

SOP: Non-compliance Handling and Corrective Actions

This SOP defines the process for **non-compliance handling and corrective actions**, detailing procedures for identifying, documenting, and addressing instances of non-compliance within an organization. It includes steps for investigating non-compliance issues, implementing corrective measures to prevent recurrence, monitoring effectiveness, and ensuring adherence to regulatory requirements and organizational standards. The goal is to maintain compliance, improve operational performance, and mitigate risks associated with deviations from established policies and procedures.

1. Purpose

To establish a standardized process for identifying, documenting, investigating, and correcting instances of non-compliance to maintain regulatory compliance, mitigate risks, and promote continuous improvement.

2. Scope

This SOP applies to all employees and contractors within the organization who are involved in identifying, reporting, or rectifying non-compliance with policies, procedures, or regulatory requirements.

3. Responsibilities

- **All Employees:** Identify and report instances of non-compliance.
- **Supervisors/Managers:** Investigate reports of non-compliance, initiate corrective actions, and ensure documentation.
- **Compliance Officer:** Oversee the non-compliance handling process, review investigations, and report outcomes to management.

4. Definitions

- **Non-compliance:** Any deviation from policies, procedures, laws, or regulations applicable to the organization.
- **Corrective Action:** Steps implemented to eliminate the root cause of a detected non-compliance to prevent its recurrence.
- **CAPA:** Corrective and Preventive Action process.

5. Procedure

1. **Identification**
 - Non-compliance may be identified through audits, inspections, employee reports, or external sources.
2. **Documentation**
 - Document all details on a **Non-compliance Report Form**, including date, description, detection method, and individuals involved.
3. **Notification**
 - Notify relevant supervisors/managers and the Compliance Officer within 24 hours of detection.
4. **Investigation**
 - Investigate the root cause by gathering facts and interviewing relevant personnel.
5. **Corrective Actions**
 - Develop a corrective action plan, assign responsibilities, and set deadlines for implementation.
6. **Implementation**
 - Implement corrective actions and document all actions taken.
7. **Verification & Monitoring**
 - Monitor the effectiveness of actions taken. Reassess if non-compliance recurs.
8. **Closure**
 - Once verified as effective, close the non-compliance report and archive records as per policy.

6. Documentation

- Non-compliance Report Form

- Investigation and Corrective Action Logs
- CAPA records

7. Review and Continuous Improvement

Regularly review trends in non-compliance, update procedures as necessary, and provide training to employees to prevent recurrence.

8. References

- Applicable regulatory standards (e.g., ISO 9001, GMP, OSHA)
- Company Policies and Procedures Manual

9. Revision History

Version	Date	Prepared By	Description of Change
1.0	2024-06-01	Compliance Officer	Initial release