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Purpose

The purpose of this procedure is to ensure that causes of detected nonconformities are eliminated in order to prevent recurrence.

Scope

This procedure applies to nonconformities found in the implementation of the quality management system.

References

Internal Quality Audit
Control of Nonconforming Outputs

Definition of Terms

Nonconformity	Non-fulfillment of a requirement
Corrective Action	Action to eliminate the cause of a detected nonconformity or other undesirable situation, and prevent recurrence

Procedure Details

Ref. No.	Key Activities		Responsible	Reference Document/ Record
5.1	Review detected and potential nonconformity	Receive and review the Request for Action Identify concerned staff who will be involved in corrective action	Process Owner	Request for Action (RFA)
5.3	Determine the cause of nonconformity	Conduct root cause analysis	Process Owner	RFA
5.4	Determine and implement the action needed	Develop, plan and recommend corrective actions Approve corrective	Process Owner	RFA

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		actions Implement corrective actions		
5.5	Review corrective action taken	Review the implementation status and evaluate the effectiveness of corrective actions	Management QMR	RFA, Corrective Action Status Report

Reviewing Nonconformity

The corrective action procedure is triggered by Request for Action from other processes/procedures in response to identified nonconformities from:

- internal quality audits
- customer/citizen complaints (from the Monitoring and Measurement of Customer Satisfaction)
- qualified nonconforming outputs (from Control of Nonconforming Outputs)
- poor process performance results and unacceptable deviations from the organization's programs and plans (from management reviews)

The initial review of the Request for Action considers:

- The extent and impact of the reported nonconformity.
- The processes contributing to and affected by the reported nonconformity.

The concerned head identifies concerned personnel who need to be involved in corrective action. This may extend to personnel outside his/her own department; coordination with the other concerned departments should be established.

Determining the Cause of Nonconformity

All occurring nonconformities are subjected to root cause analysis to be able to come up with corrective action plans.

Root cause analysis considers the different factors contributing to the nonconformity, including:

- Manpower - personnel competencies and their ability to consistently perform their functions as required.

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Machine - the availability of appropriate tools, equipment and facilities to enable effective operations

Methods - the availability and consistent application of appropriate procedures, guidelines and standards

Materials - the availability of the needed materials and supplies to enable effective operations.

Environment – the condition of the surroundings, facilities, and work environment

Where several root causes are identified, they are prioritized relative to their contribution to the nonconformity

Determining and Implementing Corrective Actions

Based on the root causes identified, corresponding corrective action plan is developed and approved by the concerned head.

Planning of corrective actions (solutions) involves the following:

generation of alternative solutions

the selection of the best solution (from the alternatives)

the identification of activities, resources, responsibilities and timeliness needed to implement the selected solution.

Reviewing the Status of Corrective Actions

The **PQR Committee** reviews the root causes and corrective action plans documented in the RFA. The Committee also monitors the implementation of the action plans.

The implementation status and effectiveness of corrective actions is also periodically reviewed and evaluated by the concerned head; any related issues are primarily addressed.

Corrective actions are collectively reviewed by the Management Committee (under management review). Depending on the nature of the solution and the associated nonconformity, monitoring and review continues for **at least 6 months after implementation**, after which the corrective action is deemed completed.

Attachment

6.1 Request for Action

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Prepared by:	Reviewed by:
NAME	NAME
Head, Internal Audit Service	QMS Leader
	Approved by:
	NAME
	Position

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