SOP: Non-conformance Management and Corrective Action Process

This SOP defines the **non-conformance management and corrective action process**, detailing the identification, documentation, evaluation, and resolution of non-conformities. It covers roles and responsibilities, root cause analysis, implementation of corrective and preventive actions, monitoring effectiveness, and continuous improvement to ensure quality standards are maintained and organizational compliance is achieved.

1. Purpose

To provide a structured process for identifying, documenting, evaluating, and resolving non-conformances and implementing corrective actions to maintain compliance with quality standards.

2. Scope

This SOP applies to all employees, processes, products, and services where non-conformities may occur within the organization.

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 taken to eliminate the causes of potential non-conformances.
- **Root Cause Analysis:** Process of investigating and identifying the underlying causes of non-conformity.

4. Responsibilities

Role	Responsibility
All Employees	Report non-conformances promptly. Cooperate during investigations.
Department Managers	Evaluate reported non-conformances, assign investigators, and oversee resolutions.
Quality Manager	Facilitate root cause analysis, track corrective actions, and monitor effectiveness.
Continuous Improvement Team	Review trends, propose preventive actions, and drive process improvements.

5. Procedure

1. **Identification of Non-conformance**
   Any employee identifying a non-conformance must document it using the Non-conformance Report (NCR) form and notify their supervisor.
2. **Documentation**
   Record details of the non-conformance including date, location, description, and immediate containment actions.
3. **Evaluation**
   The responsible manager evaluates the non-conformance for severity and potential impact.
4. **Root Cause Analysis**
   Assign a team to conduct a root cause analysis using appropriate methods (e.g., 5 Whys, Fishbone Diagram).

5. **Corrective/Preventive Action**
   Develop and implement action plans to address immediate issues and prevent recurrence. Assign responsibilities and due dates.
6. **Verification of Effectiveness**
   Review the effectiveness of implemented actions after a defined period. Document results and determine if further action is needed.
7. **Closure**
   Upon successful verification, formally close the non-conformance report. Retain documentation per record-keeping requirements.
8. **Continuous Improvement**
   Analyze non-conformance and corrective action trends during management reviews and update processes as necessary.

6. Records

- Non-conformance Report (NCR) Forms
- Root Cause Analysis Documents
- Corrective/Preventive Action Logs
- Effectiveness Review Records

7. References

- ISO 9001:2015 Quality Management Systems â€“ Requirements
- Company Quality Manual
- Industry-specific regulatory requirements (as applicable)

8. Revision History

Version	Date	Description of Change	Prepared By
1.0	2024-06-21	Initial release	Document Control