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* Superseded versions archived and labeled “Obsolete.”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

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