Standard Operating Procedure

SOP Title: Product Recall Procedure
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Approved By: [Name / Title]
Review Date: [Annually or as needed]

1. Purpose

To establish a rapid, organized process for removing or correcting Verano Virginia cannabis products that present a potential health risk or regulatory non-compliance, and for notifying regulators, dispensaries, and patients as required.

2. Scope

Applies to all finished products released to market, including bulk inventory at dispensaries and product held in distribution, when a recall or market withdrawal is deemed necessary.

3. Definitions

Term	Definition
Recall	Removal of a marketed product due to potential safety, quality, or regulatory issues.
Market Withdrawal	Correction of a product that has minor quality issues not subject to legal action.
Class I	Reasonable probability of serious health consequences.
Class II	Temporary or medically reversible health consequences.
Class III	Not likely to cause adverse health consequences (labeling/clerical errors).

4. Responsibilities

Role	Key Responsibilities
Recall Coordinator (QA Manager)	Leads recall, communicates with CCA, maintains records.
Recall Team (QA, Compliance, Distribution, Communications)	Executes retrieval, quarantine, and disposition of product; handles patient/dispensary notifications.
Compliance Director	Approves recall class, notifies leadership, liaises with legal.
Distribution Manager	Stops shipments, contacts dispensaries, coordinates returns.
Communications Lead	Drafts public and dispensary notices; manages press/social media if required.

5. Procedure

5.1 Recall Decision

- Triggered by internal deviation, out-of-spec COA, adverse event, or CCA directive.
- Compliance Director + QA Manager classify recall (Class I/II/III); document rationale on *Recall Initiation Form* (FORM-VA-007).

5.2 Notification Timeline

Recipient	Class I	Class II	Class III
CCA	Within 24 h	Within 48 h	Within 3 days
Dispensaries	"	"	Within 5 days
Public / Patients	"	As directed	Usually not required

5.3 Product Retrieval & Quarantine

- Distribution instructs dispensaries to segregate affected lots and halt sales.
- Returned product placed in secured "Recall Hold".
- BioTrack inventory adjusted.

5.4 Root-Cause Investigation & CAPA

- Follow SOP-VA-104.
- Implement corrective actions before resuming production of same SKU.

5.5 Disposition

- After CCA approval, product is destroyed or re-worked per Waste Disposal SOP.
- QA documents destruction lot weights in Recall File.

5.6 Recall Closure

- Recall Coordinator compiles final report (event timeline, quantity recovered, patient notifications, CAPA).
- Compliance Director signs closure; copy sent to CCA.
- QA retains Recall File for **5 years**.

6. Records

Record	Form Code / Location	Retention
Recall Initiation Form	FORM-VA-007	5 years
Recall Communication Log	QA\Recall	5 years
Product Return Log	QA\Recall	5 years
Final Recall Report	QA\Recall	5 years

7. References

- 21 CFR 7 Subpart C – Product Recalls
- FDA Guidance: *Initiation of Voluntary Recalls* (2022)
- Virginia CCA Recall Guidance (latest bulletin)
- SOP-VA-104 Deviation & CAPA SOP
- SOP-VA-106 Product Release SOP

- QM-VA-001 Quality Manual

8. Revision History

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