

# SOP: Compliance with Regulatory and Accreditation Requirements

This SOP ensures **compliance with regulatory and accreditation requirements** by establishing standardized procedures for monitoring, documenting, and adhering to all relevant laws, regulations, and industry standards. It covers responsibilities for maintaining up-to-date knowledge of requirements, conducting internal audits, addressing non-compliance issues, and preparing for external inspections to achieve and maintain certification and accreditation status.

## 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to establish processes to ensure compliance with regulatory and accreditation requirements, including continuous monitoring, documentation, internal audits, issue resolution, and readiness for external inspections.

## 2. Scope

This SOP applies to all employees, departments, and stakeholders involved in processes subject to regulation, certification, or accreditation within the organization.

## 3. Responsibilities

Role	Responsibility
Compliance Officer	Monitors regulations, communicates updates, oversees internal audits, and coordinates corrective actions.
Department Heads	Implement SOP requirements, maintain documentation, and ensure staff compliance.
All Employees	Adhere to procedures, participate in training, promptly report potential non-compliance.

## 4. Procedure

- Monitor Regulatory and Accreditation Requirements**
  - Regularly review laws, regulations, and industry standards applicable to organizational activities.
  - Subscribe to updates from relevant authorities and accreditation bodies.
- Documentation and Recordkeeping**
  - Maintain up-to-date records of compliance requirements, certifications, and correspondences.
  - Store audit reports, corrective action plans, and compliance assessments securely.
- Internal Audits**
  - Schedule and conduct regular internal audits according to an established calendar.
  - Document audit findings and identify areas requiring improvement.
- Non-Compliance Management**
  - Investigate and document all incidents of non-compliance.
  - Develop, implement, and track corrective action plans.
- Preparation for External Inspections**
  - Review and update documents and records regularly in preparation for inspections.
  - Conduct mock inspections and staff training as necessary.

## 5. Training

All relevant personnel must complete training on regulatory and accreditation requirements, the contents of this SOP, and participate in refresher courses annually or as needed based on regulatory changes.

## 6. Records and Documentation

Maintain all records and documentation associated with compliance activities, including audit reports, certifications, training records, and correspondence with regulatory and accreditation bodies, for a minimum of 5 years or as required by law.

## 7. Review and Revision

This SOP must be reviewed annually or when there are significant changes in regulatory or accreditation requirements. Revisions should be documented and communicated to all affected staff.

## 8. References

- List of applicable regulatory and accreditation standards/bodies
- Internal audit calendar and checklists