Standard Operating Procedure

SOP Title: Product Recall Procedure  
Document Code: SOP-VA-107  
Effective Date: 06May25  
Supersedes: [Previous Version if applicable]  
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] |