Standard Operating Procedure (SOP)

Corrective Action and Follow-up Monitoring Procedures

This SOP details the **corrective action and follow-up monitoring procedures** necessary to identify, address, and resolve non-conformities or issues within operational processes. It covers the systematic steps for root cause analysis, implementing corrective measures, assigning responsibilities, and establishing timelines. The procedure also includes continuous monitoring and review to ensure effectiveness, prevent recurrence, and promote ongoing improvement in compliance and quality standards.

1. Purpose

This SOP outlines standardized procedures for corrective action and follow-up monitoring to ensure non-conformities are effectively addressed, corrective measures are implemented, and continuous improvement is achieved.

2. Scope

Applies to all employees, contractors, and relevant stakeholders involved in operational processes where non-conformities or deviations may arise.

3. Definitions

- **Non-Conformity:** Failure to meet specified requirements, standards, or procedures.
- **Corrective Action:** Steps taken to eliminate the causes of non-conformity and prevent recurrence.
- **Follow-up Monitoring:** Activities performed to verify the effectiveness of corrective actions.
- **Root Cause Analysis:** A process to identify the underlying cause(s) of non-conformities.

4. Responsibilities

Role	Responsibility
Process Owner	Initiate corrective action, lead root cause analysis, and report progress.
Quality Assurance (QA)	Verify and validate effectiveness of corrective actions and monitor compliance.
Management	Approve corrective actions and allocate resources.
All Staff	Support implementation and adhere to corrective measures.

5. Procedure

1. **Identification of Non-Conformity**
   - Detect and document non-conformity or issue.
   - Notify relevant parties (Process Owner and QA).
2. **Containment (if needed)**
   - Implement immediate actions to contain the issue and minimize impact.
3. **Root Cause Analysis**
   - Conduct analysis using appropriate methodologies (e.g., fishbone diagram, 5 Whys).
   - Document findings and determine root cause(s).
4. **Development of Corrective Action Plan**
   - Define corrective actions addressing root cause(s).
   - Assign responsibilities, resources, and set completion timelines.
   - Obtain necessary approval.
5. **Implementation**
   - Execute corrective actions as per plan.
   - Document activities and completion dates.
6. **Follow-up Monitoring**
   - QA or designated personnel monitor the implementation and results.

    - Verify that non-conformity is resolved and actions are effective.
    - Repeat monitoring at designated intervals if needed.

7. **Closure & Review**
    - Document closure once effectiveness is confirmed.
    - Update procedures or training materials if needed.
    - Report findings and improvements to management.

8. **Continual Improvement**
    - Review trends and recurring issues.
    - Identify opportunities for process improvement and preventive actions.

6. Documentation

- Non-Conformity Report
- Root Cause Analysis Report
- Corrective Action Plan
- Follow-up Monitoring Records
- Closure Report

7. Review and Revision

This SOP shall be reviewed annually or as needed based on feedback and process changes.