

SOP Template: Follow-up Actions, Corrective Measures, and Preventive Steps

This SOP details the process for **follow-up actions, corrective measures, and preventive steps** to address identified issues or non-conformities. It includes procedures for investigating root causes, implementing timely corrective actions, monitoring their effectiveness, and establishing preventive measures to avoid recurrence. The objective is to ensure continuous improvement and compliance with quality and safety standards through systematic problem resolution and risk mitigation.

1. Purpose

To outline systematic procedures for addressing non-conformities, implementing corrective and preventive actions, and ensuring the effectiveness of such actions to prevent recurrence and improve quality and safety standards.

2. Scope

This SOP applies to all departments, personnel, and processes where issues or non-conformities are identified, necessitating follow-up, corrective, and preventive actions.

3. Responsibilities

- **Process Owner:** Initiate, track, and ensure completion of actions.
- **Quality Assurance:** Support investigation and monitor effectiveness of measures.
- **Department Heads:** Ensure staff compliance and timely implementation.
- **All Employees:** Report issues and participate in investigations and corrective actions as required.

4. Definitions

Term	Definition
Non-Conformity	Deviation from defined standards or requirements.
Corrective Action	Steps taken to eliminate the cause of a detected non-conformity or issue.
Preventive Action	Steps taken to eliminate the cause of a potential non-conformity or risk.
Root Cause Analysis (RCA)	Systematic investigation to identify the underlying cause of an issue.
Effectiveness Check	Evaluation of implemented actions to confirm non-recurrence.

5. Procedure

- 1. Identification of Issue or Non-Conformity**
 - Record the issue in the applicable tracking system (e.g., NCR log, quality incident report).
 - Notify the relevant department and quality assurance.
- 2. Initial Assessment & Prioritization**
 - Assess the impact and urgency of the non-conformity or issue.
 - Assign responsible personnel for further action.
- 3. Root Cause Analysis (RCA)**
 - Conduct an investigation using appropriate tools (e.g., 5 Whys, Fishbone Diagram).
 - Document findings and identified root cause(s).
- 4. Corrective Action Implementation**
 - Develop a plan to address the root cause and prevent recurrence.
 - Assign tasks and set deadlines.
 - Execute corrective actions and document completion.
- 5. Verification of Effectiveness**
 - Monitor the area/process to ensure the issue does not recur.
 - Record verification results and obtain approvals from process owner or QA.
- 6. Preventive Action Planning**
 - Identify similar risks or potential non-conformities.
 - Develop and implement preventive measures.
 - Document all preventive actions taken.

7. Close-Out and Documentation

- Update records/logs with all actions taken and outcomes.
- Ensure closure is formally approved by the relevant authority.

6. Documentation & Records

- Non-Conformance/Incident Reports
- Root Cause Analysis sheets/tools
- Corrective and Preventive Action records
- Effectiveness verification records

7. Review and Improvement

- Regularly review this SOP for effectiveness and update as necessary.
- Conduct periodic internal audits of corrective and preventive action processes.

8. References

- Relevant company standards and policies
- ISO 9001: Quality Management Systems
- ISO 14001: Environmental Management Systems (if applicable)