SOP: Non-conformance and Corrective Action Procedures

This SOP details the **non-conformance and corrective action procedures**, outlining the identification, documentation, investigation, and resolution of non-conformances. It establishes a systematic approach for addressing deviations from established standards, implementing corrective actions, verifying their effectiveness, and preventing recurrence. The goal is to ensure continuous improvement and maintain product quality and compliance with regulatory requirements.

1. Purpose

To define the process for identifying, documenting, investigating, and resolving non-conformances, and to outline the implementation and verification of corrective actions to ensure product quality and regulatory compliance.

2. Scope

This procedure applies to all personnel, processes, products, and services where non-conformance may be detected, whether from internal or external sources.

3. Definitions

- **Non-conformance:** Any deviation from specified requirements or standards.
- **Corrective Action:** Action to eliminate the cause of a detected non-conformance and prevent recurrence.
- **Root Cause:** The fundamental reason for the occurrence of a non-conformance.

4. Responsibilities

- **All Employees:** Must report actual or suspected non-conformances immediately.
- **Quality Assurance (QA):** Responsible for tracking, coordinating investigations, and verifying corrective actions.
- **Department Managers:** Lead investigations and implement corrective actions within their areas of responsibility.

5. Procedure

1. **Identification of Non-conformance**
    - Non-conformances can be identified during routine operations, audits, inspections, customer feedback, or through employee observations.
2. **Documentation**
    - Record all non-conformances using Form NC-01 or electronic system, including description, date, location, and reporter details.
3. **Containment Actions**
    - Immediately control/segregate affected product/material to prevent further use or distribution.
4. **Investigation**
    - Department Manager and QA initiate root cause analysis using tools (e.g., 5 Whys, Fishbone Diagram).
5. **Corrective Action**
    - Develop corrective actions addressing the root cause. Assign responsibilities and due dates.
6. **Implementation**
    - Implement corrective actions according to the plan. Document completion and results.
7. **Verification of Effectiveness**
    - QA verifies the effectiveness of implemented corrective actions after a defined period.
8. **Closure**

- Once effectiveness is verified, the non-conformance report is closed and filed.

6. Records

Record	Retention Period	Location
Non-conformance Report (Form NC-01)	3 Years	QA Office / Electronic System
Corrective Action Plan	3 Years	QA Office / Electronic System
Verification Checklist	3 Years	QA Office / Electronic System

7. References

- ISO 9001:2015, Clause 10.2 - Nonconformity and Corrective Action
- Internal Quality Manual

8. Revision History

Version	Date	Description	Approved By
1.0	2024-06-12	Initial Release	Quality Manager