

## 1.0 PURPOSE

The purpose of this Operating Standard is to describe the process requirements for how the logistics process manages electronic delivery notes and shipment notification data exchanges between internal and external distribution partners and systems.

## 2.0 SCOPE

This Operating Standard applies to all customer orders, inter-company, and intra-company outbound shipments for all North American sites and covers the movement of raw materials, work-in-progress (WIP), and finished goods products.

## 3.0 ROLES AND RESPONSIBILITIES

Role	Responsibility
Manager	<ul style="list-style-type: none"><li>• Ensures staff receive required training</li><li>• Maintains carton calculation tables</li><li>• Monitors warehouse performance</li></ul>
Staff	<ul style="list-style-type: none"><li>• Complete required training</li></ul>
Material Coordinator	<ul style="list-style-type: none"><li>• Completes required training</li><li>• Creates delivery note number</li><li>• Creates transfer orders</li><li>• Picks material</li><li>• Confirms transfer orders</li><li>• Initiates packing process (selects/scans delivery note)</li><li>• Creates, changes, and/or confirms handling unit</li><li>• Creates end-of-day processing (initiates carrier manifest, closes open truck records/shipments)</li><li>• Requests delivery status on small package shipments</li><li>• Executes post-goods issue transaction for delivery/shipment</li></ul>
Trade Operations and Production Planning and Inventory Control (PPIC)	<ul style="list-style-type: none"><li>• Create sales, returns, inter-/intra-company orders</li><li>• Correct inbound and outbound Electronic Data Interface (EDI) file errors</li><li>• Request delivery status on small package shipments</li><li>• Commit batch number to orders as applicable</li></ul>

## 4.0 REFERENCES

This Operating Standard refers to the current version of the following:

- Delivery Note
- Packing Slip
- Transfer Order
- Commercial Invoice
- Proof of Receipt
- Bill of Lading

## 5.0 GENERAL

The Operating Standard provides a general overview of the delivery note processes for manufacturing, distribution, and contract sites. It also outlines the tracking of delivery note small package shipments to Amgen customers using small package carriers. Refer to Appendix 1 for pertinent definitions.

## 6.0 REQUIREMENTS

### 6.1 Trade Operations creates a sales order to ship products to customers.

Production Planning and Inventory Control (PPIC) creates a stock transfer order to ship products and materials between Amgen sites or between an Amgen location and a contract facility.

**NOTE:** The delivery note procedure follows the delivery note process flow in Appendix 2.

6.1.1 An order is created to ship product to internal Amgen sites or external customers. When the product batch is approved for shipping (i.e., the product batch stock category is unrestricted or restricted), the order is fully approved to ship, and a delivery note is created.

**NOTE:** The delivery note can be created using various methods.

6.1.1.1 An authorized user creates a delivery note manually by providing a combination of the following data points:

- Shipping point
- Order number
- Ship date

**NOTE:** The user has the ability to create delivery for approved orders individually or collectively.

6.1.1.2 A scheduler creates a delivery note. The scheduler searches for approved orders and creates delivery notes for those orders at a predefined interval.

**NOTE:** Delivery notes require a carton calculation error if carton calculation requirements are not met. An error message appears indicating the failure to create a delivery note.

**NOTE:** Confirmation of pick, pack, and ship of third party orders is returned to Amgen for Post Goods process and creating the billing document.

6.1.2 After the delivery note is created, the status of the delivery advances to Pick. The picking process uses either the warehouse management process or the inventory management.

## **6.2 Warehouse Management**

The Warehouse Management process follows the process flow in Appendix 3.

6.2.1 Processing a delivery note for batch selection using Warehouse Management is completed either individually or collectively with the delivery note number, shipping point, or delivery creation date.

6.2.1.1 Creating a transfer order for single delivery requires the user to enter the warehouse number and delivery number.

6.2.1.1.1 Batch determination is based on Shelf Life Expiration Date (SLED) and First Expired, First Out (FEFO) and is established when the transfer order is created.

6.2.1.2 Creating a transfer order for multiple delivery notes is called a Wave Pick transaction. The user is required to select deliveries for processing and create a group. Afterwards, a Wave Pick number is assigned for the user to process.

6.2.1.2.1 Batch determination is based on FEFO or customer expiry preferences.

6.2.1.3 Regardless of processing selection, the next step is to confirm the transfer order. The Transfer Order / Wave Pick can be confirmed using either the Graphic User Interface (GUI) on the desktop or a Radio Frequency (RF) device.

6.2.1.3.1 If Warehouse Management (WM) is using the GUI to confirm the transfer order, the user enters the Transfer Order number and selects confirm.

6.2.1.3.2 If WM is using the GUI to confirm a Wave Pick, the user enters the group number and then individually confirms each Transfer Order within the group.

6.2.1.3.3 If WM is using an RF device to confirm the Transfer Order or Wave Pick, the user scans the bin and storage unit label (if applicable) and verifies the correct location and material. The user then confirms the quantity picked into the RF device. If there is no error, the user may be requested to confirm if the location is picked empty. If no error occurs, the user's Transfer or Wave Pick line item is confirmed complete.

**NOTE:** The user may change batch or quantity during pick confirmation of the Transfer Order unless the batch number is specified in the sales or stock transfer order.

6.2.1.3.4 The user can cancel a Transfer Order before or after Transfer Order confirmation. If the delivery note has been picked and a request to cancel the Transfer Order is received, the user must cancel the Transfer Order before deleting the delivery note.

## 6.3 Packing Process

The Packing procedure follows the process flow in Appendix 4.

6.3.1 After pick status is complete the delivery can be packed. The pack process can be performed manually by the user or, depending on shipping condition and shipping point, the pack process creates a carton proposal.

6.3.1.1 If the manual creation of a handling unit is required, the user enters the delivery note number and pack material into the Pack screen and saves the record, which creates the handling unit (HU). During this process the user can also select a carrier and carrier service level.

6.3.1.2 If the shipping condition and shipping point require a carton proposal for delivery, the user enters the HU number on the Pack screen. The user can confirm, change, or delete the proposal. During this process the user can also select a carrier and carrier service level.

6.3.2 After confirmation of the HU, the user may be required to create shipping documentation.

6.3.2.1 If a small package carrier is required, the HU Confirmation process initiates a request to the carrier system. If no error occurs, a carrier shipping label prints. If errors occur, users are required to correct the data in the delivery note and resend the request. This process continues until all HUs receive a carrier shipping label.

**NOTE:** For UPS small package shipments, the user processes reprint and cancel airway bill requests from the UPS Worldship system.

6.3.2.2 If a delivery is shipped via freight (truck or air), the user creates a shipment record that provides a bill of lading (if applicable).

6.3.2.3 The Enterprise Resource Planning (ERP) system prints a carrier shipping label and customs documents after confirmation of international shipment delivery note or HU.

6.3.3 After confirmation of all HUs in the delivery note, the pack status is moved to complete.

6.3.3.1 After all pick quantities have been removed and the delivery note has been cancelled, it can be deleted.

**NOTE:** Delivery notes created for Canada third-party logistics do not require packing.

**NOTE:** Delivery notes created without reference require packing.

## 6.4 Inventory Management

The Inventory Management procedure follows the process flow in Appendix 5.

6.4.1 Batch selection and product picking performed using Inventory Management are done individually, either by a user or as a background job performed immediately after the creation of a delivery note.

6.4.1.1 If batch selection and picking is done manually by the user, the user must input the batch number and pick quantity.

6.4.1.2 If batch selection and picking is done as a background job, ERP selects material based on FEFO rules or customer preferences.

**NOTE:** For Canada delivery notes shipped using third-party distribution, when the batch number is assigned the delivery note pick status is set to complete. The delivery note detail is then sent via EDI to the distributor.

**NOTE:** Delivery notes created without reference require picking.

6.3.2 Before canceling a delivery note, the user must remove the pick quantity before deleting the delivery note.

## 6.5 Transportation

The Transportation procedure follows the process flow in Appendix 6.

- 6.5.1 The user can see the shipment contents or tracking status depending on the order type.
  - 6.5.1.1 For inter-/intra-company delivery, the user reviews the contents of the delivery note (e.g., handling unit, PO number, batch).
  - 6.5.1.2 For small package delivery, the user reviews updated delivery status using the carrier airway bill.
- 6.5.2 Small package carriers require authorized user to initiate the end-of-day (EOD) process.

## **6.6 Post Goods Issue**

The Post Goods Issue procedure follows the process flow in Appendix 7.

- 6.6.1 Delivery notes with a pick and pack status of complete are processed either manually by an authorized user or by the system in a background batch job.
  - 6.6.1.1 Third-party distribution facilities return confirmation of pick and pack of delivery note to Amgen. If no errors occur the delivery initiates post goods processing.
- 6.6.2 After delivery note post goods processing an authorized user can reverse the transaction (if applicable) prior to creation of billing document. Once the billing document has been created, the reverse transaction is no longer an option.

## **APPENDIX 1**

### **Definitions**

<b>Advance shipping notice</b>	Produced during the carrier departure processing and transmitted to the host immediately via the customized send script
<b>Bill of Lading</b>	A document for truck and air shipments required by the Department of Transportation (DOT)
<b>Commercial Invoice</b>	Customs document for international shipments
<b>Trade Operations (TO)</b>	Business to consumer relationship
<b>Delivery Note</b>	Document that contains all sales order detail along with batch number
<b>Handling Unit (HU)</b>	A physical entity created as part of the packing process
<b>Inventory Management</b>	The process of managing the manufactured product
<b>Order Interface</b>	The online process by which orders are entered into the system
<b>Packing Slip</b>	Details of the individual carton or handling unit, materials, and packaging used to ship the product
<b>Picking Plan</b>	The sequence by which products are selected and removed from various storage locations
<b>Proof of Receipt</b>	A document returned to the shipper to prove receipt and acceptance of materials
<b>Production Planning and Inventory Control (PPIC)</b>	Monitors the inventory of finished products and components
<b>Radio Frequency (RF) Device</b>	A tool for monitoring and coordinating transfer order processing by the user

**Shelf Life Expiration Date (SLED)**

A time-based unit of measure that uniquely identifies when a product is next in line for shipment after FEFO requirement is determined

**Stock Categories**

Controls the picking of a batch in the delivery note. Categories are unrestricted, restricted, quality inspection, and blocked.

**Transfer Order**

The document used to retrieve materials from storage location, including storage type, section, and bin

**Transport Packaging Configuration**

The appropriate packaging for individual products

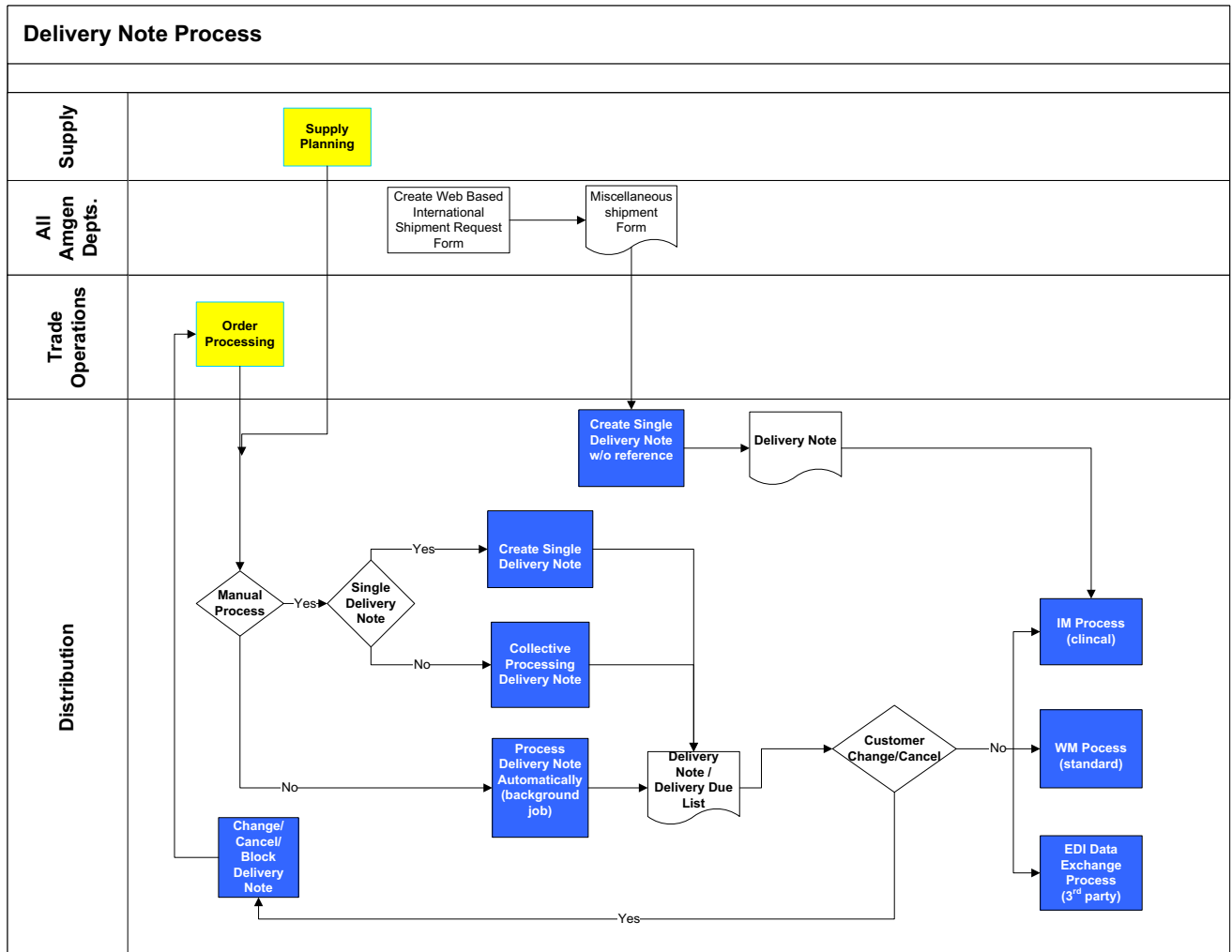
**Warehouse Management**

Managing the receipt, storage, and movement of goods to intermediate locations or to the final customer



## APPENDIX 2

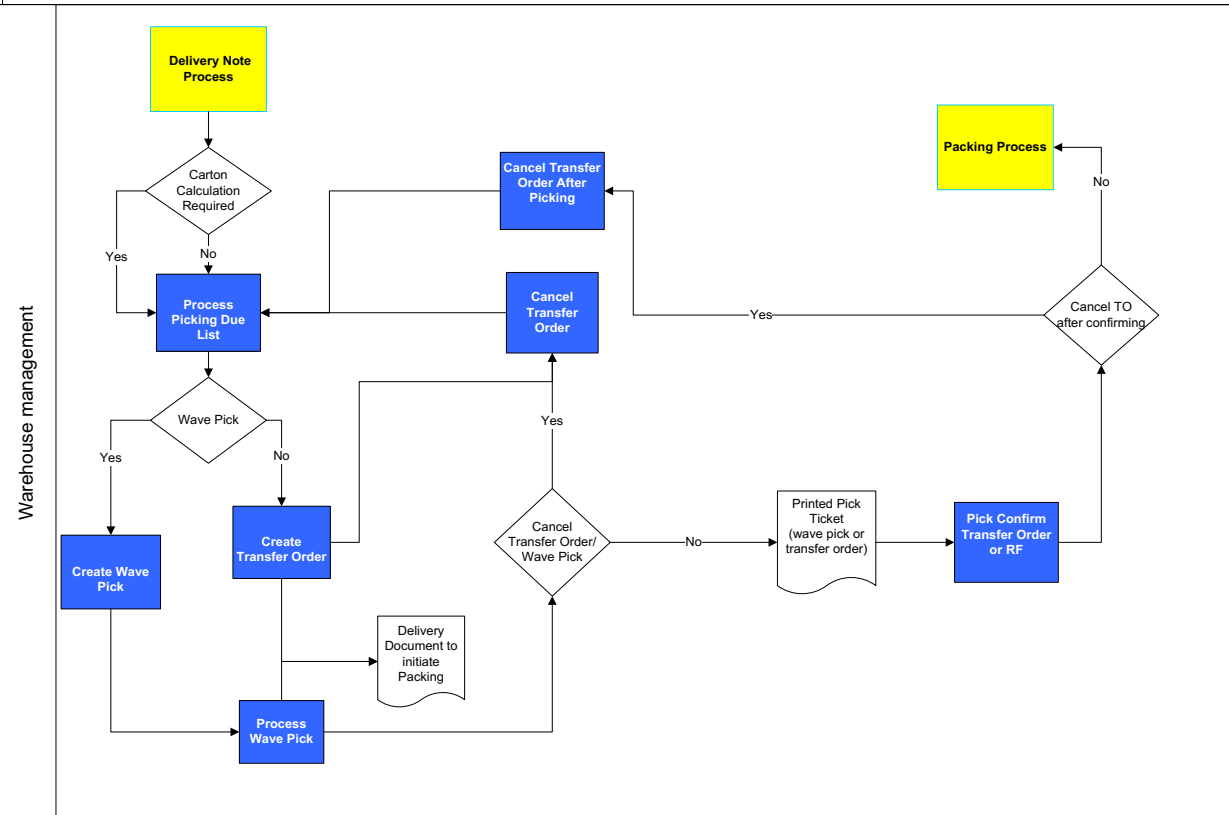
### Delivery Note



## APPENDIX 3

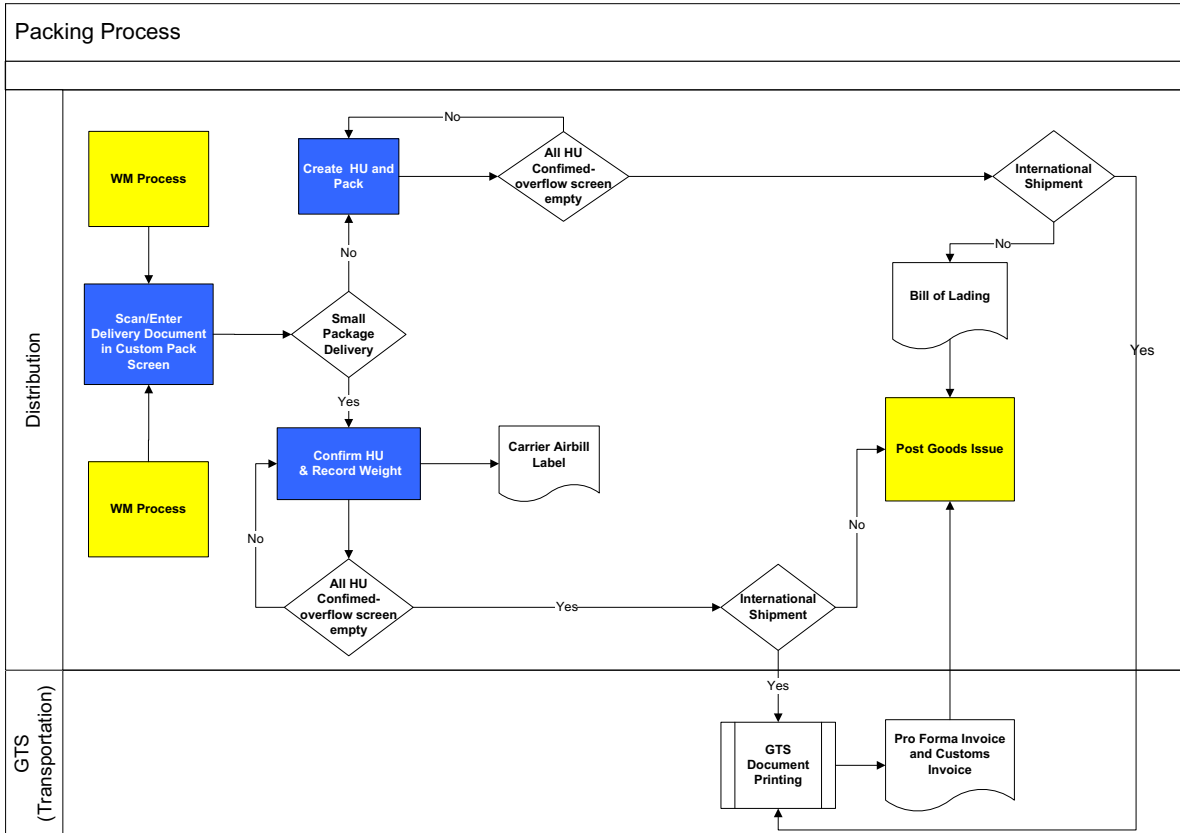
### Warehouse Management

#### Warehouse Management Process



## APPENDIX 4

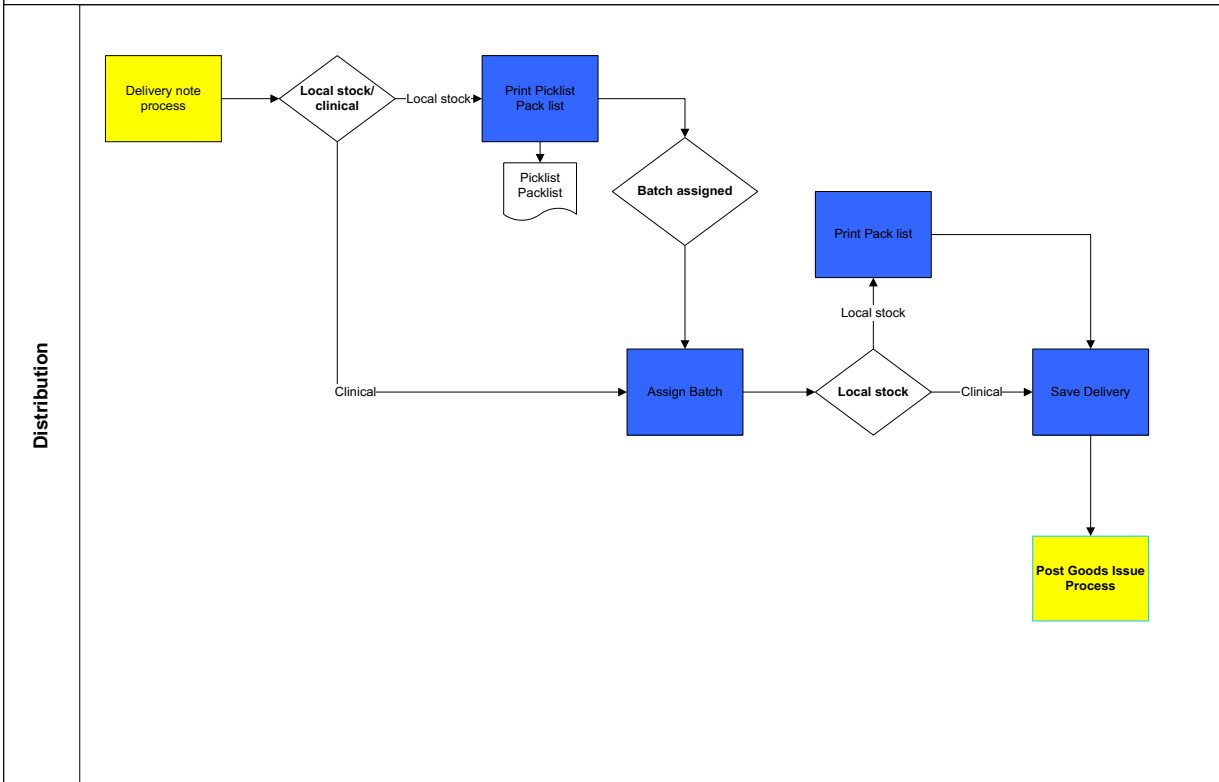
### Packing Process



## APPENDIX 5

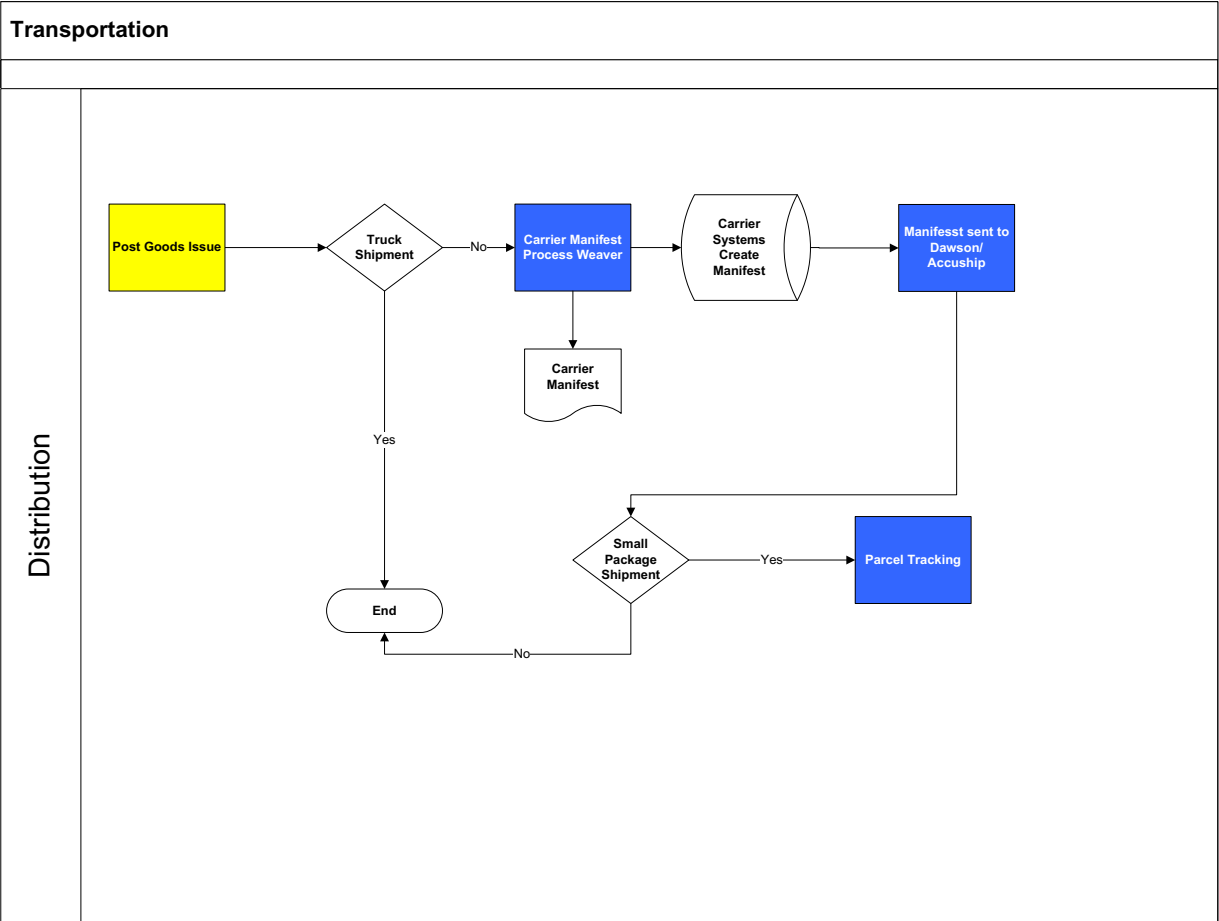
### Inventory Management

#### Inventory Management Process



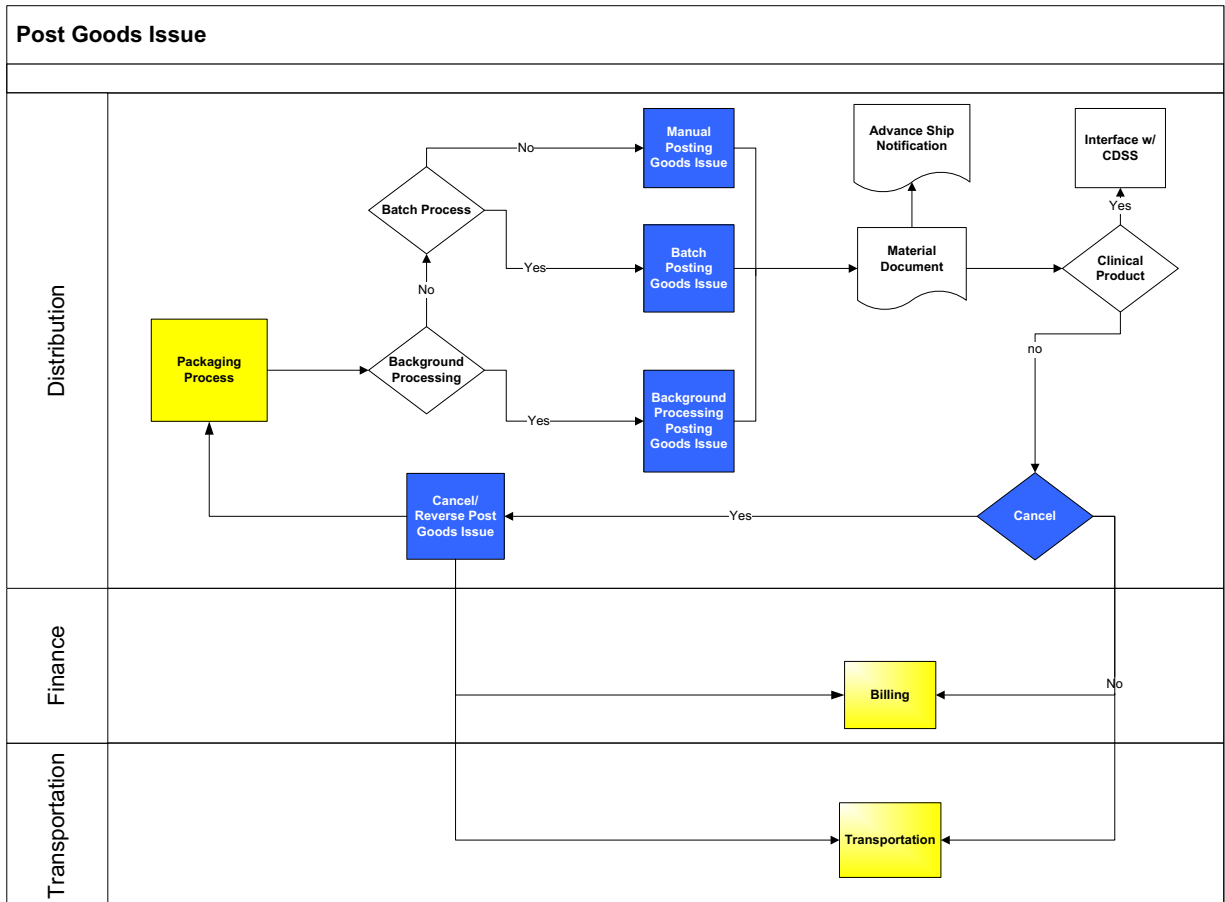
APPENDIX 6

Transportation



## APPENDIX 7

### Post Goods Issue



**Document History**

Change	Justification
1. New	Required for ERP North America implementation