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Process Characterization Guideline

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PROCESS CHARACTERIZATION GUIDELINE

Contents

	Page
1 Scope	1
2 Terms and Definitions	1
3 References	1
3.1 Industry Standards	1
3.2 Examples of Process Characterization Related Documents	1
4 General Requirements	1
4.1 Description of Process Characterization Flow	2
4.1.1 Identify Process	2
4.1.2 Define Process	2
4.1.3 Determine Characteristics and Measurables	2
4.1.4 Perform Gauge Studies	2
4.1.5 Collect Data	2
4.1.6 Characterize Process Repeatability	3
4.1.7 Does Process Meet Requirements	3
4.1.8 Perform Capability Study	3
4.1.9 Is Process Acceptable	3
4.1.10 Process Improvement	3
4.1.11 Is Process in Control	3
4.1.12 Corrective Action to Remove Special Causes	3
4.1.13 Maintenance	4
4.2 Tools	4
4.2.1 Capability Analysis	4
4.2.1.1 Example of Capability Analysis	4
4.2.2 Cost Models	5
4.2.3 Data Collection	5
4.2.4 DOE	5
4.2.5 Expert Systems	6
4.2.5.1 Example of Expert Systems	6
4.2.6 Finite Element Modeling and Analysis (FEM&A)	6
4.2.7 Flow Charting/Process Mapping	6
4.2.7.1 Example of Flow Charting/Process Mapping	7
4.2.8 FMEA – Corrections are aligned with JEP131 FMEA	7
4.2.8.1 Example of FMEA	7
4.2.9 Modeling	7
4.2.10 Measurement System Evaluation/Analysis (MSE/MSA, including Gauge Studies)	7
4.2.10.1 Example of MSE/MSA	7
4.2.11 Problem Solving	8
4.2.11.1 Problem Solving Tools	8
4.2.11.1.1 Bar Chart	8
4.2.11.1.2 Control Chart	8
4.2.11.1.3 Fishbone (Cause-and-Effect) Diagram	8
4.2.11.1.4 Histogram	8
4.2.11.1.5 Pareto Chart	8
4.2.11.1.6 Scatter Plots	8
4.2.11.1.7 Time Line Chart	9
4.2.11.2 Examples of Problem Solving Tools	9
4.2.12 Statistical Analysis	9

Contents (cont'd)

	Page
4.2.12.1 Example of Statistical Analysis (See Annex G).....	9
4.2.13 Statistical Process Control (SPC)	10
4.2.13.1 Short Production Run Process Control.....	10
4.2.13.2 Example of SPC	10
4.2.14 Yield Analysis	10
4.3 Management Commitment	10
4.4 Process Characterization Documentation	11
4.5 Training	11
4.6 Calibration	11
4.7 Self-Assessment	11
Annex A Process Characterization Flow	Error! Bookmark not defined.
Annex B Terms and Definitions	14
Annex C Examples of Process Characterization Related Documents	17
Annex D Failure Mode and Effects Analysis (FMEA).....	23
Annex E Example of MSE/MSA	24
Annex F Example of Problem Solving Tools	28
Annex G Example of Statistical Analysis.....	29
Annex H Example of Statistical Process Control	30
Annex I Self-Assessment	31
Annex J (Informative) Differences Between Revisions	32

Figures**Page**

Figure 1 — Process Characterization Flow Chart for 4.1	12
Figure 2 — Example of Problem Solving Tools.....	25
Figure 3 — Example of Statistical Analysis.....	26
Figure 4 — Example of Statistical Process Control.....	27

Tables**Page**

Table 1 — Illustration of a Basic Cost Model for New Machine, Equipment or Materials	5
Table 2 — Failure Mode and Effects Analysis (FMEA)	20
Table 3 — Example to Approach a Measurement System Evaluation/Measurement System Analysis	21

PROCESS CHARACTERIZATION GUIDELINE

Introduction

Process characterization is an essential element of process control. A process is a combination of people, procedures, methods, machines, materials, measurement equipment, and/or environment for specific work activities to produce a given product or service. When properly defined and controlled, it is a repeatable sequence of activities with measurable inputs and outputs. The characterization of a process defines distinguishing features of a process and its output on which variables or attributes data may be collected. Thus, through process characterization, a manufacturer may define and measure the stability, repeatability, sensitivity, and robustness of a process. Additionally, it supplies inputs for modeling which may be used to identify critical variables, optimize efficiency and output, and provide avenues for continuous improvement. Furthermore, once process characterization has been established, the process predictability may be used for self-validation rather than auditing. Management support is essential to the effective implementation and maintenance of a process characterization system.

In this manner, the manufacturer determines appropriate characteristics for each critical process node. Target values for each characteristic chosen will be determined with variability around that value. The variability has to be identified, quantified, and minimized to acceptable process performance levels. These steps involve the use of various techniques (e.g., DOE, off-line data analysis, process mapping, etc.).

Process characterization and capability studies shall describe the process limitations with respect to critical characteristics. Both long term and short term capability studies shall be performed and documented. Results must be substantiated by data. Process/product parameters for each node may change as process flow, process techniques, equipment, or other pertinent factors change.

The expected outcome to each clause of the characterization process is implementation of recommended actions and process changes. Implementation should result in tangible and measurable performance improvements, identification of critical variables and process capabilities, that results in a process control plan and in a controlled process.

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PROCESS CHARACTERIZATION GUIDELINE

(From JEDEC Board Ballot JCB-22-37, formulated under the cognizance of JC-13 Committee: Government Liaison.)

1 Scope

This document is applicable to any manufacturing or service process (e.g., customer service, human resources, planning). It may be conducted on part of a process or on an entire process. While many approaches to process characterization exist, this document is provided as a guideline for analyzing a process. The tools and techniques presented within this guideline are basic tools that may be used to gain an understanding of a process. A general flow of characterization is presented, along with guidelines for documenting, training, self-assessment, and organizational responsibilities (RACI/ Responsible Accountable Consulted Informed).

This document provides a general methodology for the characterization of processes to achieve ongoing tangible and measurable performance improvements.

2 Terms and Definitions

See Annex B.

3 References

3.1 Industry Standards

ANSI/NCSL Z540-1, *Calibration Laboratories and Measuring and Test Equipment General Requirements*

ISO/IEC 17025, *General requirements for the Competence of Testing and Calibration Laboratories*

JEP131, *Potential Failure Mode and Effects Analysis (FMEA)*

JESD16, *Assessment of Average Outgoing Quality Levels in Parts Per Million (PPM)*

JESD557, *General Requirements for Statistical Process Control Systems*

JESD671, *Component Quality Problem Analysis and Corrective Action Requirements*

3.2 Examples of Process Characterization Related Documents

See Annex C.

4 General Requirements

A process characterization may be performed by anyone with the knowledge of the process and tools to characterize and maintain the integrity of the effort itself. It is applicable to any process, such as those involving equipment (as in manufacturing) or people (such as finance or human resources).

4 General Requirements (cont'd)

The need for a process characterization is preferably determined proactively - that is, prior to a process being implemented. It can also be applied, however, when a process has been in place over a period of time. Process characterization may also be used as an integral part of an overall process validation. In any case, its intention is to define and reduce the variability using tools and techniques appropriate for the specific step in the characterization process.

While the approach and tools may vary from process to process or manufacturer to manufacturer, planning the actual flow of the characterization is critical in understanding its overall implications for success or failure. For example, attempting to control a process may be futile prior to defining and optimizing it. Or, a capability study may be premature if the gauge with which it is performed is inaccurate. Therefore, a careful analysis of the proposed flow of the process characterization and applicable training to personnel involved may render a more thorough and effective characterization.

Annex A visually portrays the general flow for process characterization and 4.1 herein provides a corresponding description of each clause. Noted next to selected clauses are recommended tools, briefly described in 4.2, that may be applied at that specific point in the flow. The expected outcome of each clause of the characterization process is implementation of recommended actions including process changes. Implementation should result in tangible and measurable performance improvements.

4.1 Description of Process Characterization Flow

See below, and reference Figure 1 in Annex A.

4.1.1 Identify Process

At the beginning of process characterization, the process is identified and its performance requirements are established. If these performance requirements have not been met (based on sufficient data analysis later on in the process characterization flow), process identification is reexamined.

4.1.2 Define Process

Using appropriate analysis tools, the elements or variables that make up a process (such as equipment, personnel, materials, environments) are identified. This should include the known inputs and desired outputs.

4.1.3 Determine Characteristics and Measurables

The characteristics, including measurables, are defined and evaluated. In a number of organizations key performance indicators (KPIs) / performance indicators needed to ensure effective and efficient operation and control of the process may have already been defined as part of the linkage of the process to rest of the organization.

4.1.4 Perform Gauge Studies

Gauge studies are performed to understand and minimize the source of measurement error.

4.1.5 Collect Data

Methodologies are defined and implemented for assimilation of data.

4.1.6 Characterize Process Repeatability

Data is collected for a defined interval without process changes and analyzed in order to characterize and predict process repeatability.

4.1.7 Does Process Meet Requirements

Process characteristics and product parameters are evaluated against short and long term requirements of the process and the business. A determination is made if the proper characteristics were selected and sufficient data was collected and if the process is repeatable.

4.1.8 Perform Capability Study

Once a process meets the requirements, an analysis to determine process capability is performed. Process capability is determined by comparing the target to the specification limits and understanding the natural variation of the process due to common causes. Cpk's for the process are established at this time.

4.1.9 Is Process Acceptable

Based on internal needs, requirements, risk assessments, financials, and logistics, the process acceptability is determined. A determination is made whether process improvement is warranted based on the natural variation of the process. In addition, any recommended improvements are evaluated for impact to other processes and product characteristics. Forward and backward process interrelationships are established during the process as part of this decision.

4.1.10 Process Improvement

When Process improvement efforts are made, they typically resulting in reduced variability around optimized targets. Other improvements include cost reduction, yield increase, throughput increase, and risk reduction.

4.1.11 Is Process in Control

Using various process performance analysis tools, the process control status and associated limits are determined.

4.1.12 Corrective Action to Remove Special Causes

If the process has been determined to be in control, variability will occur which may be attributable to natural causes or special causes. Natural causes are considered part of the chance happenstance or “noise” that occurs in processes; typically it is small in number and nature. It is addressed more thoroughly in 4.1.13, “Maintenance”. Special causes, however, are assigned to unnatural, unusual, unplanned and typically large events caused by unexpected variability in machine, raw materials, or human error. Special causes often drive a process out of control. When a process is identified as such, corrective actions are defined, undertaken and documented, using tools such as Problem Solving. It is imperative that the process minimize the amount of product manufactured out of control. Once special causes have been removed, the process can return to its in-control state and be maintained. Error propagation may also need to be addressed, see the NIST e-Handbook of Statistical Methods.

4.1.13 Maintenance

During maintenance, the process performance is periodically evaluated for stability and improvement over time. The process is considered to be in a sustaining mode. Typically, special causes have been removed, and only natural causes (the “noises” of the process) remain. Documented action is taken when Cp, Cpk, UCL (Upper Control Limit), and LCL (Lower Control Limit) require updating based on periodic review.

4.2 Tools

The tools listed alphabetically below correspond to recommendations during the Process Characterization Flowchart (Annex A). Where feasible, examples are included. Because these tools are not intended to be a comprehensive list, the reader is encouraged to secure further information from the references listed within this guideline (See also clause 3).

4.2.1 Capability Analysis

In the development of characterization process and prior to maintenance, the data collection and statistical analysis of data is essential in determining if a process is capable of meeting the required specification limits imposed on it. The relationship between specification limits and performance results are true determinants of the process capability in meeting performance expectations.

Users of Cpk and Cp data should have sufficient amounts of statistical process control (SPC) data available to them before determining performance levels. As a minimum, 25 batches of data are recommended before a capability determination can be made. Measurement of the Cpk and Cp data performance is recommended to be continued in maintenance mode, after the process has been fully characterized.

4.2.1.1 Example of Capability Analysis

If a process has the following characteristics:

- Average: 11 Standard deviation: 1, and
- Specification limits: 5 and 15,

then the process capability indexes would be calculated as:

$$Cp = \text{Upper Spec Limit} - \text{Lower Spec Limit} / 6 \text{ sigma}$$

$$Cp = (15 - 5) / 6 = 1.66, \text{ typically indicative the process spread is capable.}$$

$$Cpk = \text{Average} - \text{Closest Spec Limit} / 3 \text{ sigma}$$

$$Cpk = |(11 - 15)| / 3 = 1.33, \text{ typically indicative that the process centering is adequate.}$$