# SOP Template: Procedures for Root Cause Analysis Initiation

This SOP details the **procedures for root cause analysis initiation**, including identifying the problem, assembling the analysis team, gathering relevant data, defining the scope and objectives, selecting appropriate analysis tools, and establishing timelines. The aim is to ensure a systematic approach to initiating root cause analysis for effective problem-solving and prevention of recurrence.

## 1. Purpose

To establish a standard procedure for initiating a root cause analysis (RCA) to address and prevent recurrence of significant issues.

## 2. Scope

This procedure applies to all incidents, deviations, or problems where root cause analysis is required within the organization.

## 3. Responsibilities

| Role | Responsibility |
| --- | --- |
| Process Owner / Manager | Initiate RCA, assign team, approve scope and timelines |
| RCA Facilitator | Lead the RCA process, coordinate meetings, ensure documentation |
| Analysis Team Members | Participate in analysis, provide data, review findings |
| QA/QC | Ensure adherence to procedures and assist with verification |

## 4. Procedure

1. **Identify the Problem**
   - Receive report of incident, deviation, or recurring issue.
   - Assess if RCA is warranted based on impact and policy criteria.
   - Document the problem statement clearly and concisely.
2. **Assemble the Analysis Team**
   - Appoint a multidisciplinary team with relevant expertise.
   - Designate an RCA facilitator to lead the process.
   - Record team members and roles in the RCA initiation log.
3. **Gather Relevant Data**
   - Collect all available information: documentation, logs, interviews, records.
   - Ensure data is accurate, comprehensive, and timely.
4. **Define Scope and Objectives**
   - Set clear boundaries for the analysis based on available information.
   - Formulate specific objectives and success criteria for the RCA.
5. **Select Appropriate Analysis Tools**
   - Choose tools and techniques (e.g., 5 Whys, Fishbone Diagram, FMEA) suitable for the situation.
   - Provide team with relevant templates or guides.
6. **Establish Timelines**
   - Set and document deadlines for each phase of RCA (initiation, analysis, reporting, follow-up).
   - Communicate expectations and schedules to all stakeholders.

## 5. Documentation

- Log all steps, decisions, and actions in the RCA initiation log.
- Maintain records of team composition, data sources, scope, objectives, selected tools, and timelines.
- Store documentation securely for traceability and audits.

## 6. References

- Root Cause Analysis Policy
- Incident/Deviation Reporting Procedure

- Applicable regulatory or industry guidelines

# 7. Revision History

| Version | Date | Description | Author |
|---------|------|-------------|--------|
| 1.0 | 2024-06-09 | Initial template created | SOP Team |