Purpose

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for product design and design verification activities.

General

This procedure applies to design and development of new products and improvements of existing products. Either design methodology should always consider the nature, duration and complexity of the design and development activities. It should also consider the potential consequences of failure due to the nature of the products and services.

This procedure concerns the Engineering department and departments interfacing with them, such as Sales, Production, and Quality Assurance.

Procedure for Design Control

Design input

When new product development or improvement of existing product, hereafter referred to as design project, is initiated/ requested, Engineering receives a product brief "overview", either by the customer/end user directly and or sales representative.
The brief describes desired product in terms of:

- general concept
- performance characteristics
- aesthetic design characteristics
- applicable standards
- if required, regulatory requirements
- and other relevant functional information, such as the nature, use and intended lifetime of the product and/or service.

When a purchased order has been issued by the customer or internal design project, a Job Traveler will be generated in order to track design times and progress of the project. All information pertaining to the design project will be reviewed by the Engineering Dept along with Upper management.

- During the review, the functional, performance, appearance, and other relevant requirements will be clearly defined, to include characteristics that are not specified by the customer but are necessary for intended use;
    - Applicable regulatory and legal requirements are identified; and
    - Information derived from previous similar designs, or other similar products, is relevant and reliable.
    - Ambiguous or conflicting requirements are resolved prior to the start of the design.

Documents defining design input can be in any form, including but not limited to data sheets, customer drawings and specifications, photographs, samples, emails, references to standards, and so forth. All documents constituting design input are assembled and maintained as documented information and can stored electronically and/or printed copy. Any emails pertaining to the design project are to be stored on the Rosewood Exchange Server; this is achieved through the use of Microsoft Outlook.

Design input may be changed and/or amended as the design evolves. Changes may be introduced by the customer or be initiated internally within the company. All proposed changes and additions are reviewed by Engineering and or upper Management; and must be approved by the customer when the initially stated customer requirements are modified or affected in any way.

Design planning and activity assignment

The Engineering Manager and or upper management are responsible for generating a Job Traveler. The Job Traveler divides the design process into phases, identifies design activities, assigns responsibilities for carrying out these activities, and specifies design verification requirements.

- For small and simple design projects Design Development Review, *QMSF-1018 Design Development Review* maybe used. QMSF-1018 may include phases and activities and, for each activity, defines the source of design input, assigns personnel or design groups, defines verification requirements, and schedules start and finish dates.

Organizational and technical interfaces

- The Engineering Manager and upper management establishes rules for transmitting information and communication between various groups involved in the design project. The Job Traveler establishes due dates for release of critical information by each design group and/or activity. The Engineering Manager and upper management has overall responsibility for coordinating design groups.

Design aids and methods

- The Engineering Manager determines which methods and criteria are used in carrying out calculations and other design activities.

Design output

- Primary design output may consist of documents that define the product and instruct how to manufacture it. These documents include drawings, Job Traveler, specifications, procedures, workmanship standards, inspection procedures, acceptance criteria, etc.
- Design output also includes specifications and procedures for packaging and labeling of the product. Product characteristics and aspects that affect safety, intended use, performance, and reliability are defined in the design output.
- Secondary design output consists of documents supporting the design. These documents include calculations, risk analysis, test results, verification and validation reports, and references to other documents supporting the design.
- All primary design output documents are reviewed and approved prior to issue. Only the Upper Management, Engineering Manager, or a formally designated representative has the authority to issue and release these documents. Design output documents are controlled. Their establishment, review, authorization, issue, distribution, and revisions are carried out in conformance with *QMSP-1001 Control of Documents*.

Design reviews

- Design reviews are conducted throughout the design process. For new product design, at least two reviews are conducted. One proceeds early in the project, and its purpose is to evaluate and finalize the design input and review conceptual solutions. The other occurs after the design is substantially completed, and its objective is to verify that design output meets the design input requirements, and to approve the final design.
- In addition to Engineering, other departments and outside parties may participate in the design reviews. The participation will depend on the project and the design phase. The Engineering Manager or Upper Management decides who should participate in the reviews.
- The purpose of design reviews is to audit the evolving design and assess how well it meets the design input requirements at each stage. Design reviews address such issues as attainment of safety, functional, and aesthetic requirements; unintended

uses; environmental compatibility; reliability; the ability to manufacture; serviceability; acceptance and rejection criteria; capability to inspect and test; availability of qualified suppliers to provide specified materials and components; etc.

Design verification and validation

- The purpose of design verification is to demonstrate that the design output meets the design input requirements. The purpose of design validation is to demonstrate that the designed product performs satisfactorily under real or simulated conditions of intended and unintended use. Assess the outcome of a catastrophic failure and the dangers along with parties that may be involved.
- At a minimum, the design is verified and validated by holding and documenting design reviews and, where relevant, undertaking prototype tests and demonstrations. Other forms of verification, such as carrying out alternative calculations and comparing the new design with a similar proven design, are also used when appropriate. All design verification and validation activities and results are documented.
- Prior to production, all approved designs are transferred into shop drawings and/or written manufacturing specifications. These drawings and specifications are reviewed by Upper Management along with Quality Assurance, and are issued as controlled documents, in accordance with *QMSP-1001 Control of Documents*.

Design changes

- As the design evolves, required design changes may be identified from preliminary studies, design reviews, prototype testing, etc. During development of the design project, proposed design changes are reviewed and authorized by the Engineering Manager or Upper Management.
- Any design changes made during the manufacturing process are marked in red ink on the detail drawing, signed and dated by the individual making the change. All changes are reviewed by the Engineering Manager prior to revision changes and release of controlled drawing. Any changes marked on the drawing prior to Engineering approval are to be considered reference only unless approved by Engineering and or designee.
- All design and design verification activities related to implementation of a design change follow the same rules and controls that apply to the initial design and are described in this procedure.