Standard Operating Procedure

SOP Title: Document Control SOP
Document Code: SOP-VA-101
Effective Date: 05May2025
Supersedes: [Previous Version if applicable]
Approved By: [Name / Title]
Review Date: [Annually or as needed]

1. Purpose

To define the control, approval, revision, and distribution of documents within the Quality Management System (QMS) to ensure accuracy, traceability, and regulatory compliance.

2. Scope

This SOP applies to all controlled documents used at the facility, including Standard Operating Procedures (SOPs), forms, logs, policies, and manuals that directly impact quality or compliance.

3. Responsibilities

• Quality **Assurance (QA):** Responsible for issuing, revising, approving, distributing, and archiving all controlled documents.

• Department **Managers:** Ensure staff access only current, approved versions of applicable documents.

• All **Staff:** Must comply with Good Documentation Practices (GDP) and use only the most current, approved versions of forms and SOPs.

4. Procedure

4.1 Document Creation & Approval

- Drafted by Subject Matter Expert (SME) or department lead.
- Reviewed and approved by QA and Management.

- Assigned a document code and version number per Master Index format.
- Stored digitally in a controlled document repository.

4.2 Document Revision

- Changes must be proposed via Change Request Form.
- QA reviews and assigns new version number.
- Superseded versions archived and labeled “Obsolete.”

4.3 Document Distribution

- Controlled documents distributed digitally via read-only access.
- Printed copies marked “Controlled Copy” and tracked in distribution logs.

4.4 Archiving and Obsolescence

- Obsolete versions are archived electronically and stored for at least 3 years.
- Paper versions are stamped “Obsolete” and removed from circulation.

5. Records

- Change Request Forms
- Document Approval Forms
- Master SOP Index
- Document Distribution Log

6. References

- 21 CFR Part 211.100-211.180

- Virginia Cannabis Control Authority (CCA) Regulatory Requirements

- Company Quality Manual (QM-VA-001)

7. Revision History

Version	Date	Change Description	Approved By
2.0	05May2025	Aligned with updated Quality Manual QM-VA-001 and Master Batch Record SOP.	[Name / Title]