

SOP Template: Root Cause Analysis and Evaluation

This SOP describes the process of **root cause analysis and evaluation**, which involves identifying the fundamental reasons for problems or incidents, systematically investigating contributing factors, and evaluating findings to develop effective corrective and preventive actions. The goal is to enhance organizational performance, prevent recurrence, and support continuous improvement through data-driven decision making and structured problem-solving techniques.

1. Purpose

To establish a standardized approach for conducting root cause analysis (RCA) and evaluation of incidents or problems, ensuring consistent identification of root causes and implementation of effective corrective and preventive actions.

2. Scope

This SOP applies to all employees, teams, and departments involved in root cause analysis and problem-solving processes across the organization.

3. Responsibilities

- **Process Owner:** Oversees the RCA process and ensures implementation of corrective and preventive actions (CAPA).
- **RCA Team:** Performs investigations, collects data, conducts analysis, and reports findings.
- **Department Managers:** Ensure incidents are reported and support staff participation in investigations.
- **Quality Assurance:** Reviews RCA reports and monitors effectiveness of actions taken.

4. Definitions

- **Root Cause:** The underlying reason or origin of a problem, detectable and correctable, which if addressed prevents recurrence.
- **Corrective Action:** Steps taken to eliminate the root cause and prevent recurrence.
- **Preventive Action:** Measures implemented to eliminate the potential for similar problems before they occur.
- **Contributing Factor:** Secondary issue or circumstance that increased the likelihood or severity of the main problem.

5. Procedure

1. **Identification and Reporting**
 - Identify incidents or problems that require RCA.
 - Document incidents using the organization's reporting mechanism.
2. **Team Formation**
 - Assemble a cross-functional team with relevant expertise, including subject matter experts.
3. **Data Collection**
 - Gather and review all relevant data (logs, records, witness statements, physical evidence, etc.).
4. **Root Cause Analysis Methods**
 - Use at least one recognized method (e.g., 5 Whys, Fishbone/Ishikawa diagram, Fault Tree Analysis, etc.).
5. **Identification of Root and Contributing Causes**
 - Systematically analyze data to distinguish between symptoms, contributing factors, and root causes.
6. **Development of Corrective and Preventive Actions (CAPA)**
 - Propose actions specific to each root cause and contributing factor.
7. **Implementation**
 - Assign responsibilities and timelines for action implementation.
8. **Effectiveness Evaluation**
 - Monitor implemented actions to verify successful resolution and prevention of recurrence.
9. **Documentation and Reporting**
 - Prepare an RCA report summarizing findings, actions taken, and effectiveness assessment.

6. Documentation

- Incident/Problem Report Forms
- RCA Worksheets and Diagrams
- Corrective/Preventive Action Plans
- Effectiveness Review Checklist
- Final RCA Report

7. References

- Industry standards (e.g., ISO 9001, ISO 31000)
- Organizational policy documents relevant to incident management
- Guidelines for root cause analysis tools and techniques

8. Revision History

Version	Date	Description	Author
1.0	2024-06-07	Initial Release	[Your Name/Department]