1.0 Purpose

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for performing and recording the receiving and incoming QA inspections and receipt of purchased products from suppliers.

2.0 Responsibilities

Receiving under Manufacturing control is responsible for receiving activities and inspections. QA is responsible for detailed incoming inspections.

3.0 Policy

Purchased product is inspected to verify compliance to specifications and proper fulfillment of purchase orders.

4.0 Application

4.1 All materials, components, and other supplies received that are to be incorporated into the company's products (i.e., have a Product Resources part number) shall be subject to a receiving inspection. The received goods shall be inspected by Receiving in terms of completeness, handling/transit damage, and proper and complete documentation. The received goods shall be identified and inspected visually.

4.2 Parts that have been sent out for special processing shall be inspected, when returned, only for the processing performed and handling/transit damage. Materials that have been source inspected, upon receipt, shall be examined only for handling/transit damage. The completeness and correctness of the accompanying documentation (such as certificates and test reports) shall be reviewed in all cases. All parts built to Product Resources' specifications, under revision control as a "-" or letter revision, shall be accompanied by a certificate of compliance.

4.3 See 90-2000-7.4.2, Purchasing Information, for the criteria for items placed in QA incoming inspection. In addition, individual items regardless

of the criteria described in 90-2000-7.4.2 shall be subjected to QA incoming inspection activities due to a poor past history of compliance, due to a customer requirement, due to the critical nature of a part, or due to the part being a regulated item for which the compliance cannot be verified after manufacture. In this case of an item being singled out for QA incoming inspection, QA or Engineering shall place a note in the item record* giving incoming inspection instructions and shall ensure that for the item's Item Stockroom Locations record that INC_INSP (Incoming Insp.) is present and set as Rank 1. This instructs Receiving personnel to direct product to the QC inspection area rather than directly to the stockroom or to a work cell. Refer also to procedure 43-1355, Additional Receiving Inspection Procedure.

*If an item's record contains a note stating the need for an inspection, the INC_INSP Rank 1 status SHALL NOT be removed from the item. Always check for this.

4.4 Product Resources permits the pre-release of materials only when it is controlled by the method described in this paragraph and when initiated by authorized employees. Authorized employees are department managers and supervisors. If the pre-release of materials is required to meet urgent manufacturing needs, the process is initiated by completing the Material Pre-Release Form 80-2025. The initiator will record the part number taken, the quantity, and the job number that is using it. The initiator's name and the date will be recorded, and the initiator shall be responsible for the material taken. The Material Pre-Release Form is a two-part form. The original white copy is left with QA. The second yellow copy remains with the job using the pre-released material. Manufacturing must be able to identify the pre-released parts. To facilitate this, the Material Pre-Release Form contains areas to write in the serial numbers or lot of the parts as well as the serial numbers or lot of the assembly receiving these parts, and all to be filled out when and where applicable to assist in identification. Segregation of items may be necessary if lot and serial numbers are not available to perform this function. Release of the material continues by QA in parallel with Manufacturing. QA must have signed a release on the Material Pre-Release Form as a condition of the item being received into stock. In this way no product shall be shipped before its parts are released. QA will file the form with the inspection report. Manufacturing will file the form with the job.

5.0 Reference

Receiving Procedure (43-4503)
Additional Receiving Inspection Procedure (43-1355)

6.0 Associated Materials

Receiving Tag (80-1001)
Material Pre-Release Form (80-2025)

7.0 Receiving and Carrying Out the Receiving Inspection

7.1 The receiving clerk checks identification of the received goods. Upon unloading of deliveries, the receiving clerk checks marking and identification of packages and inspects all packages for any signs of tampering or damage. If all the checks and inspections are satisfactory, he or she signs the delivery receipt. If not, any shortages or damages shall be noted on all copies of the delivery receipt.

7.2 All packages are stamped with the date of receipt. This includes the month, day, and year. Packages not yet received shall be kept separate from packages already received.

7.3 Next, the received packages shall be staged to be received in the manufacturing computer system, and the packing slips shall be removed from the packages. Upon opening the packages, the goods shall be counted, their part numbers shall be verified, and the goods shall be examined visually for any signs of damage or visible Quality problems. Any documentation delivered with the product (i.e., material certification, certificate of compliance, etc.) shall be reviewed.

7.4 The goods are then received in our manufacturing computer system. See 43-4503, Receiving Procedure, for the details of the receiving process. The packing slip shall be marked RECEIVED along with the receipt date, and it shall be signed or initialed by the clerk. The receipt of an item in our manufacturing computer system provides a record of receiving inspection. Packing slips and Quality documents and Certificates of Compliance received with the products shall be scanned and efiled by Manufacturing.

7.5 The goods shall then be labeled with a Receiving Tag or Syteline generated receiving label (includes the part number, quantity, PO number, and date of receipt) and placed in the appropriate stockroom or sent to QA for additional inspection.

7.6 Packages shall not pass receiving inspection and shall be quarantined if one or more of the following applies:

- Proper documentation is missing. If the Certificate of Compliance is missing the item will be moved to incoming inspection and Purchasing will be notified. The item will be held at incoming until all the documentation is received. A reject tag will be applied, with a notation indicating that the material is waiting for the Certificate of Compliance from the supplier.
- The wrong material is sent and Purchasing is awaiting further instructions, or
- Contents of the package are damaged.

7.7 If a nonconforming product is identified, refer to procedures 90-2000-8.3, Control of Nonconforming Product, and 90-2000-8.5.2, Corrective Action.

8.0 Incoming Inspection by the Customer

It may happen that a customer requests to perform incoming inspection activities on an item used in product being built for the customer. If requested, the customer shall be given the opportunity to do so. However, this shall not release Product Resources from any of its responsibilities; in other words, it is in addition to the processes that must always take place as outlined in this procedure and elsewhere in the Quality Manual.

9.0 Source Inspection

Product Resources may request to perform incoming inspection activities at the supplier's facility, or the supplier may request this of Product Resources. In this case, QA may perform all incoming inspection activities or a portion of them as appropriate at the supplier's facility. Product Resources' performing a source inspection shall not release the supplier from any of its responsibilities.

10.0 Supplier Audit of Product or Process for ATEX_CRITICAL or MD_CRITICAL Product

Product Resources or a contractor to Product Resources may audit the product or process of suppliers providing product used in ATEX or MD (medical devices) product for sale. This would primarily be practiced when the conformance of purchased critical product cannot be verified by inspection.

In addition, regulatory bodies may, at their option, audit such suppliers for product or process. Product Resources shall permit and facilitate such an audit request. Via the Supplier Guidelines Manual (43-2248), suppliers of ATEX_CRITICAL and MD_CRITICAL product have been informed of this, and the Supplier Guidelines Manual is a component of every PO contract.