Standard Operating Procedure (SOP)

Root Cause Analysis and Corrective Action Workflow

This SOP details the **root cause analysis and corrective action workflow**, covering the systematic process for identifying underlying issues, analyzing contributing factors, implementing corrective measures, and monitoring their effectiveness. The procedure aims to enhance problem-solving accuracy, prevent recurrence of issues, and improve overall organizational performance through structured investigation and timely corrective action.

1. Purpose

To establish a standardized process for effective root cause analysis (RCA) and implementation of corrective actions, ensuring continuous improvement and prevention of issue recurrence.

2. Scope

This SOP applies to all departments/employees engaged in reporting, investigating, and resolving organizational issues, non-conformances, incidents, or process failures.

3. Definitions

- **Root Cause Analysis (RCA):** A systematic approach to identify the fundamental cause(s) of a problem.
- **Corrective Action:** Measures taken to eliminate the root cause of a detected issue or nonconformity.
- **Non-conformance:** Any deviation from a set standard, procedure, or expectation.
- **CAPA:** Corrective and Preventive Action.

4. Responsibilities

- **Process Owner:** Oversees the RCA and corrective action process.
- **Investigation Team:** Conducts the root cause analysis; documents findings.
- **Quality/Compliance:** Reviews, approves, and monitors corrective actions.
- **All Employees:** Report issues and support investigations as required.

5. Procedure

1. **Issue Identification & Reporting**
    - Detect and document the issue or non-conformance.
    - Report through established channels (e.g., incident report form, ticketing system).

2. **Containment Actions**
    - Implement temporary measures to mitigate immediate impact.

3. **Root Cause Analysis (RCA)**
    - Assemble a qualified investigation team.
    - Collect relevant data and evidence.
    - Use appropriate RCA tools (e.g., 5 Whys, Fishbone Diagram, Fault Tree Analysis).
    - Document all findings and identified root causes.

4. **Develop Corrective Action Plan**
    - Propose actions to address and eliminate root cause(s).
    - Assign responsibilities and deadlines for corrective actions.

5. **Implementation of Corrective Actions**
    - Execute approved corrective actions as per the plan.
    - Document actions taken, including dates, persons responsible, and outcomes.

6. **Verification of Effectiveness**
    - Monitor outcomes to ensure that corrective actions are effective and sustainable.
    - Reassess the area or process affected; if unsuccessful, repeat the RCA process.

7. **Documentation and Closure**
    - Complete all documentation (investigation report, action logs, verification results).
    - Obtain approvals for closure from relevant authorities (Quality, Management).

6. Documentation

Document	Description	Retention
Issue/Incident Report	Initial issue reporting form	5 years
Root Cause Analysis Report	Details investigation methods, findings, and root causes	5 years
Corrective Action Plan	Actions, responsibilities, timelines	5 years
Verification Records	Evidence of corrective action effectiveness	5 years

7. Review and Continuous Improvement

- Review SOP annually or post-major incident to ensure continued relevance.
- Update procedures based on feedback and improvement opportunities.

8. References

- ISO 9001: Quality Management Systems
- Internal CAPA Policy
- Incident Management Guidelines

9. Revision History

Version	Date	Description	Author
1.0	2024-06-07	Initial release	SOP AI Generator