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# DESIGN AND PROTOTYPE QUALITY PLANNING

**Operational Procedure: QOP-02-02**

**Rev.: A**

**Pg. 1 of 4**

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**NOTE: Use in conjunction with QOP-02-01 Quality Planning.**

### I PURPOSE

The purpose of this procedure is to provide policies and a general system for product quality planning in the design and prototype phase. This procedure instructs how to develop the following activities and documents:

- Special Product Characteristics
- Prototype Control Plan
- Team Feasibility Commitment
- Design FMEAs

### II APPLICATION

This procedure applies only when customer contract requirements include product design and/or prototype development and testing. This procedure applies to quality planning for new or significantly modified products.

This procedure concerns all departments and managers involved in product quality planning, and in particular the Design Engineering, Production Engineering, and Quality Assurance departments.

### III PROCEDURE

#### 1. Cross Functional PQP Team

1.1 In design and prototype phase the core members of the Product Quality Planning (PQP) Team are representatives from Design Engineering, Production Engineering and Quality Assurance. In this procedure the representatives will be referred to as Design Engineer,

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# DESIGN AND PROTOTYPE QUALITY PLANNING

Operational Procedure: QOP-02-02

Revision: A

Page 24 of 4

Production Engineer, and Quality Engineer, respectively. For other rules governing PQP Teams refer to Operational Procedure QOP-02-01 Quality Planning.

## 2. Special Product Characteristics

- 2.1 Special Product Characteristics are those characteristics that can affect safety, compliance with governmental regulations, fit, function, appearance, or quality of subsequent manufacturing operations.
- 2.2 Special Characteristics symbols and notations used by customers are defined in QS-9000 Section III, Customer Specific Requirements, and in QS-9000 Appendix C. Early in design planning, Design Engineer contacts the customer to confirm that the definitions in QS-9000 apply, and to inquire whether there are any additional requirements with regard to selection and approval of Special Characteristics.
- 2.3 Special Characteristics are selected progressively as the design and prototype testing evolves. Recognizing that Special Characteristics are subject to customer approval (refer to Production Part Approval Process), the design team seeks to encourage the customer to participate in selecting Special Characteristics.
- 2.4 As the design progresses, Design Engineer maintains and updates a list of Special Characteristics. The list is reviewed and discussed by the PQP Team at every design review meeting. Upon completion of design, the list of Special Characteristics is approved and signed off by all core members of the PQP Team.

## 3. Design Failure Mode and Effect Analysis (D-FMEA)

- 3.1 Design Engineer, assisted by other members of the PQP Team, is responsible for developing D-FMEAs. At a minimum, all potential failure modes that are associated with Special Characteristics are analyzed.
- 3.2 D-FMEAs are developed using the methodology and forms provided in the Process Failure Mode and Effect Analysis (FMEA) Reference Manual. For the purpose of developing D-FMEAs, the manual is considered to be a part of this procedure.
- 3.3 Risk Priority Numbers (RPN) are calculated for each potential cause of product (subsystem or system) failure. When the numbers are high the team proposes appropriate improvement actions to 1) decrease the likelihood of occurrence of specific failure causes; and/or 2) improve design controls (design verification/validation) to increase detectability of potential design failures. Development of improvement actions is assigned to specific functions or personnel, and is completed within specified target dates. Upon completion, the PQP Team assesses the effectiveness of the actions by assigning new rankings and calculating the new RPNs.
- 3.4 Design FMEAs are controlled documents that must be approved and signed off by all core members of the PQP Team.

# DESIGN AND PROTOTYPE QUALITY PLANNING

Operational Procedure: QOP-02-02

Revision: A

Page 34 of 4

## 4. Prototype Control Plan

- 4.1 When a prototype build is required, all members of the PQP Team participate in development of the Prototype Control Plan. The plan specifies all inspections and tests to be carried out during prototype build. The Control Plan pays particular attention to verification and validation of Special Characteristics.
- 4.2 The Prototype Control Plan is developed using the methodology and forms provided in the APQP manual. For the purpose of developing Control Plans, APQP Reference Manual Section 6, Control Plan Methodology, is considered to be a part of this procedure.
- 4.3 The Prototype Control Plan is a controlled document that must be approved and signed off by all core members of the PQP Team.

## 5. Team Feasibility Commitment

- 5.1 When design planning and preliminary design are completed, the core members of the PQP Team, with the addition of the President and Contracts Manager, prepare and sign a Team Feasibility Commitment.
- 5.2 As a minimum, the Feasibility Commitment considers the company's ability to meet requirements for product performance, tolerances, process capability, statistical process control, delivery schedule, and capital equipment and tooling cost.
- 5.3 Feasibility Commitment is prepared using the Team Feasibility Commitment form provided in APQP Reference Manual, Appendix L — Forms. The form is considered to be a part of this procedure.

## 6. Other Design/Prototype Verification and Validation Activities

- 6.1 In addition to the quality planning activities defined in this procedure, the PQP Team and design team have other design verification and validation responsibilities specified in Procedure EOP-04-01 Design Control.

## IV ASSOCIATED DOCUMENTS

- Quality Planning — Oper. Proc. QOP-02-01
- Pre-Launch Quality Planning — Oper. Proc. QOP-02-03
- Production Quality Planning — Oper. Proc. QOP-02-04
- Design Control — Oper. Proc. EOP-04-01
- Advanced Product Quality Planning (APQP) Manual
- Potential Failure Mode and Effect Analysis (FMEA) Manual

# DESIGN AND PROTOTYPE QUALITY PLANNING

Operational Procedure: QOP-02-02

Revision: A

Page 44 of 4

