1.0 Purpose

This procedure describes how Product Resources plans for product realization. For this procedure we shall define product realization as the procurement and manufacturing processes (purchasing, assembly, special processes, test and inspection) that yield finished goods for sale and components and assemblies for finished goods for sale. Supporting processes include Customer Related Processes (see 90-2000-7.2.X) and Design and Development (see 90-2000-7.3.X).

2.0 Policy

Product realization and the associated Quality plans are designed for each product and documented on the product's manufacturing routing as described below. The routing shall contain or shall point to all information required to allow product to be purchased, built, calibrated, tested, documented, etc. The documented plans shall be compatible with Product Resources' Quality system.

3.0 Responsibility and Procedure

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).

The processes for Manufactured parts are described in procedures 90-2000-7.5.X (Production and Service Provision) while the processes for Purchased parts are described in 90-2000-7.4.X (Purchasing).

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

3.1 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 product controlled under the ATEX Directive and MD-suffixed family codes for product controlled under the Medical Device Directive, medical devices. See also 90-2000-5.4.2.

It is the Manufacturing Manager's responsibility to ensure that serialization is enabled in the ERP system for finished goods parts controlled under the ATEX Directive or under the Medical Device Directive (medical devices), finished goods with family codes containing ATEX or MD suffixes. See also 90-2000-7.5.3.

It is the QA Manager's responsibility to ensure that, for product controlled under the ATEX or Medical Device Directives (medical devices), 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. See also 90-2000-7.5.3.

It is the QA Manager's responsibility to ensure that, for product controlled under the ATEX or Medical Device Directives (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. See also 90-2000-7.5.3.

For product controlled under the Medical Device Directive (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. Per 90-2000-4.2.3, Control of Documents, and specifically per its Changing Released Documents (ECN) procedure, the revision of the Device Master Record, the routing revision of the product for sale, shall always be incremented when any change is made to product and/or its documentation. 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.

In addition for product controlled under the Medical Device Directive (medical devices), requirements for Risk Management are documented throughout the procedures 90-2000-7.X for Product Realization. Product Resources' Risk Management strategy includes steps that we will take for all medical device product as well as a product-specific component. Steps that we will take for all medical device product are stated throughout the 90-2000-7.X procedures. These are stated as additional requirements or additional policies that apply to medical devices. They are based on risks that apply to all medical device product and for the scope of Product Resources' operations. (See 90-2000-4.1 for Scope and Exclusions.) These additional requirements and policies represent risks that have been pre-mitigated.

The product-specific component for medical device product is that, for each medical device product put into production, Product Resources shall complete a process FMEA, or PFMEA. The PFMEA shall examine failure modes that could occur at all points in the Product Realization processes, including in the processes of Product Resources suppliers for purchased

items and shall assess these failures modes for their severity, for their likelihood of occurring, and for the ability to detect occurrence. For each failure mode, a Risk Priority Number (RPN) is calculated. On a 1000-point scale, RPNs of 200 or greater (by default, or otherwise a threshold RPN number agreed upon between Product Resources and its customer and/or included in a project-specific Quality Plan) shall require mitigation such that the RPN will be lowered to be under 400 post-mitigation. In addition, severity scores of 8 or higher, regardless of the RPN, shall require mitigation.

When there are items in the PFMEA that require mitigation, the PFMEA shall be revisited to record the nature of the mitigations and to recalculate the RPNs. The PFMEA shall also be revisited upon significant change to product or process to determine if the change alters the PFMEA either by introducing new failure modes or by altering existing failure modes' severity, lilelihood of occurrence, and/or detection ability. If so, the process described above is repeated.

The completion of the PFMEA process is indicated in Product Resources' specific RTM procedure for medical devices. See 90-2000-7.3.3 (Design and Development Outputs) as well as medical device RTM procedure 43-4521.

ISO 14971 is available at Product Resources as an external standard and shall serve as guidance for Risk Management for medical device product.

While required for medical devices, a PFMEA may be undertaken for any Product Resources product or service based on a project scope of work or simply to improve a process.

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.

4.0 Related Procedures

See also these procedures related to this topic:

The use of Family Codes to identify product controlled under the ATEX Directive or the Medical Device Directive, medical devices, is discussed in 90-2000-5.4.2, Quality Management System Planning.

Documents are issued to a job by Document Control and are part of the plan by reference in the manufacturing routing. See 90-2000-4.2.3, Control of Documents.

The creation of the routing and those documents referenced by the routing is the Primary Design Output described in procedure 90-2000-7.3.3, Design and Development Outputs. See 43-4477, the Engineering RTM (release to Manufacturing) Procedure. Among other topics related to RTM, this procedure discusses norms for Product Resources routings. See also 43-4521, Procedure/Checklist, Medical Device RTM, for additional RTM requirements related to product controlled under the Medical Device Directive, medical devices.

Procedure 90-2000-7.5.1, Control of Production and Service, describes how the product realization and Quality plan is used in production jobs and how those jobs are controlled.

Procedure 90-2000-7.5.2, Validation of Processes for Production and Service, gives additional requirements when special processes are to be used and also gives a procedure for specifying required production equipment or tools.

Procedure 90-2000-7.5.3, Identification and Traceability, discusses product serialization, critical components, and the creation of serial-number-based final test and configuration records, also known as Device History Records (DHRs) when applied to medical devices.

Procedure 90-2000-8.2.4, Monitoring and Measurement of Product, describes inspection and test steps.