Standard Operating Procedure (SOP)
Product Segregation and Quarantine Guidelines

This SOP details **product segregation and quarantine guidelines** to ensure proper handling, storage, and tracking of products. It covers procedures for identifying and isolating non-conforming or suspect products, requirements for quarantine area setup, labeling standards, monitoring and documentation practices, and protocols for release or disposal of quarantined items. The goal is to maintain product quality, prevent contamination, and comply with regulatory standards by enforcing rigorous segregation and quarantine measures.

1. Purpose

To provide clear guidelines for the segregation and quarantine of non-conforming or suspect products to prevent contamination, ensure product quality, and comply with regulatory requirements.

2. Scope

This procedure applies to all staff involved in the identification, handling, storage, and disposition of products requiring segregation and quarantine within the facility.

3. Responsibilities

Role	Responsibility
Operations Staff	Identify and segregate non-conforming/suspect products; ensure proper labeling.
Quality Assurance	Approve quarantine areas; monitor and document quarantine status; authorize release or disposal.
Warehouse Staff	Maintain organization and security of segregation/quarantine areas.
Supervisors/Managers	Oversight and training regarding adherence to SOP.

4. Definitions

- **Segregation:** Physical separation of products to prevent cross-contamination or mix-up.
- **Quarantine:** Isolation of products that are non-conforming, suspect, or pending disposition.
- **Non-conforming Product:** Any product failing to meet acceptance criteria.

5. Procedures

5.1 Identification of Non-Conforming/Suspect Products

- Identify products that are damaged, expired, recalled, or otherwise non-conforming.
- Immediately notify Quality Assurance (QA) upon discovery.

5.2 Segregation and Quarantine Area Setup

- Designate a physically separated, clearly marked quarantine area.
- Restrict access to authorized personnel only.
- Ensure the area prevents commingling with conforming products.

5.3 Labeling Standards

- All quarantined items must be labeled with a â€œQUARANTINEâ€ tag indicating:
  - Product name/ID
  - Batch/lot number
  - Date of quarantine
  - Reason for quarantine
  - Authorized by (signature/initials)
- Labels must be legible and securely attached to each item or container.

5.4 Monitoring and Documentation

- Maintain a quarantine log detailing all items in segregation, including dates, reasons, and actions taken.
- Regularly inspect quarantine areas for compliance with this SOP.

5.5 Release or Disposal Protocols

- Only QA may authorize the release or destruction of quarantined products.
- Document all disposition actions in the quarantine log with signatures and dates.
- Dispose of destroyed products per environmental and regulatory guidelines.

6. Records and Documentation

- Quarantine Logbook or Database
- Quarantine Labels (Retain copies as appropriate)
- Release/Disposition Authorizations

7. Training

All relevant staff must be trained on this SOP before performing product segregation or quarantine activities. Training records must be maintained.

8. References

- Applicable regulatory standards (e.g., FDA, EU GMP, ISO 9001)
- Company policies on product quality and handling

9. Revision History

Version	Date	Description of Change	Approved by
1.0	2024-06-15	Initial SOP release	QA Manager