SOP Template: Non-conformance Detection and Corrective Action Steps

This SOP describes the process for **non-conformance detection and corrective action steps**, including identification of non-conformities, documentation and reporting procedures, root cause analysis, development and implementation of corrective actions, verification of effectiveness, and continuous monitoring to prevent recurrence. The goal is to ensure quality standards are met and to maintain operational efficiency by addressing issues promptly and systematically.

1. Scope

This procedure applies to all departments and personnel responsible for the detection, reporting, and resolution of non-conformances within the organization.

2. Definitions

Term	Definition
Non-conformance	Deviation from specified requirements, standards, or procedures.
Corrective Action	Action to eliminate the cause of a detected non-conformance to prevent recurrence.
Root Cause Analysis	Systematic process to identify the underlying cause(s) of a non-conformance.

3. Responsibilities

- **All Employees:** Identify and report suspected or actual non-conformances.
- **Supervisors/Managers:** Review reports, initiate corrective action, assign investigation teams.
- **Quality Assurance (QA):** Oversee root cause analysis, verify corrective actions, maintain records.

4. Procedure

1. **Identification of Non-conformance**
   - Detect through inspection, testing, audits, or reports.
   - Immediately isolate affected product/process, if applicable.
2. **Documentation and Reporting**
   - Document details using the Non-conformance Report (NCR) form (date, description, personnel involved, etc.).
   - Notify supervisor and Quality Assurance.
3. **Root Cause Analysis**
   - Assigned team investigates to identify fundamental cause.
   - Use appropriate tools (e.g., 5 Whys, Fishbone diagram).
4. **Development of Corrective Action**
   - Determine corrective action(s) to eliminate root cause.
   - Establish action plan with responsible persons and deadlines.
5. **Implementation of Corrective Action**
   - Carry out corrective actions as per plan.
   - Document all actions taken.
6. **Verification of Effectiveness**
   - QA verifies that corrective action resolved the issue.
   - Monitor for recurrence over a defined period.
7. **Continuous Monitoring and Improvement**
   - Review trends and implement preventive actions as needed.
   - Update SOPs and training if necessary.

5. Records

- Non-conformance Report (NCR) forms
- Root cause analysis documentation

- Corrective action plans and completion records
- Verification and monitoring records

6. References

- Quality Management System Manual
- Related SOPs
- Industry Standards (e.g., ISO 9001)

7. Revision History

Version	Date	Description	Approved By
1.0		Initial release	