Version History

Ver. No.	*Authors*	*Date*	*Reviewers*	*Review Date*	*Release Date*
1.0	Management Representative	27-Aug-2018	QMF	31-Aug-2018	03-Sep-2018
2.0	Management Representative	16-Dec-2019	QMF	13-Dec-2019	16-Dec-2019
3.0	Management Representative	02-Nov-2020	QMF	06-Nov-2020	10-Nov-2020

Change History

Ver. No.	*Section*	*Date*	*Change Information*	*RFC No.*
1.0	All	03-Sep-2018	New Release	-
2.0	All	16-Dec-2019	Annual Review and no changes	-
3.0	All	10-Nov-2020	Annual Review	-

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Corrective Action Process

1.0 Objectives

The objective of this document is to describe the process for identifying, analyzing, and implementing corrective actions..

2.0 Scope

This process applies to all the business / operations.

3.0 Policy

3.1 Policy Statement

- NA

3.2 Framework to Support or Implement this Policy

- NA

4.0 References to (checklists, forms, guidelines, lists, standards, templates, other processes)

Process Element	*Description*	*ID*
Checklists	*NA*	NA
Forms	*Corrective Action Report*	QMS-L4-FR-MR-15
	Customer Complaint / Issue Form	QMS-L4-FR-MR-16
	Root Cause Analysis	QMS-L4-FR-MR-17
Guidelines	*Guidelines for Causal Analysis*	QMS-L4-GD-MR-02
Lists	*Master List of Auditors*	QMS-L4-FR-MR-22
Standards	*NA*	NA
Templates	*NA*	**NA**

5.0 Entry Criteria

Inputs	*Source Processes*
Action Requests	Internal Quality Audit Process
Audit Summary Report	Internal Quality Audit Process
Defects / Observations / Areas of Improvements identified during testing, project reviews etc.	Various Processes
Action Items from Management Review Meeting	Management Review Process
Analysis of Quality Records	Control of Quality Records Process
Customer Feedback / Complaints	Customer Satisfaction Survey Process
Decision to address a concern, issue or problem by MR	Management Review Process

6.0 Responsibilities

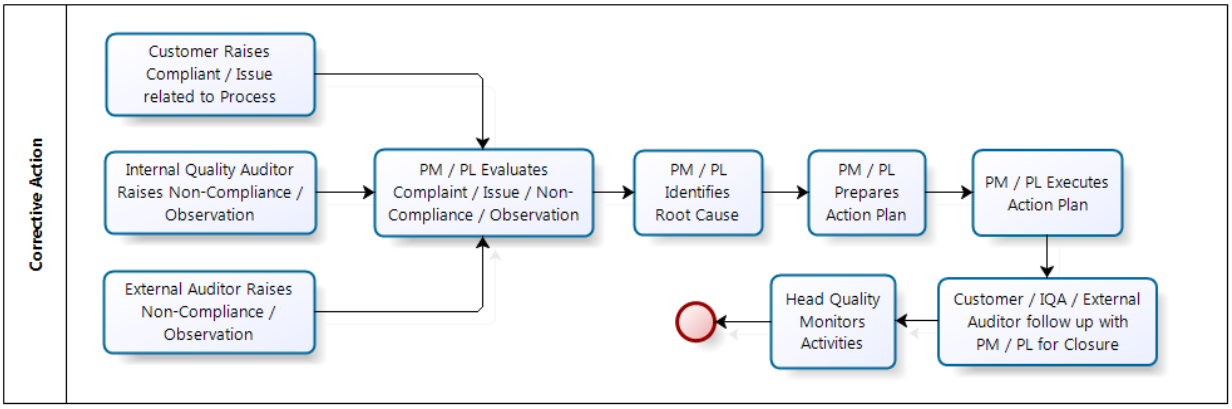
Role	Responsibilities
PM/PL/Team	• Receives request for Non-Compliance / Observation from IQA / External Auditor • Receives request for Complaints / Issues from Customer • Evaluate Issue & identifies impacts • Identifies Root Cause of the Issue / Non-Compliance / Observation • Prepares / sets action for closure of Issue / Non-Compliance / Observation • Executes actions related to Issue / Non-Compliance / Observation
Customer	• Raises Complaints / Issues related to processes • Approves Closure of Issues
IQA	• Sends request for Non-Compliance / Observation identified during Internal Audit • Approves closure of Non-Compliance / Observation identified during Internal Audit
External Auditor	• Raises Non-Compliance / Observation during External Audit • Approves closure of Non-Compliance / Observation identified during External Audit
Head Quality	• Monitors the progress of closure of Complaints / Issue / Non-Compliance / Observation raised by Customer / IQA / External Auditor

7.0 Process Description

Overview Diagram

Refer below to specific process for flowchart.

7.1 Corrective Action Process



7.2 Identify Issue

- Customer raises Complaint / Issue related to process
- IQA raises issue related to non-compliance / observation during internal audit
- External Auditor raises issue related to non-compliance / observation during external audit
- PM/PL
  - Identifies the issue/s that require action
  - Determines the source of the information and the available evidence/s
  - Updates the information in the Issue Identification section of the *Corrective Action Form*

7.3 Evaluate the Issue

- PM/PL

- Determines the possible impact of the issue/s in terms of cost, function, product quality, safety, reliability and customer satisfaction etc.
- Identifies the immediate / remedial action to be taken, if necessary, and updates the actions in the Issue Analysis section of the Corrective Action Form, accordingly

7.4 Identify the Root Cause of the Issue

- PM/PL
  - Identifies all the possible / potential causes of the issue/s and evaluates each cause against the problem description and data using the Root Cause Analysis : Fishbone Diagram Form
  - Determines the root cause of the issue/s using the Guidelines for Causal Analysis

7.5 Prepare an Action Plan

- PM/PL
  - Identifies all the activities and tasks that must be accomplished to correct the existing problem or eliminate a potential problem, to prevent a recurrence
  - Updates the action plan in the Action Plan section of the Corrective Action Form
  - Obtains approvals on the Action Plan from the Approver

7.6 Execute Action

- PM/PL/Team
  - Ensures that all the identified tasks and activities are completed as per the Action Plan
  - Summarizes and lists all the actions and modifications done to the documents, processes, etc.

7.7 Follow-up & Closure

- PM/PL
  - Verifies the successful completion of the identified tasks and evaluates the appropriateness and effectiveness of the actions taken
  - Ensures that appropriate information has been recorded to prove that all actions have been completed successfully
- Customer / IQA / External Auditor validates & closes issue subject to:
  - The root cause of the problem has been appropriately addressed / removed
  - Any resulting secondary situations have been addressed adequately
  - Proper controls have been established to prevent a similar occurrence
  - Similar issues existing in other processes and work products are also resolved
  - The extent to which the selected change has influenced the process performance

8.0 Quality Mechanisms

- Approval of Corrective Action

9.0 Quality Objectives

Sr. No	*Objectives*	*Responsibility*	*Frequency of Measurement*	*Reporting of Measurement*	*Target to Achieve*
1	Closure of Corrective Action Reports within given timelines	MR / CISO	Monthly	Corrective Action Report	100%

10.0 Identified Risk

- NA

11.0 Exit Criteria

Outputs
Corrective Action Form
Root Cause Analysis : Fishbone Diagram Form