PURPOSE:
To ensure that nonconformities are addressed by taking corrective action to eliminate the root cause thus preventing recurrence of nonconformity

SCOPE:
This procedure starts from the identification of nonconformities up to the closure of the nonconformity.

DEFINITION OF TERMS, ACRONYMS:

Corrective Action	Process of investigating and taking action on existing problems. Action taken to eliminate the cause of nonconformities in order to prevent their recurrence
Request for Action (RFA) Form	Form which captures all stages of the corrective action process from problem identification, to root-cause-analysis, to plan of action, to verification of effectiveness
Nonconformities	Nonfulfillment of requirement
Correction	Immediate Action to correct nonconformity

RESPONSIBILITIES

Process Owner	Initiates a required action upon identification of a problem or a non-conformance; Conducts root cause analysis, develops, plans and implements corrective actions
Initiator/Internal Quality Auditor (IQA)	Identifies nonconformities and request action to address it Ensures that nonconformities are addressed on time thru follow-up activities and reports status of RFA and effectiveness of corrective action process to Top Management
QMS Internal Audit Team Leader/QMS Head/President	Reviews and endorses identified nonconformities
ManCom	Ensures that actions are taken without undue delay to prevent the recurrence of nonconformities Ensures the provision of resources for the implementation of corrective actions. Reviews the status and effectiveness of corrective actions.

PROCEDURE DETAILS:

ACTIVITY	RESPONSIBILITY	DETAILS	C	REFERENCES
Start				
Identification of nonconformity	Initiator/Internal Quality Auditor (IQA)	A. Receives and evaluates validity of customer complaints and nonconformities B. Accomplishes Request for Action (RFA) Form and forwards to QMS Internal Audit Team Leader/QMS Head/President for review and endorsement		RFA Form
Review of nonconformity	QMS Internal Audit Team Leader/QMS Head/President	C. Receives, reviews validity and endorses RFA to Process Owner D. Creates and updates RFA Register	C	Accomplished RFA
	Process Owner	E. Evaluates acceptability of RFA and affix signature in the designated section of RFA		Accomplished RFA
Formulation and implementation of correction	Process Owner	F. Determines and undertakes immediate action (correction) and records it in the RFA Form		Accomplished RFA
Root Cause Analysis and Establishment of Corrective Action	Process Owner	G. Reviews the risk register for any controls that may have failed or is not yet recognize which resulted to the nonconformity H. Checks for similar nonconformity, if any I. Conducts root cause analysis using appropriate technique/s J. Formulates corrective actions to address nonconformity based on the identified root cause K. Accomplishes section in RFA for Root Cause/s and Corrective Actions		Accomplished RFA

ACTIVITY	RESPONSIBILITY	DETAILS	C	REFERENCES
	Initiator/IQA Auditor QMS Internal Audit Team Leader and/or ManCom	L. Evaluates acceptability of the root causes and corrective action plan and informs Process Owner on the acceptability of actions identified	C	Accomplished RFA
Implementation of corrective action	Process Owner	M. Implements and/or facilitates implementation of corrective action on a timely manner		Accomplished RFA
Verification of corrective action	Initiator/Internal Quality Auditor (IQA)	N. Evaluates the effectiveness of corrective actions taken O. Obtains objective evidence supporting effectiveness of action P. Updates the risk register, as needed Q. Records results of verification in the RFA R. Recommends closing of RFA (Nonconformities) and other recommended courses of action, if warranted and forwards to IQA Head or ManCom for approval		Accomplished RFA Risk Register
	QMS Internal Audit Team Leader and/or ManCom	S. Receives and evaluates assessment of IQA on the effectiveness of actions taken T. Approves RFA for closing and returns RFA to IQA Auditor U. Updates RFA Register and facilitate filing of RFA	C	Accomplished RFA Risk Register
Monitoring and Reporting of Status of RFA	Initiator/IQA	V. Requests Corrective Action Status Report for all open RFA to Process Owners		RFA Registry
	Process Owner	W. Prepares Corrective Action Status Report for all open RFA and forwards it to IQA Head for review and updating of RFA monitoring sheet		

DC: MASTER FILE

ACTIVITY	RESPONSIBILITY	DETAILS	C	REFERENCES
	QMS Internal Audit Team Leader and/or ManCom	X. Receives and consolidates RFA (open) status report Y. Reports on the status and effectiveness of corrective actions during the Management Review		RFA Registry
End				

DC: MASTER FILE

GUIDELINES:

1. DETERMINATION OF NONCONFORMITY
   - 1.1. RFA shall be used to address nonconformities in which common sources are.
     - 1.1.1. Customer feedback and/or complaints with significant impact on customer satisfaction
     - 1.1.2. Failure in achieving quality objectives
     - 1.1.3. Audit nonconformities (External and internal)
     - 1.1.4. Process Deviation
     - 1.1.5. Nonconforming services
     - 1.1.6. Management review action items
     - 1.1.7. Other Lapses and Deviation in QMS
   - 1.2. Potential nonconformities are subject for validation prior to issuance of RFA.
   - 1.3. All employees are empowered to submit a RFA when they discover an existing nonconformity against ISO 9001:2015 requirements, company procedures, customer requirements, or statutory/regulatory requirements.
   - 1.4. Details of nonconformities include but not limited to:
     - 1.4.1. Criteria which may come from ISO 9001:2015 requirements, QMS documents, or statutory/regulatory requirements.
     - 1.4.2. Nonconformity statement which must include requirement and Objective Evidence.
     - 1.4.3. RFA No. which must follow the control number system: YYYY-AAA
       Where: *YYYY – Corresponds to the year RFA is generated*
       AAA – sequential number
     - 1.4.4. If with similar issues in other areas of the organization, the auditor must determine details of similar NCs which may include RFA No., requirements violated and nature of NC.
     - 1.4.5. In case the Group/Unit does not accept the issuance of RFA, the Management Committee will decide on the issue.

2. DETERMINATION OF CAUSE OF NONCONFORMITY
   - 2.1. Review and analysis of nonconformities may include more than one Group/Unit depending on the severity of nonconformity:
   - 2.2. The Group/Unit Head can delegate to another Group/Unit personnel the investigation and identification of correction and corrective actions. The assigned personnel is typically the person who has the most in-depth understanding of the variables involved.
   - 2.3. Non-Conformities (NC) should be investigated to determine the root cause or source of the problem. If necessary, a committee or team may be formed to perform the investigation and analysis due to the complexity or nature of the NC
   - 2.4. Tools to be used in the determination of root cause/s may include cause and effect diagram, 5 Whys and Pareto analysis.
   - 2.5. Root cause must be process centric instead of person centric.

2.6. Root causes may involve external factors which are beyond the control of the organizations, e.g., delays due to regulatory bodies, natural forces.

3. EVALUATION, DETERMINATION AND IMPLEMENTATION OF ACTION NEEDED

3.1. Corrective actions must remove or reduce the causes of the problem. The plan for corrective action on a nonconformity must include these elements:

Action	what must be done exactly, which is spelled out in simple terms that can be verified. Action taken should be appropriate to the effects or magnitude of the potential problems or nonconformities encountered. Considerations should be given impact to customers, cost considerations, and potential savings, and safety. Plan of Actions may cover revisions of procedures, actual practices, or recording of activities. Changes to procedures and supporting documents resulting from the corrective actions should be done according to Document Control Procedures. Nonconformities which cannot be resolved by the department are brought up to management
Responsibility	who is responsible for taking action
Resources	what tools, equipment, supplies, personnel, or capital are necessary to perform the actions
Target date of completion	when exactly do we expect the action to be completed, taking into consideration the level of effort expected, costs, risks, etc.; for example, some actions may take months to correct and resolve, while others may take days or less.

4. RECORDING AND REVIEW OF ACTIONS TAKEN

4.1. IQA must register the RFA on RFA log for monitoring and provide trend data on the system for management review.

4.2. There should be at least three types of evidence the auditor must gather:

- Evidence that the action was related to the identified root cause
- Evidence that the proposed action was actually implemented
- Evidence that the action was effective in preventing recurrence of the problem

4.3. Additional documentation can be referenced or attached to support the key ideas stated in the RFA Form

4.4. The review or verification is performed by an independent party e.g. QMR, or Internal Auditor, within 2 months after the Corrective Action was identified. For corrective action requiring considerable amount of time, the status/progress of action taken will be monitored until completion;

4.5. If the corrective action is found to be ineffective, additional actions will have to be made until the nonconformance is sufficiently addressed

4.6. Prior to closing corrective action, IQA must revisit risk register specifically to:

4.6.1. modify any ratings for the risk that has been addressed; and/or

4.6.2. add to the risk register, if the nonconformity revealed a risk that hasn't even been identified

4.7. Changes to QMS may include but not limited to:

- Revision of existing procedures
- Development of new documentation
- Establishment of new record keeping
- Establishment of new monitoring and measurement
- Revision of existing training materials
- Changes in or additional communication plan and/or awareness program
- Revision of roles, responsibilities and authorities
- Enhancement of company's organizational knowledge
- Revision of change management process

FORMS/ATTACHMENTS/REFERENCE:

1. Request for Action (RFA)
2. RFA Registry

DC: MASTER FILE