



# NAIL ALLIANCE

## RECALL PLAN

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## **Recall Plan Version Verification**

Nail Alliance Recall Plan shall be reviewed annually and revised as necessary when personnel, procedures, suppliers, or as other factors change. The plan will also be reviewed after any company recall.

Version: HNH001-1

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Approved by

Operations, General Manager

Title

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Date Approved

## **Introduction**

The primary goal of a recall is to protect public health by removing products from commerce that have been determined to be unsafe. A recall plan can aid in the execution of a recall by apportioning duties, centralizing current contact information, and providing prewritten templates for communications. Key individuals that will be participating in a company recall will review the recall plan and be familiar with the execution of the plan.

## **Definitions**

**Class I Recall** – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

**Class II Recall** – A situation in which use of, or exposure to, a violative product will cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**Class III Recall** – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

**Depth of Recall** – The level of product distribution for the recall (consumer, retail).

**Distribution List** – A product specific distribution list which identifies accounts that received the recalled product. Requested information includes type of business, account name, addresses and contact information.

**Market Withdrawal** – A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the regulatory agency or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

**Press Release** – A notice that alerts the public which includes regulators, retailers, consignees and consumers that a product presents a serious hazard to health.

NOTE: Not all recalls require a press release. Regulatory bodies may advise if a press release is necessary.

**Recall** – The removal or correction of a marketed product that a regulatory agency considers to be in violation of the laws it administers and against which the agency would initiate legal action. Recall does not include a market withdrawal or a stock recovery.

**Recall Strategy** – A planned specific course of action to be taken in conducting a specific recall, which addresses the depth and scope of recall, need for public warnings, and extent of effectiveness checks for the recall.

**Scope of Recall** – Defines the amount and kind of product in question.

**Stock Recovery** – The removal or correction of a product that has not been marketed or that has not left the direct control of the company and no portion of the lot has been released for sale or use.

## **Statement of Recall Plan**

Nail Alliance maintains a recall plan which provides specific procedures, defines terms, and assigns roles and responsibilities when a safety issue arises with any of our products.

The plan will be activated whenever a potential recall requirement arises and includes the following elements:

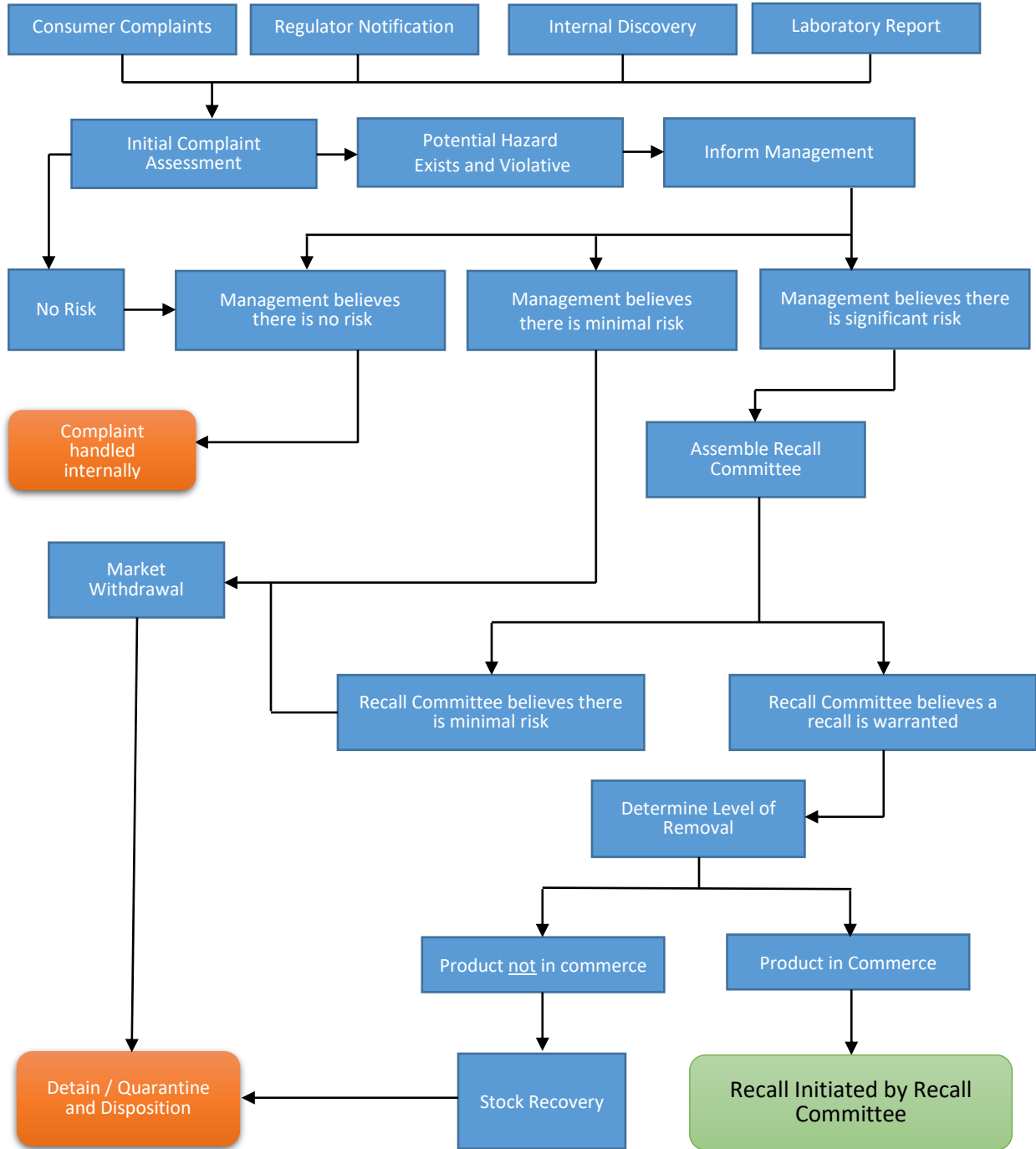
1. Recall committee member designations
2. Recall responsibility assignments
3. Key personnel and external contact information
4. Recall procedures
5. Communication templates

## **Recall Plan Flow Charts**

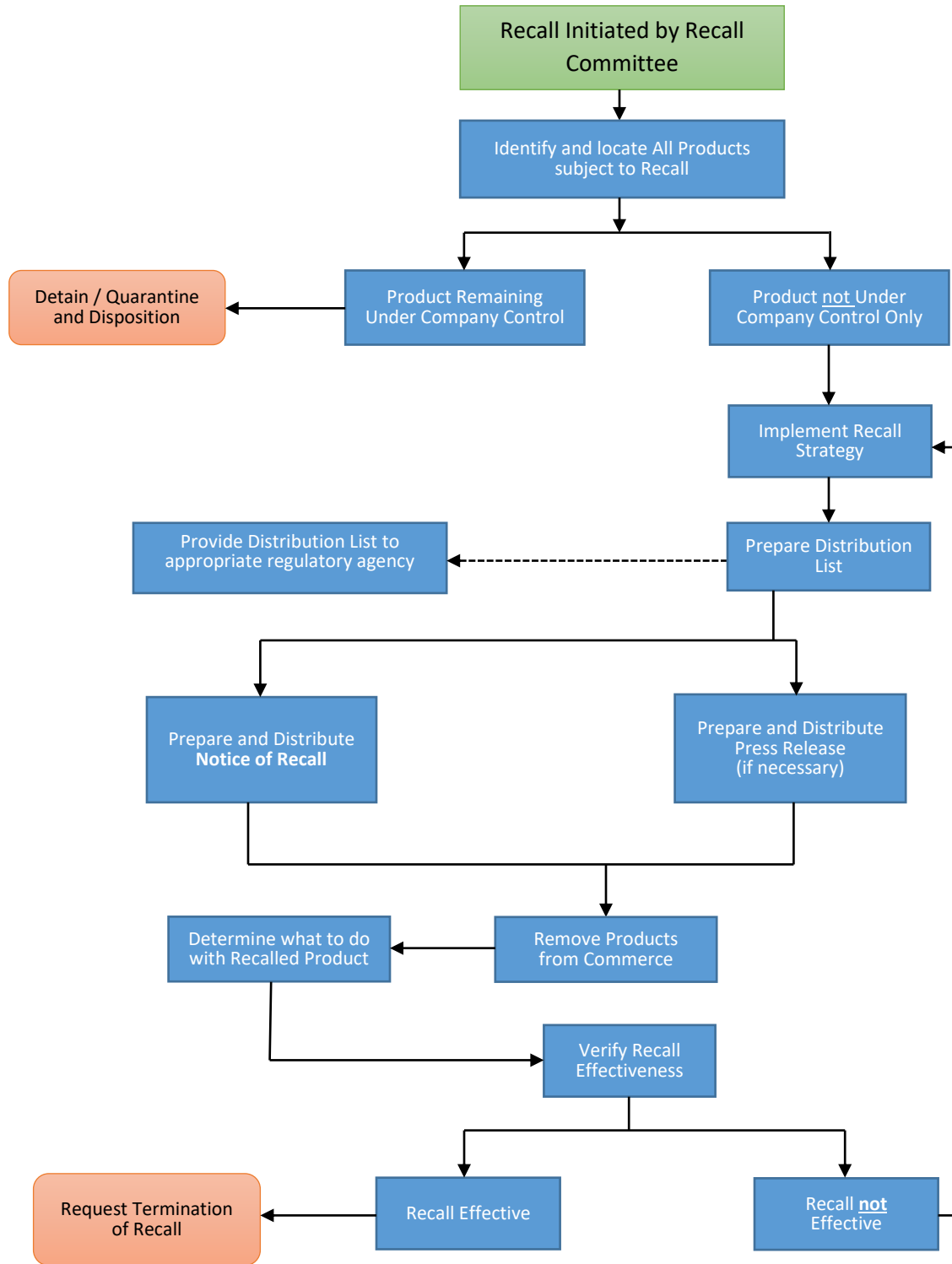
The following two diagrams are graphical representations of the various steps of a recall.

- Figure 1, illustrates the typical evaluation of complaints or conditions which may lead to a recall.
- Figure 2, outlines the various steps of a recall.

**FIGURE 1: Complaint/Condition Evaluation Flow Chart**



**FIGURE 2: Recall Flow Chart**



## **Recall Procedures**

The recall procedure outlines the activities that Nail Alliance will take to manage the recall of our product(s) which has/have been determined to be unsafe and/or subject to regulatory action. The procedure contains the major recall elements below:

- Assignment of Roles and Responsibilities
- Evaluation of the Complaint or Condition
- Identification of Implicated Products
- Notification of Affected Parties
- Removal of Affected Products

### **Assignment of Roles and Responsibilities**

Each individual found on the Recall Committee understands their role and responsibility within the recall plan. It is important to note that individuals may be responsible for more than one recall element.

#### **Recall Coordinator**

The recall co-coordinator, has been given authority by the management of Nail Alliance to execute the activities of the recall. Responsibilities of the Recall Coordinator include, but are not limited to:

- Assure the documentation of all recall decisions and actions in a master recall file.
- Initiate the formation of the recall committee
- Activate various components within the company for priority assistance.
- Make recall decisions on behalf of Nail Alliance
- Manage and coordinate the implementation of the company's product recall.
- Keep management informed at all stages of the recall.

#### **Recall Committee**

Nail Alliance Product Recall Committee is composed of the various components of the company's organization. The following areas are represented:

- Management Administration
- Recall Coordinator
- Quality Assurance
- Customer Service
- Production
- Distribution and Supply
- Marketing
- Information Technology
- Legal Counsel
- Regulatory Affairs

\*See Appendix A for Recall Committee and Key Personnel Contact Information

## **Evaluation of the Complaint or Condition**

Complaint receipt, processing and evaluation are the first steps in the recall process. The steps involved in the evaluation process are:

- Receive the complaint – A file will be maintained containing any product complaints the company receives. Information which will be maintained in the product complaint file is:
  - Complainant contact information
  - Reported problem with the product
  - Product Identification
  - Product Storage
  - Product purchase date and location
  - Illness and Injury details
- Provide the complaint to knowledgeable staff for initial evaluation. If an initial assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Committee for a full evaluation.
- Determine the hazard and evaluate the safety concerns with the product.
- Determine the product removal strategy appropriate to the threat and location in commerce.
- Contact the appropriate regulatory authorities.
- Maintain a log of the events of the recall including information such as dates, actions, communications and decisions.

## **Identification of Implicated Products**

It is Nail Alliance's responsibility to ensure the identification of all products and quantities of products implicated in the recall. In addition, a determination will be made if any other codes, brands or sizes of product handled by the company are affected.

A distribution list will be prepared as part of the Identification process. The distribution list will contain, at a minimum:

- Account name (consignees) that received the recalled product(s)
- Account addresses
- Contact names
- Contact telephone numbers
- Type of account (e.g., distributor, retailer)

Additional information relating to product information may include:

- Amount of product received/shipped
- Product ship date(s)
- Amount of product returned
- Amount of product consumed

## **Notification of Affected Parties**

Notifications during a recall must be done in a timely manner and should include the appropriate regulatory agencies, the product distribution chain, and consumers when necessary. Recall notices are typically used to notify regulatory agencies and those businesses in the distribution chain. Press releases are generally oriented to consumers, but may be used to notify any affected party.

- Regulatory Agencies should be notified at the earliest opportunity after the decision has been made to conduct a recall.
- Distribution Chain contacts will be notified by appropriate means (telephone, fax, email, letter, etc.).
- Consumers will be notified by the most effective method available. If appropriate, a press release can be used to notify consumers.

## **Removal of Affected Product**

The procedure for product removal can be divided into five components including: removal, control, disposition of affected product, recall effectiveness and recall termination.

### **Removal**

All reasonable efforts will be made to remove affected product from commerce.

- Products in commerce will be detained, segregated and handled in a manner determined by the recalling firm.
- Products that are still in the recalling firm's control (e.g. inventory located onsite, in transit, in off-site storage and in offsite distribution) should be detained and segregated.
- All quantities and identification codes will be documented to assist in the reconciliation of product amounts.

### **Control of Recalled Product**

When Nail Alliance chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

- All affected product returned will be clearly marked, not for sale or distribution and stored in an area that is separated from any other products. All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

### **Product Disposition**

The final disposition of the recovered product must be determined. The final disposition must be reviewed and approved by appropriate parties. Options include:

- Destruction – Products determined to be unsafe for consumer usage may be destroyed or disposed by appropriate means.
- Reworked – Product may be reworked to remove the safety risk.

## Recall Effectiveness

Nail Alliance is responsible for determining whether the recall is effective. Recall Effectiveness Checks verify that all consignees have been notified and have taken appropriate action. Steps include:

- Verifying that all consignees have received the notification.
- Verifying that consignees have taken appropriate action.
- If the response from our consignees is less than 100%, then the recall should be deemed ineffective and the recall strategy should be reassessed.

## Termination of a recall

Termination of the recall will be considered after all reasonable efforts have been made to remove the affected products from commerce, including reconciliation, recall effectiveness and disposition.

## **Appendix A – Recall Committee and Key Personnel Contact Information**

### **Contact Information**

On-call 24/7 contact person:

Primary: Napoleon Espinoza

Contact#: (562) 753-1452

Secondary: Steve Malynn

Contact#: (816) 377-3505

### **Recall Committee**

Danny Haile

Chief Executive Officer

David Daniel

Chief Executive Officer

Gari-Dawn Tingler

Chief Executive Officer

Napoleon Espinosa

Operations, General Manager

Andrea Nawalanic

Legal

Johnny Rodriguez

Recall Coordinator/Lab Director

Claudia Espinoza

Customer Service Manager (International)

Maria Griffiths

Customer Service Manager (Domestic)

Sheila Haile

Human Resources

Jason Naohara

Marketing Director

Jorge Ruvalcaba

International Sales Manager