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	Operational Procedure: EOP-04-01	Rev.: A	Pg. <u>1</u> of 7

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I 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.

II APPLICATION

This procedure applies to design and development of new products and product improvements.

This procedure directly concerns the Design Engineering department and departments interfacing with it, such as Marketing, Sales, Contracts, Production Engineering, Production, and Quality Assurance.

III PROCEDURE

1. Design Input

- 1.1 When new product development or improvement of existing product is initiated internally within the company, Design Engineering receives from Marketing a product brief. The brief describes the desired product in terms of its performance characteristics, aesthetic design characteristics, applicable standards and statutory requirements, packaging requirements, and other relevant information defining the product.
- 1.2 When a product is to be designed or modified to meet specific customer requirements, Design Engineering receives from Contracts either a design or design modification order containing all requirements stated by the customer. The product brief and the design order contain the same type of information, and both provide Design Engineering with design input.
- 1.3 Product briefs and design orders are reviewed by Marketing/Contracts, Design

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DESIGN CONTROL

Operational Procedure: EOP-04-01

Revision: A

Page 22 of 7

Engineering, and QA prior to issue and release. When required, Production Engineering, Production, and Purchasing may be added to the review team. Design input review is integrated with contract review activities (refer to Procedure MOP-03-02 Contract Review for Custom Products). Ambiguous or conflicting requirements are resolved prior to release.

- 1.4 Design input is documented. Documents defining design input can be in any form, including data sheets, customer drawings and specifications, photographs, samples, references to standards and codes, and so forth. All documents constituting the design input are assembled and/or referenced in the design project book.
- 1.5 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 Marketing/Contracts, Design Engineering, and QA, and must be approved by the customer when the initially stated customer requirements are modified or affected in any way.
- 1.6 When design input and/or design output is transmitted or stored in CAD/CAE systems format, Design Engineering is responsible for ensuring that the computer systems are compatible with customer systems. If compatibility cannot be achieved, the customer is formally notified.

2. Design Planning and Activity Assignment

- 2.1 Every design project is managed by a Project Engineer, who is ultimately responsible for all aspects of the project.
- 2.2 The Project Engineer is responsible for establishing a design plan prior to commencement of any design activities. The plan divides the design process into phases, identifies design activities, assigns responsibilities for carrying out each specific activity, and specifies the design verification requirements. The plan also schedules design and verification activities, including design reviews.
- 2.3 For small and simple design projects, the design plan, schedule, and assignment of activities are documented in the design project plan, an example of which is enclosed at the end of this procedure. The plan lists all major design phases and activities and, for each activity, defines the source of design input, assigns personnel or design groups, defines the verification requirements, and schedules the start and finish dates.
- 2.4 For large and complex design projects, in addition to the design project plan, the Project Engineer also develops: a CPM-type project schedule; a schedule with due dates for releasing drawings, specifications, and other design output documents; a design verification and validation (prototype) plan; logs for receipt and transmittal of documents and information; and other such schedules, plans, and procedures necessary for efficient management of the design project.
- 2.5 Personnel assigned to design activities are qualified in skills and techniques appropriate

DESIGN CONTROL

Operational Procedure: EOP-04-01

Revision: A

Page 32 of 7

to their activities. The skills may be, as appropriate: Geometric Dimensioning and Tolerancing (GD&T), Quality Function Deployment (QFD), Design for Manufacturing and Assembly (DFM/DFA), Value Engineering (VE), Design of Experiments (DOE), Failure Mode and Effect Analysis (FMEA), Finite Element Analysis (FEA), Solid Modeling, Simulation Techniques, Computer Aided Design and Engineering (CAD/CAE), and Reliability Engineering.

3. Organizational and Technical Interfaces

- 3.1 The Project Engineer establishes rules for transmitting information and communication between the various groups involved in the design project. The design schedule establishes due dates for release of critical information by each design group and/or activity. The Project Engineer has overall responsibility for coordinating the design groups.

4. Design Aids and Methods

- 4.1 Computer software used for carrying out calculations and other design activities is qualified and approved. Standard software, purchased from commercial sources, is ordered with validation certificates whenever possible. Software developed in-house is validated and approved prior to release. Software documentation comprises testing specification approved by the Project Engineer and validation records demonstrating its correct functioning. Software that has been used in design for at least one year prior to implementation of this procedure, and that has given satisfactory and correct performance on previous design projects, may be authorized for use without validation testing. Each new revision of software is also tested, approved, and identified with a release number.
- 4.2 Standards and other reference materials required for design are available in the standards library, maintained by the Design Engineering department. Unless otherwise specified, the latest standard issues and revisions are used. Standards and reference materials that directly provide design input data are controlled in accordance with Procedure QOP-05-02 Document Control.
- 4.3 Project Engineer determines which methods and criteria are used in carrying out calculations and other design activities.

5. Design Reviews

- 5.1 Design reviews are conducted at predetermined design stages and are scheduled in the design project plan. No less than two reviews are conducted. One proceeds early in the project, evaluating and finalizing the design input and Special Characteristics, and reviewing conceptual solutions. The other occurs after the design is substantially completed, verifying that design output meets design input requirements, and otherwise evaluating the design.
- 5.2 Design reviews are initiated by the Project Engineer but are conducted by the managers

DESIGN CONTROL

Operational Procedure: EOP-04-01

Revision: A

Page 42 of 7

(or other designated personnel) from Marketing or Contracts, Production Engineering, Production, and Quality Assurance. At a minimum, all core members of the Product Quality Planning (PQP) Team participate in the design reviews.

- 5.3 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 functional and aesthetic requirements; design FMEAs; unintended uses; environmental compatibility; reliability; manufactureability; serviceability; acceptance and rejection criteria; capability to inspect and test; availability of qualified suppliers to provide specified materials and components; and so forth. An important function of design reviews is to track the progress of design verification and validation activities. Design reviews are coordinated with product quality planning activities (refer to Procedure QOP-02-02 Design and Prototype Quality Planning).
- 5.4 The final design review meeting for a major new product development project is chaired by the President. The meeting usually takes place following completion of prototype testing. The review panel of this final design review has the authority to approve the design and release it for production.
- 5.5 Design reviews are recorded in minutes of meetings and/or reports prepared and issued by the Project Engineer.

6. Design Process and Output

- 6.1 Design process includes efforts to simplify and optimize the product and implement innovative solutions. The process also focuses on reduction of production cost and waste. The techniques used to achieve these goals are, as appropriate: Quality Function Deployment (QFD); Geometric Dimensioning and Tolerancing (GD&T); Design for Manufacturing and Assembly (DFM/DFA); Value Engineering (VE); Design of Experiments (DOE); Failure Mode and Effect Analysis (FMEA); Cost/Performance/Risk Analysis; and use of feedback from testing, production, and field experience.
- 6.2 Primary design output consists of documents that define the product and instruct how to manufacture it. These documents include drawings, specifications, procedures, workmanship standards, acceptance criteria, process operator instructions, and so forth.
- 6.3 Secondary design output consists of documents supporting the design. These documents include calculations, analysis, test results, verification and validation reports, and references to other documents supporting the design.
- 6.4 All primary design output documents are reviewed and approved prior to issue. Only the Project Engineer 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 compliance with Procedure QOP-05-02 Document Control.

DESIGN CONTROL

Operational Procedure: EOP-04-01

Revision: A

Page 52 of 7

7. Design Verification and Validation

- 7.1 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.
- 7.2 At a minimum, the design is verified and validated by holding and recording design reviews, prototype testing (when required), and by inspection and testing of finished products from the production trial run. Other forms of verification, such as carrying out alternative calculations and comparing the new design with a similar proven design, may also be used when appropriate.
- 7.3 Design verification and validation activities are identified in the design project plan and in the design and prototype Control Plan (refer to Procedure QOP-02-02 Design and Prototype Quality Planning). Production processes and readiness for mass production are also verified and validated. These activities are documented in pre-launch and production Control Plans (refer to Procedures QOP-02-03 Pre-Launch Quality Planning, and QOP-02-04 Production Quality Planning). Design verification and validation are concluded with complete layout inspection, material testing, and performance testing of products that have been manufactured during the production trial run (refer to Procedure QOP-02-04 Production Quality Planning).

8. Prototype Program

- 8.1 For complex new products, and when there is no experience with similar products, the design is verified by a prototype build and testing. When the design team and the PQP Team deems that prototype build is not necessary, the customer is formally requested to waive the requirement for a prototype program.
- 8.2 The prototype is built to be as close as possible to the final product. Whenever possible and practical, the same materials, subcontractors, tooling, and processes are used.
- 8.3 Prototype testing focuses on verification of Special Characteristics and performance, including product life, reliability, and durability. The scope of prototype testing is specified in the design and prototype Control Plans (refer to Procedure QOP-02-02 Design and Prototype Quality Planning).

9. Design Changes

- 9.1 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 Project Engineer. As long as the customer-defined design input is not affected, design changes implemented prior to release of the design do not need to be approved by the customer.

DESIGN CONTROL

Operational Procedure: EOP-04-01

Revision: A

Page 62 of 7

- 9.2 Design changes to released products, i.e., products approved for mass production, are requested using an ECR (Engineering Change Request) form. A model of the form is provided at the end of this procedure. ECRs are evaluated, and are either rejected or recommended for implementation, by Design Engineering, Production, and Quality Assurance. When an ECR is recommended for implementation, it is forwarded to the customer for a written approval or waiver of such approval. Design changes may not be implemented without written approval from the customer. Impact of a design change on Production Part Approval Process (PPAP) is always investigated and discussed with the customer. Approved ECRs initiate and provide design input for design change implementation projects.
- 9.3 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.

IV ASSOCIATED DOCUMENTS

- Contract Review for Custom Products — Oper. Proc. SOP-03-02
- Design and Prototype Quality Planning — Oper. Proc. QOP-05-02
- Pre-Launch Quality Planning — Oper. Proc. QOP-05-02
- Production Quality Planning — Oper. Proc. QOP-05-02
- Document Control — Oper. Proc. QOP-05-02
- Production Part Approval Process (PPAP) Manual
- Advanced Product Quality Planning (APQP) Manual
- Potential Failure Mode and Effect Analysis (FMEA) Manual

Insert **DESIGN PROJECT PLAN FORM** from file FRM0401.DOC

Insert **DESIGN CHANGE REQUEST FORM** from file FRM 0402.DOC