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I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for

- Conducting preliminary process capability study, and
- Monitoring ongoing process performance.

II APPLICATION

This procedure applies to those production and assembly processes that directly affect Special Characteristics.

This procedure directly concerns Production Engineering, Production, and Quality Assurance functions.

III PRELIMINARY PROCESS CAPABILITY STUDY

1. General

- 1.1 Preliminary process capability studies are conducted to verify that processes responsible for Special Characteristics are capable of producing products that meet customer requirements. The study is conducted by the Production Engineer, usually during the production trial run. Operational Procedure QOP-02-04 Production Quality Planning assigns the responsibility and provides general rules for conducting the studies.

2. Data Collection and Charting

- 2.1 Procedure for conducting preliminary process capability studies is provided in the Production Part Approval Process (PPAP) Manual, Section V-D, Preliminary Process Performance Evaluation. This section of the PPAP Manual is considered to be a part of

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this procedure.

- 2.2 Only variables data are used for preliminary process capability study. Attributes data are not suitable for calculating short term process performance and process capability indices for stable processes. However, when variables data cannot be obtained, attributes data are also charted to understand the process and to begin control charts for process performance monitoring.
- 2.3 Unless there is a reason to use other charting methods, the Average & Range (X-bar & R) chart is used for preliminary process capability studies. For a X-bar & R chart, the study is based on at least 25 subgroups containing 100 or more individual readings. The Production Engineer makes the ultimate decision which charting method to use and what should be the number and the size of subgroups.
- 2.4 Blank chart samples and detailed instructions for calculating averages and ranges and for plotting the charts are provided in the Statistical Process Control (SPC) Reference Manual.

3. Evaluation of Charts and Calculation of Performance Indices

- 3.1 After the ranges and averages are charted, the average range, process average, and control limits are calculated and are drawn on the charts. The charts are then evaluated for signs of process instability. Instructions for interpreting and evaluating charts are provided in the SPC Manual.
- 3.2 When the process appears unstable, special causes of variation are investigated and, if possible, eliminated. When the process is stable, or is chronically unstable (with predictable special variation) with output meeting specification, the process performance index Ppk and, for stable process, the process capability index Cpk are calculated. Instructions for calculating the indices are provided in the SPC Manual.

4. Acceptance Criteria and Customer Approval

- 4.1 The customer determines the criteria for acceptable processes. Guidelines for acceptable performance and capability indices are provided in PPAP Manual, Section V-D, Preliminary Process Performance Evaluation, and in QS-9000, Section 4.9.2, Preliminary Process Capability Requirements. The Cpk and Ppk values provided in PPAP and QS-9000 are default values, i.e., they are used as criteria for acceptance of processes only when the customer does not specify other, higher or lower, values.
- 4.2 If the attained Ppk and/or Cpk values are lower than those specified by the customer, the Production Engineer initiates a study to identify the special causes of variation and, if necessary, the common causes of variation; and implements corrective actions to eliminate or reduce the causes.
- 4.3 If a process cannot be improved to attain the performance and/or capability indices required in PPAP and QS-9000, but the process appears capable of producing acceptable

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products, the customer is contacted and, when appropriate, is asked to accept lower index values. It may also be that traditional control chart methods are not suitable for the process evaluation, in which case the customer is asked to accept other methods of demonstrating acceptability of the process.

- 4.4 If the process is clearly not capable, the customer is contacted and is asked to accept a temporary reaction plan, for example, containment of process output and 100 percent inspection. While the temporary containment plan is implemented, a corrective action plan is developed to ensure that the process becomes stable and capable.

5. Process Changes

- 5.1 When there is a change of a part number, engineering revision level, material source, manufacturing location, or production process, a new preliminary process capability study may be required. In the event of any such change the customer is informed and asked whether a new study should be conducted.

IV ONGOING PROCESS PERFORMANCE MONITORING

1. General

- 1.1 Performance of processes responsible for Special Characteristics is continuously monitored using SPC methods. The Production department is responsible for collection of data, charting, and calculation of performance indices. The Production Engineer is responsible for making decisions with regard to process acceptability and corrective actions when required.

2. Data Collection and Charting

- 2.1 The characteristics to be monitored, evaluation/measurement techniques, sample sizes, and sampling frequencies are specified in Production Control Plans. Instructions on how to collect and analyze process performance data are provided in process operator instructions.
- 2.2 The Production Engineer determines the charting method to be used. Unless there is a reason for using other methods, the Average & Range (X-bar & R) chart is used for process performance monitoring. Operators are instructed how to use control charts in process operator instructions (refer to Procedure OOP-09-02 Process Operator Instructions).
- 2.3 Such process events as tool change, machine repair or maintenance, or adjustment of any process parameter are noted on the control charts. The information is necessary to study the correlation between these process variables and process performance.

3. Process Performance Evaluation

- 3.1 Process operators continuously interpret and evaluate the control charts. When a point

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(or a number of points) is outside the control limits, or the pattern in non-random, operators initiate an appropriate response action. Response action instructions are provided on the chart or in separate instructions. When the process instability is serious, or when response actions fail to improve the process, the Production Engineer is called upon to make appropriate decisions.

- 3.2 Process performance Ppk and/or process capability Cpk indices are calculated at intervals prescribed by the Production Engineer. When the Cpk value falls below 1.33 or the Ppk value falls below 1.67, process performance may no longer satisfy customer requirements.

4. Response Actions

- 4.1 In response to unsatisfactory process performance, the Production Engineer initiates a study to identify the special causes of variation and, if necessary, the common causes of variation; and implements corrective actions to eliminate or reduce the causes.
- 4.2 If a process cannot be improved to attain the specified performance and/or capability indices, but the process appears capable of producing acceptable products, the customer is contacted and, when appropriate, is asked to accept lower index values. It may also be that traditional control charting methods are not suitable for the process evaluation, in which case the customer is asked to accept other methods of demonstrating acceptability of the process.
- 4.3 If the process is clearly not capable, the customer is contacted and is asked to accept a temporary reaction plan, for example, containment of process output and 100 percent inspection. While the temporary containment plan is implemented, a corrective action plan is developed to ensure that the process becomes stable and capable.
- 4.4 When a process is highly capable, the Production Engineer may reduce the sampling frequency and/or change the process monitoring method. Customer approval of the proposed changes is required.

5. Continuous Improvement

- 5.1 Even when processes attain the required capability and/or performance, they may be further improved, especially when reduction of variation within tolerance is desired by the customer. The decision whether satisfactorily performing processes should be further improved is made on the basis of a cost-benefit analysis, i.e., comparison of the cost and effort required to further improve the process, versus the benefit the improvement will bring the customer (refer to Procedure QOP-22-01 Continuous Improvement).

6. Control Charts Are Quality Records

- 6.1 Control charts are identified and are traceable to batches and/or individual products that have been processed in the charted interval. When it is a contractual requirement, the charts, or copies, are enclosed with shipments of finished products, to evidence that the

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products comply with specified requirements.

- 6.2 Control charts are retained as quality records. Storage location and retention period are specified in Procedure QOP-16-01 Quality Records.

V ASSOCIATED DOCUMENTS

- Production Work Order — Oper. Proc. OOP-09-01
- Process Operator Instructions — Oper. Proc. OOP-09-02
- In-Process Inspections — Oper. Proc. QOP-10-02
- Statistical Process Control (SPC) Manual
- Production Part Approval Process (PPAP) Manual