

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 1 of 10
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1.0 Purpose of Procedure

This document describes Product Resources' Design and Development Process. It also provides a home for other, related Engineering processes. This document provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The scope of this process involves preliminary planning for a design project, design engineering including iteration and verification, and finally manufacturing engineering to prepare a product for production. The scope also includes the non-project work of maintaining current product definition / DMR when new documentation, changed documentation, or the request to make a change comes from sales, production, or other functions.

2.1 Overview of Documentation Storage

Product Resources uses multiple methods of storing documents to ensure security from IT breaches and allow for the recovery of documents while limiting the scope of damage.

- Engineering Project Files are stored in a Microsoft Teams Team designated for the project.
- Engineering CAD model databases, software, etc. are stored on the Eng Models share.
- Once Closed, Engineering Project Files are moved to the Engineering share, to be Archived.

2.2 Guide to starting a new Project

There are multiple tasks to set up a new Engineering Project in Product Resources systems. Once a Purchase Order or other permission to start is received, the tasks are:

- Initiate the Project in the ERP System, assigning a Project Number and Name per procedure 43-1801, Create a Project in ERP.
- Update the Project_Rate_Table Spreadsheet per procedure 43-1802, Update Project Rate Table.
- Create a new Team in Microsoft Teams per procedure 43-1803, Create a Project in Teams.

Once a project is closed, there are steps to Archive the Project Files per 43-1804, Closing a Project.

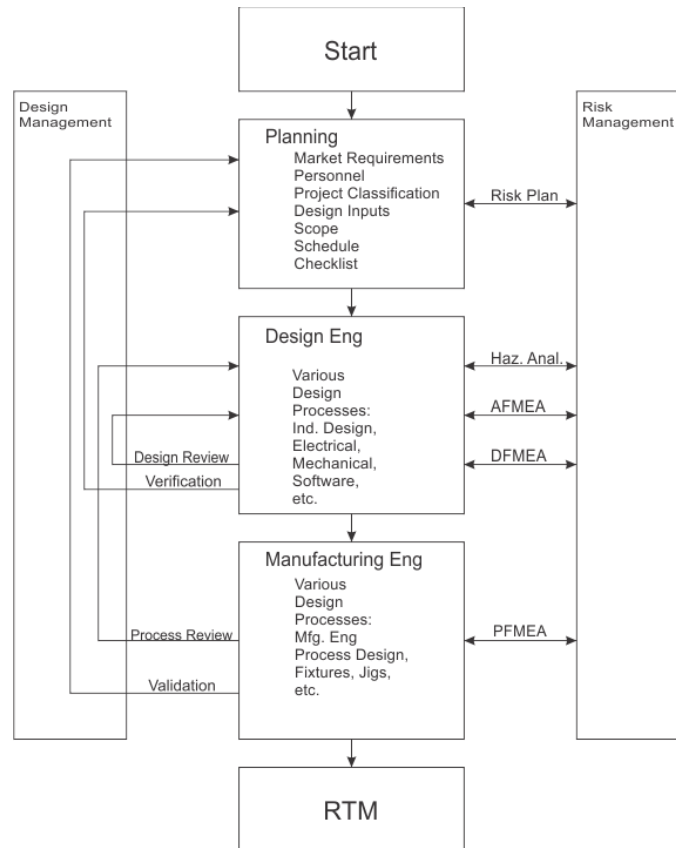
3.0 Process Owner(s)

3.1 Engineering Manager

DOCUMENT NUMBER	REVISION	TITLE	REV DATE	
91-2001	F	Design, Development, and Engineering Processes	09/2022	Page 2 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

4.0 Procedure

4.1. Process Flow



Design and Development Process Flow

The Design and Development Process Flow Chart shows the overall flow of a project from Start to RTM (Release to Manufacturing). The general flow is from top to bottom, but within the major process steps there is considerable iteration using the Design and Process Reviews, Verification, Validation, and various FMEAs.

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 3 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

4.2. Organization of Information

4.2.1. Design Files

All information related to the design and development of products shall be stored in its appropriate location per the following table:

Document Type	Location
Active Project Files: <ul style="list-style-type: none"> • Planning Documents • Design Inputs • Design Outputs • Risk Management Documents • Design Reviews • V&V Documents • Manufacturing Procedures and BOMs • Calculations and Analyses • Other files that can be stored and utilized for the project. 	Microsoft Teams Project Team
CAD Models: <ul style="list-style-type: none"> • SolidWorks • Eagle • Software Projects • Firmware Projects • Similar Computer-Aided-Design files that require multiple files to run. 	Eng Models share Customer/Product/: <ul style="list-style-type: none"> • CAD Model • PCB Models • Software
Archived (Inactive) Project Files: All files included in the Active Project Files above.	Engineering share /By Customer/Customer/Product/Projects
Released Design Output	QT9 Document Control

4.2.2. Spare Parts and Accessories

This subdirectory contains working files, datasheets and reference material related to spare parts and accessories for the product. It is located in:
Engineering/By Customer/Customer/Product

4.2.3. Production Support (Sustaining Engineering)

This directory is used for pre-project work, or as a temporary holding area for files related to engineering changes affecting multiple documents (unless there's a project to make the relevant changes). It is located in:
Engineering/By Customer/Customer/Product

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 4 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

4.3. Planning

The Planning phase of a project defines the scope of work and design inputs for a project. Design Management and Risk Management activities occur in parallel, and these processes inform the progression of Design and Development process.

4.3.1. Scope of Work

Engineering design and development projects shall contain documentation outlining the scope of work. This documentation generally takes the form of a quotation to a customer for engineering design and development services. The scope of work documentation shall be stored in the Planning>Scope of Work directory of the Engineering Project File, and updated as required by project needs.

The scope of work documentation typically includes the following information:

- A summary of the project
- A schedule or timeline for the project
- An assignment of project responsibilities, if applicable, among Product Resources, the customer, and any other relevant parties
- Internal and external resources required for the project
- A description of project deliverables

4.3.2. Project Classification

Projects are classified by risk, as well as Product Resources' degree of design and development responsibility for a given project. The project classification informs the degree of risk management, verification, and validation activities appropriate for a given project. Creation or maintenance of manufacturing documentation (exclusive of any Special Manufacturing Processes) may be included within the scope of work without impacting the classification of a project.

Engineering also has the ability and responsibility to change a project classification from its original classification. If engineering feels the original classification is no longer accurate based on a change to the amount of risk or design and development responsibility involved, engineering can update the classification as necessary.

Not all Engineering processes occur in the context of a project. When Product Resources is acting as a contract manufacturer wherein the customer not only has a completed design but also a complete set of manufacturing documentation, a project does not apply, and Engineering will perform the function of implementing the existing manufacturing documentation into Product Resources' systems to a state described in 91-6004, Planning for Product Realization and DMRs; see also 4.7 below.

All medical device or explosive atmospheres product, even those that have a complete set of manufacturing documentation as initiated with Product Resources, will take a project path upon initial product adoption in order to ensure that all controls associated with those product classes are satisfied.

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 5 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

Project classes follow:

4.3.2.1. Class 0

A project is Class 0 typically when it is not a design or development project and/or when it is for special services or for a selective or narrow scope. In all of these cases the project requirements and deliverables are described by a scope of work normally contained in the proposal and quotation issued to the customer. Some of these projects may involve a considerable amount of the work outsourced to specialty service providers such as product or materials testing, regulatory bodies, labs, software development, other engineering consultants, tooling development, and so on, where the primary task for Product Resources is provider selection, project management, customer communication, and facilitation.

An example of a such a project is Product Resources selecting and working with a regulatory body to obtain NRTL certification for a customer's product that we may or may not have designed and developed. Another example is outsourcing a specific piece of software development. In all of these Class 0 cases, these are being approached as standalone projects with custom scopes of work. When they are not, these tasks might be integrated into larger design and development projects, in other words part of projects of other classes.

4.3.2.2. Class 1

A project is Class 1 when project inputs include a complete set of design documentation, and the project scope of work does not include any product or Special Manufacturing Process design responsibility for Product Resources.

An example of a Class 1 project is creation of manufacturing documentation for a customer's product from an existing design, where no Special Manufacturing Processes must be created for the build. Another example would be a project for which Product Resources is providing or coordinating testing services for a customer on an established design, and possibly recommending design changes based on the results of the testing.

4.3.2.3. Class 2

A project is Class 2 when project inputs include an incomplete set of design documentation, and the project Scope of Work gives Product Resources design responsibility for product form or fit, with no responsibility related to performance requirements.

Class 2 projects are generally cosmetic updates or manufacturability optimization for an existing product.

4.3.2.4. Class 3

A project is Class 3 when the project scope of work involves changes to an existing product with no changes made to functional or performance requirements. Class 3 projects often involve obsolescence of a major component of an existing product, or a change of manufacturing method for a product.

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 6 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

4.3.2.5. Class 4

A project is Class 4 when the project scope of work involves changes to functional or performance requirements of an existing product, where non-trivial changes are isolated to a single subsystem. This designation also applies to new products with a single subsystem, or the addition of a new subsystem to an existing product.

4.3.2.6. Class 5

A project is Class 5 when the project scope of work involves changes to multiple subsystems of an existing product or the design and development of a new product with multiple subsystems.

4.3.2.7. Medical or Explosive Atmosphere Modifiers

Projects for products which fall under the auspices of medical device or explosive atmosphere regulations have a higher documentation burden than a similar project on a product that is not of special concern. We capture the heightened requirements in the project classification by appending the modifiers M (for medical devices) or A (for explosive atmosphere products). For example, a project which would otherwise be Class 3, but is for a product that must be built to medical device standards (a designation determined by the Quality Department), would be instead a Class 3M project.

4.3.3. Design and Development Inputs

4.3.3.1. Project Checklist

Once a project class has been determined, the Project Manager shall initiate a Project Checklist, 80-4652 YYPJXX-10 rev 01 Project Checklist, for the project. The Checklist names various classes of documents (such as product specification documents, risk management documents, and states if they are needed for a particular project based on the Project Class.

As the project progresses, the project manager should update the Checklist with the status of various documents to track the project status. Once all documents are complete and the product has been released to manufacturing, the project manager shall close the Checklist and project by signing the Checklist for approval. For Class 4 or 5 projects, or for projects with an A or M designation, the Project Document Checklist must also be signed for approval by the Quality Manager.

4.3.3.2. Existing Documentation

If there is existing design and development documentation related to the project, this information should be used as project input. These documents shall be stored in appropriate directories within the Engineering Project Team Files.

Any existing documentation relevant to the project supplied by the customer shall be stored in the Customer Input channel or directory of the Engineering Project Team Files.

4.3.3.3. Requirements Specifications

If required per the Project Checklist, Product Resources shall document requirements as input for the design effort. These requirements may take the form

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 7 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

of standalone documents (such as Product Requirements Document, Software Requirements Document), or may be embedded in other documents such as Design Verification protocols.

Where applicable, Requirements Specifications shall relate to the requirements of existing, similar designs.

The documented requirements includes the following information, as applicable to the scope of work:

- i. Functional Requirements
- ii. Performance Requirements
- iii. Usability Requirements
- iv. Safety Requirements
- v. Regulatory Requirements
- vi. Other requirements relevant to the product

Requirements shall be sufficient to completely define all product characteristics necessary for the product application, as relevant to the project scope of work. Each requirement statement shall be indexed for traceability. Individual requirement statements shall be unambiguous, and not conflict with other requirement statements.

The customer shall have the opportunity to review the Requirements Specifications for approval before release.

Released requirements specifications shall be stored in the location indicated by the Project Checklist. Requirement specifications shall be reviewed and updated as necessary.

4.3.4. Project Initiation

A new project is usually initiated by the Engineering Manager, who designates a Project Manager for the project. However, for smaller, less complicated projects, a Project manager can assume the responsibility of initiating a project. The Project Manager is generally the lead engineer on the project, and is the person responsible for completion of administrative tasks related to the project. The Project Manager is also responsible for delegation of tasks among engineers working on the project, as well as controlling the interfaces between tasks.

The Project Manager shall cause the Project Structures to be set up within Product Resources' File and Collaborations systems by:

- Initiate the Project in the ERP System, assigning a Project Number and Name per procedure 43-1801, Create a Project in ERP.
- Update the Project_Rate_Table Spreadsheet per procedure 43-1802, Update Project Rate Table.
- Create a new Team in Microsoft Teams per procedure 43-1803, Create a Project in Teams.

4.3.5. Closing a Project

Once a project is completed, the project shall be closed and archived per 43-1804. This will save all relevant information to the Engineering share, Eng Models share and QT9, and delete the Project Team from MicroSoft Teams.

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 8 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

4.4. Design Engineering

The Design Engineering phase of a project takes the design inputs generated in the Planning phase, and generates a product design that meet the inputs. This phase is an inherently iterative process, with concepts being created and refined to address issues as they become apparent. Design Management and Risk Management activities occur in parallel, and these processes inform the progression of Design and Development process. Usually, one or more proof of concepts or prototypes are generated during this project phase for the purposes of design verification.

4.4.1. Design Engineering Output (Product Design)

The output of the Design Engineering phase of an Engineering Project consists of a set of all documents which define the form, fit, and function of a product, as relevant to the project scope of work. Examples of components of the product design include:

- Fabricated Component Documentation
 - Released mechanical detail drawings
 - Released circuit board schematics, drawings, and Gerber files
- System Functionality Documentation
 - Process and Instrumentation Diagrams (P&ID)
 - System schematics and flow charts
 - Software (source code and executables)
- Preliminary Assembly Documentation
 - 3D mechanical models
 - Bill of Materials
- Regulatory Certifications and Reports
- Prototypes

The product design documents at this stage shall be sufficiently detailed to allow a person knowledgeable about the product to cause a new prototype (i.e. in addition to any prototypes which were generated as part of the design outputs) to come into existence. The product design shall provide sufficient detail about characteristics of the design critical to the product's safety and functionality in the application to allow these characteristics to be reliably reproduced.

Where required by the Project Checklist, the product design shall be verified against the design inputs and any deficiencies addressed (see 91-2002, Design Management Process).

4.4.2. Prototyping

During the Design Engineering phase of a project, Engineering may build prototypes themselves, or use Production resources to cause prototypes to be built. In the latter case, any work performed shall be under the supervision of an engineer knowledgeable about the product. It is the responsibility of Engineering to ensure that prototypes do not ship to a customer without indications that such units are in fact prototypes for V&V or evaluation purposes.

4.5. Manufacturing Engineering

The Manufacturing Engineering phase of a project takes the product design generated in the Design Engineering phase of the project and converts them into Design Outputs suitable for

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 9 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

Release to Manufacturing. Design Management and Risk Management activities occur in parallel, and these processes inform the progression of Design and Development process.

4.5.1. Manufacturing Engineering output (Design Output)

The output of the Manufacturing Engineering phase of a project consists of a set of documentation sufficient to allow Product Resources to manufacture the product without the need for Engineering oversight.

The final design output shall include the following elements:

- Released Workflow Routing
- Released Assembly Documentation

The final design output may also include the following elements, if applicable:

- Service Plan, if applicable to the product and within the project scope of work
- Inspection Procedures
- Manufacturing Procedures
- Test Procedures
- Tooling or Fixtures

Procedures used to produce a product shall note any equipment required to monitor the output of the process described by that procedure. Inspection and test procedures shall also include acceptance criteria.

The various design outputs shall be stored in the locations indicated below. Outputs not listed shall be stored in document control.

<u>Type of Output</u>	<u>Storage Location</u>
Released Workflow Routing	Product Resources ERP System (e.g. SyteLine)
Released Assembly Drawing	Product Resources Document Control (QMS system)
CAD Assembly models	Current Product Definition directory
Service Plan	Per Project Checklist
Inspection/Manufacturing/Test Procedures	Product Resources Document Control
Tooling / Fixture Designs (working files, Datasheets, reference material)	Current Product Definition directory
Released Tooling/ Fixture Design output (Documentation)	Product Resources ERP System for Routings and QMS system for Controlled Documents (Drawings, wire run list etc)
Product Validation Reports	Per Project Checklist
Process Validation Reports	Per Project Checklist

4.5.2. Control of Design Changes

All V&V activities shall be performed on documents released per the Control of Documents procedure 91-6001. Any change to released documents related to the product that occur after Design Verification has begun shall be implemented via Product Resources' Engineering Change Notification (ECN) Procedure (43-2627). Note that the act of documenting an assembly or process is not considered a change if the contents of the document do not contradict the design intent.

ECNs which do implement a change to the product design shall be reviewed to ensure they do not adversely impact the conformance of the product to its requirements or any V&V activity already performed. The results of this review shall be noted on the ECN implementing the change, and any relevant V&V reports shall be updated as appropriate. Further actions required to mitigate adverse impacts as the result of a change shall be

DOCUMENT NUMBER 91-2001	REVISION F	TITLE Design, Development, and Engineering Processes	REV DATE 09/2022	Page 10 of 10
PRODUCT RESOURCES NEWBURYPORT, MA	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.			

noted on the ECN. In certain instances, the customer will be involved in the ECN process to an extent established during the planning phase. Refer to 91-1003, Customer Communication, Satisfaction and Property, for information on customer communication and Production deviation process.
ECNs shall be authorized as per the ECN procedure. QA shall be notified for all ECNs that affect V&V activities.

4.6. Release to Manufacturing

Once all lines of the Project Checklist have been closed, and all design outputs have been released, verified, and validated as appropriate, the product is ready for Release to Manufacturing. The Project Manager shall create a PDF of the completed Project Checklist and sign for approval. This signed PDF will be stored in the 'Planning' folder. Refer to 43-4477, Engineering RTM Procedure and 43-4521, Procedure/ Checklist, Medical Device RTM for specific instructions on releasing products to manufacturing.

Once Released, the Project should be archived per 43-1804.

4.7. Creation and Maintenance of Manufacturing Documentation

A project in which Product Resources will manufacture the product will have yielded manufacturing documentation implemented in Product Resources' systems, or manufacturing documentation will need to be implemented if Product Resources is acting as a contract manufacturer and a project is not required. In the former case, manufacturing documentation will need to be maintained in the face of changes needed and errors corrected, or for continual improvement. In both cases, the sales function needs to provide to Engineering the new or changed documentation received from the customer, and all functions need the ability to communicate the need for change or improvement.

The ECR (Engineering Change Request), part of the QMS system, is the vehicle for this communication. The ECR will carry the request along with the associated documentation for Engineering's implementation.

5.0 Control of Records

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