# SOP Template: Non-Conformance Identification and Corrective Action Processes

## Purpose

This SOP details the **non-conformance identification and corrective action processes**, including procedures for detecting deviations from standards, documenting non-conformities, analyzing root causes, implementing corrective and preventive actions, monitoring effectiveness, and maintaining records. The aim is to ensure continuous improvement and compliance with quality management systems by promptly addressing and rectifying any discrepancies.

## Scope

This procedure applies to all departments and personnel involved in processes where product or service non-conformities may occur or be identified, as well as those responsible for implementing corrective and preventive actions.

## Definitions

| Term | Definition |
|---|---|
| Non-Conformance (NC) | Any deviation from specified requirements, standards, or procedures. |
| Corrective Action | Actions taken to eliminate the cause of a detected non-conformance. |
| Preventive Action | Actions taken to eliminate the cause of potential non-conformance. |
| Root Cause Analysis (RCA) | Systematic investigation to determine the underlying cause(s) of a non-conformance. |

## Responsibilities

- **All Staff:** Identify, report, and record non-conformances promptly.
- **Supervisors/Managers:** Review reported non-conformances, assign responsibility for investigation, and ensure timely resolution.
- **Quality Management Team:** Oversee the effectiveness of corrective and preventive actions and maintain non-conformance records.

## Procedure

1. **Identification of Non-Conformance**
    - Non-conformances can be identified during inspections, audits, routine processes, or customer feedback.
    - Any staff member who detects a non-conformance must document it immediately using the Non-Conformance Report (NCR) form.
2. **Documentation**
    - Complete all required fields in the NCR form, including date, description, detection source, and immediate actions taken.
    - Submit the completed form to the supervisor/manager for review within 24 hours of identification.
3. **Evaluation and Segregation**
    - Supervisors assess the impact of the non-conformance and determine if product segregation or process stoppage is warranted.
4. **Root Cause Analysis**
    - An RCA (e.g., 5 Whys, Fishbone Diagram) must be performed for each non-conformance with significant impact.
    - Document findings and recommended actions in the NCR form.
5. **Corrective and Preventive Action**
    - Develop and implement action plans to address both the immediate and root causes of the non-conformance.
    - Assign responsibility and set deadlines for each action item.
    - Record implemented actions in the NCR form and track progress until completion.

6. **Verification of Effectiveness**
    - After completion, verify the effectiveness of corrective/preventive actions (e.g., through audits or inspections).
    - Document evidence and results of verification.
7. **Closure and Record Keeping**
    - Once effectiveness is confirmed, close out the NCR and file all documentation electronically and/or physically as per record retention policy.
    - Review records periodically to identify trends and opportunities for continuous improvement.

## Records

- Non-Conformance Reports (NCR)
- Corrective and Preventive Action Plans
- Root Cause Analysis Documents
- Verification and Closure Records

## References

- Quality Management System Manual
- ISO 9001:2015-Clause 10.2 (Non-Conformity and Corrective Action)
- Internal Audit Procedures

## Revision History

| Version | Date | Description | Author |
|---|---|---|---|
| 1.0 | 2024-06-01 | Initial release | Quality Manager |