



Document Control Procedure Template

1. Purpose:

The purpose of this document control procedure is to ensure the effective management of documented information within [Organization Name], in accordance with ISO 9001:2015 requirements. This procedure establishes the processes for creating, reviewing, approving, distributing, and revising documents to maintain accuracy, consistency, and compliance with quality management standards.

2. Scope:

This procedure applies to all documented information generated, utilized, or maintained by [Organization Name] as part of its Quality Management System (QMS).

3. Responsibilities:

- **Quality Manager:** The Quality Manager is responsible for overseeing the implementation of this document control procedure and ensuring compliance with ISO 9001 requirements. Responsibilities include:
 - Establishing document control processes and procedures.
 - Providing training and guidance on document control requirements.
 - Monitoring the effectiveness of document control activities and initiating improvements as necessary.
- **Document Owners:** Document Owners are responsible for creating, updating, and maintaining documents within their area of expertise. Responsibilities include:
 - Ensuring that documents are accurate, up-to-date, and aligned with relevant standards and procedures.
 - Reviewing and approving documents before distribution.
 - Notifying the Quality Manager of any changes or updates to documents.
- **Document Controllers:** Document Controllers are responsible for managing the day-to-day activities related to document control. Responsibilities include:
 - Maintaining a central repository of all documents and records.
 - Ensuring that document numbering, naming, and version control are maintained consistently.



- Distributing documents to relevant personnel and departments as per defined procedures.
- Monitoring document access and ensuring confidentiality and security.

4. Document Control Process:

4.1 Document Creation:

- Document Owners are responsible for creating new documents or revising existing ones as necessary to support the QMS.
- Documents should be created using approved templates and formats and include relevant information such as title, purpose, scope, and revision history.

4.2 Document Review and Approval:

- Document Owners are responsible for initiating document reviews and obtaining approvals from relevant stakeholders, including management, subject matter experts, and quality assurance personnel.
- Reviewers should assess documents for accuracy, completeness, relevance, and compliance with applicable standards and procedures.
- Approved documents should be dated, signed, and stamped with a unique identifier indicating their approval status.

4.3 Document Distribution:

- Document Controllers are responsible for distributing approved documents to authorized personnel and departments electronically or in hard copy as per defined distribution lists.
- Distribution records should be maintained to track document recipients and ensure that all relevant parties have access to the latest versions of documents.

4.4 Document Revision and Control:

- Document Controllers are responsible for managing document revisions and ensuring that only current, approved versions are available for use.
- When revisions are required, Document Owners should initiate the revision process, update the document accordingly, and obtain re-approval from relevant stakeholders.



- Revised documents should be clearly identified with a new version number and date, and obsolete versions should be archived or disposed of as per defined procedures.

5. Document Retention and Disposal:

- Document Controllers are responsible for maintaining records of document retention periods and disposal schedules in accordance with legal, regulatory, and organizational requirements.
- Obsolete or superseded documents should be securely archived or disposed of to prevent unauthorized use or access.

6. Training and Awareness:

- All personnel involved in document creation, review, approval, distribution, and control should receive appropriate training on document control procedures and their responsibilities.
- Regular awareness sessions and updates should be provided to ensure that personnel remain informed about document control requirements and changes.

7. Monitoring and Review:

- The Quality Manager is responsible for monitoring the effectiveness of document control processes through regular audits, inspections, and reviews.
- Non-conformities, deviations, or opportunities for improvement identified during monitoring activities should be documented, investigated, and addressed promptly to prevent recurrence.

8. Documented Information:

- This document control procedure, along with associated forms, templates, and records, constitutes documented information required by ISO 9001:2015 and should be maintained and controlled accordingly.

9. Revision History:

- Version 1.0: [Date] - Initial release.
- Version 2.0: [Date] - Updated to incorporate feedback and improvements.