

**SUPPLIER QUALITY ASSURANCE MANUAL  
FOR PARTS AND RAW MATERIALS**

\*\*\*\*\* QUALITY ASSURANCE FOR TRIAL PRODUCTION \*\*\*\*\*

**SECTION 18 - CRITICAL CONTROL CHARACTERISTICS AND PROCESS  
CAPABILITY STUDIES**

**PURPOSE:** To define the requirements for process capability studies of Critical Control Characteristics.

**SCOPE:** Applies to Suppliers of production parts and raw materials when specified on the Notification of Quality Assurance Requirements or otherwise identified by the Supplier as critical.

**EXPLANATION:**

1. Critical Control Characteristics are part characteristics that significantly affect performance, fit, function or workability on the completed vehicle, and therefore require application of statistical measures for capability assessment and control.
2. It is recommended that the Supplier use the AIAG manual "Statistical Process Control- SPC" or other recognized materials as a reference for conducting process capability studies.

**SUPPLIER RESPONSIBILITIES:**

1. Prior to Mass Production, the Supplier must analyze the stability and capability of the processes which contribute to variation in the Critical Control Characteristics (Gage R & R studies must be conducted on critical items as listed on the NQAR).
2. For each designated characteristic, the Supplier must submit a process capability study with dimensional data to DENSO QA/QC from final tooling. See Table 1 "Process Capability Study Requirements" on page 2 for specific requirements.
3. Long term process capability studies are recommended for Supplier's continuous process improvement. The results of these studies should be made available to DENSO QA/QC upon request. See Tables 1 "Process Capability Study Requirements" and Table 2 "Long Term Process Capability Requirements" on pages 2-3 for specific requirements.

**Note: Mass Production long term capability studies must include all sources of variation (e.g. new shift, die set, material source, etc.).**

<b>ISSUE</b> 1	<b>REVISION</b> 01	<b>DENSO MANUFACTURING</b>	<b>SECTION</b> 18
October 2005			<b>PAGE</b> 1 OF 4

**SUPPLIER QUALITY ASSURANCE MANUAL  
FOR PARTS AND RAW MATERIALS**

\*\*\*\*\* QUALITY ASSURANCE FOR TRIAL PRODUCTION \*\*\*\*\*

4. Process and part capability studies are not the same. Process study is related to process parameters such as temperature and pressure that could significantly affect part characteristics.
  
5. Capability studies can be affected by Engineering Change Instructions, Process Change Requests, Design Change Requests, or part tolerance changes and therefore must be re-submitted for characteristics affected by change.

**Table 1: Process Capability Study Requirements**

	<b>Short Term</b>	<b>Long Term</b>
<b>Number of Samples</b>	30 minimum	50 or as required to determine sources of variability
<b>Expectation:</b>		
<b>1) Process</b>	Stable	Stable
<b>2) Cpk</b>	1.67 or greater	1.67 or greater
<b>If expectation is not achieved:</b>	Provide Countermeasure	<b>See Table 2</b>

Note: Critical Control Items require the use of appropriate statistical control techniques. Refer to the AIAG manual Statistical Process Control- SPC for appropriate examples of statistical controls.

**SUPPLIER QUALITY ASSURANCE MANUAL  
FOR PARTS AND RAW MATERIALS**

\*\*\*\*\* QUALITY ASSURANCE FOR TRIAL PRODUCTION \*\*\*\*\*

**Table 2: Long Term Process Capability Requirements**

The most recent point indicates that the process (see below):	<b>ACTIONS ON THE PROCESS OUTPUT</b> Based on the Historical Process Capability (Cpk)		
	Less than 1.33	1.33 - 1.67	Greater than 1.67
Is in control <sup>1</sup>	Contact DENSO QA/QC to discuss appropriate countermeasure.	Accept product. Continue to reduce process variation. Pursue Cpk of 1.67 or greater.	Accept product. Continue to reduce process variation.
Has gone out of control in an adverse direction. All individuals in the sample are within specification <sup>1</sup>	<b>IDENTIFY AND CORRECT SPECIAL CAUSE</b>		
	Contact DENSO QA/QC to discuss appropriate countermeasure.	a). Perform sampling <sup>2</sup> on existing product, construct histogram from those samples, take appropriate action.  b) Increase sampling frequency until stability is re-established.	Accept product. Continue to reduce process variation.
Has gone out of control and one or more individuals in the sample are outside specification <sup>1</sup>	<b>IDENTIFY AND CORRECT SPECIAL CAUSE</b>		
	Inspect 100% since the last in-control point.	Inspect 100% since the last in-control point.	Inspect 100% since the last in-control point.

Note<sup>1</sup>: Control refers to the status of process stability. An “out of control” condition is defined by evidence of special causes of variation on the Statistical Process Control Charts (SPC) with control limits defined from the data. A process is considered “in control” when no evidence of special causes is found.

Note<sup>2</sup>: See Table 3 for the acceptable sample size.

**SUPPLIER QUALITY ASSURANCE MANUAL  
FOR PARTS AND RAW MATERIALS**

\*\*\*\*\* QUALITY ASSURANCE FOR TRIAL PRODUCTION \*\*\*\*\*

**Table 3: Sampling Size Determination**

<b>LOT SIZE OR SHIPMENT SIZE</b>	<b>SAMPLE SIZE PER CHARACTERISTIC CLASSIFICATION ACCEPTANCE NUMBER =0<sup>1</sup></b>
0 - 25	100% Inspection
26 - 50	25
51 - 75	35
76 - 125	40
126 - 425	45
426 and up	50

Note<sup>1</sup>: If one or more individuals in the sample are out of specification, inspect 100% since last in-control point.