Standard Operating Procedure (SOP)

Non-conformance and Corrective Action Management

This SOP details the process for **non-conformance and corrective action management**, including identification, documentation, evaluation, and resolution of non-conformances. It outlines responsibilities for reporting and investigating issues, implementing corrective actions, monitoring effectiveness, and preventing recurrence to ensure continuous quality improvement and compliance with organizational standards and regulatory requirements.

1. Purpose

To establish a standardized process for identifying, documenting, evaluating, and resolving non-conformances; assigning responsibilities for corrective actions; and monitoring effectiveness to prevent recurrence.

2. Scope

This SOP applies to all employees, processes, products, and services within [Organization Name].

3. Definitions

- **Non-conformance:** Deviation from specified requirements or standards.
- **Corrective Action:** Steps taken to eliminate the root cause of a detected non-conformance.
- **Preventive Action:** Measures implemented to prevent the occurrence of potential non-conformances.

4. Responsibilities

- **Employee:** Report observed or suspected non-conformances promptly.
- **Quality Manager:** Review, document, and evaluate non-conformances; assign investigations and actions.
- **Investigators:** Conduct root cause analysis and recommend corrective actions.
- **Process Owners:** Implement corrective actions and monitor effectiveness.
- **Management:** Review non-conformance trends and overall system effectiveness.

5. Procedure

1. **Identification and Reporting**
    - Identify potential or actual non-conformances in products, processes, or systems.
    - Report non-conformances using the *Non-conformance Report (NCR)* form.
2. **Documentation**
    - Document all relevant details (who, what, when, where, and how).
    - Assign unique identifier to each NCR.
3. **Evaluation**
    - Review the non-conformance for severity and potential impact.
    - Determine if immediate action is required (e.g. product recall, process halt).
4. **Containment**
    - Implement immediate measures to contain and mitigate the effects.
5. **Investigation and Root Cause Analysis**
    - Assign investigator(s) to analyze the root cause(s) using appropriate tools (e.g., 5 Whys, Fishbone diagram).
    - Document investigation findings and root cause(s).
6. **Corrective Action**
    - Develop corrective action plan addressing identified root cause(s).
    - Assign responsibilities and deadlines for implementation.
7. **Implementation**
    - Execute corrective action plan as approved by management or Quality Manager.
8. **Verification of Effectiveness**
    - Monitor and verify corrective action effectiveness after implementation.
    - If ineffective, reinitiate investigation and further action as needed.
9. **Closure**
    - Close NCR upon successful verification; document evidence and closeout date.
10. **Prevention**
    - Review and update relevant procedures, training, or controls to prevent recurrence.

6. Documentation and Records

- Maintain Non-conformance Reports and corrective action documentation for [minimum record retention period] in

accordance with [company/regulatory requirements].
- Records must be readily accessible for audits and reviews.

7. Review and Continuous Improvement

- Regularly review non-conformance and corrective action data to identify trends.
- Implement continuous improvements based on analysis outcomes.
- Update this SOP as needed to address systemic issues.

8. References

- [Relevant standard e.g., ISO 9001:2015, Section 10.2]
- [Organization-specific policies and procedures]

9. Revision History

Version	Date	Description	Author	Approval
1.0	[YYYY-MM-DD]	Initial release	[Name]	[Name/Title]