SOP Template: Root Cause Analysis and Preventive Action Guidelines

This SOP provides comprehensive **root cause analysis and preventive action guidelines** to identify the underlying causes of problems, defects, or non-conformities within processes or systems. It details systematic investigation techniques, including data collection and analysis, to uncover root causes effectively. The SOP also outlines the development and implementation of preventive actions to eliminate recurrence, improve processes, and enhance overall quality and efficiency. By following these guidelines, organizations can ensure continuous improvement and minimize risks associated with operational failures.

1. Purpose

To establish a standardized approach for conducting root cause analysis (RCA) and implementing preventive actions to address process deviations, defects, or non-conformities.

2. Scope

This SOP applies to all departments and personnel responsible for processing, quality control, compliance, and continuous improvement initiatives.

3. Responsibilities

- **Process Owners:** Ensure timely initiation and execution of RCA and preventive actions.
- **Quality Assurance:** Facilitate investigations, validate root cause findings, and monitor implementation of preventive actions.
- **Team Members:** Actively participate in data collection, analysis, and solution brainstorming.
- **Management:** Review root cause reports, approve actions, and allocate necessary resources.

4. Definitions

- **Root Cause:** The fundamental reason for the occurrence of a problem, defect, or non-conformity.
- **Preventive Action:** Steps taken to eliminate the root cause and prevent recurrence.
- **Non-Conformity:** A deviation from standard processes or requirements.

5. Procedure

1. **Problem Identification**
    - Document the problem, defect, or non-conformity.
    - Gather preliminary data and evidence.
2. **Containment Actions**
    - Implement temporary measures to control the issue and limit impact.
3. **Root Cause Analysis**
    - Utilize appropriate RCA tools such as:
        - 5 Whys Analysis
        - Fishbone (Ishikawa) Diagram
        - Failure Mode and Effects Analysis (FMEA)
        - Pareto Analysis
    - Assemble a cross-functional team for investigation.
    - Collect and analyze relevant data.
    - Conduct interviews if required.
4. **Develop Preventive Actions**
    - Identify corrective and preventive actions targeting the actual root cause.
    - Assign responsibilities and timelines for implementation.
5. **Implementation**
    - Execute the preventive actions as per the established plan.
6. **Verification and Effectiveness Review**
    - Monitor results to ensure the actions are effective.
    - Document findings and adjust actions if recurrence is observed.
7. **Documentation**

- Maintain complete records of analysis, actions, and results.
- Communicate outcomes with relevant stakeholders.

6. Documentation and Records

Document	Description	Retention Period
RCA Report	Summary of findings, analysis, and actions taken	3 Years
Action Plan	Details of preventive measures with timelines and responsibilities	3 Years
Verification Logs	Records of action verification and effectiveness monitoring	3 Years

7. References

- ISO 9001:2015 â€“ Quality Management Systems
- Internal Quality Management Manuals

8. Revision History

Version	Date	Description	Author
1.0	2024-06-10	Initial version	SOP Team

Note: Always tailor this SOP to your organization's specific processes, regulatory requirements, and industry standards.