

ABC, Inc.
AD-P-004 – Document Control Procedure

NOTE: This document is an example. Your document control processes will be unique to your organization.

1. Scope and Purpose

This procedure describes the process for creating, reviewing, approving, storing, distributing, and changing procedures, forms, customer instructions, manuals, and other documents related to the ABC, Inc QMS.

2. Responsibilities

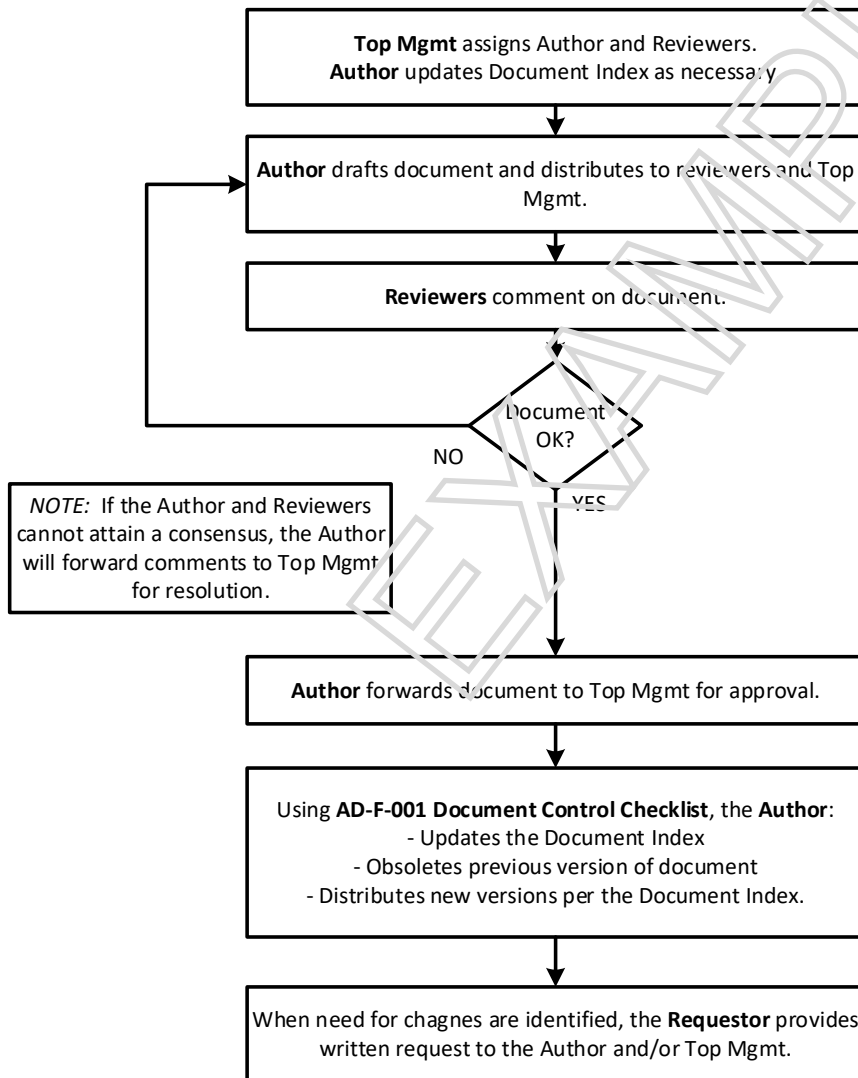
Top Management, or designee, is responsible for assigning authors and reviewers, as well as approving documents.

Author is responsible for editing, storing and distributing documents.

Any employee may request a new document or change to existing documents.

3. Instructions

Document control process



Document Format Requirements

Document templates are available at **S:\QUALITY SYSTEM - SOPs\3 Templates** and was used for this procedure. Their use is encouraged, but optional, provided the formatting requirements below are addressed.

Regardless of the application used for creating and managing documents (Word, PowerPoint, Visio, PDF, etc.) all documents must include the following:

- Unique title and/or unique document number.
- Purpose and Scope, if not evident from the title.
- Responsibilities, which may be in a separate section or embedded in the text.
- Revision level, preferably numeric: 2.0 = major revision. 2.1 = minor revision. This needs to be on each page if the document can be printed.
- Status (Draft, Current, Obsolete). This needs to be on each page if the document can be printed.
- Evidence of approval (e.g. signature), or reference to an approval (e.g. a separate, traceable signature page or email)
- Date approved.
- Revision history, which may be on the document or otherwise recorded and stored with the document.

Document storage and protection

Electronic copies of documents are stored and distributed from the Shared (S:) folder. Access to the folders will be controlled. Below is an example of folders for each document:



Folder Permissions:

Current folder:

- Read – all staff
- Read, Edit and Save – Author and top management.

Draft, Obsolete and Delete folders:

- Read – Management Review Group
- Read, Edit and Save – Author and top management.

Folder permissions will be set in accordance with **AD-W-016 Setting Quality System Folder Permissions**.

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Document reviews (new and revised)

Assigned **reviewers** will consider:

- Overall correctness of the document
- Risks, including when the document is changed
- When changes may impact ISO 9001 compliance, compare with ISO 9001:2015
- The need for training or retraining
- Resources needed to implement the process.

Document approval and distribution

Using **AD-F-001 Document Control Checklist**, the **Author** will:

- Change the status from “Draft” to “Current” on the new document to be approved.
- Print the document and obtain signature approval.
- Mark the previous version “Obsolete” and move it to the Obsolete folder. PDFs will be watermarked as obsolete.
- Signature-approved hardcopies will be the Master Copy, and filed in QA files with any review comments and marked obsolete copies.
- Update the Document Index to reflect the current version level and any changes to distribution.
- Distribute hard copies of the new Current version per the Document Index.

Document Protection

Documents on the Shared (S:) drive are backed up every 24 hours per **MT-P-001 Maintenance Procedure**.

Hard copies (e.g. signed master copy, review comments, obsolete versions) in file folders, protected from damage.

Document Retention Periods

ABC, Inc. documents shall be maintained for not less than 7 years, electronic and hard copies.

External Documents

External documents, such as standards and regulations, are controlled by the external organization that issues them, e.g. ISO, UL, MIL STD, etc. Therefore, it is necessary to periodically verify their currency, or verify their currency before use. **Users of external documents** need to confirm they are using the current version of the document. External documents are listed in the **Ext Docs & SW** tab of the **Document Index**, with information on how and when to verify their currency.

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4. Related Documents: Procedures, Work Instructions, Forms and Records

Document Index

AD-F-001 Document Control Checklist

AD-W-016 Setting Quality System Folder Permissions

MT-P-001 Maintenance Procedure

ISO 9001

5. References

ISO 9001:2015 sections:

7.4 Communication

7.5 Documented information

8.5.1 Control of production and service provision

6. Author, Reviews and Approvals

	NAME	FUNCTION	APPROVAL SIGNATURE	DATE
Author	Charles III	QA	N/A	N/A
Reviewer	Cathy F	Planning	N/A	N/A
Reviewer	Lady G	Administration	N/A	N/A
Reviewer	Rocky B	Machinist	N/A	N/A
Approval	Jimmy D	President	<i>Original signed by Jimmy D</i>	4-29-2021

7. Document Revision History

04-24-2020	Rev 1.0	Initial Release
12-3-2020	Rev 2.0	Master copy now is the signed copy and is not scanned. Electronic copies are now annotated as signed and may be printed for hard copy distribution. Removed "Document Hierarchy Concept" diagram. Added footer text that "Printed hardcopies are uncontrolled".
04-29-2021	Rev 3.0	Added External Documents requirements. Updated folder location and permissions. Added reference to AD-W-016 Setting Quality System Folder Permissions. Added reference to MT-P-001 Maintenance Procedure for electronic document protection. Updated flowchart to reflect current work flow. Added Document Reviews section.

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