## 1.0 Purpose

The purpose of this procedure is to describe the methods by which purchase orders are issued and approved and the information that can be found on or included with purchase orders. It also discusses the additional controls for purchased parts used in regulated product.

## 2.0 Requirements

2.1 Any materials or services used in manufacturing are to be purchased by the Purchasing Department in accordance with the latest specifications. Engineering is responsible for the specifications of all material used in manufacturing.

2.2 A purchase order for materials and/or services may be requested by (2.2.1) Purchase Requisitions, by (2.2.2) Order Action Requests, or by (2.2.3) Planner Workbench Requests:

2.2.1 Purchase Requisitions

Occasionally a purchase order is required outside of the normal ERP purchasing, most often from the Engineering Department. An email request is sent to purchasing with specific details of the requested item(s). Typically, the department manager is copied on the email for notification purposes. All Department managers may authorize requisitions for material, other than raw material for production, up to a value of $1,000. Requisitions for amounts greater than $1,000 must be approved by a second Department manager, a partner in the Company or the President.

Upon receipt of an email request Purchasing processes the requests and creates a purchase order. A copy of the purchase order will be available upon request. If it is necessary to change the purchase order the Purchasing Department must be informed immediately. This includes, but is not exclusive to, any changes to the vendor, quantities, goods or price.

2.2.2 Order Action Requests

The MRP system, a component of Product Resources' ERP system, requests the purchase order from Purchasing.

2.2.3 Planner Workbench Requests

The MRP system, a component of Product Resources' ERP system, requests the purchase order from Purchasing.

2.3 All purchase orders are entered into the ERP system via the Vendor module.

2.4 Upon entering a PO, it is Purchasing's responsibility (except where noted differently) to assess the item's need for QA incoming inspection using these rules: An item is setup for QA incoming inspection when the item is a custom item (built to Product Resources spec.) and if any of the following conditions are true:

- It is the first purchase of the item.
- The revision of the item has changed since the last purchase. (QA, upon releasing, and distributing an ECN containing changes to a custom, purchased item, takes the opportunity at that time to set up the item for QA incoming inspection.)
- The revision of the item has changed since the last purchase. (It is recommended that Purchasing, upon receiving ECN notification of changes to a custom, purchased item, take the opportunity at that time to set up the item for QA incoming inspection.)
- We will be purchasing the item from a new supplier.
- The supplier's current rating is Probation - Quality (P-Q).
- It is an ATEX_CRITICAL or MD_CRITICAL item. (Such items always go to QA incoming inspection, regardless of any of the above statuses.)

If true, then Purchasing must set up the ERP system to indicate QA incoming inspection for the item by taking the following action: In the Item Stockroom Locations, the location named INC_INSP (Incoming Insp.) must be present and set to Rank 1. Doing so will provide instruction for Receiving to forward the item to the QC area to receive a detailed incoming inspection. A statement for the

reasoning an item is being placed in Incoming Inspection shall be documented in the "Incoming Inspection" note (create a new note if none exists), under the item.

2.5 If required, purchase orders are printed. Approval of a purchase order is signified by the order status being changed to "Ordered" from "Planned" within the ERP system. The computer system has security features to limit access to the Vendor module. If a purchase order is printed, the purchasing agent's signature on the purchase order form also signifies purchase order approval.

## 3.0 Transmittal of Purchase Order Information to Suppliers

The purchase order communicates the part number ordered and the revision, if applicable. It communicates the due date, which is the date that the part is to arrive on Product Resources' dock, if not earlier within the window given in the Supplier Guidelines Manual. Every PO makes reference to the Supplier Guidelines Manual, 43-2248.

For items with specification documentation (such as purchase specifications, detail drawings, bills of material, procedures, etc.), that documentation at its current revision is sent with the PO. The Quality requirements are contained in this documentation. For catalog, off-the-shelf items, the manufacturer and manufacturer's part number is contained on the PO instead to define the part ordered.

For items with a routing, the routing at its current revision is forwarded with the PO along with any additional documentation referred to by the routing.

Purchasing may choose to not re-send the documentation for a new order when the supplier has produced the item before and the revision has not changed. (Suppliers may request current documentation at any time.)

POs and documentation are transmitted to suppliers by e-mail (preferred) or fax or by mail if needed.

Suppliers are required to confirm PO's and to resolve differences with Purchasing if the PO cannot be confirmed as-is.

Purchasing shall ensure that complete and current-revision documentation is issued to suppliers for quotations and purchases.

Purchasing shall supply suppliers with updated documentation upon an ECN when there are open POs impacted by the ECN. The impact to open POs is dependent on the Class and Disposition stated on the ECN. Purchasing shall update the revisions of parts on open POs impacted by an ECN. Changed POs shall be re-forwarded to the supplier.

## 4.0 Regulated Items / Regulated Product

There is a field in the ERP system, in Items, called Family Code. When this field states a Family Code with one of these suffixes – ATEX (for products regulated under the ATEX Directive, intrinsically safe, or IS, products) or MD (for products regulated under the Medical Device Directive, medical devices) – the part belongs to a regulated product. Under no circumstances for such a part may Purchasing permit the supplier to provide a part in any way changed from the part as documented. If the Family Code is GEN, this means that the part is used in more than one family of products; in this case the ERP system's Where Used report or equivalent must be used when it is needed to determine if at least one of the part's uses is in a regulated product.

If a change to an ATEX or a MD part must be pursued, Purchasing must first consult with Engineering or Quality Assurance. Engineering and Quality will follow the change control procedure for regulated items outlined in 90-2000-7.3.7.

Critical items used in ATEX-Directive-regulated product or Medical-Device-Directive-regulated product may be purchased. Where such items cannot or will not be 100% verified for their critical characteristics upon receipt, additional requirements shall be placed on the supplier. These additional requirements are described in the Supplier Guidelines Manual, which is in turn referenced on every PO.

It shall be the responsibility of Quality Assurance to determine in the planning stages what these items are and to add a suffix to their part numbers. The suffix is ATEX_CRITICAL for product regulated under the ATEX Directive and MD_CRITICAL for product regulated under the Medical Device Directive. The Supplier Guidelines Manual describes to suppliers these ATEX_CRITICAL and MD_CRITICAL suffixes, what these Directives are, and what the additional requirements are. See also the Supplier Guidelines Manual. Purchasing should communicate this distinction when requesting a quotation or placing an order for such items.

It shall also be the responsibility of Quality Assurance to construct purchase specifications for such items that outlines the additional information or materials that must be provided with product shipment so

that Quality Assurance can verify conformance. Quality Assurance will consult the product's listing report and/or type certificate and/or factory audit manual (the terminology differs by regulatory body) and the ISO 80079-34 (for ATEX Directive) or ISO 13485 (for Medical Device Directive) standards to determine the requirements.

## 5.0 Documentation and Records

Purchasing documents are electronically retained as important records. The storage location and retention period are specified in procedure 90-2000-4.2.4, Control of Records.