SOP: Root Cause Analysis and Documentation Process

This SOP details the **root cause analysis and documentation process**, encompassing the systematic identification of underlying causes of issues, data collection methods, analysis techniques, corrective action planning, and comprehensive documentation standards. The goal is to enhance problem-solving effectiveness, prevent recurrence, and support continuous improvement initiatives across the organization.

1. Purpose

To provide clear guidelines for performing root cause analysis (RCA) and documenting findings in order to resolve issues effectively and prevent their recurrence.

2. Scope

This SOP applies to all employees involved in process improvement, incident management, and quality assurance activities across the organization.

3. Definitions

Term	Definition
Root Cause Analysis (RCA)	A systematic process for identifying the fundamental causes of issues.
Corrective Action	Measures taken to eliminate the causes of an identified problem and prevent recurrence.

4. Responsibilities

- **Process Owner:** Responsible for initiating and overseeing the RCA process.
- **RCA Team:** Executes the RCA and documents findings.
- **Management:** Reviews documentation, approves corrective actions, and monitors implementation.

5. Procedure

1. **Initiation**
   - Identify and define the problem or incident.
   - Assemble an RCA team with relevant expertise.
2. **Data Collection**
   - Gather data using interviews, observations, process maps, logs, or relevant documents.
   - Ensure data accuracy and completeness.
3. **Root Cause Analysis**
   - Apply analysis techniques (e.g., 5 Whys, Fishbone Diagram, Fault Tree Analysis).
   - Identify underlying causes and contributing factors.
4. **Corrective Action Planning**
   - Develop corrective actions addressing each root cause.
   - Assign responsibilities and deadlines for each action.
5. **Implementation & Follow-Up**
   - Implement corrective actions and monitor progress.
   - Review effectiveness and adjust actions as necessary.
6. **Documentation**
   - Complete the RCA report, including:
     - Problem Description
     - Data Collected

- Analysis Method Used
- Root Cause(s) Identified
- Corrective Actions & Responsible Parties
- Follow-Up Results
- Sign-offs

6. Documentation Standards

- All RCA reports must be dated, signed, and stored in the designated document management system.
- Reports must be clear, concise, and include all supporting data and analysis artifacts.

7. References

- ISO 9001:2015 - Quality Management Systems
- Company Incident Management Policy

8. Revision History

Version	Date	Description	Author
1.0	2024-06-12	Initial SOP release	Quality Team