved. Closure should be effected within a period ranging from 5 to 20 working days depending on the severity and requirements necessary for closure. The QMR will monitor these timeframes.

3.3.2 The CAR shall be signed–off and closed if the corrective and preventive actions are satisfactory. If the results are not satisfactory,

the new non–conformance observed shall be treated as per this procedure.

3.3.3 Section 8 of the CAR shall be completed by the auditor or QMR or his nominated representative.

3.4 Records:

3.4.1 Records of CAR's shall be maintained by the QMR.

3.4.2 A CAR log shall also be maintained by the QMR for ready reference. The data from this will be used as one of the inputs for management review meetings.

3.4.3 All CAR's related to customer complaints shall be maintained in a separate file in order to quickly judge the effectiveness of the quality system in handling and reducing the customer complaints.