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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 launch and mass production quality planning. Specifically, the procedure instructs how to develop the following activities:

- Production Trial Run,
- Measurement System Evaluation,
- Preliminary Process Capability Study,
- Complete Layout Inspection,
- Material Testing,
- Performance Testing,
- Production Control Plan, and
- Quality Planning Sign-Off.

II APPLICATION

This procedure applies to quality planning and part approval for mass production of new or significantly modified products.

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

III PROCEDURE

1. Cross Functional PQP Team

1.1 In the Production 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. Production Trial Run

2.1 Upon completion of pre-launch development projects, and prior to commencement of mass production, the product and production processes are validated in a production trial run. The Production Manager is responsible for conducting the trial run.

2.2 The trial run is conducted using the same materials, equipment, tooling, operators, and process parameters that will be used in mass production. The minimum required product quantity for the run is stipulated in the PPAP Manual, or is otherwise determined by the customer. If the customer does not require any specific quantity, the PQP Team determines the quantity, considering how many units (cycles or time) are necessary for a meaningful statistical evaluation of processes and measurement systems.

2.3 Production trial run provides samples for product validation testing (complete layout inspection and performance testing), and is used to conduct preliminary process capability study and measurement system evaluation.

3. Measurement System Evaluation

3.1 Prior to (or during) the production trial run all new measurement systems referenced in the Control Plan are evaluated. Systems that have been previously evaluated do not need to be evaluated again, unless the old evaluation studies are incompatible with the new proposed applications. Quality Engineer is responsible for conducting the measurement system evaluation studies.

3.2 As a minimum, a repeatability and reproducibility study (Gauge R&R) is conducted. When relevant, the measurement system is also checked for stability, bias, and linearity.

3.3 Detailed procedures for evaluating measurement systems are provided in the Measurement System Analysis (MSA) Reference Manual. The Quality Engineer selects appropriate procedures to be used for specific studies. Detailed instructions for conducting measurement system evaluation are provided in Operational Procedure QOP-11-02 Measurement System Evaluation.

4. Preliminary Process Capability Study

4.1 Preliminary process capability studies are conducted during the production trial run. At a minimum, capability is determined for all processes affecting Special Characteristics. The Production Manager is responsible for conducting the studies.

4.2 Preliminary capability studies are short term, i.e., they do not account for long-term variations in materials, equipment, operators, etc.

4.3 The PQP Team defines the methods and parameters for the process capability study, including the type of charting to be used, the number of subgroups and their size, and the criteria for evaluation of results. The studies are developed and evaluated using the techniques, procedures and acceptance criteria provided in the SPC Reference Manual, PPAP Manual, and QS-9000 Section 4.9.2 — Preliminary Process Capability Requirements. Detailed instructions for conducting preliminary process capability studies are provided in Operational Procedure OOP-09-03 Statistical Process Control.

5. Complete Layout Inspection

5.1 At least one part from the production trial run is thoroughly inspected, to include all dimensions and characteristics defined in drawings and specifications. The Quality Engineer is responsible for conducting the layout inspection.

5.2 Detailed requirements and instructions for conducting the complete layout inspection are provided in the PPAP Manual, Section V-F, Dimensional Evaluation. This section of the PPAP Manual is considered to be a part of this procedure.

6. Material Testing

6.1 When chemical, physical, or metallurgical requirements are specified, at least one part from the production trial run is subjected to material testing. The Quality Engineer is responsible for conducting (or subcontracting) material testing.

6.2 Material testing is usually subcontracted to outside laboratories. Only qualified laboratories, i.e., those included in the approved vendor list, are used. When it is a contractual requirement, customer designated and/or accredited laboratories are used.

6.3 Detailed requirements and instructions for conducting material testing are provided in the PPAP Manual, Section V-G, Material Tests. This section of the PPAP Manual is considered to be a part of this procedure.

7. Performance Testing

7.1 When performance or functional requirements are specified, at least one part (unit or subsystem) from the production trial run is thoroughly tested to verify that it meets the performance specifications. The Design Engineer is responsible for performance and/or

functional testing.

7.2 Detailed requirements and instructions for conducting performance testing are provided in the PPAP Manual, Section V-H, Performance Testing. This section of the PPAP Manual is considered to be a part of this procedure.

8. Production Control Plan

8.1 All members of the PQP Team participate in development of the Production Control Plan. In this phase the Control Plan specifies the inspections, tests, and process control measures required to ensure that products comply with specified requirements, and that production process variation stays within acceptable limits. At a minimum, all Special Product Characteristics and associated processes are considered in the Control Plan.The plan is based on the data, knowledge, and experience acquired during the production test run and associated studies.

8.2 The Production 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.

8.3 Production Control Plan is a controlled document that must be approved and signed off by all core members of the PQP Team.

9. Process Instructions

9.1 Process instructions provide process operators with data and instructions explaining how to operate process equipment and machines, how to set up the machines, how to chart and evaluate process variation data, how to carry out inspections, and so forth. Process instructions are developed by the Production Manager. Operational Procedure OOP-09-02 Process Operator Instructions explains in detail how to establish process instructions.

10. Quality Planning Sign-Off

10.1 Upon completion of the production quality planning process, the PQP Team reviews results of all activities prescribed in this procedure and verifies that the Control Plans and process instructions are implemented, and that the specified gauges and test equipment are available and are being properly used.

10.2 When satisfied that the quality plan is completely and satisfactorily developed, and that it is properly implemented, the PQP Team formally signs off the Product Quality Planning Summary form. A model of the form is provided in Appendix F of the APQP Reference Manual.

IV ASSOCIATED DOCUMENTS

- Quality Planning — Oper. Proc. QOP-02-01
- Design and Prototype Quality Planning — Oper. Proc. QOP-02-02
- Pre-Launch Quality Planning — Oper. Proc. QOP-02-03
- Measurement System Evaluation — Oper. Proc. QOP-11-02
- Statistical Process Control — Oper. Proc. OOP-09-03
- Process Operator Instructions — Oper. Proc. OOP-09-02
- In-process Inspections — Oper. Proc. QOP-10-02
- Final Inspection — Oper. Proc. QOP-10-03
- Advanced Product Quality Planning (APQP) Manual
- Measurement System Analysis (MSA) Manual
- Statistical Process Control (SPC) Manual
- Production Part Approval Process (PPAP) Manual