1.0 Purpose of Procedure

This document is intended to describe the Design Management process for Product Resources Quality System. It provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The Scope of this procedure is to describe the how an engineering Design project will be managed.

3.0 Process Owner(s)

3.1 Engineering Manager

4.0 Procedure

4.1. Responsibilities

4.1.1. Operational Responsibilities

The Project Manager has the responsibility to oversee the Design Management Process for the Project.

4.1.2. Approval Responsibility

The Project Manager has the responsibility and authority to approve Design Management output documents, if any, for less complex projects, Class 1-4, non-Medical and non-Explosive atmosphere.
On complex projects (Class 5) or projects for Medical Devices or explosive atmosphere compliant products, the Project Manager has oversight of the Design Management Process, but the Quality Manager must approve the V&V output documentation.

4.2. Process Description

Depending upon the Project Classification, there are required Design Management tasks that must be performed, and they are listed in the Project Checklist. These range from simple Document Review and Approvals for the simplest of projects, and as the complexity increases, there must be one or more Design Reviews to verify that the design is appropriate and to involve other engineers in a review of the work to date. In the most complex projects, there will be formal Design Verification activities and if required, Design Validation.

4.2.1.Document Review and Approval

Any time Product Resources releases a document into our Document Control System (QT9), the document must be reviewed by another person familiar with the document and project requirements. Reference the section on Releasing Documents, in document 91-6001, Control of Documents.

4.2.2. Design Review

When the Project Manager has indicated on the Project Checklist that Design Reviews are to be included in the project, or if the engineer desires a Design Review of all or a portion of the design, a Design Review meeting shall be held, and notes taken to show evidence of the Design Review.

There are Design Review forms available in the Engineering Drive's Document Templates directory, or available through the Project Checklist links. The Design Review must have the following information:

- **Design Review Number**
  Use a sequential number or other method of uniquely identifying the Design Review.

- **Project number**

- **Subject**
  A Brief Description of the scope of the review

- **Attendees**
  A list of people who attend the review, including outside engineers, customers, etc. Attendees of a design review shall include representatives of the project team knowledgeable with the aspect of the design being reviewed. Other personnel with applicable knowledge (i.e. a specialist in a relevant field, or an engineer with experience on similar design projects) should also be included when appropriate.

- **Documents Reviewed**
  A list of the documents reviewed in the Design Review.

- **Requirements and Standards**
  A list of Specification Documents or Standards used during the Review. Quality System standards are implied and do not have to be listed. Here we need references to specific regulatory standards that are relevant to the document(s) and subject(s) being reviewed. For example, if the review covers a Cable Assembly and IPC-620 class standards are relevant to the subject of the review, list the IPC standard and class.
  When Reviewing a Design, evaluate the design's ability to meet the requirements of the design. If there is a formal Requirements Document or Design Document relevant to the Review, record it and use it as a reference.

- **Review Comments**
  Note any Comments or Issues with the reviewed documentation.

- **Action Items**
  Include Any:
  - Actions that must be taken
  - Who is responsible for those actions
  - When the action is expected to be completed

The Design Review Documentation shall be filed in the project File, in the directory specified on the project Checklist

4.2.3. Process Review

A Process Review is required if the Project Manager has designated the Review as required on the Project Checklist. The Process Review requirements are the same as the Design Review requirements and use the same format, but focus on the process involved with manufacturing the Product rather than the design of the Product.
There are Process Review forms available in the Engineering Drive's Document Templates directory, or available through the Project Checklist links. The Design Review must have the following information:

- **Process Review Number**
  Use a sequential number or method of uniquely identifying the Design review
- **Project Number**
- **Subject**
  A brief Description of the scope of the review
- **Attendees**
  A List of people who attend the review, including outside engineers, customers, etc
- **Documents reviewed**
  A list of documents reviewed in the Design review
- **Requirements and Standards**
  A list of specification documents of standards used during the Review
- **Comments**
  Note any comments or issues with the reviewed Documentation
- **Action Items**
  Include any actions that must be taken, who is responsible for those actions, and when the action is expected to be completed.
  When Reviewing a Process, evaluate the process' ability to meet the requirements of the design. If there is a formal Requirements Document or Design Document relevant to the Process Review, record it and use it as a reference.
  The Process Review Documentation shall be filed in the Project file, in the directory specified on the Project Checklist.
  If a process is determined to be a "Special Process", where the output of the process cannot be verified by subsequent monitoring of the measurement, see Process Validation below.

4.2.4. Design Verification

A Design Verification is required if the Project Manager so designates on the Project Checklist. The Design Verification compares the Design Outputs – mechanical and electrical drawings, process flows, graphics, software, etc. – meet the Design Inputs.
The designs used for Design Verification activities shall be released designs under revision control.
Any issues discovered during design verification activities shall be recorded. Issues that cause a failing result during verification activities shall be mitigated and documented.
The Design Verification may utilize custom forms designated by contract, or forms that follow the Requirements Documents for the Product, but the Verification Documentation

must demonstrate compliance of the Design Outputs with each of the requirements of the Design Inputs.
The Design Verification Documentation shall be filed in the Project file, in the directory specified on the Project Checklist.

4.2.5. Design Validation

A Design Validation is required if the Project Manager so designates on the Project Checklist. The Design Validation compares the Product performance and design to the Marketing Requirements of the Product, which detail the Application and User Requirements.
The designs used for Design Validation activities shall be released designs under revision control.
Any issues discovered during design validation activities shall be recorded. Issues that cause a failing result during validation activities shall be mitigated and documented.
The Design Validation may utilize custom forms designated by contract, or forms that follow the User (or Market) Requirements Documents for the Product, but the Validation Documentation must demonstrate compliance of the Design with each of the requirements of the User and Market Requirements.
The Design Validation Documentation shall be filed in the Project file, in the directory specified on the Project Checklist.

4.2.6. Process Validation

Any special process that is included with the manufacturing output of the product requires a process validation. Engineering, along with Quality, has the responsibility to identify any special process to manufacture a product as well as outline procedures for execution in production. It shall be the responsibility of Manufacturing to maintain the process. Once a special process has been identified and outlined, a Validation protocol must be developed, executed and reported on for each individual given process. Process Validation Documentaion shall be filed in the project file, in the directory specified on the project checklist. Refer to 91-7006 for more detailed instructions on process validation.

5.0 Control of Records

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