Standard Operating Procedure (SOP)

Non-conformance Handling and Corrective Action Procedures

This SOP describes the processes for **non-conformance handling and corrective action procedures**, including identification, documentation, analysis, and resolution of non-conformances. It aims to ensure timely corrective actions, prevent recurrence, and maintain compliance with quality standards by involving relevant personnel and continuous monitoring of effectiveness.

1. Purpose

To establish a standardized procedure for identifying, documenting, investigating, and resolving non-conformances and implementing corrective actions to prevent their recurrence.

2. Scope

This procedure applies to all employees, processes, materials, products, and services where non-conformances may occur.

3. Definitions

- **Non-conformance:** Any deviation from specified requirements, standards, or procedures.
- **Corrective Action:** Action taken to eliminate the root cause of a detected non-conformance to prevent recurrence.
- **Preventive Action:** Action to eliminate the cause of a potential non-conformance or other undesirable situation.

4. Responsibilities

- **All Employees:** Identify and report non-conformances immediately.
- **Quality Assurance (QA):** Review and record non-conformances, coordinate investigations, and monitor corrective actions.
- **Department Heads:** Ensure implementation of corrective actions and communicate outcomes.
- **Management:** Provide resources and support for corrective action activities.

5. Procedure

1. **Identification**
   - Detect and report non-conformance by any employee via designated channels (e.g., forms, reporting system).
2. **Documentation**
   - Complete a Non-conformance Report (NCR), including description, location, date, and person(s) involved.
3. **Immediate Containment**
   - Take action to contain the non-conformance (isolate product, pause process, etc.) if needed.
4. **Investigation and Root Cause Analysis**
   - Conduct an investigation to determine the root cause using tools such as 5 Why's or Fishbone Diagram.
5. **Corrective Action**
   - Identify and implement corrective actions to address the root cause.
   - Assign responsibilities and completion dates.
6. **Verification of Effectiveness**
   - Verify the implementation and effectiveness of corrective actions.
   - Monitor results to ensure the issue does not recur.
7. **Closure**
   - QA reviews documentation and, if non-conformance is resolved, closes the NCR.
8. **Records**
   - Maintain records of all non-conformances and corrective actions in accordance with the company's documentation policy.

6. Documentation and Records

Document / Record	Retention Period	Responsibility
Non-conformance Report (NCR)	3 Years	QA
Corrective Action Forms	3 Years	Department Head
Investigation Reports	3 Years	QA

7. Review and Continuous Improvement

This SOP shall be reviewed annually or as needed to ensure effectiveness. Trends in non-conformances and corrective actions shall be analyzed for continual improvement.

8. Reference Documents

- ISO 9001:2015 â€“ Quality management systems
- Internal Audit Procedures
- Relevant company policies

9. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-01	Initial Issue	QA Manager