

DOCUMENT NUMBER 91-1003	REVISION F	TITLE Customer Communication, Satisfaction, and Property	REV DATE 07/2023	Page 1 of 5
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1.0 Purpose of Procedure

This document describes the processes by which Product Resources communicates with customers, handles customer complaints, assesses customer satisfaction, and handles customer property. It establishes procedures and assigns responsibility.

2.0 Scope of Process

The scope includes communication in general, for notification of change and nonconformance, and for the receipt of complaints. The scope also includes the handling of customer supplied property and material.

3.0 Process Owner(s)

- 3.1 Sales
- 3.2 Purchasing
- 3.3 Quality

4.0 Procedure

4.1 Customer Communication

Sales is responsible for responding to requests for information about the company's products and services, including requests for quotations and order confirmations in response to customer purchase orders.

In addition, the following special types of customer communication apply, handled by Sales and other parties:

4.1.1 Notification of QMS Change

Certain customers or regulatory bodies may choose to be notified on changes to the Quality system. Some may choose to be notified on all changes, and some may choose to be notified only on major changes. The QA Manager assigns the change classification as described in 43-2627. If there is a customer or regulatory body requiring notification for the given class of change, the QA Manager, who is also the Management Representative, is responsible for addressing the change with that party and for fulfilling any requests or instructions related to the change.

4.1.2 Notification of Nonconformance

Customer Supplied Material

Any customer supplied material (CSM) that is found to be nonconforming is handled in a manner equivalent to nonconforming material received from a supplier (see 91-4002). In the case of CSM, however, Sales shall be involved in executing the disposition of the nonconforming CSM and shall consult with the customer before executing the disposition.

See also Customer Property below.

Post-Shipping Notification and Action on Nonconforming Product

If it is determined that nonconforming product has been shipped, the actions that Product Resources takes depends on the both the nature of the product (regulated or not) and whether or not Product Resources is acting as a contract manufacturer of another

DOCUMENT NUMBER 91-1003	REVISION F	TITLE Customer Communication, Satisfaction, and Property	REV DATE 07/2023	Page 2 of 5
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company's product. The Management Representative is responsible for the customer and/or regulatory body communication.

If Product Resources is acting as a contract manufacturer, Product Resources will, as soon as the nonconformance is identified, notify the customer of the nonconformity and, as required, provide the identity of the affected product by serial number, lot, or date code as is applicable to the specific product. If the product is a regulated product, in this scenario it is the responsibility of the customer to notify the regulatory body. The customer, along with the regulatory body as required, makes the determination of the need for end user or distributor notification or product recall.

If Product Resources is selling product directly to end users or distributors, Product Resources will notify the regulatory body as soon as it is detected of the nonconformance in the case of a regulated product. In this case, the regulatory body will take part in the impact determination. In all cases, Product Resources Quality Assurance and Engineering Departments will review the impact of the nonconformance and, with the regulatory body if required, determine whether end user and distributor notification is required and whether or not a product recall is required.

4.1.3 Notification of Product and Process Change (Product Deviation and Change Request)

For medical devices and for explosive atmospheres product, for customers which require this change control provision per Quality agreements or alike, or at Product Resources' discretion, one-time deviations and ongoing changes from current manufacturing documentation or from current specification shall have a Product Deviation and Change Request Form (PD for short), 80-3205, created. This is applicable to both product and process, non-trivial and non-administrative changes.

The PD is completed describing the applicability of the change and the nature of the change. This form is reviewed and approved by Product Resources Engineering and Quality, and then it is forwarded to the customer for approval to produce and ship product containing the change. Two approvals spots are present on the PD form for the customer, one for Supply Chain approval and one for Quality or Technical approval. While the PD should be initiated as soon as the deviation or change is realized, all approvals are required before affected product can ship.

The initiator of the PD will indicate in the ERP system that the item must go through an Outgoing inspection where QC can ensure the PD is fully approved before releasing affected product to ship. QA will indicate the PD associated with the shipment by inclusion in the item's CoC notes in the ERP system, where these notes are included on the CoC that travels with the product shipment.

PDs are stored on the Quality drive, also shared as Product Deviations for direct access. They are organized by item number. Each PD has a unique identity made up by the item number followed by a sequential number suffix.

Inter-Relationship with Process Validation: See also 91-7006 for Process Validation. When a DMR release is accompanied by a validation package acknowledged and accepted by the customer, this establishes a new product and process change control baseline. Changes that meet the above conditions after that validation baseline are subject to the PD process.

Inter-Relationship with Contract Review: See also 91-1002 for contract review and order acceptance. This is a point in the overall process where there may be disagreement between the ordered revision of an item and the revision of the item that Product

DOCUMENT NUMBER 91-1003	REVISION F	TITLE Customer Communication, Satisfaction, and Property	REV DATE 07/2023	Page 3 of 5
PRODUCT RESOURCES NEWBURYPORT, MA	NOTICE: THIS DOCUMENT IS PROPRIETARY AND ITS CONTENTS ARE THE EXCLUSIVE PROPERTY OF PRODUCT RESOURCES. THIS DOCUMENT MAY NOT BE REPRODUCED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN PERMISSION FROM PRODUCT RESOURCES.			

Resources has defined or the revision of the item that Product Resources believes is intended to be built.

4.1.4 Complaints Handling

When a customer complaint is received, the party receiving the complaint documents it in the Customer Feedback module of the eQMS system QT9. Exceptions: If the customer has initiated with a corrective action request that Product Resources is to complete, proceed directly to CAR entry of type Customer Complaint as described in 91-7002, Corrective Action, and skip the Customer Feedback entry. Also, if the complaint involves returning product, instead handle this per 91-5001, Service and Returns, and the RMA process, skipping the type of Customer Feedback described below.

To document a customer complaint, a New Feedback is created in QT9, with these guidelines on fields that must be filled:

Customer: Select the customer making the complaint.

Given By: The customer party giving the information, if known.

Category: Customer Complaint

Type: Customer Complaint

Received By: The Product Resources party receiving the complaint, if different than the party entering it.

Responsible Party: See below discussion on assigning the responsible party.

Feedback Details: Describe the problem here.

Additional Product Info fields are available to assist in describing the subject of the complaint. When the complaint is about product, the Product field should be filled to later be able to see all complaints related to a given product.

Assigning Responsible Party: Select the Product Resources party most knowledgeable to evaluate the complaint. Note that Responsible Party may be changed during the course of handling the complaint, potentially handing off the customer complaint to the party best able to complete the complaint's next needed phase. Note further to keep the Responsible Party as yourself until you are complete adding the initial set of customer complaint information.

The responsible party then evaluates the complaint and documents the outcomes under Evaluation. Evaluation means comparing what the customer did receive to what the customer should have received and verifying or failing to verify the stated problem. Investigation may be used in tandem with Evaluation and is found supporting information.

Disposition: If a problem is verified, the responsible party is empowered to provide or arrange the customer service needed to correct the problem. How the problem is corrected is entered in Disposition Notes along with the Disposition "Addressed Customer Concern". "No Action Required" can be selected as the Disposition when the problem has not been verified.

Determination to Assign Corrective Action: If the evaluating party has revealed a condition that is systemic in nature and that by product or process design would tend to result in future complaints or nonconformance, or if a problem with high severity is found, or if it is known that the problem is recurring, the evaluating party selects "Corrective Action Required", initiating a Corrective Action Request (CAR) to potentially investigate further, to determine root cause, to initiate new or additional containment actions, and to

DOCUMENT NUMBER 91-1003	REVISION F	TITLE Customer Communication, Satisfaction, and Property	REV DATE 07/2023	Page 4 of 5
PRODUCT RESOURCES NEWBURYPORT, MA	NOTICE: THIS DOCUMENT IS PROPRIETARY AND ITS CONTENTS ARE THE EXCLUSIVE PROPERTY OF PRODUCT RESOURCES. THIS DOCUMENT MAY NOT BE REPRODUCED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN PERMISSION FROM PRODUCT RESOURCES.			

initiate corrective actions. QT9 will prompt for these pieces of information before creating a linked CAR; for this scenario of a customer complaint transitioning to a CAR, complete these fields as follows:

CAR Type: Customer Complaint
 Problem Type: Customer Feedback (we essentially use this as the origin)
 Responsible Party: Select the party most knowledgeable to complete the CAR.
 Priority: Select Normal unless there is a cause to elevate its priority (Hot) or lower its priority (Cold).

For CAR handling, see 91-7002, Corrective Action.

4.2 Customer Satisfaction

Periodically, the Sales department will initiate communication with customers to assess their satisfaction with Product Resources. Sales will use the following methods and measurements to assess customer satisfaction:

- Customer Surveys
- On-Time Delivery,
- Customer Complaint Corrective Actions (CARs)
- Customer Reports of Product Resources' Performance (incl. Quality and delivery ratings)

The assessment of customer satisfaction takes place at least once a year. The output of the assessment becomes is a component of objectives, measures, and goals, in turn a component of Management Review.

4.3 Customer Property

When necessary or when contractually agreed to, Product Resources may have control of customer owned property. Generally these are materials used to manufacture product or can be test equipment used to test product.

4.3.1 Purchasing Requirements

Any materials to be supplied by the customer are coordinated by the Sales Department. Sales notifies Purchasing when customer supplied material is required and Purchasing can then order and schedule the material via the Planner Workbench (ERP system) and a purchase order to the Customer. Sales will provide Purchasing with a customer contact when Purchasing is to directly communicate with the customer. It is the responsibility of Sales to determine whether the communications with the customer will be through Sales or Purchasing.

Any expediting is the responsibility of the department that is communicating with the customer regarding the customer supplied materials. The Sales Department is ultimately responsible for resolving any conflicts with the customer regarding customer supplied material.

DOCUMENT NUMBER 91-1003	REVISION F	TITLE Customer Communication, Satisfaction, and Property	REV DATE 07/2023	Page 5 of 5
PRODUCT RESOURCES NEWBURYPORT, MA	NOTICE: THIS DOCUMENT IS PROPRIETARY AND ITS CONTENTS ARE THE EXCLUSIVE PROPERTY OF PRODUCT RESOURCES. THIS DOCUMENT MAY NOT BE REPRODUCED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN PERMISSION FROM PRODUCT RESOURCES.			

4.3.2 Inspection and Storage

Customer supplied materials are received, inspected, and tested in the same manner as other purchased products. Marking, storage, and handling of customer supplied materials also follow the same procedures applicable to purchased materials.

4.3.3 Special Requirements

When specified in the contract, special instructions for handling customer supplied materials are followed. When requested, the customer's materials may be segregated and labeled to identify them as the customer's property.

4.3.4 Loss, Damage, or Unsuitability

Any occurrence of loss, damage, or unsuitability of customer supplied material is reported in writing by email to the customer by the Sales Department or the Purchasing Department. Copies of these email communications shall be retained in the corresponding sales order confirmation folder.

See also Customer Supplied Material above.

5.0 Control of Records

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