

STANDARD OPERATING PROCEDURE

Title: Materials Control-Receiving Procedures

Effective Date: _____

Approvals (Signature and Date):

Responsible Department Head

Technical Authority

QA/QC

1. PURPOSE

- 1.1 To describe a method for accepting, tracking and processing purchased goods intended for use in manufacturing product.

2. SCOPE

- 2.1 These procedures apply to all products purchased for use in manufacturing under assigned part numbers.
- 2.2 These procedures include but are not limited to the procurement of raw materials, (i.e. chemicals, reagents, buffers, etc.) sub-components, (i.e. molded plastic parts, pre-cut screens, etc.) and finished goods (i.e. tube sets, PBS bags, RPMI bags, Pall filters, etc.).

3. RESPONSIBILITY

- 3.1 Materials Control ensures that components used in manufacturing shall be received, labeled, stored and handled in a manner designed to prevent damage, mix-up, contamination, and other adverse effects.
- 3.2 Quality Control verifies quarantine labels are applied by Materials Control and provides proper labeling for approval and expiration dating or rejection of incoming raw materials (i.e. Approval labels, Reject labels, etc.).
- 3.3 Materials Control maintains the timely and accurate input of data (i.e. item status, expiration dates, lot number, etc.) into the Inventory Management/MRP database.
- 3.4 Materials Control physically moves all received inventory as to properly reflect its current MRP location, status, and disposition (Quarantine, Approved, Rejected, etc.).

4. REFERENCES AND APPLICABLE DOCUMENTS

- 4.1 09-0003-SOP-1.0, Raw Material Quality Assurance Procedure
- 4.2 09-0004-SOP-1.0, Discrepancy Report Procedure
- 4.3 09-0015-SOP-1.0, Material Review Board
- 4.4 10-0012-SOP-1.0, Material & Cost Transfer (MCT) Procedures
- 4.5 10-0024-SOP-1.0, Return of Non-Conforming Product to Suppliers
- 4.6 12-0012-SOP-1.0, Lot Number Assignment
- 4.7 Purchase Order
- 4.8 Attachment A, Receiving Log
- 4.9 Receiving Document/Traveler

5. MATERIALS AND EQUIPMENT

- 5.1 Inventory Management/MRP system
- 5.2 Quality Control Status Labels (i.e. Quarantine, Approved, Reject)

6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1 All activities are to be performed in accordance with Company Safety Manual and the individual PNS for each product.

7. DOCUMENTATION REQUIREMENTS

- 7.1 Receiving Log
- 7.2 Receiving Traveler
- 7.3 Material & Cost Transfer Form

8. PROCEDURE

- 8.1 The Receiving Material Handler confirms that the received goods, as labeled by the supplier, agree with the Purchase order under which the item was ordered. Material Handler shall verify purchase order number, line item number, part number, description, quantity, unit of measure, lot number (manufacturer's lot number if requested on purchase order), manufacturer's expiration or shelf life date and the receipt of certificate of analysis/conformance, if required.
 - 8.1.1 If there is a discrepancy between the information listed on the packing slip and the purchase order information, the goods are not received into the Inventory Management/MRP system and the Receiving Material Handler notifies the Purchasing Agent for corrective action.
- 8.2 After verification of the purchase order information, the Material Handler logs the goods as received in the Receiving Log where a receiving lot number (i.e. RXXXXXX) is assigned in accordance with 12-0012-SOP-1.0, Lot Number Assignment.
- 8.3 Each container will be checked for obvious container damage, and evidence of broken seals or gross contamination.
 - 8.3.1 Material damaged in transit will be received into a Materials Management Hold inventory location until the cause of the damage may be determined.
 - 8.3.1.1 Damage occurred due to negligence in shipping will be processed as a freight claim with the carrier.
 - 8.3.1.2 Damage occurred due to negligence in manufacturer packaging will be processed as a claim with the manufacturer.
 - 8.3.2 The Receiving Materials Handler will notify Purchasing that damaged materials have been received and the quantity put into the MM Hold location. Where vendor notification and corrective action are required, Purchasing will document the actions taken and notify Receiving of the disposition of the materials.
 - 8.3.3 Non-conforming materials to be received into a Receiving Inspection location shall be processed in accordance with 09-0004-SOP-1.0 Discrepancy Report Procedures.
- 8.4 If there is no discrepancy between the information listed on the packing slip and the Purchase Order, the Inventory Management/MRP system is updated with the receipt of the materials.
 - 8.4.1 This transaction will reduce the quantity ordered on the open Purchase Order by the amount received, or close the Purchase Order if the entire order has been received.