SOP: Documentation and Record-Keeping Requirements

This SOP details the **documentation and record-keeping requirements** essential for maintaining accurate, organized, and compliant records. It covers the procedures for creating, storing, and managing documents related to operational activities, legal compliance, quality control, and audit readiness. The objective is to ensure data integrity, facilitate efficient information retrieval, support decision-making processes, and uphold regulatory standards.

1. Purpose

To establish standardized procedures for creating, handling, retaining, and disposing of all documentation and records in compliance with organizational and regulatory requirements.

2. Scope

This SOP applies to all documents and records generated, received, or maintained by employees as part of business operations, including but not limited to:

- Operational records
- Legal and regulatory documents
- Quality control and assurance documents
- Audit and inspection records
- Personnel or HR documents

3. Responsibilities

- **All Employees:** Ensure accurate and timely creation and filing of required documents and records.
- **Department Heads:** Oversee compliance with this SOP within their departments.
- **Records Management Officer:** Monitor, audit, and maintain the integrity and security of records.

4. Procedure

1. **Document Creation**
   - Use approved templates and formats wherever applicable.
   - Include essential information: date, author, version, and subject.
2. **Record Storage**
   - Store physical documents in secure, designated areas.
   - Digital records must be saved in approved, access-controlled systems.
   - Protect records from unauthorized access, alteration, or loss.
3. **Record Maintenance**
   - Regularly review and update records as required.
   - Retain records for the minimum period specified by applicable laws or policies.
4. **Record Disposal**
   - Dispose of obsolete records securely following the record retention schedule.
   - Ensure confidential information is irreversibly destroyed before disposal.

5. Documentation Format

Record Type	Format	Storage Method	Retention Period
Operational Reports	Digital/Paper	Departmental drive/Archive cabinet	5 years
Financial Records	Digital/Paper	Secure enterprise system	7 years
Quality Control Documents	Digital	Quality management system	3 years
Employee Records	Digital/Paper	HR secure archives	Employment + 6 years

6. Audit and Review

- Conduct periodic audits to ensure adherence to documentation standards.
- Address discrepancies or non-compliance through corrective actions.
- Review and update SOP annually or as required by regulatory changes.

7. References

- Record Retention Policy
- Data Protection Regulations (e.g., GDPR, HIPAA)
- Internal Control Guidelines

8. Revision History

Version	Date	Description	Author
1.0	2024-06-01	Initial Release	Document Control Team