SOP: Corrective Actions and Implementation Tracking

This SOP details the process for **corrective actions and implementation tracking**, including identifying root causes of issues, developing effective corrective measures, assigning responsibilities, monitoring progress, verifying completion, and ensuring continuous improvement. Its aim is to systematically address non-conformities, enhance operational efficiency, and maintain compliance with quality standards through thorough follow-up and documentation.

1. Purpose

To provide a systematic approach for identifying, correcting, and preventing recurrence of non-conformities and deficiencies within the organization. This ensures ongoing improvement, compliance with quality standards, and documentation of all corrective actions taken.

2. Scope

This SOP applies to all employees and departments involved in reporting, investigating, and resolving issues related to process failures, audit findings, regulatory non-conformities, or other areas requiring corrective actions.

3. Responsibilities

- **Process Owner:** Initiates corrective action, oversees the root cause analysis, and ensures timely implementation and follow-up.
- **Assigned Personnel:** Carry out corrective measures, document actions, and provide updates.
- **Quality Assurance (QA)/Compliance:** Reviews and verifies completion of actions, maintains records, and reports on status to management.
- **Management:** Reviews critical non-conformities and effectiveness of implemented actions; supports resource allocation.

4. Procedure

1. **Identification of Issues**
    - Detect non-conformities via audits, inspections, incident reports, or employee feedback.
    - Log issues in the Corrective Action Tracking System (CATS).
2. **Root Cause Analysis**
    - Assign responsible team/person to investigate root cause (e.g., use Fishbone Diagram, 5 Whys).
    - Document findings in the Corrective Action Report (CAR).
3. **Development of Corrective Actions**
    - Define corrective measures to eliminate root cause(s).
    - Assign responsibilities and set clear timelines.
4. **Approval and Implementation**
    - Obtain management/QA approval, where required.
    - Implement actions as per defined plan.
5. **Monitoring and Tracking Progress**
    - Regularly update status in CATS.
    - QA/Process Owner monitors action completion and provides support as needed.
6. **Verification of Completion**
    - QA or assigned reviewer verifies corrective action implementation.
    - Ensure intended outcomes and no recurrence of the problem.

7. **Documentation and Reporting**
    - Maintain records of non-conformities, causes, actions, and verifications.
    - Provide regular status reports to management as required.
8. **Continuous Improvement**
    - Conduct periodic review of corrective action data for trends.
    - Update policies and training as necessary.

5. Corrective Action Tracking Table (Example)

ID	Non-conformity/Issue	Root Cause	Corrective Action	Owner	Due Date	Status	Verification
CA-001	Late shipment	Inadequate inventory levels	Revise stock re-order process	Inventory Manager	2024-07-01	In progress	Pending
CA-002	Data entry error	Insufficient training	Conduct refresher training	HR	2024-06-20	Completed	Verified

6. Definitions

- **Non-conformity:** Non-fulfillment of a requirement or deviation from a procedure or standard.
- **Corrective Action:** Steps taken to eliminate the cause of a detected non-conformity.
- **Root Cause Analysis:** Method of identifying the fundamental reason for a problem.

7. References

- ISO 9001:2015 â€“ Quality Management Systems
- Company Quality Manual
- Internal Audit Procedures

8. Revision History

Version	Date	Description of Change	Approved by
1.0	2024-06-07	Initial SOP release	QA Manager

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