

# Inovar Supplier Lot Traceability Standard

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This document is controlled by:

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All prior editions are obsolete and should not be used.

**It is the user's responsibility to assure that only the latest revision of this standard is used. (Go to [www.inovar-inc.com](http://www.inovar-inc.com) for the current standard.)**

## 1.0 Introduction

- 1.1 **Purpose:** To clearly define requirements for Lot Traceable materials to Inovar's suppliers.
- 1.2 **Scope:** This standard applies to all material procured on PO when "lot traceability" is invoked by Inovar. This includes all direct material items shipped to Inovar. It applies to all suppliers including customers and other Inovar departments/plants.
- 1.3 **Partnership:** Documentation development requires partnership. It can only function as intended when both supplier and customer work together from proposal through implementation. And then, it is absolutely crucial that both parties adhere to authorized packaging. The key is open, two-way communication.
- 1.4 **Delivery Performance Rating:** A supplier's conformance to this standard is factored into the supplier's "Delivery Performance Rating."

## 2.0 Supplier Responsibility

### 2.1 General Statements:

- 2.1.1 Inovar will state on the purchase order if this document is invoked for the specific order. If the part number carries the "LT" prefix, the supplier shall also treat the part as requiring this document to be invoked.

### 2.2 Documentation Requirements:

- 2.2.1 The supplier shall provide the following, as a minimum, for each delivery:
  - 2.2.1.1 One Packing Slip
  - 2.2.1.2 One Certificate of Conformance
  - 2.2.1.3 Any other documentation required by purchase order, drawings or provided specifications

All orders will be processed through Inovar Receiving Inspection department and documentation shall be verified. Any discrepancies shall be cause for rejection and a NCMR/SCAR will be issued to the supplier.

**2.2.2 At a minimum, the Supplier Packing List will contain the following information:**

- 2.2.2.1 **Inovar's Purchase Order Number**
- 2.2.2.2 **Inovar PO Change Order #(if applicable)**
- 2.2.2.3 **Inovar Part Number**
- 2.2.2.4 Revision for the device (If applicable)
- 2.2.2.5 **Manufacturer's Name**
- 2.2.2.6 **Manufacturer's Part Number**
- 2.2.2.7 Quantity Supplied

Note: multiple parts purchased on the same purchase order may be placed on a single packing slip if delivered in same shipment. All new shipments will require a new packing slip and C of C.

**2.2.3 At a minimum, the Supplier Certificate of Conformance will contain the following information:**

- 2.2.3.1 **Inovar's Purchase Order Number**
- 2.2.3.2 **Inovar PO Change Order #(if applicable)**
- 2.2.3.3 **Inovar Part Number**
- 2.2.3.4 Revision for the device (If applicable)
- 2.2.3.5 **Manufacturer's Name**
- 2.2.3.6 **Manufacturer's Part Number**
- 2.2.3.7 Quantity Supplied

2.2.3.8 Lot and/or Date Code of the delivered lot

2.2.3.9 A signature (Original or copied) from a relevant authority within the organization that assures the quality of the products supplied.

Note 1: Multiple parts purchased on the same purchase order may be placed on a single C of C if delivered in same shipment. All new shipments will require a new packing list and C of C

Note 2: Lot and/or Date Code listed on the C of C shall be EXACTLY as found on the part/part packaging. Any variance will be grounds for lot rejection (e.g. C of C shows lot "0711M" and packaging is labeled as "0711")

Note 3: The C of C may be contained on the packing list providing that information required in section 2.1.4 of this procedure is contained on it.

**2.3 Date / Lot Code Requirements**

2.3.1 The Date/Lot code provided to Inovar shall be a unique identifier for a production run. This identifier will be used in our traceability program to reduce the scope of potential recalls that may occur. For this reason, accuracy of this data is extremely important to Inovar and its customers.

2.3.2 When possible, product supplied on a PO shall be from the same Date/Lot Code. This will eliminate several hours of paperwork at Inovar to account for the use of multiple lots. If multiple lots are supplied, each lot shall be individually recorded on the C of C with correct quantities.

2.3.2.1 Each lot must be adequately identified to prevent mixing in inventory.

**2.3.2.2 Under no circumstances may multiple lots be packaged in the same reel, tray, tube, etc.**

2.3.3 Handwritten changes to packing list or C of C are not permitted.

2.3.4 Any product that is received and found to not comply with the requirements of this document shall be rejected and dispositioned appropriately per Inovar procedure unless prior written approval has been received from Inovar Quality Assurance.

**3.0 Revision Record**

<b>Revision Date</b>	<b>Summary of Change</b>	<b>Document Owner</b>	<b>Date of Approval</b>
7-10-09	Initial Release	Don McFarland	Draft Only