Standard Operating Procedure (SOP)

Corrective Action and Non-Conformance Management

This SOP details the process for **corrective action and non-conformance management**, covering identification, documentation, investigation, root cause analysis, implementation of corrective measures, monitoring effectiveness, and continuous improvement. It aims to ensure systematic handling of non-conformances to maintain quality standards and prevent recurrence.

1. Purpose

To describe the steps for managing non-conformances and implementing corrective actions to ensure quality standards are maintained and continual improvement is achieved.

2. Scope

This procedure applies to all employees, processes, and products where non-conformances may be detected within the organization.

3. Definitions

- **Non-Conformance:** Failure to meet specified requirements.
- **Corrective Action:** Action to eliminate the cause of a detected non-conformance.
- **Root Cause Analysis:** Process of identifying the fundamental cause of a non-conformance.

4. Responsibilities

- **All Staff:** Report non-conformances promptly.
- **Quality Manager:** Oversight of the entire process, root cause analysis, and follow-up.
- **Department Heads:** Ensure corrective actions are implemented effectively.

5. Procedure

1. **Identification**
    - Non-conformance detected through inspections, audits, complaints, or observations.
2. **Documentation**
    - Record the non-conformance using the **Non-Conformance Report (NCR)** form.
    - Include details: date, description, person reporting, reference documents, etc.
3. **Containment Action**
    - Immediately contain the effect of the non-conformance to prevent further impact.
4. **Investigation & Root Cause Analysis**
    - Investigate the non-conformance and perform root cause analysis using appropriate tools (5 Whys, Fishbone Diagram, etc.).
5. **Corrective Action Plan**
    - Develop and document corrective actions to eliminate root causes.
    - Assign responsibilities and set deadlines.
6. **Implementation**
    - Implement corrective actions as per the plan.
    - Communicate changes to relevant personnel.
7. **Verification & Effectiveness Monitoring**
    - Verify the correction and monitor effectiveness over a suitable period.
    - Document results and close the NCR if successful.
8. **Continuous Improvement**
    - Review trends, identify potential for systemic improvements, and update processes if necessary.

6. Documentation and Records

- Non-Conformance Report (NCR)
- Corrective Action Plan
- Root Cause Analysis Records
- Verification and Monitoring Records

7. References

- Relevant company policies and procedures
- Applicable industry standards (e.g., ISO 9001)

8. Revision History

Version	Date	Description of Changes	Approved By
1.0	YYYY-MM-DD	Initial release	[Name]