1.0 Purpose

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

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 Design Output

Output from the design process includes primary design output and secondary design output, as follows:

3.1 Primary Design Output

The primary design output is a set of manufacturing documentation released to Document Control and entered in our ERP system for Manufacturing including manufacturing routings, drawings, specifications, schematics, manufacturers and manufacturers' part numbers for COTS (catalog, off-the-shelf) parts, procedures, forms, acceptance criteria, and so on – everything needed to fully define the product or assembly to allow it to be manufactured or purchased as designed.

See procedure 90-2000-4.2.3 (Control of Documents) for how documents are released into the system.

See 43-2537, Entering a New Part Number, for Product Resources' policies and norms related to the entry of parts (Items) in the ERP system. This includes how COTS parts are specified.

See our Release to Manufacturing (RTM) procedure, 43-4477, for how RTM is controlled in our ERP system and the conditions that must be met for the RTM of a part

or its routing. This procedure describes Product Resources' standards and conventions for the construction of parts and routings.

Additional Requirements for Primary Design Output for Regulated Product:

In the case of product regulated under the ATEX Directive or the Medical Device Directive (medical devices), any drawings, specifications, and procedures created for the product must be approved by the customer prior to release unless a special agreement is put in place.

For product controlled under the Medical Device Directive, medical devices, there are additional RTM requirements. These additional requirements are stated in 43-4521, Procedure/Checklist, Medical Device RTM. (Note that the "standard" RTM procedure 43-4477, which applies to all product including medical devices, also points the user to 43-4521.)

As included in the Medical Device RTM procedure and checklist, primary design output for medical devices includes a Device Master Record (DMR) and provisions for the creation of Device History Records (DHRs). See also 90-2000-7.1 (Planning of Product Realization) for a description of what constitutes the DMR in Product Resources' system.

As included in the Medical Device RTM procedure and checklist, primary design output for medical devices includes cleaning procedures as required for the given product.

In the case of product regulated under the ATEX Directive or the Medical Device Directive (medical devices), all product for sale (i.e., 41-XXXX and 99-XXXX part numbers) have their Family Codes augmented with ATEX or MD, respectively; this is the responsibility of the CQO. Through the use of a utility that runs weekly, the ATEX and MD designations are propagated down through all parts numbers associated with the regulated product (i.e., subassemblies, components, and associated documents). This serves to identify and communicate parts associated with regulated product. Special requirements for such product are communicated throughout this Quality Manual. For more information, see 90-2000-5.4.2, Quality Management System Planning.

3.2 Secondary Design Output

The secondary design output supports the primary design output and includes:

3.2.1 Project Documentation File:

For class I through class V projects: An electronic file will be maintained and archived for each project. This file should be organized and may contain:

1. All customer supplied input documentation including the statement of work and or the URS.

2. All findings, reports, etc. not otherwise recorded in the Manufacturing and Document Control (MRP/QC) system documentation system
3. All design drawings, test procedures, construction information, firmware, and software not recorded in the formal MRP/QC system. This is particularly applicable to engineering prototypes.
4. For projects that have been stopped before full release to manufacturing, a set of notes on what needs to be done (including proposed modifications to the design, etc.) before the project can be fully released to manufacturing.
5. All significant correspondence with the customer including meeting notes.
6. All formal evidence that the project meets the specifications as stated in the Statement of Work and or the URS or related documents. This includes design review notes as well as test results, and critical design calculations.
7. Manufacturer's specification sheets for highly critical purchased parts.
8. For class I through class V projects: A brief statement of the project which may be noted on the PWS or as a stand alone document or as part of the customer quotation.
9. For class II - class V projects: A statement of work.
10. For class IV projects: User Requirement Specifications (URS). The customer should provide the URS to PRI.
11. For class I through class V projects: A table of customer requested changes (changes not part of the original agreement) to the project and their resolution.
12. For class III and class V Project: A set of design specifications or a pointer to an external document. The customer should approve the design specifications.
13. For class III and class V projects: A summary of critical design calculations.
14. For class III and class V projects: evidence that the design meets its specifications or evidence that the customer has accepted the design. Again the tracking-sheet may point to external documentation. In the case of product test procedures, this requirement may be extended to class II projects.

3.2.2 Project Work Sheet (PWS):

For class I through class V projects, a PWS may be maintained. This is an online form accessible via the company intranet and is a private document. Alternatively, all documents related to the customer and the project are maintained in the electronic project folder.

The purpose of this online form is to capture project specific details, such as customer contact information, product name, etc. The online form also contains

links to the Project Documentation File and links to the associated database of Action Items and Design Reviews.

4.0 Definitions

Item	Definition
User Requirements Specifications (URS)	This is a document that lists all critical product specifications including but not limited to: ❑ Performance specifications ❑ Regulatory specifications ❑ Environmental Specifications ❑ Physical Specifications ❑ Language Specifications ❑ Power Specifications 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.

5.0 Records

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