Standard Operating Procedure (SOP): Corrective and Preventive Action Implementation Steps

This SOP describes the **corrective and preventive action implementation steps**, detailing the process of identifying root causes of non-conformities, developing effective corrective actions, verifying their implementation, and monitoring their effectiveness to prevent recurrence. It covers documentation requirements, responsibilities, timelines, and follow-up procedures to ensure continuous improvement and compliance with quality standards.

1. Purpose

To define a standardized process for implementing corrective and preventive actions (CAPA) to address and prevent non-conformities, ensuring compliance with applicable quality standards and continual improvement.

2. Scope

This procedure applies to all incidents of actual or potential non-conformity identified within the organization's processes, products, or systems.

3. Responsibilities

Role	Responsibility
Process Owner	Initiate and oversee CAPA activities; ensure timely implementation.
CAPA Coordinator/Quality Team	Facilitate root cause analysis, monitor progress, and maintain records.
Department Manager	Allocate resources, provide support, and ensure corrective actions are effective.
All Staff	Report non-conformities and participate in corrective actions as required.

4. Procedure

1. **Identification of Non-conformity**
    - Document and report detected non-conformities (internal audits, customer complaints, process monitoring, etc.).

2. **Containment Actions**
    - Implement immediate measures to contain or mitigate the impact of the non-conformity.

3. **Root Cause Analysis**
    - Use structured problem-solving tools (e.g., 5 Why's, Fishbone Diagram) to determine the underlying cause(s).

4. **Corrective Action Plan Development**
    - Develop action plans to eliminate root causes.
    - Assign responsible persons and set deadlines.

5. **Implementation of Corrective & Preventive Actions**
    - Execute the assigned corrective and preventive actions as per the plan.

6. **Verification of Action Implementation**
    - Review and confirm completion and adequacy of actions taken.

7. **Effectiveness Evaluation**
    - Monitor results over a defined period to ensure non-conformity does not recur.

8. **Documentation & Closure**
    - Record all activities, findings, and evidence.
    - Close the CAPA once effectiveness is confirmed.

9. **Follow-up & Continuous Improvement**
    - Conduct periodic reviews and trend analyses to improve CAPA processes.

5. Documentation Requirements

- Non-conformity reports
- Root cause analysis records
- Corrective and preventive action plans
- Evidence of implementation
- Verification and effectiveness review records
- CAPA closure documentation

6. Timelines

- Immediate containment: < 48 hours
- Root cause analysis: Within 5 business days
- Action plan development: Within 7 business days
- Implementation: As per action plan (typically within 30 days)
- Verification and effectiveness monitoring: Up to 3 months after implementation

7. References

- ISO 9001:2015 Quality Management Systems â€“ Requirements
- Internal Quality Policy and Procedures Manual

8. Revision History

Version	Date	Description of Change	Prepared By
1.0	2024-06-18	Initial release	Quality Team