1. **PURPOSE**

To identify the responsibilities associated with reviewing nonconformities (including Customer Complaints), the process of creating and/or approving Corrective Actions, and evaluating the effectiveness of any actions taken

2. **PROCEDURES**

2.1 All members of our organization are responsible for reacting to nonconformities in order to take action to control the issue, correct the issue, and deal with the consequences.

2.2 The Management Representative (or designee) is responsible for reviewing nonconformities and Customer Complaints. The Management Representative has the authority to determine if a Corrective Action is required and is responsible for notifying relevant members of the Management Team.

2.3 QF-05-01, Corrective Action is used to document the details of the issue, and must be generated in response to

a) Internal Audit Findings

b) External Audit Findings (*Note: External Customer or Registrar forms and documentation may be used in lieu of QF-05-01, but a record of the Corrective Action must be retained.*)

c) Customer Complaints that formally request Corrective Action

2.4 Results of Corrective Action related to External Customer or Registrar Audits will be verified for effectiveness during the Internal Audit process.

2.5 QF-05-01, Corrective Action may be generated for any issue at the discretion of the Management Representative, such as trends in nonconforming product, failure to achieve Quality Objectives, etc. and shall take into consideration the potential for human factors when determining root cause, up to and including physical capability, physical condition, mental state, mental stress, behavior and skill level.

2.6 QF-05-01, Corrective Action:

2.6.1 Determination of the Root Cause of the nonconformity (including Human Factors)
2.6.2 Evaluation of actions to eliminate the possibility of reoccurrence
2.6.3 Definition of a Corrective Action Plan and implementation of the defined actions
2.6.4 Containment actions that have been taken, including determination of additional nonconforming product
2.6.5 Review of the effectiveness of the actions taken

2.7 When necessary, relevant risks and opportunities determined during planning shall be updated as a result of the Corrective Action.

2.8 Corrective Action requirements shall be flowed down to the external provider when it is determined that the external provider is responsible for the nonconformity.

2.9 Corrective Action responses are generally due within 30 days of issuance. Corrective action responses that are not timely and/or effective will be escalated to Top Management's attention for resolution.

2.10 Corrective Actions are periodically reviewed during the Management Review Process.

2.11 Records of all Corrective Actions are retained in accordance with SOP-02, Record Control.

3. **RECORDS**

QF-05-01, Corrective Action

4. **RELATED DOCUMENTATION**

SOP-02, Record Control
SOP-09, Risk Management