

# Standard Operating Procedure



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Approval:	Initial	Date
Director of Quality Compliance	DG	11SEP23

## Title: Crisis Management Team, Mock Recall and Recalls

### Purpose:

To outline the steps required with Food Crisis Management. Provide a timely response in the event of an actual food safety crisis.

### Designation of Responsibilities:

President / CEO or designee

VP Operations or designee

Director Quality or designee

Quality Lead

Inventory Control

Production Manager

Customer Service Representative (CSR)

### Materials Needed:

Normal production documentation for traceability

Form QA0-007F1 Mock Recall Template

### Process / Procedure:

- 1) The Crisis Management Team must be available to activate immediately.
- 2) Mock Recalls, Recalls, and Trace Team must consist of but is not limited to:
  - A. Lead – Director of Quality, Quality Lead, or designee
  - B. Team Member 1: Customer Service Representative
  - C. Team Member 2: Inventory Control
- 3) Mock Recalls, Recalls, and Traces will be start when:
  - A. A Customer Service Representatives is contacted by a customer asking for a recall/ mock recall/ or trace to be done.
  - B. When initiated by Action Pak as either an exercise or part of a CAPA.
  - C. When requested by an auditor.
  - D. If requested by the FDA.

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4) CSR will then forward the information needed (Customer, Item, Lot/Date Codes, etc.) to start the process to the Director of Quality. If the Director of Quality is not available, then the backups are as follows:

1. Quality Lead
2. Customer Service Representative
3. Inventory Control
4. Production Manager

5) Assess the criticality of potentially serious incidents, which could indicate:

- A. Possible failures of process safety controls
- B. Product contamination
- C. Product Tampering
- D. Regulatory Actions
- E. Consumer illness or injury
- F. Situations that may result in adverse corporate publicity.
- G. Other situations that may result in the need to consider product recalls.

### 6) Production / Lot Code Documentation:

Production paperwork must be created in such a manner that the customer's lot codes are traceable from the supplier to the distributor. Because of the nature of the process of joining multiple products into a single tray or sealable unit ActionPak, Inc. may create a new lot code in accordance with an agreed process with the customer. In some cases, the existing lot codes could be used.

The new lot code cross reference will be kept on file according to SOP QA0-003 Storage of Quality / Production Records SOP.

### 7) Notification:

Upon notification from a customer or supplier the following events should transpire Notification will be by direct contact, including during evenings, weekends, or holidays.

- A. Crisis Management Team is notified.

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1. Crisis Management Team consists of the following representatives:
    - a) Executive – President – CEO, Vice President, or Designee
      - (1) Communicates and directs all activities.
      - (2) Communicates all formal information to the media and authorities.
    - b) Quality – Quality Compliance Director or Designee
      - (1) Communicates with customer representatives through CSR or Directly.
      - (2) Determine Root Cause
      - (3) Monitor Communication flow: Internally, to customs and authorities.
      - (4) Generates notes recording time of activity, responsible parties, and other important details.
    - c) Product Management – Production Manager or Designee
      - (1) Inform and direct all site personnel of any hazards.
  - B. Retrieve all related documentation for the product in question.
    1. Identify related information for the following:
      - a) Quantity Received and when?
      - b) Quantity Shipped, where it went and when did it ship?
      - c) Quantity in the warehouse?
      - d) Dispensation of material?
      - e) Customer Service Representative
- 8) Mock Recalls:**
- A. ActionPak, Inc. will conduct a mock recall at a minimum of twice a year to ensure accuracy.
  - B. The recall must be documented for customers review, third party auditor review or regulatory agency review.

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- C. Use form QA0-007F1 or customer supplied form to document the recall.
- D. Mock recalls should take less than 2 hours to collect information including:
  - 1. Receiving
    - a) Date of Receipt, Receipt From (Address), Raw Product Manufacturing Date, BOL Number, Seal Number, Lot Number, Quantity, Unit of Measure.
    - b) Copies of the BOL, Packing List, any COA, or COC must be included with form QA0-007F1.
  - 2. Production
    - a) Production Date, Work Order Number, Raw Product Manufacturing Date, APK Lot Number, Quantity Used, Quantity Scrapped, Total Used, Unit of Measure.
    - b) Copies of MP0-005 Shift Reconciliation for each shift that ran this product must be included with form QA0-007F1.
  - 3. Remaining Inventory on Hand
    - a) Production Date, Work Order Number, Raw Product Manufacturing Date, Lot Number, Quantity on Hand, Quantity on Hold, Total in Building, Unit of Measure.
    - b) Copies of Inventory Logs, and any hold logs must be included with form QA0-007F1.
    - c)
  - 4. Shipping
    - a) Date Shipped, shipped to (Address), Lot Number, BOL Number, Seal Number, Quantity Shipped, Unit of Measure.
    - b) Copies of BOL and Packing List must be included with form QA0-007F1.

### Reference Documents:

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## Title: Crisis Management Team, Mock Recall and Recalls

SOP QA0-001 Crisis Management - Building Security and Emergency Call List

SOP QA0-003 Storage of Quality / Production Records.

SOP AD0-013 Roles and Responsibilities

### Revision History:

Revision	Date	Description of Change
A	7/25/14	Added Form
B	9/17/18	Changed 2 hours to 4 hours
C	4/15/19	Added Chain of Command
D	2/20/22	Identified Crisis Management team and identified roles and responsibilities.
E	12/19/2022	Changed 4 hours to 2 hours
F	3/23/2023	Updated to list the Recall/Mock Recall/ Trace team
G	9/8/23	Updated the requirements for form QA0-007F1

End SOP: SOP No: QA0-007 Title: Crisis Management Team, Mock Recall and Recalls

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