Standard Operating Procedure (SOP)

Non-conformance Identification and Corrective Action

This SOP details the process for **non-conformance identification and corrective action**, encompassing the detection, documentation, and evaluation of non-conforming products or processes. It outlines procedures for initiating corrective actions, root cause analysis, implementation of remedial measures, and verification of effectiveness to ensure continuous improvement and compliance with quality standards.

SOP Number:	NCI-CA-001	**Effective Date:**	
Department:		**Revision Number:**	1.0
Prepared By:		**Approved By:**	

1. Purpose

To establish a systematic method for identifying, documenting, addressing, and preventing non-conforming products or processes, ensuring swift corrective actions and continual improvement within the organization.

2. Scope

This SOP applies to all products, processes, and operations where non-conformance to specified standards, requirements, or procedures may occur.

3. Definitions

- **Non-conformance:** Failure to meet specified requirements for a product, process, or system.
- **Corrective Action:** Action to eliminate the causes of a detected non-conformance to prevent recurrence.
- **Root Cause Analysis:** A systematic process to identify the underlying causes of a non-conformance.

4. Responsibilities

- **All Employees:** Promptly report and document any observed or suspected non-conformance.
- **Quality Assurance (QA):** Review, investigate, recommend corrective actions, and verify effectiveness.
- **Department Managers:** Implement corrective actions and ensure compliance in their teams.

5. Procedure

1. **Identification of Non-conformance**
    - Any employee who detects a non-conformance must report it immediately to their supervisor or the QA department.
    - Complete a Non-conformance Report (NCR) with details of the issue and initial observations.
2. **Documentation**
    - NCRs must be logged in the Non-conformance Register, including date, description, location, and person reporting.
3. **Evaluation and Segregation**
    - QA reviews the NCR, evaluates the impact and severity, and determines if immediate segregation or containment is required.
4. **Root Cause Analysis**
    - QA coordinates a root cause investigation using methods such as 5 Whys, Fishbone Diagram, etc.
5. **Corrective Action Plan**
    - A corrective action plan must be developed to address the root cause(s), including responsibilities, actions, and timelines.
6. **Implementation**
    - Responsible department implements the corrective measures as per the plan and documents completion.
7. **Verification of Effectiveness**
    - QA verifies the effectiveness of corrective actions through follow-up audits or review of quality data.
8. **Closure**
    - QA closes the NCR once satisfactory evidence of correction and prevention of recurrence is confirmed.
9. **Continuous Improvement**
    - Lessons learned should be communicated, and trends analyzed periodically to drive systemic quality improvement.

6. Records

- Non-conformance Reports (NCRs)
- Root Cause Analysis documentation
- Corrective Action Plans and evidence of implementation
- Verification and closure records
- Non-conformance Register

7. References

- ISO 9001: Quality Management Systemâ€“Requirements
- Company Quality Manual
- Related SOPs and Work Instructions

8. Revision History

Revision	Date	Description	Approved By
1.0		Initial release	