STANDARD OPERATING PROCEDURE

Document Control SOP

Document no.	SOP-QA-001
Revision	1.0
Owner	Document Controller
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To make sure controlled documents are uniquely numbered, reviewed and approved before use, distributed so only the current revision is accessible, and withdrawn from active use once superseded.

2. Scope

Applies to the lifecycle of controlled documents, including SOPs, work instructions, forms and policies, from numbering through approval, distribution, revision and obsolescence. Writing the actual content and structure of a new SOP is covered by the SOP for Writing SOPs.

Definitions

Controlled document	A document whose creation, revision and distribution follow a formal process to keep only the current version in use.
Document master list	The register of every controlled document, its current revision and effective date.
Obsolete document	A superseded revision that has been withdrawn from active use and archived.
Effective date	The date a document revision becomes the official version in use.

3. Responsibilities

Document Controller	Numbers, publishes, distributes and archives controlled documents and maintains the master list.
Document Owner	Drafts and updates the document content and incorporates review feedback.
Approver	Formally approves the document before it is released for use.
Quality Manager	Audits work areas and the master list to confirm only current revisions are in use.

RACI matrix

Activity	Document Controller	Document Owner	Approver	Quality Manager
Number and draft the document	R/A	R	I	I
Review and approve the document	C	C	R/A	I
Publish and update the master list	R/A	I	I	I

Activity	Document Controller	Document Owner	Approver	Quality Manager
Withdraw obsolete revisions	R/A	I	-	I
Audit work areas for current revisions	C	I	-	R/A

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- Document management system
- Document master list
- Document numbering convention
- Revision history template

5. Procedure

Step	Task	Owner	Done
5.1	**Assign a document number** When a new controlled document is requested, the Document Controller assigns a unique document number and title using the numbering convention. **Checkpoint:** The assigned number is not already in use anywhere on the master list.	Document Controller	☐
5.2	**Draft the content** The Document Owner drafts the document content covering its purpose, scope and required detail.	Document Owner	☐
5.3	**Route for review** The Document Controller routes the draft to the relevant technical and quality reviewers and tracks their feedback.	Document Controller	☐
5.4	**Incorporate review comments** The Document Owner updates the draft to address reviewer comments and resolves any open questions before resubmitting.	Document Owner	☐
5.5	**Submit for approval** The Document Controller submits the finished document for formal approval once review comments are resolved.	Document Controller	☐
5.6	**Approve the document** The Approver reviews the final draft and records their approval with name, date and approval method. **Checkpoint:** Approval is recorded with a name and date before the document is released for use.	Approver	☐
5.7	**Assign the effective date** The Document Controller assigns the effective date and revision number for the newly approved document.	Document Controller	☐
5.8	**Publish the document** The Document Controller publishes the approved document to the controlled repository in the document management system.	Document Controller	☐

Step	Task	Owner	Done
5.9	**Update the master list** The Document Controller updates the master list with the new revision number, effective date and storage location.	Document Controller	☐
5.10	**Withdraw the previous revision** The Document Controller withdraws the previous revision from active circulation and archives it, marking it clearly as obsolete. **Warning:** An obsolete document left accessible in an active work area can lead someone to follow outdated instructions.	Document Controller	☐
5.11	**Notify affected teams** The Document Controller notifies the teams affected by the new or revised document and flags any required training.	Document Controller	☐
5.12	**Distribute controlled copies** The Document Controller distributes physical or digital copies with access restricted to the current revision only.	Document Controller	☐
5.13	**Audit work areas** The Quality Manager periodically audits the master list and physical or shared work areas to confirm only current revisions are accessible.	Quality Manager	☐

6. Quality checks

- Every controlled document on the master list has a recorded approval.
- Obsolete revisions are removed from active work areas.
- Document numbers on the master list are unique with no duplicates.
- Periodic audits confirm only current revisions are accessible to staff.

7. Records

- Document master list
- Approval record for each revision
- Obsolete document archive
- Notification or training record for affected teams

8. KPIs

- Percentage of documents past their scheduled review date
- Average time from draft to approval
- Number of obsolete-document findings during audits
- Document master list accuracy rate

9. Common mistakes

- Editing a controlled document without going through review and approval.
- Leaving an old printed copy in a work area after a revision is released.
- Issuing a new revision without updating the master list.
- Skipping the notification step so teams keep using the old version.

10. Revision history

Revision	Date	Description	Reviewed by

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1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

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