

SOP Template: Immediate Containment Actions for Affected Products

This SOP details **immediate containment actions for affected products**, outlining essential steps to promptly isolate and control compromised items to prevent further contamination or distribution. It includes procedures for identifying affected products, initiating quarantine measures, notifying relevant personnel, documenting containment activities, and ensuring safe storage until resolution. The aim is to safeguard product quality, protect consumer safety, and maintain regulatory compliance through swift and effective containment responses.

1. Purpose

To establish a standardized procedure for the immediate containment of affected or compromised products to prevent further contamination, ensure consumer safety, and maintain regulatory compliance.

2. Scope

This SOP applies to all personnel involved in product handling, quality control, storage, logistics, and distribution within the organization.

3. Responsibilities

- **Quality Assurance (QA):** Oversee and verify containment actions, documentation, and communication.
- **Production/Operations Staff:** Identify, isolate, and report affected products.
- **Warehouse/Logistics Staff:** Implement quarantine measures and secure storage.
- **Management:** Authorize further action as required and communicate with external bodies if needed.

4. Procedure

1. **Identification of Affected Products**
 - Detect compromised products through internal checks, customer reports, or regulatory notifications.
 - Record batch/lot numbers, quantity, location, and nature of the issue.
2. **Immediate Quarantine**
 - Stop movement and use of affected products immediately.
 - Physically separate and clearly label affected products in a designated quarantine area.
3. **Notification**
 - Inform relevant QA, supervisory, and management personnel.
 - If required, escalate to regulatory bodies and/or customers.
4. **Documentation**
 - Complete containment activity log with time, date, personnel involved, product details, and actions taken.
 - Maintain records in accordance with internal and regulatory requirements.
5. **Secure Storage Until Resolution**
 - Ensure quarantined products are stored securely and access is restricted to authorized personnel only.
 - Maintain quarantine status until investigation, corrective actions, and disposition decisions are completed.
6. **Follow-up Actions**
 - Participate in root cause analysis and corrective action planning as required.
 - Release, rework, or dispose of affected products according to final disposition instructions.

5. Records and Documentation

Record Type	Responsible Person	Retention Period
Containment Activity Log	QA	5 years
Quarantine List	Warehouse Supervisor	5 years
Notification Forms	Operations Manager	5 years

6. Revision and Approval

Prepared by: _____
Reviewed by: _____
Approved by: _____
Effective Date: _____