

DRAWING NUMBER 90-2000-7.3.2	REVISION C	TITLE Design and Development Inputs	REV DATE 7/2016	PAGE 1 of 3
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1.0 Purpose

The purpose of this document is to define the policies, responsibilities, and procedures for product design and development inputs.

2.0 Scope

This document is limited to design activities that involve an actual product that is to be manufactured by Product Resources. This product can be a piece of hardware, software, or both.

From time to time, Product Resources will engage in engineering consultation that is not in support of a product that will be manufactured by Product Resources. Such engineering consultation is beyond the scope of this document. Responsibilities for such activities will be set solely by contract with the customer.

3.0 Reference

Customer quotation including the statement of work

4.0 Design Input

Engineering receives design input from Sales/Marketing via a copy of Product Resources' quotation including the statement of work, the customer's purchase order and/or a URS or other customer supplied specifications.

Design input is neither static or fixed but is fluid and normally will change over the duration of the product development. The initial design input and its subsequent changes need to be documented.

The Custom Product Worksheet is initiated by Engineering if necessary. See procedure 90-2000-7.2.1.

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5.0 Customer Notification Policy

In general, the customer and the PR sales department must be notified of any non-trivial change in the design input. Exact policy for customer notification of change is dependent on the class of the project (see 7.3.1). When a customer must be notified, then the following policy must be adhered to:

- ❑ A full written disclosure of the proposed change must be presented to the customer. This should include updated design drawings and or manufacturing drawings, policies, procedures, etc.
- ❑ A reasonable time must be allowed for customer feedback. Customer feedback includes:
 - ❑ Agreement to the change as written
 - ❑ Agreement to the change with modifications as described by the customer
 - ❑ Veto of the change
 - ❑ A request for more time to study the change or a request for more information concerning the change.
- ❑ If after a reasonable time has elapsed, and if there is no feedback from the customer, and if the project engineer has no other reason to believe the customer would not agree to the change, the change may be implemented. This clause does not apply to a regulated product that has already been submitted to the regulatory agency and approved. We must obtain feedback in this scenario.
- ❑ A written log of all customer notifications and feedback must be kept and archived. Generally customer notifications and feedback are communicated through email. Important emails are shared/maintained as part of the project (and customer) files on the engineering drive.

6.0 Policy on Change of Classifications

Once a project is started, it may become necessary to change its classification. The engineering manager must approve the change in status.

7.0 Definitions

Item	Definition
"new product"	A product or service that has not been previously released to manufacturing. This may include products that have been previously released to manufacturing when the product has been extensively modified. Also certain products or services need not be considered new even when the product or service has not been released to manufacturing. Such products or services will be formally classified as

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<u>Item</u>	<u>Definition</u>
	a class 0 project.
Written	Via paper (hard copy), or via an electronic transfer of the documents. Electronic transfer includes faxes, email attachments, and WEB postings. In the case of electronic transfers, the method and format of the transfer must be one that the customer can reasonably be assumed to support.
Reasonable time for feedback	Normally a reasonable time for feedback can be considered 5 working days after the customer can reasonably be assumed to have obtained the written document. Extensions to this period must be made when the intended recipient is not available due to vacation, sickness, etc.
Manufactured Product	A product built by the manufacturing department using released documentation found in the MRP system and the formal QC system.

7.1 Project File

A Project File may contain a copy of the original contract, design documentation, test policies and procedures, validation data, and milestone reports. The bulk of the design output will be released to Document Control when the product is released to Manufacturing. The Project File has limited access.

8.0 Records

The ownership, locations, retention periods, and storage requirements for records described in this procedure are specified in 90-2000-4.2.4.