Standard Operating Procedure (SOP): Root Cause Analysis Procedures

This SOP details the **root cause analysis procedures**, including methodologies such as the 5 Whys and Fishbone Diagram. It provides systematic approaches to identify the underlying causes of problems or incidents by asking iterative questions and visually mapping contributing factors. The purpose is to enable effective problem-solving, prevent recurrence, and improve overall organizational processes through thorough investigation and analysis.

1. Purpose

To establish a standardized process for conducting root cause analysis (RCA) using structured methodologies, ensuring comprehensive problem investigation and effective corrective actions.

2. Scope

This procedure applies to all employees and departments required to investigate incidents, process deviations, nonconformities, or recurring issues.

3. Responsibilities

- **RCA Facilitator:** Leads and documents the analysis process.
- **Team Members:** Participate by sharing insights and contributing to discussions.
- **Management:** Reviews findings and approves recommended corrective actions.

4. Definitions

- **Root Cause:** The fundamental reason for the occurrence of a problem, which if resolved, prevents recurrence.
- **5 Whys:** An iterative interrogative technique used to explore cause-and-effect relationships.
- **Fishbone Diagram (Ishikawa):** A visual tool for categorizing potential causes of a problem.

5. Procedures

5.1 General Steps

1. Define the problem or incident clearly.
2. Gather necessary data and evidence.
3. Select and assemble an analysis team.
4. Choose an appropriate RCA method (5 Whys, Fishbone Diagram, or both).
5. Conduct the analysis as detailed below.
6. Document findings and proposed corrective actions.
7. Implement corrective actions and track outcomes.

5.2 5 Whys Technique

1. Write down the specific problem.
2. Ask "Why did this happen?" and note the answer.
3. If the answer does not reveal the root cause, ask "Why?" again about the previous answer.
4. Repeat at least five times or until the fundamental cause is identified.
5. Verify that the identified root cause will prevent recurrence if addressed.

Example Table:

Level	Question	Answer
1	Why did the machine stop?	Because it overloaded.
2	Why did it overload?	Because the lubricant ran out.
3	Why did the lubricant run out?	Because it was not regularly checked.
4	Why was it not checked?	No maintenance schedule in place.
5	Why was there no schedule?	Lack of procedures.

5.3 Fishbone Diagram (Ishikawa)

1. Define the problem statement at the â€œheadâ€ of the fishbone diagram.
2. Draw major cause categories as main â€œbonesâ€ (e.g., People, Methods, Machines, Materials, Measurement, Environment).
3. Brainstorm contributing factors within each category using team input.
4. Analyze and identify the most likely root causes.
5. Document findings for further review.

Example Categories:

- People
- Process/Methods
- Equipment/Machines
- Materials
- Environment
- Management/Measurement

6. Documentation

- Keep detailed records of the analysis process and findings.
- Attach completed 5 Whys tables and Fishbone diagrams to the incident report.
- Track implementation and results of corrective actions.

7. Review and Continuous Improvement

- Review outcomes to assess the effectiveness of corrective actions.
- Revise procedures and preventatives based on lessons learned.

8. References

- Quality Management System Manual
- Incident/Problem Reporting Procedures
- Root Cause Analysis Tools and Templates