1.0 Purpose of Procedure

This document describes Product Resources' Purchasing process. It provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The scope of this process to describe the process for requesting and purchasing material and/or services for use on Product Resources' products or for outsourced services that impact the QMS.

3.0 Process Owner(s)

3.1 Manufacturing Manager

3.2 Purchasing

4.0 Procedure

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

Outsourced services that impact the QMS are also to be purchased by the Purchasing Department. Examples of such services are key software that supports the QMS (see also 91-9001, "QMS Software"), calibration services, engineering design/development consultants and consulting companies, regulatory bodies and regulatory test labs, and so on. Such outsourced services require the completion of the Service Provider Questionnaire, 80-3010, in advance of or in parallel with the request when this supplier is being used for the first time. The requesting party is responsible for completion, and Purchasing is responsible for requesting it if not already completed.

Purchasing has the authority to issue purchase orders in response to any of the request types mentioned below.

A purchase order for materials and/or services may be requested by any of the following processes.

4.1.1 Purchase Requisitions outside of the ERP System

Occasionally, a purchase order is required outside of normal ERP purchasing. 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.

4.1.2 Purchase Requisitions within the ERP System

Order Action Requests

The MRP function of the Product Resources ERP system, requests the purchase order from Purchasing

Planner Workbench Requests

The MRP function of the Product Resources ERP system, requests the purchase order from Purchasing.

Project Module Requests

Typically, when Engineering is executing a project, they will request items via the projects module in the ERP system. Items can be entered one at a time under the project, as a resource for that project. Items are either requisitioned, meaning the item does not have a Product Resources part number, or requested from inventory, meaning there exists a Product Resources part number. Requisitions will be seen by Purchasing by periodic review of Requisitions, and inventory will be seen as MRP output as above. For a more detailed procedure on how to request items via the projects Module in the ERP system, reference 43-4757, Procedure, Requisitions via the Projects Module.

4.2 All purchase orders are entered into the ERP system via the Vendor Module. 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 it is a material, custom item (built to Product Resources' spec) and if any of the following conditions are true:

4.2.1 It is the first purchase of the item.

4.2.2 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.)

4.2.3 We will be purchasing the item from a new supplier.

4.2.4 The supplier's current rating is Probation - Quality (P-Q).

4.2.5 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. **Note:** Unless otherwise noted, an item that was placed in

incoming inspection due to a quality issue, new supplier, or new revision, the Incoming status may be removed at QA's discretion once a comfortable level of conformity has been established with the item and supplier.

If required, purchase orders are printed. Confirmation 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.

4.3 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.

There are occasions where there can be a manufacturer and manufacturer part number, but a document could also exist. Examples of this could be, a customer created a document describing a mfg and mfg #, or a supplier could create a mfg p/n based on our documentation. In this case the document shall be chosen as the governing factor and this is what should be issued to the supplier.

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.)

PO's 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.

4.4 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 explosive atmospheres products) or MD (for 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.

Critical items used in explosive atmospheres product or medical device 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 in turn is 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 explosive atmospheres product and MD_CRITICAL for medical devices. The Supplier Guidelines Manual describes to suppliers of these ATEX_CRITICAL and MD_CRITICAL suffixes what is meant by these suffixes 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 explosive atmospheres prioduct) or ISO 13485 (for medical devices) standards to determine the requirements.

5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.