DISTRIBUTION

__ President	__ Purchasing	__ Human Resources
__ Design Engineering	__ Service	__ Quality Assurance
__ Production	__ Marketing	__ Quality Control
__ Production Engineering	__ Sales	__ Production Areas
__ Materials Control	__ Contracts	__ Office Areas

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

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for production pre-launch quality planning. Specifically, the procedure instructs how to develop the following activities and documents:

- Special Product Characteristics,
- Process Flowchart,
- Special Process Characteristics,
- Process Failure Mode and Effect Analysis (P-FMEA),
- Pre-Launch Control Plans, and
- Team Feasibility Commitment.

II APPLICATION

This procedure applies to quality planning for new or significantly modified products and for development of new processes.

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

III PROCEDURE

1. Cross Functional PQP Team

1.1 In the Pre-Launch phase the core members of the Product Quality Planning (PQP) Team

are representatives from Production Engineering, Production, and Quality Assurance. In this procedure the representatives will be referred to as Production Engineer, Production Manager, 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 **Application:** This Section 2, Special Product Characteristics, applies only when COMPANY NAME Inc. is not responsible for product design and/or prototype testing. When design is included in the contract, the list of Special Characteristics is established in the Design and Prototype Quality Planning phase (refer to QOP-02-02 Design and Prototype Quality Planning). In this case, the Pre-Launch PQP Team only reviews the list and, when appropriate, may add new Special Characteristics.

2.2 Special Product Characteristics are those characteristics that can affect safety, compliance with governmental regulations, fit, function, appearance, or quality of subsequent manufacturing operations. Special Characteristics are designated by customers, using special symbols and notations. Special Characteristics symbols are defined in QS-9000 Section III, Customer Specific Requirements, and in QS-9000 Appendix C. The PQP Team may define new Special Characteristics in addition to those designated by customers.

2.3 Production Engineer prepares a list of Special Characteristics. Customer-designated Special Characteristics are identified in drawings, specifications, and other technical documentation provided by the customer. Additional special characteristics may be identified by the Production Engineer and other members of the PQP Team.

2.4 The list of Special Characteristics is a controlled document that must be approved and signed off by all permanent members of the PQP Team.

3. Process Flowchart and Special Process Characteristics

3.1 Production Engineer prepares the Process Flowchart. The flowchart identifies production and inspection stations, holding areas, and equipment for moving product in between stations; and illustrates the sequence of all operations. Areas, processes, stations, and equipment are precisely identified with unique numbers, codes or names, to be used for referencing in other quality planning and production documents. Other members of the PQP Team review the Process Flowchart and revert their comments and suggestions to the Production Engineer.

3.2 The Production Engineer, assisted by other members of the PQP Team, analyzes the process flow and identifies those processes and process characteristics that directly affect Special Product Characteristics. The identified process characteristics are referred to as Special Process Characteristics, and are documented in the Process Flowchart.

3.3 The Process Flowchart is a controlled document that must be approved and signed off by

all permanent members of the PQP Team.

4. Process Failure Mode and Effect Analysis (P-FMEA)

4.1 Production Engineer, assisted by other members of the PQP Team, is responsible for developing the P-FMEAs. At a minimum, all processes that affect Special Product Characteristics, i.e., all Special Process Characteristics, are considered in the P-FMEAs.

4.2 P-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 P-FMEAs, the manual is considered to be a part of this procedure.

4.3 Risk Priority Numbers (RPN) are calculated for each potential cause of process failure. When the numbers are high the team proposes appropriate improvement actions to decrease occurrence of the causes and/or increase detectibility of failures (nonconformances). The actions focus on prevention rather than detection of nonconformances. 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.

4.4 Process FMEAs are controlled documents that must be approved and signed off by all permanent members of the PQP Team.

5. Pre-Launch Control Plan

5.1 All members of the PQP Team participate in development of the Control Plan. In this phase the Control Plan specifies the inspections, tests, and process control measures required to develop adequate manufacturing processes. At a minimum, all Special Product Characteristics and associated processes are considered in the Control Plan.

5.2 The Pre-Launch 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.

5.3 The Pre-Launch Control Plan is a controlled document that must be approved and signed off by all permanent members of the PQP Team.

6. Measurement Systems and Process Capability Planning

6.1 Concurrently with developing manufacturing processes, the PQP Team plans how processes will be studied and evaluated, and what measurement systems will be used to verify processes and products. Formal measurement system evaluation and process capability study are carried out in the Production Quality Planning phase. However, in this Pre-Launch phase, the QA Manager is responsible for ensuring that adequate measurement systems and process evaluation techniques are available for the process

development project.

7. Team Feasibility Commitment

7.1 **Application:** This Section 7, Team Feasibility Commitment, applies only when COMPANY NAME Inc. is not responsible for product design and/or prototype testing. When design is included in the contract, the Team Feasibility Commitment is prepared in the Design and Prototype Quality Planning phase (refer to QOP-02-02 Design and Prototype Quality Planning).

7.2 When preliminary planning for manufacturing process is completed, the core members of PQP Team, with the addition of the President and Contracts Manager, prepare and sign a Team Feasibility Commitment.

7.3 At a minimum, 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.

7.4 Feasibility Commitment is prepared using Team Feasibility Commitment form provided in APQP Reference Manual, Appendix L — Forms. The form is considered to be a part of this procedure.

IV ASSOCIATED DOCUMENTS

- Quality Planning — Oper. Proc. QOP-02-01
- Design and Prototype Quality Planning — Oper. Proc. QOP-02-02
- Production Quality Planning — Oper. Proc. QOP-02-04
- Measurement System Evaluation — Oper. Proc. QOP-11-02
- Statistical Process Control — Oper. Proc. OOP-03-03
- Receiving Inspection — Oper. Proc. QOP-10-01
- In-process Inspections — Oper. Proc. QOP-10-02
- Final Inspection — Oper. Proc. QOP-10-03
- Advanced Product Quality Planning (APQP) Manual
- Potential Failure Mode and Effect Analysis (FMEA) Manual
- Measurement System Analysis (MSA) Manual
- Statistical Process Control (SPC) Manual
- Production Part Approval Process (PPAP) Manual