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1.0 Purpose of Procedure

This document defines the processes that Product Resources uses to review product requirements pertaining to quotations and order acceptance.

2.0 Scope of Process

The scope of this procedure is all processes pertaining to product requirements when gathering information for a customer quotation and confirming a customer order.

3.0 Process Owner(s)

3.1 Sales

4.0 Procedure

It is assumed that at this point Product Resources is working to deliver a quote to the customer. Upon completion of this procedure a quote will be delivered to the customer. For a product that has been previously manufactured and sold a quote (Standard Product) may not be necessary and only an order confirmation required; see below.

4.1 Repeat Business (Standard Product)

Upon receiving the customer purchase order to order more of a Standard Product, the following questions must be answered:

- Can the product requested still be provided or has it been marked obsolete? Note that some products marked as obsolete can actually be built if there is a sufficient order size to justify putting the item back in production. Sales is to obtain Manufacturing's approval if continuing the order as a Standard Product for such an item marked obsolete. Otherwise, the Custom Product path must be taken.
- Is the product requested at the same revision level as when Product Resources last built it? If not, the Custom Product path must be taken.
- Is the pricing still valid? If not, the Standard Product may need to be re-quoted.
- Can Product Resources make the quantities and meet the delivery dates? The Material Availability Report in the manufacturing computer system is used for this determination. A record is made of the results of this report. Manufacturing is brought in when there is a discrepancy between the report and the customer request and at any other time at Sales' discretion.

If all is in order, this process ends with the creation of a sales order (customer order) in the ERP system and delivery of an order confirmation to the customer. Otherwise, discrepancies must be resolved or a re-quote must be delivered to the customer. This process may need to be repeated to be able to ultimately create a sales order and deliver an order confirmation.

The work instructions document 43-2333, Order Confirmation, describes in detail the order confirmation process and the verification that must take place before confirming.

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4.2 New Business (Custom Product)

The process of establishing a comprehensive quotation (the output of this section) is still a collaborative effort between Sales/Marketing, Finance, Purchasing, Manufacturing, Quality, and Engineering. However, at this point in the process the overall task can be divided into sub-tasks, and principal contributor or responsible party can be assigned. The overall responsibility for this procedure is assigned to Sales/Marketing.

4.2.1 Input

The input discussed in document 91-1001 carries forward. This includes the initial draft of the Statement of Work, which may be written into the Quote instead of being a standalone document, particularly for projects that are not large. The input also includes copies of all relevant correspondence from the customer.

Sub-Tasks

All sub-tasks will be documented. The sub-tasks include the following:

Development of a Detailed Statement of Work. This sub-task should include information about the following:

Tasks Explicitly Defined by the Customer,
 Tasks Implicitly Defined by the Customer,
 Limitations or Scope (a list of tasks that may or may not have been defined but nonetheless are not included in Product Resources' offer),
 List of Specific Assumptions Made to Create the Statement of Work, Assumption of the Degree of Freedom that Product Resources Has to Modify, Alter, or Create Documentation,
 Regulatory Requirements (especially for product controlled under the Explosive Atmosphere Directive or the Medical Device Directive;

Establishment of Time and Materials Required for Nonrecurring This subtask should include information about the following:

Quality should be consulted in these cases)

- Time and Labor Required to Review Customer Documentation and to Resolve Issues,

 Time and Labor Required to Enter Customer Documentation into the
- Time and Labor Required to Enter Customer Documentation into the ERP and/or the Document Control System,
- Time and Labor Required to Create a Bill of Materials (BOM) and to Enter the Material Descriptions into the ERP System
- Time and Labor Required to Create Routings in the ERP System
- Time and Labor Required to Create Additional Required Documentation Not Supplied by the Customer,
- Time and Labor Required for Design and/or Other Services as Explicitly or Implicitly Requested by the Customer,
- Cost and Availability of Tooling Required by Manufacturing (including the Test Department)

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Establishment of the Cost of Materials and Availability of Materials for the **Product** This sub-task should include information about the following:

J	Expediting Fees
J	Excess Materials
J	List of Pre-Order Materials
J	List of Materials Excluded from the Estimate (The most common
	reason for exclusion is that the materials are customer supplied.)

Establishment of an Estimate of the Labor Required to Produce the Product or Provide the Service.

Establishment of a Reasonable Schedule to Produce the Product or Service.

Establishment of Financial Guidelines. It should be noted that such guidelines are expected to be established as company policies and reviewed on a routine basis. It is not expected that new guidelines are established for each new product.

4.2.2 Output

The output of the process is a quotation and/or proposal. The responsible party is Sales. The quotation shall be based on the inputs from the various sub-tasks defined above. Amortization of nonrecurring costs shall be based on reasonable estimates of both the volume realized and the potential business. The quotation will also take into consideration the overall business strategy and how the customer fits in this strategy. The quotation shall include these things but is not limited to them:

J	Price,
Ĵ	Delivery,
Ĵ	Statement of Work,
Ĵ	Payment Terms,
Ĵ	Related Charges for Cancellation or Changing the Delivery Schedule,
Optional,	as applicable:
·	Generic Material Substitution Policy,
Ĵ	Cost of Customer-Initiated In-Process Changes,
Ĵ	Cost of Orphan Materials Due to Cancellation or
Ĵ	Policy Relative to Customer Supplied Materials. (this section should include a
,	list of customer supplied materials).

4.2.3 Purchase Order, Sales Order, and Order Confirmation

If the quote is accepted, the customer places a purchase order, and this process ends with the creation of a sales order in the ERP system and delivery of an order confirmation to the customer. Otherwise, discrepancies may need to be resolved or a revised quotation may need to be delivered to the customer. This process may need to be repeated to be able to ultimately create a sales order and deliver an order confirmation.

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The work instructions document 43-4497, Creating Customers in SyteLine, describes in detail the process for and the guidelines for the creation of customers in our ERP system.

The work instructions document 43-2333, Order Confirmation, describes in detail the order confirmation process and the verification that must take place before confirming.

4.3 Service Business

The Service Department provides services to existing customers for products that Product Resources has manufactured, such as repairs, preventive maintenance, calibration, and product updates. The Service Manager is responsible for customer communication, order entry, and order tracking for these services. Service follows its own process for tracking and accounting for these services and the returning product. The Service process is described in 91-5001, Service and Returns, and does not always follow the above process for product sales such as up-front quotations, customer purchase order verification, up-front sales/customer order creation, and order confirmation. The Service process is tracked in the QMS system, QT9, using its Customer Feedback module that handles product return. See 91-5001, Service and Returns, for more detail.

4.4 Handling and Communication of Customer-Provided Documentation

Customer-provided documentation as used here refers to product specification and/or manufacturing documentation that the customer has provided to Product Resources, received by Sales, that describes the customer's product. How this documentation is handled depends on whether or not an Engineering project must be initiated to manufacture this product, a Class 1 or higher project as described in 91-2001, Design, Development, and Engineering Processes, in which Product Resources will need to produce manufacturing documentation or more; this will be answered by the scope of the quotation.

4.4.1 Engineering Project, Class 1 or Higher

In the case of an Engineering project, Engineering will set up project folders and will be responsible for obtaining documentation from the quotation process and/or the customer directly and pulling it into a project.

Note that all new medical device and explosive atmospheres products are handled as a project in order to ensure satisfying the specific release to manufacturing (RTM) requirements, even if the below definition is met. Subsequent changes will be handled as per below.

4.4.2 All Other Scenarios

This includes Product Resources having only contract manufacturing responsibility in which the task is limited to implementing the customer-provided

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documentation into Product Resources' systems, either when the product is new to Product Resources or is a new revision to Product Resources.

In this case, Sales creates an ECR (Engineering Change Request) in the QMS system, describing the new or changed product and attaching the customer-provided documentation.

5.0 Control of Records

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