SOP Template: Corrective Actions for Non-Conformance or Test Failure

This SOP details the process for identifying and implementing **corrective actions for non-conformance or test failure**. It covers the steps for detecting deviations, documenting discrepancies, analyzing root causes, developing and applying corrective measures, and verifying effectiveness to prevent recurrence. The objective is to ensure product quality, compliance with standards, and continuous improvement within the organization.

1. Purpose

To describe the procedure for identifying, documenting, investigating, correcting, and verifying non-conformances and test failures to maintain compliance and product quality.

2. Scope

This SOP applies to all personnel involved in manufacturing, testing, and quality assurance where non-conformance or test failure is detected within the organization.

3. Responsibilities

- **Quality Assurance (QA):** Oversee implementation and effectiveness of corrective actions.
- **Department Managers:** Ensure staff adherence to SOP and facilitate corrective action implementation.
- **All Employees:** Report and document non-conformances or test failures as observed.

4. Definitions

- **Non-conformance:** Failure to meet specified requirements, standards, or procedures.
- **Corrective Action:** Action to eliminate the cause of a detected non-conformance or other undesirable situation.
- **Root Cause Analysis:** Investigation to identify the origin of a problem.

5. Procedure

1. **Detection:**
    - Monitor processes, inspections, and tests to identify deviations or test failures.
    - Employees report discrepancies immediately to supervisors or QA.
2. **Documentation:**
    - Record all non-conformances or test failures using the *Non-Conformance Report (NCR)* form.
    - Include details: date, time, location, description, involved personnel, and initial containment actions.
3. **Investigation and Root Cause Analysis:**
    - Assign a responsible team to investigate the issue using tools such as the 5 Whys, Fishbone Diagram, or FMEA.
    - Document the identified root cause(s).
4. **Development of Corrective Actions:**
    - Develop corrective actions targeting the root cause to prevent recurrence.
    - Document the action plan, responsible persons, resources required, and deadlines.
5. **Implementation:**
    - Implement corrective actions as per the approved plan.
    - Provide necessary training to involved staff if required.
6. **Verification of Effectiveness:**
    - QA reviews the outcome of corrective actions through audits, re-testing, or monitoring.
    - If non-conformance persists, repeat the investigation and action process.
7. **Closure:**
    - Once effectiveness is confirmed, close the NCR with documented evidence of results.

6. Documentation

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

7. References

- ISO 9001:2015 Quality Management Systems
- Internal company guidelines and policies

8. Revision History

Version	Date	Description of Change	Approved by
1.0	2024-06-10	Initial creation	Quality Manager