1.0 Policy

Production Control shall administer the issuance of material and documentation in accordance with planned production. The control of quality in manufacturing shall be accomplished through design, training, documentation, inspection, supervisor control, and employee awareness. Any equipment critical to the quality of PRI's products is regularly checked and maintained. Production areas shall be clean and provide a suitable working environment.

Only qualified personnel using approved procedures shall perform servicing on company products. Product returned by the customer because of field failure shall be evaluated to determine the cause of failure and any corrective action required.

2.0 Responsibility

Production Control is responsible for production scheduling and for ensuring that all required documentation is issued with each job. The Manufacturing Department under the direction of the Manufacturing Manager is responsible for the production environment and production equipment.

The Service Department has responsibility for the servicing, support, and repair of the company's products. The Quality Assurance Department has responsibility for quality data analysis and reports.

3.0 Specific Additional Requirements for Medical Devices

For ISO 13485, to which Product Resources' Quality system applies when handling medical devices, there are specific requirements for cleanliness of product, for installation activities, and for sterile devices.

For cleanliness, all requirements are product specific and shall be documented on the product's manufacturing routing. This shall be accomplished via the design and development outputs procedure 90-2000-7.3.3 and controlled via the medical device RTM procedure that it calls for, 43-4521.

Installation is excluded from Product Resources' scope for medical devices / for ISO 13485; see 90-2000-4.1. Should installation be included in the future, the Quality Manual shall be amended with specific policies, procedures, and responsibilities to govern the installation process.

Sterility is excluded from Product Resources' scope for medical devices / for ISO 13485; see 90-2000-4.1. Should sterility be included in the future, the Quality Manual shall be amended with specific policies, procedures, and responsibilities to govern the sterilization of devices and the handling of devices that have been sterilized.

MANUFACTURING DOCUMENTATION AND THE MANUFACTURING CYCLE

1.0 Purpose

This procedure describes the manufacturing cycle, including the establishment, use and responsibility for the documentation controlling the manufacturing process.

2.0 Job Order and Manufacturing Cycle

2.1 Every order to manufacture a product is transmitted to Production using a either a job order for batch builds, or a production schedule for cell builds.

With batch manufacturing, the job order is identified by a job order number and accompanies the product through all production phases. Production Control establishes a job order based on either a sales order or a manufacturing order to stock. The job order package is based on the product's routing and consists of the job header, the job order traveler, the job pick list, the job order time sheet, and the bill of materials. All manufacturing documentation referenced by the routing (assembly drawings, test procedures, etc.) is added by Document Control. This package is then released by Production Control to the Stockroom. The job order package and all materials for the job are then issued by the Stockroom, per procedure 43-2141, to production as the kit.

With cell manufacturing, there is no job order or job order package, but rather a production schedule, which is set up by Production Control in the manufacturing computer system. All documentation is kept within the cell, and maintained by Document Control. All material and routings required for cell manufacturing are also kept within the cell.

2.2 Listed on the job order header are product and scheduling information. The PRI assembly number and a description of the product to be built provide a reference to the routing. The product revision level provides product traceablility. The date ordered and date issued provide job traceability. The quantity released, quantity completed, start date, and end date provide records of production scheduling.

Cell manufactured items are built per the shipping dispatch, which gives a record of the quantity and date to be shipped.

2.3 Based on the job order documentation package, the product is assembled, tested, and inspected. The job order time sheet form (80-2030) contains a record of assembly, testing, inspection, and first piece visual inspection.

Cell builds do not require a job order time sheet, as they are set up with standard costing, and all assembly/test times are automatically figured in the operations.

2.4 All measurements instructed to be taken are to be done using calibrated instruments. An instrument's calibration status will be evident by its dated calibration sticker. See procedure 90-2000-7.6 for more details on the calibration program.

2.5 When the job order is completed, the product is received back into the stockroom. When accepted by the stockroom, the job is closed per procedure 43-2140.

When material from a cell is completed, the quantity completed is entered into the production schedule by Production Control, and all raw material is then backflushed from the system upon completion of final product.

2.6 After a product is completed, its job order is retained as an important record. The storage location and retention period are specified in procedure 90-2000-4.2.4 Control of Records.

Production schedules are kept within the manufacturing system as record of completion.

2.7 See procedure 90-2000-7.5.5 for how PRI conducts delivery activities for finished product.

3.0 Manufacturing Routing and Documentation

3.1 The routing defines all production operations, materials, and documents that are required for assembly, inspection, and testing of the product. Work instructions may be listed directly on the routing, or documents may be referenced on the routing as assembly drawings, test procedures, test/pack checklists, special manufacturing instructions, or any other technical documents.

3.2 The routing and all documents are normally established by Engineering.

3.3 Copies of the routing and supporting documents are enclosed with the job order through all production phases.

3.4 The routing specifies the Quality plans by referencing appropriate documents; it provides the work, process, and inspection instructions and criteria, and it provides for final inspection and testing records.

ESD PROTECTION

1.0 Purpose

Refer to procedure 43-2621 ESD Protection Procedure for a description of PRI's system for ESD protection.

SERVICE RETURNS

1.0 Purpose

To provide procedures by which servicing and repairs are accomplished.

2.0 Policy

Service jobs are follow the same process as all other manufacturing jobs, but there are some special considerations and provisions for Service jobs, and they are described below.

3.0 Service and Repairs

3.1 Any material being returned by a customer must be accomplished in accordance with Material Return Procedure 43-2133. All service and repair root part numbers are prefixed with “C/O”, which signifies that the product has been returned from the field for service or repair.

3.2 The Service Department is responsible for the verification of material and recording the date received in QT9. Once logged in, the material is segregated.

3.3 The Service Department is responsible for the servicing and repair of the company’s products.
In the absence of specific repair procedures, the product is brought up to the latest functional specification. The latest functional specification is identified by the root part number (XX-XXXX).

3.4 The Service Department in cooperation with the Sales Department and QA determines warranty status. Status of the specific material can be located under its PRI serial number and/or job order number, sales order number, or customer reference number.

3.5 The Service Department records all product failure information in QT9. Quality Assurance is responsible for analyzing the data and making reports.

4.0 Documentation and Record

All product failure data is recorded and saved as quality records. The storage location and retention period for these documents are specified in procedure 90-2000-4.2.4, Control of Records.