

SOP: External Document Control and Integration

This SOP defines the processes for **external document control and integration**, covering the receipt, review, approval, distribution, and archiving of external documents to ensure accuracy and compliance. It establishes procedures for integrating external documents into internal systems, maintaining version control, and facilitating effective communication between departments and external stakeholders. The aim is to streamline document management, reduce risks associated with outdated or incorrect information, and support regulatory compliance and operational efficiency.

1. Purpose

To establish standardized procedures for controlling, integrating, and communicating external documents within the organization, ensuring documents remain current, accurate, and compliant with regulatory requirements.

2. Scope

This SOP applies to all external documents received from customers, suppliers, regulatory agencies, or other stakeholders that are used in operations, processes, or decision-making.

3. Definitions

- **External Document:** Any document originating outside the organization used internally (e.g., standards, specifications, certificates).
- **Document Owner:** Person responsible for ensuring the document is reviewed, approved, distributed, and controlled.
- **Version Control:** Process to ensure all users access the latest approved document.

4. Responsibilities

Role	Responsibilities
Document Control Coordinator	Maintain document register, coordinate review and distribution, ensure archiving.
Department Heads	Ensure compliance within departments, assign document owners.
Document Owners	Review, approve, and update documents; facilitate integration and communication.

5. Procedure

1. **Receipt of External Documents:**
 - Documents are received by mail, email, portal, or other agreed channels.
 - Receipt is logged in the External Document Register.
2. **Review and Approval:**
 - Document owner reviews for relevance, completeness, and accuracy.
 - Relevant departments and subject matter experts approve as required.
3. **Integration and Distribution:**
 - Document is assigned a unique identification and version number.
 - Integrated into relevant internal systems (DMS, ERP, etc.).
 - Distributed to impacted departments or personnel with notification of changes.
4. **Archiving and Retention:**
 - Obsolete or superseded versions are archived and access restricted.
 - Retention period is defined by regulatory or contractual requirements.
5. **Control of Changes:**
 - All changes tracked; version history maintained.
 - Notifications of changes issued to affected users/departments.
6. **Communication and Training:**
 - Relevant staff trained on new or revised external documents as required.

6. Records

- External Document Register
- Review and approval logs

- Distribution and acknowledgment records
- Archived document versions

7. References

- ISO 9001:2015 (Documented Information)
- Applicable regulatory or industry standards

8. Revision History

Version	Date	Description of Change	Author
1.0	2024-06-01	Initial template release	Document Control Team