1.0 Purpose of Procedure

This document describes Product Resources' routing, requirements for regulated product and device master record processes. It provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The scope of this process is the establishment and explanation of the routing, which provides the plan for product realization, guiding Purchasing, Manufacturing, and Service in its activities. It further gives additional conventions for regulated product as well as explains Product Resources' process for Device Master Records for medical devices.

3.0 Process Owner(s)

3.1 Engineering

3.2 QA Manager

4.0 Procedure

4.1 Purchase Orders and production jobs are made based on established manufacturing routings and item definitions. Both are normally designed by Engineering.

A routing is similar to a BOM (bill of materials) but contains more information than a BOM would, as follows: A routing is broken down into operations, for instance, assembly and test operations, or special operations, for instance, burn-in, cleaning, encapsulation, etc. The operation is where the activity is to take place, i.e., in what department or in what area. The sequence of operations is significant; the operations are completed in order from low operation number to high operation number. They will be listed this way in production jobs.

Within operations there will be part numbers and quantities for materials used in the operation. There will also be assembly drawing and procedure (such as assembly, work instruction, test, etc.) numbers that permit access to the given document. Additional reference documents may be included on the routing (such as a schematic). This will include Quality plans such as test plans (including acceptance criteria), record-keeping plans, forms and checklists, configuration sheets, etc. There may be text notes that go with either the entire operation or with a particular part inside of an operation. This includes item number references or "bubbles" to match parts in the routing to their depiction in an assembly drawing, or reference designators to indicate where a part is placed in a circuit board assembly. Finally, required equipment or tools for the job will be given their own operation and referenced by their part number.

It may take many routings to fully define the product requirements. For instance, a final assembly may be made from many subassemblies, and one of those subassemblies may have its own lower-level subassemblies, and so on.

For any part number entered, where the part number is an assembly and has a manufacturing routing, Product Resources' ERP system is capable of showing that part's current routing on its own, an indented current BOM showing the given part's BOM plus the entire BOM hierarchy below it presented in hierarchal view, and finally a summarized

current BOM showing all parts that make up the assembly presented flat with the hierarchal information stripped out.

All part numbers that represent physical parts and assemblies* are indicated in the ERP system as to their Source, either Manufactured (we make it) or Purchased (we buy it).

*Document-only part numbers have their Source as “Transferred”; they are provided by Document Control.

4.2 Additional Requirements and Information for Regulated Product:

In the planning for product realization phase, it is the QA Manager’s responsibility to assign “ATEX” suffixed family codes for explosive atmospheres product and “MD” suffixed family codes for medical devices.

It is the Manufacturing Manager’s responsibility to ensure that serialization is enabled in the ERP system for finished goods that are explosive atmospheres product or medical devices, finished goods with family codes containing ATEX or MD suffixes.

It is the QA Manager’s responsibility to ensure that explosive atmosphere product or medical device, critical components have been identified and that a collection method – a form – has been created to identify the critical components for technicians and to capture the serial or lot numbers of such components.

It is the QA Manager’s responsibility to ensure that, explosive atmospheres product or medical devices, provision has been made in the routing to yield a final test/configuration record, or Device History Record (DHR). Typically, the requirements of this paragraph and the above paragraph are encapsulated in one form.

Finally, in this planning for product realization phase and for regulated product, it is the QA Manager’s responsibility to ensure that, for product controlled by a regulatory report, all stated requirements of the manufacturer have been fulfilled in the routing and the associated manufacturing documentation.

4.3 Device Master Record

For medical devices, the Device Master Record (DMR) is the full and current set of manufacturing routings that define the product. The Device Master Record will have a revision, and the revision is the routing revision of the product for sale, i.e., the 41-XXXX or 99-XXXX number. The revision of the Device Master Record, the routing revision of the product for sale, shall always be incremented when any physical or functional change is made to product and/or its documentation. Minor, more trivial changes do not require an increment of the DMR, but consideration should always be given when a change is being made to the product. The ERP system’s indented current BOM report shows the current Device Master Record. ECNs written against the product for sale will show changes made to the Device Master Record.

5.0 Control of Records

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