1.0 Purpose of Procedure

This document describes Product Resources' process for shipping a customer order, including CoC preparation, shipping inspection, and outgoing inspection steps that precede customer order shipping. It provides for a procedure and assigns responsibilities. It is to ensure that products arrive to the customer location with the correct documentation, with the correct contents, and in the expected quantity. It is further to ensure the quality of the product and specification compliance and that Device History Records (DHRs) as applicable have been recorded.

2.0 Scope of Process

All customer order shipments of items that utilize Product Resources part numbers are in the scope of this process. Service shipments which utilize C/O items are not in the scope of this process with the exception of make-as-new items.

3.0 Process Owner(s)

3.1 Manufacturing Manager

3.2 Shipping

3.3 Stockroom

3.4 Quality

4.0 Procedure

4.1 Shipping Department: Shipping Documentation Preparation

The following are the minimum shipping inspection requirements for standard product. The shipper is responsible for the following:

- **Preparation of the packing slip**. (Note: When a Certificate of Compliance (CoC) is required in advance of the actual shipment a pre- ship packing slip may be used to fulfill the requirement of this procedure.)

- **Preparation of a CoC using the ERP system** (automated during the shipping routine) **OR**

- **Preparation of a CoC using form 80-2012** as a backup if ERP system is unavailable or unusable in any way. When using form 80-2012, there are multiple versions of the CoC from which to select; each version is on its own tab, and each tab is named to describe its contents.

  In the scenario in which Quality is going to conduct an outgoing inspection, use the QC Inspection CoC, otherwise use the Standard CoC. Finally, there may be versions present in 80-2012 for specific products; when shipping one of those products, use the corresponding version of the CoC.

In all cases that form 80-2012 is used, a second inspector is required to review all aspects of the CoC and the shipment for completeness and correctness. The second inspector shall inspect and confirm the information on the CoC and the packing slip and the product/packaging label.

Note – Identifying information should be clearly marked on the shipping documentation (packing slip, CoC and shipping label) and should be inspected for uniformity and conformity with the physical product. The following are examples of acceptable information; product description, product quantity,customer purchase order, customer part number, Product Resources part number, Product Resources revision, and ERP item revision, shipping date (within 2 days), customer revision,serial numbers on the product, lot number on the product (and in compliance with customer requirements)

Note – Quality or the Manufacturing Manager may have included additional information that appears on the CoC via the item's CoC Notes field, especially for Explosive Atmospheres or Medical Device product, to state more details about the item's compliance or to note any discrepancies between / exceptions to the content of the shipment as compared to the current specification that may have been permitted by the customer beforehand, in the form of a PD (Product Deviation and Change Request, 80-3205) or otherwise. Quality or the Manufacturing Manager may also use the CoC Notes field to pass any special instructions along to the shipper, typically related to additional materials to bundle with the CoC.

- **Collection of all other test or packing data** required as identified on the routing for forwarding with the product shipment.

When all the applicable requirements outlined above are met, the shipper authorizes shipment of product by signing the standard CoC (ERP generated), or the QC Inspector authorizes shipment of product by signing form 80-2012. If Quality is to inspect the shipment (see below), the QC Inspector signature space (standard CoC) or the Quality signature space (form 80-2012, versions of for QC inspection for specific products) is left open for QC to sign.

4.2 Quality Department: Outgoing Inspections

Quality may elect to perform outgoing inspection activities on any single product or on a group of products. This election may be based on the compliance history of product, the complexity of the product, or contractual/customer requirements. QC will always perform outgoing inspection on Explosive Atmosphere and Medical Device product and on product for which the CoC states deviations in the form of PDs or otherwise. Finally, all newly created products or significantly changed products are to be set by Engineering to receive an outgoing inspection.

Quality, or Engineering in concert with Quality, identifies the products that are required to have an outgoing inspection in one of two ways with the method chosen based on how to best have access to the scope of the outgoing inspection, including whether or not sampling will be used. Method 1: An Inspct operation is inserted into the product's routing. This will cause the product to be passed to QC when that operation becomes the next operation to complete. (Routing and job operations are covered in full in 91-4001, Manufacture, Inspection, and Test of Material and Product.) This method, when placed ahead of a packaging operation, gives maximum product access. Method 2: The first stockroom location of the product is set to OUT_INSP (Outgoing Inspection). This will cause the finished product to be received to Outgoing, physically in the QC area or otherwise product clearly marled as to its Outgoing status if space or mobility does not

permit, instead of to Stock. This method may involve a packaged product for QC. The pros and cons of each method relative to the needed scope of inspection are to be considered. There are select cases where both Methods 1 and 2 will be combined if needed to permit control.

If Quality, the Manufacturing Manager, or Engineering has added CoC notes to a product's item record describing exceptions or discrepancies to the current specification in the form of PDs of otherwise, this party is to ensure that one of the two above methods of sending a product for an outgoing inspection is in place so that QC may assess the product against these notes before product ships.

Quality's outgoing inspection can be 100% or using sampling at Quality's or the QC inspector's discretion; Medical Device and Explosive Atmospheres product will always be 100%. The following aspects are examined by / steps are performed by the QC inspector:

- Perform specifically given procedures or instructions, using specifically given forms where applicable. In the case of Method 1 (refer above), these are given by notes to the operation and/or by including inspection procedure and form references in the operation. In the case of Method 2, these outgoing inspection instructions are given in item Outgoing-titled notes.
- Comparing what has been presented with either the customer purchase spec, or if a customer purchase spec does not exist or is not descriptive, our own routing and/or product spec.
- Visual inspection for workmanship and cleanliness.
- Is the quantity what is expected.
- Review of product ID and traceability information such as serial and lot numbers -- do they agree with DHR records and are they consistent across all physical items.
- DHR records (includes test records): Are they present and complete when called for; do they reflect passing product; complete any Quality approval lines.

If a product-specific form to record the outgoing inspection does not exist, 80-1099, General Outgoing Inspection Form, is used. In all cases, records created in outgoing inspection are deposited in the product's DHR folder.

On a passing outgoing inspection, QC takes the following actions depending on where in the overall process the outgoing inspection was placed. If Method 1 was used, QC indicates completion of the inspection operation by signing/initialing and dating the job operation time sheet. QC then passes the product to the next operation. If Method 2 was used, QC moves the accepted quantity and specific serial numbers where applicable from OUT_INSP to STOCK, making the product available to ship and creating a record in the ERP system. In either case and where applicable, QC will sign the CoC upon a passing inspection when the CoC is presented by Shipping.

Upon a failed inspection, QC causes the nonconforming aspect to be corrected and a passing status achieved if handled inline with the outgoing inspection. Otherwise QC handles the product according to the Control of Nonconforming Material procedure 91-4002, identify the status with a reject tag. Upon a failed outgoing inspection, Quality initiates a corrective action request at its discretion.

Upon a successful outgoing inspection without nonconformances to be corrected, Quality where there is discretion may elect to not perform outgoing inspection on the product going forward. This discretion is available when the product is not Medical Device or Explosive Atmospheres, where there are not contractual obligations, and where there is

not direct QC involvement in the completion of DHR records. If in doubt, consult the Quality Assurance Manager.

4.3 Shipping Department: Finished Goods and Order Shipping

The Shipping Department is not permitted to ship product from the OUT_INSP location. This will require the Shipping Department to hold these products until QC has completed an outgoing inspection with passing results and until QC has moved these products from the OUT_INSP location to the STOCK (Main Stockroom) location.

The Stockroom and Shipping are responsible for identifying products that require an outgoing inspection by QC by watching for the stockroom location. Shipping alerts QC when products requiring outgoing inspection are ready to ship and all other shipping procedures are complete.

After all inspections, products may be shipped immediately or may be stored in the stockroom. Refer to procedure 43-4641(Shipping from the ERP System) for detailed instruction on determing when product should be shipped and how to make a shipment from the ERP system. Products are packaged immediately following the final inspection (unless no packaging is specified). Adequate storage conditions and specified packaging protect the products against damage at those stages. Nonetheless, shipping personnel are instructed to watch for any damaged products before packaging and report such to a QC inspector.

Finished products shall be packaged to ensure cleanliness, preservation, and protection and labeled for delivery or for subsequent storage by qualified personnel. Appropriate materials and equipment necessary for shipping to perform its function shall be available in the shipping department.

Packaging material and packaging are normally specified by Engineering. The specifications are communicated to the shipping personnel through the bill of materials. Use of alternative packaging materials and methods must be authorized by Engineering. If packaging material and packaging are not specified by Engineering, standard packaging practices are followed when shipping products. Reference Procedure 43-2625.

Material and/or manufactured products must be packaged and transported in such a way to protect their cosmetic and functional integrity. Packaging materials and design must be suitable for the intended means of delivery. No mode of transportation or method of packaging shall be used when it could jeopardize the quality of the product. When delivery is required by contract, the company will guarantee the safety of the product through shipping to the destination.

5.0 Control of Records

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