SOP Template: Corrective Action Process for Non-Compliance Findings

This SOP details the **corrective action process for non-compliance findings**, outlining the steps to identify, document, and address instances of non-compliance within an organization. It covers the procedures for investigating non-compliance issues, assigning responsibilities for corrective measures, implementing action plans, monitoring effectiveness, and ensuring continuous improvement to maintain regulatory and internal standards.

1. Purpose

To establish a consistent and effective process for addressing non-compliance findings, ensuring root causes are identified and corrective actions are implemented to prevent recurrence and maintain regulatory/institutional standards.

2. Scope

This procedure applies to all employees, departments, and processes where non-compliance with policies, procedures, or regulatory requirements is identified.

3. Definitions

- **Non-Compliance Finding:** An instance where processes or actions deviate from established standards or regulations.
- **Corrective Action:** Measures taken to eliminate the causes of a detected non-compliance and prevent recurrence.
- **Responsible Person:** The individual assigned to implement and oversee corrective actions.

4. Responsibilities

Role	Responsibility
Department Managers	Initiate investigation, assign responsible persons, and monitor corrective actions.
Quality/Compliance Team	Provide oversight, facilitate root cause analysis, and ensure closure of non-compliance findings.
Employees	Report non-compliance and assist in investigation/implementation as needed.

5. Procedure

1. **Identification of Non-Compliance**
   - Detect and report non-compliance via audits, inspections, complaints, or observations.
2. **Documentation**
   - Record the finding in the Non-Compliance Log, including date, location, description, and reporter's details.
3. **Investigation**
   - Responsible person/team investigates the cause and extent of non-compliance within 5 business days.
   - Perform root cause analysis (e.g., 5 Whys, Fishbone Diagram).
4. **Development of Corrective Action Plan**
   - Develop a plan outlining actions, responsible parties, resources required, timelines, and monitoring methods.
5. **Implementation**
   - Carry out corrective measures as per the action plan. Document all activities and communications.
6. **Verification of Effectiveness**
   - Monitor and review outcomes to ensure non-compliance does not recur.
   - Conduct follow-up audits or checks within a specified period (e.g., 30 days).
7. **Closure**
   - Once verified, document closure in the log and communicate resolution to all stakeholders.

6. Records

- Non-Compliance Log
- Investigation Reports
- Corrective Action Plans
- Verification/Audit Reports
- Closure Documentation

7. Continuous Improvement

- Analyze trends from non-compliance data to identify areas for process improvement.
- Regularly review this SOP for effectiveness and update as necessary.

8. References

- Relevant industry regulations and standards
- Internal policies and procedures

9. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-28	Initial creation	[Name/Position]