

DRAWING NUMBER <b>90-2000-7.3.1</b>	REVISION <b>C</b>	TITLE <b>Design and Development Planning</b>	REV DATE <b>7/2016</b>	PAGE <b>1 of 5</b>
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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 planning.

## **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**

Online form: Custom Product Worksheet also called Project Worksheet (PWS)  
Statement of Work from the quotation file  
Engineering/Sales Project folders

## **4.0 Organizational and Technical Interfaces**

The responsible person within Engineering is the designated project manager. If no project manager has been named, then the Engineering Manager shall be considered the project manager. Sales/Marketing and Quality assist the project manager in Engineering when additional customer input is required, when clarification is needed, when difficulties arise, etc.

## **5.0 Design and Development Planning**

Product Resources' business is to design and build instrumentation, electro-mechanical equipment, and alike for external customers and for support of a product base sold directly by Product Resources. As such, Engineering responsibility can be anywhere from simply reviewing and implementing an external customer's documentation package prior to manufacturing to complete turnkey design and manufacturing of a product. In

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planning for design and development, Product Resources shall identify the task as belonging to a class (given in the order of least to greatest responsibility). It is the responsibility of the Engineering Department manager and the Engineer assigned to the project to determine the class category. The category chosen will dictate the subsequent review, verification, and validation requirements:

#### 5.1 Class 0

A class 0 project is directly released to full manufacturing. Engineering's responsibility is limited to the establishment of a BOM and a routing. The characteristics of a class 0 project are **no** non-trivial manufacturing processes or testing processes are required. A prime example of a class 0 project is a spare part whereby a fully manufactured and tested part (or purchased part) is bagged, labeled, boxed (usually including some instructional inserts), and shipped. All documentation is directly released to the MRP system and the formal QC system.

#### 5.2 Class I

A class I project is characterized by the customer providing a full set of documentation including all non-trivial manufacturing procedures and test procedures. The customer must be notified of all non-trivial changes. (Simple workflow routings do not normally constitute a change.) The customer has full responsibility for the design, non-trivial assembly procedures, and testing procedures.

#### 5.3 Class II

A class II project is characterized by the customer providing full design documentation but incomplete manufacturing and or test procedures are provided. The customer is completely responsible for the design. PRI is responsible for manufacturing documentation. The customer must be notified of any non-trivial changes to the design and any non-trivial changes to whatever partial manufacturing documentation was provided by the customer.

#### 5.4 Class III

The customer has provided an engineering prototype and a set of engineering documentation that do not constitute a complete set of documentation required for production. The customer and Product Resources' Engineering Department jointly hold the overall design responsibility. Product Resources is responsible for the manufacturability and overall quality of the manufactured product.

#### 5.5 Class IV

This project is characterized by PRI being requested to co-design selected sections of the project. Overall design responsibility is shared with the customer. Once the customer has

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approved the design, the customer must be notified of any non-trivial changes to the design.

## 5.6 Class V

Overall design responsibility for the project is held by PRI. The customer, including an internal customer, should supply a User Requirements Specification (URS). Once the customer has approved the design, the customer must be notified of any non-trivial changes to the design. PR may participate in the process of creating a URS.

## 6.0 Definitions

<u>Item</u>	<u>Definition</u>
Trivial Change	For purposes of this document a change is either trivial or non trivial. The project engineer is responsible for determining if a change is trivial or not. In general, a trivial change is a change that is obvious to an expert or is obvious from other related documents and which does not change the intended output of the document or procedure. Examples of trivial changes are: <ul style="list-style-type: none"> <li><input type="checkbox"/> Spelling errors</li> <li><input type="checkbox"/> Addition of clarifying notes</li> <li><input type="checkbox"/> Addition of illustrations or photos</li> <li><input type="checkbox"/> Document format changes</li> </ul> Guidelines to help make this determination are included in this document. In any case, any change to form fit or function of the product must be considered non-trivial.
Change to form fit or function	If the end customer can reasonably be expected to be able to determine a change was made then you have changed the form fit or function.
Non-Trivial manufacturing process	A change to the manufacturing process cannot be considered trivial if: <ul style="list-style-type: none"> <li><input type="checkbox"/> There is a change in form fit or function of the intended output of the process</li> <li><input type="checkbox"/> There is a definable (and reasonable) risk of reducing the reliability or quality of the product or service</li> </ul>
Non-Trivial change to materials	If the old material and the new material are not interchangeable then you have made a non-trivial change to materials.
Trivial change to design	For a design change to be considered trivial in must pass the following two tests: <ul style="list-style-type: none"> <li><input type="checkbox"/> The change cannot change the intended input or output specifications to the module.</li> <li><input type="checkbox"/> For existing products, if notification to service of field service is required, then the change <b>cannot</b> be considered trivial.</li> </ul>

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<u>Item</u>	<u>Definition</u>
Statement of work	This is a statement or list normally provided by the customer. This list details what tasks PRI is expected to perform and what the deliverables are. This can be in the form of a quote from PR to the customer outlining the scope of work.
User Requirements Specifications (URS)	This is a document that lists all critical product specifications including but not limited to: <ul style="list-style-type: none"> <li><input type="checkbox"/> Performance specifications</li> <li><input type="checkbox"/> Regulatory specifications</li> <li><input type="checkbox"/> Environmental Specifications</li> <li><input type="checkbox"/> Physical Specifications</li> <li><input type="checkbox"/> Language Specifications</li> <li><input type="checkbox"/> Power Specifications</li> </ul> Normally these specifications are "blackbox" in nature and much like a detailed catalog description. Design strategy is not normally part of this document
Design Specifications	The design specification is the design engineering response to the statement of work and or URS. The statement of work and the URS are statements of what must be done; the design specification is a statement of how it will be done. This is a strategic document that may contain some high level schematic (electrical or otherwise). It is not the detailed design.
Engineering Prototype	A product built under the direction of engineering. Formal documentation may or may not be released to the MRP system and or the formal QC system.

## 6.1 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. The Project File is used to keep all documentation and design information in one place.

The Project File, also known as Project Folder, is a folder on the Engineering drive, by Customer

Engineering has developed a folder template to organize the Project File which can be found on the Engineering drive, Templates. All new engineering projects are created in the Customer Process System, which creates a new project, from the template, in the engineering drive.

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Engineering will augment the template folder structure as required to fit the needs of the project with the goal always being the organized storage of design data.

Projects with a Class Category 0 or 1 may not require a Project number or the creation of a Project Folder. In the case that a Project Folder is not created, any engineering documentation will be stored in a product folder in the customer files.

## **7.0 Records**

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