

# Standard Operating Procedure (SOP)

## Quarantine Procedures for Recalled Products

SOP No.	[Insert Number]	Effective Date	[Insert Date]
Department	[Insert Department]	Revision No.	[Insert Revision]
Prepared By	[Name & Title]	Approved By	[Name & Title]

### 1. Purpose

This SOP details the **quarantine procedures for recalled products**, including identification and segregation of affected items, documentation and labeling of quarantined products, secure storage conditions, communication protocols with relevant departments, and disposal or return processes. The goal is to prevent distribution or use of recalled products, ensure traceability, and maintain compliance with safety and regulatory standards.

### 2. Scope

This SOP applies to all employees involved in product recall management at [Organization Name], including but not limited to warehouse, quality assurance, regulatory, and distribution staff.

### 3. Definitions

- **Recall:** The process of removing a product from distribution or use due to safety, compliance, or quality concerns.
- **Quarantine:** The isolation of products to prevent their unintentional use or distribution.
- **Affected Product:** Any product identified as subject to recall, whether in storage, at third-party locations, or in transit.

### 4. Responsibilities

- **Quality Assurance (QA):** Initiates recall, verifies quarantine, oversees documentation, and coordinates investigation.
- **Warehouse Staff:** Executes identification, segregation, labeling, and secure storage of recalled products.
- **Regulatory/Compliance:** Ensures procedures meet applicable regulatory requirements.
- **All staff:** Report suspected affected products immediately to supervisors or QA.

### 5. Procedure

1. **Recall Identification**
  - QA issues recall notification with product details (name, batch/lot, quantity, reason) to all relevant departments.
2. **Product Segregation**
  - Warehouse staff locate all affected products in inventory, transit, or other storage areas.
  - Physically separate these products from other inventory to prevent accidental distribution.
3. **Documentation and Labeling**
  - Identify and tag all quarantined products with a distinct “QUARANTINED – RECALLED PRODUCT” label, including date/time, reason, and responsible personnel initials.
  - Complete a Recall Quarantine Log (see Section 7).
4. **Secure Storage**
  - Transfer quarantined products to a designated, secure area, access restricted to authorized personnel only.
  - Ensure products are protected from damage, contamination, and unauthorized removal.
5. **Internal Communication**
  - QA communicates the status and location of quarantined products to all relevant departments.
6. **Disposition of Recalled Products**
  - Upon conclusion of investigation, QA determines final disposition (destruction, return to supplier, etc.), in line with regulatory requirements.
  - Document all actions taken, including method and date of destruction or return, in the Quarantine Log.
7. **Release from Quarantine (If Applicable)**
  - Only after written authorization from QA and/or regulatory authority, products may be released from quarantine (e.g., if found unaffected).

### 6. Records

- Recall Notification Forms
- Quarantine Labels

- Quarantine Logs (see below)
- Disposal/Return Certificates
- Communication Records

## 7. Quarantine Log Template

Date	Product Name/Code	Batch/Lot Number	Quantity	Location	Reason for Quarantine	Action Taken	Initials
[dd/mm/yyyy]	[Product]	[Batch/Lot]	[Qty]	[Storage Area]	[Recall/Defect]	[Segregated/Disposed/Returned]	[Staff]

## 8. References

- [Relevant internal SOPs]
- [National/International Regulatory Guidelines]

## 9. Revision History

Revision No.	Date	Description of Change	Approved By
[#]	[dd/mm/yyyy]	[Details]	[Name/Title]