

DRAWING NUMBER <b>90-2000-7.3.456</b>	REVISION <b>1</b>	TITLE <b>Design and Development Review, Verification, and Validation</b>	PAGE <b>1 of 2</b>
WRITTEN BY: <b>NL/AR/CRL</b>	DATE: <b>1/15/2014</b>	APPROVED BY: <b>JMC</b>	DATE:
PRODUCT RESOURCES BEVERLY, MA USA	<b>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.</b>		

## 1.0 Purpose

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

## 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: Customer Process System

## 4.0 Design Review, Verification, and Validation

Reviews, as detailed below, will be recorded in the product design file.

### 4.0.1 Design Review

For class I –V projects a formal design review or reviews will be documented. The design review will review the manufacturing documentation for error and consistence. As part of this process the “issues” section of the project tracking sheet shall be reviewed.

### 4.0.2 Design Verification

For class IV and class V projects, the design, particularly those parts of the design provided by PRI, will be formally reviewed to establish the design input requirements have been meet. Such a review may use design calculations and vendor supplied data sheets as a basis for determining the product will

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consistently conform to input specifications. The scope and detail of such a review should be mutually agreed on between PRI and the customer.

#### 4.0.3 Design Validation

For class V projects, the design and the prototype product shall be reviewed to establish that the product is capable of meeting its requirements for the specified application and or its intended use. Both calculations and physical product testing may be used as the basis for this review. The scope and detail of such a review should be mutually agreed on between the customer and PRI. This agreement on scope is particularly important in the case of software and firmware.

### **5.0 Definitions**

Any required definitions for terms used in this procedure are located here.

#### 5.1 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.

### **6.0 Records**

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