1.0 Policy

Product Resources shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at the appropriate stages of the product realization process in accordance with the planned arrangements (see 90-2000-7.1, Planning of Product Realization).

Evidence of conformity with the acceptance criteria shall be maintained; see 90-2000-4.2.4, Control of Records. Records shall indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until the planned arrangements (see 90-2000-7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

2.0 Responsibilities

Unless stated otherwise in the manufacturing routing, Production is responsible for in-process testing and inspections, and the Test Department is responsible for final testing. Shipping and Quality Assurance are responsible for Outgoing Inspections.

3.0 In-Process Inspection and Testing

3.1 Purpose

To provide for a system and instructions, and to assign responsibilities for performing in-process inspections.

3.2. Application and Responsibilities

All in-process inspections are specified on the job operation listing accompanying the product during its manufacturing phases. Inspections are often performed by the assembler (self-inspection). However, for complex or critical inspections, the Test Department

may be called on to carry out the inspections, which would be indicated on the job operation listing.

3.3 Carrying Out the Inspection

The purpose of in-process inspections is to verify that an operation or a process was performed satisfactorily and a product can pass to the next processing stage. An in-process inspection also includes a general visual check of all previous operations.

If an in-process inspection/test requires the use of measuring or testing equipment, the inspectors are provided with, and are instructed in the use of, controlled and calibrated equipment suitable for carrying out the inspection. For more complex inspections, personnel are also provided with written instructions – a procedure – explaining how to carry out the inspections and stating the acceptance criteria.

3.4 Record

Record of the in-process inspections is made according to instructions in the manufacturing documentation. For handwritten data, all corrections shall be made by crossing out the incorrect data with a single line, writing in the correct data, and signing/dating the entry.

3.5 Nonconforming Products

If a nonconforming product is identified, reference Control of Nonconforming Product 90-2000-8.3.

4.0 Final Inspection and Testing

4.1 Purpose

To provide for a system and instructions, and to assign responsibilities for performing and recording the final inspection.

4.2 Application and Responsibility

Most of the company's products, upon their completion, are subjected to a final test/inspection. (All of the company's products are subjected to a First Piece Visual Inspection. See 90-2000-7.5.1, Control of Production and Service.) The test/inspection is

specified in the manufacturing documentation and is carried out by the Test Department.

All products controlled under the ATEX Directive or the Medical Device Directive upon their completion are subjected to a final test/inspection.

4.3 Carrying Out the Inspection

The scope of the final inspection is determined by Engineering in cooperation with QA, and is communicated to the Test Department by written procedures. As a minimum, the scope comprises:

- Review of the job order to ascertain that all First Piece Visual Inspections are signed off;
- Visual inspection of the product to ascertain that all specified operations are complete and to detect any visible quality problems;
- Taking measurements and testing as required; and
- Recording the actual measurements (when required) and test results.

If a final inspection/test requires the use of measuring or testing equipment, the inspectors are provided with, and are instructed in the use of, controlled and calibrated equipment suitable for carrying out the inspection. For more complex inspections, personnel are also provided with written instructions – a procedure – explaining how to carry out the inspections and stating the acceptance criteria.

If a product passes all the reviews, inspections, and testing, it is processed according to the manufacturing documentation. For example, a TESTED sticker is affixed to the product or a test checklist is signed off at this time to signify that the product has been tested. A TESTED PRODUCT tag may be created in place of a TESTED sticker when necessary (i.e., use of a sticker is forbidden by contract, a sticker will not fit, etc.) to signify that a product has been tested. A sticker or plate displaying a product's serial number is also affixed to the product at this stage if required. The product is then received into the stockroom.

4.4 Record

To establish a final inspection record, the inspector signs (or initials) and dates the job order time sheet 80-2030 in the appropriate space. The job order together with other product Quality records, such as documents established during various tests/inspections, are preserved. Their storage locations are specified in 90-2000-4.2.4, Control of Records.

For medical devices, the Device History Record, or DHR, is completed. See 90-2000-7.5.3, Identification and Traceability, for more information about the DHR. Quality Assurance reviews and signs/releases DHRs.

For handwritten data, all corrections shall be made by crossing out the incorrect data with a single line, writing in the correct data, and signing/dating the entry.

4.5 Nonconforming Products

If a nonconforming product is identified or quality documents are incomplete, the Test Department labels the product with a REJECTED tag that states the problem. The product is then segregated. Further processing of the product is explained in 90-2000-8.3, Control of Nonconforming Product.

5.0 Outgoing Inspection

5.1 Purpose

To ensure that Product Resources products arrive at the customer's location with the correct documentation, contents, and quantity, this procedure will detail the outgoing inspection requirements for Product Resources products.

5.2 Applicability

All Product Resources shipments that utilize the Product Resources part numbering system are subject to this procedure. Items with a prefix of C/O are not subject to this procedure unless they are "make as new" items; see Service Returns in 90-2000-7.5.1 for more details about the Service process including make as new. QA, at its discretion, may augment the requirements of this

procedure at any time to audit the effectiveness of the Quality system.

5.3 Policy

All known exceptions to the customer or Product Resources specification or to regulatory reports must be stated on the C of C. The Manufacturing and QA Managers are jointly responsible for implementing this policy. All shipments with exceptions must receive a QA outgoing inspection, and QA must sign its C of C, authorizing the shipment. The customer shall be made aware of the exceptions prior to making the shipment.

5.4 Shipping Department

The following are the minimum shipping inspection requirements for standard product:

5.4.1 The shipper is responsible for the following:

- Preparation of the packing slip. (Note: When a C of C 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 Certificate of Compliance (C of C) using the C of C generator from the Order Shipping screen in the ERP system or using form 80-2012 as a backup if the C of C from the ERP system is unavailable or unusable in any way. When using form 80-2012, there are multiple versions of the C of C 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 QA is going to conduct an outgoing inspection, use the QA Inspection C of C, otherwise use the Standard C of C. Finally, there are versions present in 80-2012 for specific products; when shipping one of those products, use the corresponding version of the C of C.

- Note that QA or the Manufacturing Manager may have augmented the text that appears on the C of C via the item's C of C Notes field, especially for product regulated under the ATEX Directive or the Medical Device Directive 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. QA or the Manufacturing Manager may also use the C of C Notes field to pass any special instructions along to the shipper, typically related to additional materials to bundle with the C of C.

- Preparation of the final package per 90-2000-7.5.5.

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

5.4.2 In all cases that the Certificate of Compliance (C of C) was not generated directly from the ERP system but was created instead on form 80-2012, a second person – the inspector – is required to review all aspects of the C of C and the shipment for completeness and correctness. The second person shall inspect and verify the following:

- Confirm that the product description on the C of C and, when available, on the product agree with the packing slip.

- Confirm that the customer purchase order on the C of C agrees with the packing slip.

- Confirm that the customer part number on the C of C and, when available, on the product agree with the packing slip.

- Confirm that the Product Resources part number on the C of C and, when available, on the product agree with the packing slip.

- Confirm that the shipping date on the C of C falls within a window of the packing slip date plus two business days.

- Confirm that the customer revision on the C of C and, when available, on the product agree with the packing slip.

- Confirm that the serial numbers on the C of C match the serial numbers on product.
- Confirm that the quantity on the C of C and in the shipment agree with the packing slip.
- Confirm that the lot number on the C of C matches the lot number on product. Ensure that the lot number, if any, is in compliance with the following customer requirements:

Customer	**Procedure**
No special customer lot number requirements at this time	*No special customer lot number procedure at this time*

- Confirm that the Product Resources revision on the C of C and, when available, on the product agree with the Product Resources revision in the ERP system.

When all the requirements of 5.4.1 and 5.4.2, when applicable, are met, the shipper shall authorize shipment of product by signing the C of C as the QC Inspector for the ERP-generated C of C case, or the inspector shall authorize shipment of product by signing form 80-2012 as the QC Inspector. If QA is to inspect the shipment (see below), the QC Inspector signature space (ERP-generated C of C) or the Quality Assurance signature space (form 80-2012, versions of for QA inspection for specific products) is left open for QA to sign.

5.5 Quality Assurance Department

QA 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, based on the product being one controlled by the ATEX Directive or the Medical Device Directive (these always receive a QA outgoing inspection), based on the complexity of the product, or based on contractual/customer requirement.

QA shall always perform outgoing inspection on product regulated under the ATEX Directive or the Medical Device Directive and on product for which the C of C states exceptions or discrepancies.

QA shall identify the products that are required to have a QA outgoing inspection by setting the first stockroom location of those products to OUT_INSP (Outgoing Inspection). If it is the Manufacturing Manager who has added C of C Notes related to exceptions or discrepancies to the current specification, the Manufacturing Manager shall simultaneously set the first stockroom location for the product to OUT_INSP.

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 QA has completed an outgoing inspection with passing results and until QA has moved these products from the OUT_INSP location to the STOCK (Main Stockroom) location from which Shipping ships.

Shipping personnel are responsible for identifying products that require an outgoing inspection by QA by watching for the stockroom location.

Shipping alerts QA when products requiring QA outgoing inspection are ready to ship and all other shipping procedures are complete. QA's inspection consists of a review of the verifications described in 5.4.2, a comparison of the product to be shipped with the current customer specification when one exists (or the current Product Resources specification when one does not), and a general workmanship/visual check. Finally, if data is to ship with product, QA's inspection consists of a review of that data.

Some products, particularly those controlled under the ATEX or Medical Device Directives, have specific QA outgoing inspection procedures. When so, QA shall follow the procedure and shall complete any accompanying form.

QA signs the C of C upon a successful inspection and moves the product quantity from the OUT_INSP and to the STOCK location, authorizing shipment of the product. Upon a failed inspection, QA initiates a corrective action request at its discretion, notifies the responsible individuals, and causes the problem to be corrected prior to signing the C of C and permitting shipment.

5.6 Record

A copy of the C of C is to be electronically stored on the company file server in the following directory: Manufacturing\Shipping\C of C\Archives [current year]. The retention period for this document shall be in compliance with 90-20000-4.2.4. The file name will consist of the Product Resources part number followed by the sales order number, the ship date (mmddyy), and then the file extension (examples: 41-2501 10S185 072010.pdf, 99-1001 10S272 072010.xls).