Standard Operating Procedure (SOP)

Document Control and Record Retention

Requirements

1. Purpose

This SOP details **document control and record retention requirements**, establishing standardized procedures for managing, storing, and securing organizational documents and records. It includes guidelines for document creation, review, approval, distribution, revision tracking, and archiving to ensure accuracy, confidentiality, and accessibility. The purpose is to maintain compliance with regulatory standards, support operational efficiency, and provide a reliable audit trail for accountability and historical reference.

2. Scope

This SOP applies to all employees, contractors, and third-party partners engaged in handling, creating, or managing documents and records within the organization.

3. Responsibilities

- **Document Owner:** Responsible for creation, accuracy, periodic review, and updates.
- Document Controller: Ensures appropriate document identification, storage, access, distribution, and archiving.
- All Employees: Comply with this SOP and report any discrepancies or non-conformance.

4. Definitions

- Document: Any written or electronic information that provides evidence of organizational activities.
- Record: A specific type of document created as evidence of completed activities (e.g., reports, forms, logs).
- Retention Period: The required length of time a document or record must be kept before it may be disposed of.

5. Procedures

1. Document Creation:

- Use standard templates for all documents.
- Clearly assign titles, unique identification numbers, version codes, and effective dates.

2. Review and Approval:

- o Conduct a formal review by designated subject matter experts.
- o Obtain documented approval (signature or electronic approval) before distribution.

3. Distribution and Access:

- o Control distribution via secure, access-restricted repositories (physical or electronic).
- Ensure employees have access only to current and relevant versions.

4. Revision and Change Control:

- Track revisions using a revision log or audit trail.
- Obsolete or superseded versions must be archived and labelled as such to prevent accidental use.

5. Record Retention:

- Maintain documents and records for mandated retention periods (see Table 1).
- o Store in secure locations with controlled access.

6. Destruction and Disposal:

- Destroy records past retention in accordance with confidentiality requirements (e.g., shredding, secure electronic wipe).
- o Document destruction date, method, and responsible individual.

7. Archiving:

· Archive critical documents securely and ensure they are retrievable for audits and inspections.

6. Record Retention Schedule (Table 1)

Record Type	Retention Period	Storage Location	Disposal Method
Policies & SOPs	Current version + 5 years after obsolescence	Electronic repository / Physical archive	Secure deletion/shredding
Training Records	5 years after employee separation	HR system / Secure file	Secure shredding
Audit Logs	5 years	Secure server	Secure deletion
Financial Documents	7 years	Finance archive	Secure shredding
Email Correspondence	3 years	Email archive	Permanent deletion

7. Confidentiality & Security

- · Limit access to confidential documents and records to authorized personnel only.
- Use encrypted storage and secure physical storage where applicable.
- · Regularly review access and update permissions as necessary.

8. Compliance & Audit

- Conduct routine audits to ensure adherence to document control and retention procedures.
- Maintain written logs of audits and non-conformance incidents.
- Provide records promptly upon request for regulatory review.

9. References

- Applicable regulatory requirements (e.g., ISO 9001, GDPR, HIPAA, SOX, local data protection laws)
- · Internal company policies

10. Revision History

Version	Date	Description	Approved By
1.0	2024-06-01	Initial document creation and implementation	Document Owner