Standard Operating Procedure (SOP)

Document Control and Version Management

This SOP defines the processes for **document control and version management**, including document creation, review, approval, distribution, revision tracking, archiving, and access control. The purpose is to ensure accuracy, consistency, and traceability of all documents, preventing unauthorized changes and maintaining up-to-date records across the organization.

SOP Number	[Enter SOP Number]	Effective Date	[Enter Date]
Version	[Enter Version]	Review Date	[Enter Date]
Author	[Enter Author]	Approval	[Enter Approver]

1. Purpose

To establish a standardized process for controlling organizational documents and their versions to ensure accuracy, traceability, and authorized distribution.

2. Scope

This procedure applies to all controlled documents within the organization, including but not limited to policies, SOPs, work instructions, forms, and records.

3. Responsibilities

- Document Owner: Initiates document creation and ensures timely review and update.
- **Reviewers:** Evaluate the document for accuracy and compliance.
- Approvers: Give final approval prior to release.
- Document Control Officer: Manages document distribution, access, archiving, and version tracking.
- All Staff: Follow the current, approved version of documents and report discrepancies.

4. Procedure

1. Document Creation

- Draft document using standard template.
- Assign a unique document number and version identifier.

2. Review and Approval

- Submit draft for review to designated reviewers.
- Incorporate review feedback as necessary.
- o Submit revised document for final approval and sign-off.

3. Distribution

- Store approved documents in a controlled repository with restricted access.
- o Distribute notifications of new or revised documents to relevant personnel.

4. Version Management

- Increment version with each approved revision (e.g., 1.0, 1.1, 2.0).
- Track and record changes in a change log or revision history table.

5. Archiving

- Archive superseded versions in an access-controlled archive.
- o Ensure archived documents are clearly marked as obsolete.

6. Access Control

- $\circ\;$ Restrict access to draft, approved, and archived documents based on roles.
- Prohibit unauthorized changes to controlled documents.

7. Periodic Review

- Review all controlled documents at defined intervals or as needed.
- Update and re-approve documents if changes are required.

5. Revision History

[E.1.6] [E.1.6] [E.1.6] [E.1.6] [E.1.6]	[e.g., 1.0]	[Enter Date]	[Initial Issue/Revision Details]	[Enter Author]	[Enter Reviewer/Approver]
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6. References

- Document Control Policy [Document Number/Link]
 Relevant Regulatory Requirements [Details/Links]
 Related SOPs and Work Instructions