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Process Characterization Guideline

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PROCESS CHARACTERIZATION GUIDELINE

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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 ~~or~~ 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 result~~ing~~ 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 = Upper Spec Limit minus Lower Spec Limit / 6 sigma

Cp = (15 - 5) / 6 = 1.66, typically indicative the process spread is capable.

Cpk = Average minus Closest Spec Limit / 3 sigma

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

4.2.2 Cost Models

Cost models are a management tool for reducing the cost of a process. The models include labor, materials, machine cost, set-up time, and other costs that depend on the process. Corporate overhead, executive overhead, supervisory overhead, and clerical overhead must be fairly assigned to each process module or manufacturing activity. Cost of maintenance, calibration, quality assurance, and facilities should also be allocated fairly across the manufacturing operation. With this information, management can intelligently make decisions on what are the real cost drivers in the manufacturing operation and prioritize resources to cost and then measure the improvement.

Table 1 — Illustration of a Basic Cost Model for New Machine, Equipment or Materials

Cost Model					
Area	Projected Cost	Training Cost (operation/handling)	Installation Cost (HW/SW)	Calibration Maintenance	Depreciation
Machine/Equipment					
New Materials					

4.2.3 Data Collection

In order to collect usable data, there should be a well-defined purpose and plan. Decisions should be made as to:

1) What characteristic will be assessed?
2) What data will be collected?
3) How much data will be collected?
4) When and how often will data be collected?
5) Who will collect the data?
6) What measurement tools will be used?
7) How reliable will the measurements be?

For much of the data collection efforts, GR&R should be used. Gage R&R, gage repeatability and reproducibility, is a statistical tool that measures the amount of variation in the measurement system arising from the measurement device and the people taking the measurement.

4.2.4 DOE

Design of Experiments (DOE) refers to techniques for collecting and analyzing data. Most DOE applications involve multiple factors at multiple levels and one or more responses. DOE provides an efficient way of deriving the most information from the least amount of data. There are eight basic steps to DOE:

1) Define objectives -There should be a clear understanding of what is purpose of the experiment, why the experiment is necessary and criteria for success.
2) Select responses and factors -The choice of these parameters should be made by a team of experts from the areas involved in the experiment.
3) List restrictions - If some treatments cannot be completely randomized then they must be identified in order to properly design and analyze the experiment.
4) List source of experimental error - An estimate of the amount of variation in the experiment is necessary if it is desired to perform statistical tests concerning the significance of a factor’s influence on the response.

4.2.4 DOE (cont'd)

5) Choose experimental design - Choosing the right design is crucial in reaching the correct conclusion from the experiment. Different designs and their uses are well documented in a variety of DOE textbooks and references.
6) Conduct experiment - This step is where the experiment is done and the data is collected according to the experimental design established in step 5.
7) Analyze experimental data -In addition to determining which experimental factors have a significant impact on the response, statistical model diagnostics should also be performed to insure the necessary assumptions are satisfied.
8) Generate conclusions and recommendations -The results of the experiment should be properly documented and should include a recommended action or change to the process under experiment...

4.2.5 Expert Systems

An expert system is a computer software system that has been integrated into the control functions of a fully characterized process module. Decisions can then be made by the computer as the process is occurring to take corrective action before the process goes out of control, thus preventing producing out of specification material.

4.2.5.1 Example of Expert Systems

The metal deposition module is a typical example of a process that has been fully implemented in an expert system. Sensors are located within the module that measures residual gas pressure, deposition rate, temperature, bias, and power. If any of these parameters start to drift the computer compares the input data and determines what corrective action should take place. In the case of a low deposition rate, the computer may increase the reactor power to compensate for the low rate. The end result is a metal thickness that is always within control limits. The system is called expert since it has been preprogrammed with a decision tree based on knowledge of the process parameters and their interaction

4.2.6 Finite Element Modeling and Analysis (FEM&A)

FEM&A is a computer simulation tool used for calculating stresses that are applied to a device during processing, testing, and screening. The method is numerical in nature and can be used to solve a wide variety of engineering problems. A "model" is created which is comprised of discrete parts called elements. These elements are joined together at common points called nodes. The elements may be of the same type or a mixture of different types depending on the geometry of the model. Once the boundary conditions are defined, a load is applied and a solution is obtained. Various types of loading can be examined such as mechanical and thermal, and the results used to predict the behavior of the part under these conditions. In electronic hardware applications, FEM&A is typically used to predict component reliability and robustness, determine coupling effects due to material interactions at material interfaces (e.g., Coefficient of Thermal Expansion mismatches), and simulate the processes used in screening hardware.

4.2.7 Flow Charting/Process Mapping

Flow charts and process maps are pictorial representations of the key value-added steps and sequences involved in a process and how these steps relate to one another. It includes inputs and outputs of the process flow and may define sources of variation within the flow. During process mapping, it is encouraged to analyze opportunities to reduce repetitive or non-value-added steps in order to maximize throughput.

4.2.7.1 Example of Flow Charting/Process Mapping

See Process Characterization Flow in Annex A.

4.2.8 FMEA – Corrections are aligned with JEP131 FMEA

Failure Mode and Effects Analysis (FMEA) is a tool that estimates the occurrence, severity, control, response, and detectability of a failure. Failures may be related to products, people, processes, or equipment.

The typical steps for completing an FMEA are:

1) Assemble cross-functional team for specific process/equipment module.
2) Brainstorm a subset of all process/equipment problems, identified by e.g. pareto analysis
3) Identify process/equipment problems as failure modes.
4) Assign causes to failure modes.
5) Assign effects to failure modes.
6) Identify or Brainstorm all in-line process controls
7) Assign severity ranking to failure mode/effect
8) Select each failure mode
9) Select a cause, determine occurrence and detection controls and ranking
10) Assign containments or preventive actions for each failure mode/effect/cause to reduce RPN number
11) Calculate and analyze the risk priority number.
12) Maintain periodic review and updates of FMEAs, new failure modes, reassess RPN numbers, etc.

4.2.8.1 Example of FMEA

See Annex D.

4.2.9 Modeling

Modeling provides an architecture or framework on which further characterization, ideas, or applications may be based. Modeling may be approached in a variety of methods, such as mathematically or organizationally. It typically considers ramifications from a hierarchical point of view and allows a more systematic view of an entire problem, process, or characterization.

4.2.10 Measurement System Evaluation/Analysis (MSE/MSA, including Gauge Studies)

MSE/MSA is a systematic approach for determining the types of errors affecting process and product measurements and the effects of those errors. The error types to be evaluated may include repeatability, reproducibility, bias, linearity, stability, and discrimination.

4.2.10.1 Example of MSE/MSA

See Annex E.

4.2.11 Problem Solving

Problem Solving is the process of defining a problem and establishing a systematic approach to solving and preventing its recurrence (see JESD671). Within this process a number of problem solving tools are utilized. The steps involved in problem solving include:

1) Define the problem.
2) Analyze the problem. The tools cited in 4.2 are useful during this step. Gather factual information or data to determine cause and propose solutions to the problem.
3) Identify and implement containment actions
4) Brainstorm potential adaptive, corrective, and preventative actions and rank their importance. The severity of the problem and also the ease of implementation, cost, and logistics can impact ranking.
5) Develop a plan to implement the actions.
6) Implement the actions.
7) Evaluate the effectiveness of the actions in preventing recurrence of the problem for both short and long term.

4.2.11.1 Problem Solving Tools

4.2.11.1.1 Bar Chart

Provides visual comparison of data from different categories.

4.2.11.1.2 Control Chart

Used to monitor the performance of a process over time. Graphic display of either attributes (distinctive feature) or variables data show natural occurring (within the capability of the process), and unnatural (special cause) occurring variations in a process. Typically used to represent data associated with statistical process control (SPC).

4.2.11.1.3 Fishbone (Cause-and-Effect) Diagram

Provides graphic representation of the relationship between a problem (effect) and its potential cause(s).

4.2.11.1.4 Histogram

Visual representation of the dispersion of variables data within a group or groups. It is used to help identify a shift in a process and (2) to establish process limits (1). It displays the data in a frequency distribution mode.

4.2.11.1.5 Pareto Chart

An ordered chart that places the category with the highest frequency on the far left, followed in rank order by second, third, fourth, etc. The Pareto Chart typically indicates that most of the defects, failure modes, problems, etc., occur within the first few categories. The Pareto Chart typically totals 100%.

4.2.11.1.6 Scatter Plots

Provides a visual pattern which compares two separate variables to determine if there is a correlation between the events of one to the other.

4.2.11.1.7 Time Line Chart

Graphic representation of changes in a process over time.

4.2.11.2 Examples of Problem Solving Tools

See Annex F.

4.2.12 Statistical Analysis

Statistical analysis provides for organization and summation of data. It also ensures that conclusions that are drawn from experiments or characterizations are based on statistically valid analyses. It can be applied at almost any step in the characterization process, but must be carefully planned and executed to ensure that the resulting data is objective. Use statistical analysis for repeatability studies, to compare group(s) of variables, or to derive appropriate sample sizes.

4.2.12 Statistical Analysis

The utilization of computer software to assist in final calculations provides ease of analysis. Statistical analysis may include:

1) Sampling
2) Discrete and random variabilities and probability distributions
3) Hypothesis testing procedures
4) Interval estimation
5) Single and multiple analysis of variance ANOVA
6) Simple linear regression and correlation
7) Nonlinear and multiple regression
8) Analysis of categorical data
9) Distribution-free procedures

Consult clause 3 herein for references in statistical applications.

4.2.12.1 Example of Statistical Analysis (See Annex G)

The statistical analysis is the result of an experiment to study the relationship between age x and vocabulary y for young children. 10 children of particular ages were selected and vocabulary size (measured by testing) was determined for each child, resulting in the "Actual Values" noted in Annex G. (Data based on an article which appeared in *Scientific American*, November 1978). Based on the interpretation of the analysis, there is strong evidence to suggest that there is a linear relationship between age and vocabulary. For detailed interpretation, refer to clause 3.

4.2.13 Statistical Process Control (SPC)

SPC is a tool that, after a process has been characterized using statistical techniques (i.e., design of experiments, capability studies, etc.), can be applied to the process to control, optimize, and reduce variability. Where feasible, SPC emphasizes the use of in-process data (rather than "end-of-line" data) in order to better control and forecast system quality. This proactive use of SPC in conjunction with other techniques and the appropriate responsiveness to out-of-control situations serve to make SPC techniques critical in continuous improvement programs.

4.2.13 Statistical Process Control (SPC) (cont'd)

During process characterization, critical process nodes, measurables, and normality are defined, along with insuring measuring equipment integrity. Once these have been defined, a control chart is selected that is applicable to the process, such as x-bar, R-bar, C, or U chart. Control limits, typically based on three sigma standard deviations and updated periodically, are applied to the chart to track the probability of the reading occurring within these limits. Rules for when to respond and how to respond to these out-of-control situations (either exceeding lower or upper control limits) drive continuous improvement.

JESD557, General Requirements for Statistical Process Control Systems, provides an extensive reference in SPC.

4.2.13.1 Short Production Run Process Control

For products that are typically batch processed in smaller, shorter runs, a different approach in statistical process control may be warranted than typical x-bar, R charts. Consideration of a "rationale subgroup" may be necessary to ensure that a measure of the intrinsic, short term, run-to-run variation is performed. A rationale subgroup is a sampling representing items produced under conditions in which only random, short-term effects are operating. Three charts that may be applicable are: 1) a control chart for individual run values; 2) a moving range chart, and 3) a within-range chart.

4.2.13.2 Example of SPC

See Annex H.

4.2.14 Yield Analysis

Yield analysis is an ongoing, evolutionary approach to maximizing output and quality while minimizing excursions and cost. Investigative procedures, root cause analysis, and implementation of short term and long term corrective action are key to continuous improvement in yield. Analysis of low as well as high yield, near-misses, misprocesses, reworks, and scrap ensure that the reactive engineering provides for future proactive improvements. If yield is unacceptably low, then actions to reduce process variation, re-center the process output, validate the data measurement system, or modify specifications are necessary. Yield improvements may favorably affect equipment, people, and process systemic issues.

Yield analysis may be used in conjunction with other tools, such as SPC and Problem Solving, and can provide a communication and feedback apparatus to line manufacturing. Ideally, yield analysis should be utilized as a tool after the bulk of process characterization has been completed; premature analysis may lead to incorrect reactions.

4.3 Management Commitment

Management shall empower personnel with responsibility, authority, and provide sufficient resources to implement and maintain a process characterization system. They shall periodically review and document the status of the process characterization system. Management shall also take appropriate actions to continuously improve the effectiveness of the Process Characterization system.

4.4 Process Characterization Documentation

A manufacturer shall be cognizant of its approach to process characterization and include its methodology, the elements selected, and the variety of tools applied in an appropriate manner easily reviewed and communicated internally and externally. Of key importance are the specific results of the characterization itself, in order to provide sufficient data for continuous improvement or response to unpredictable excursions.

Documentation must be maintained and retained in accordance with the manufacturer's quality system.

4.5 Training

Adequate and appropriate training to support process characterization is necessary. Typically, a cross-functional process characterization team is formed with a collective membership that is proficient in the process characterization process and selected tools. A facilitator, who possesses a sound understanding of how and when to apply the appropriate tools for process evaluation, will generally lead the team. All personnel who participate should receive training in the principles and concepts of process characterization and fundamentals and theory of the tools they use. Much of this training is tied to specific tools that a company chooses to use. An effective process characterization system will utilize a number of tools which makes it difficult for any one person to be proficient in all those employed. Therefore, developing a training plan that addresses team membership, areas of expertise, and plans for distributed training of all pertinent tools will help to manage this activity. Suggested topics for a Process Characterization training program are:

Standard Training (i.e., facilitators, engineers)

a) Definitions, terminology, flow, and philosophy of Process Characterization
b) Basic Statistics
c) Basic Problem Solving (pareto analysis, cause and effect diagrams, histograms, etc.)
d) Statistical Process Control

Advanced Training (i.e., specific engineers responsible for specific equipment, processes)

a) Standard Training above
b) Process Mapping
c) Failure Mode Effect and Analysis
d) Design of Experiments
e) Gauge Analysis
f) Capability Analysis

4.6 Calibration

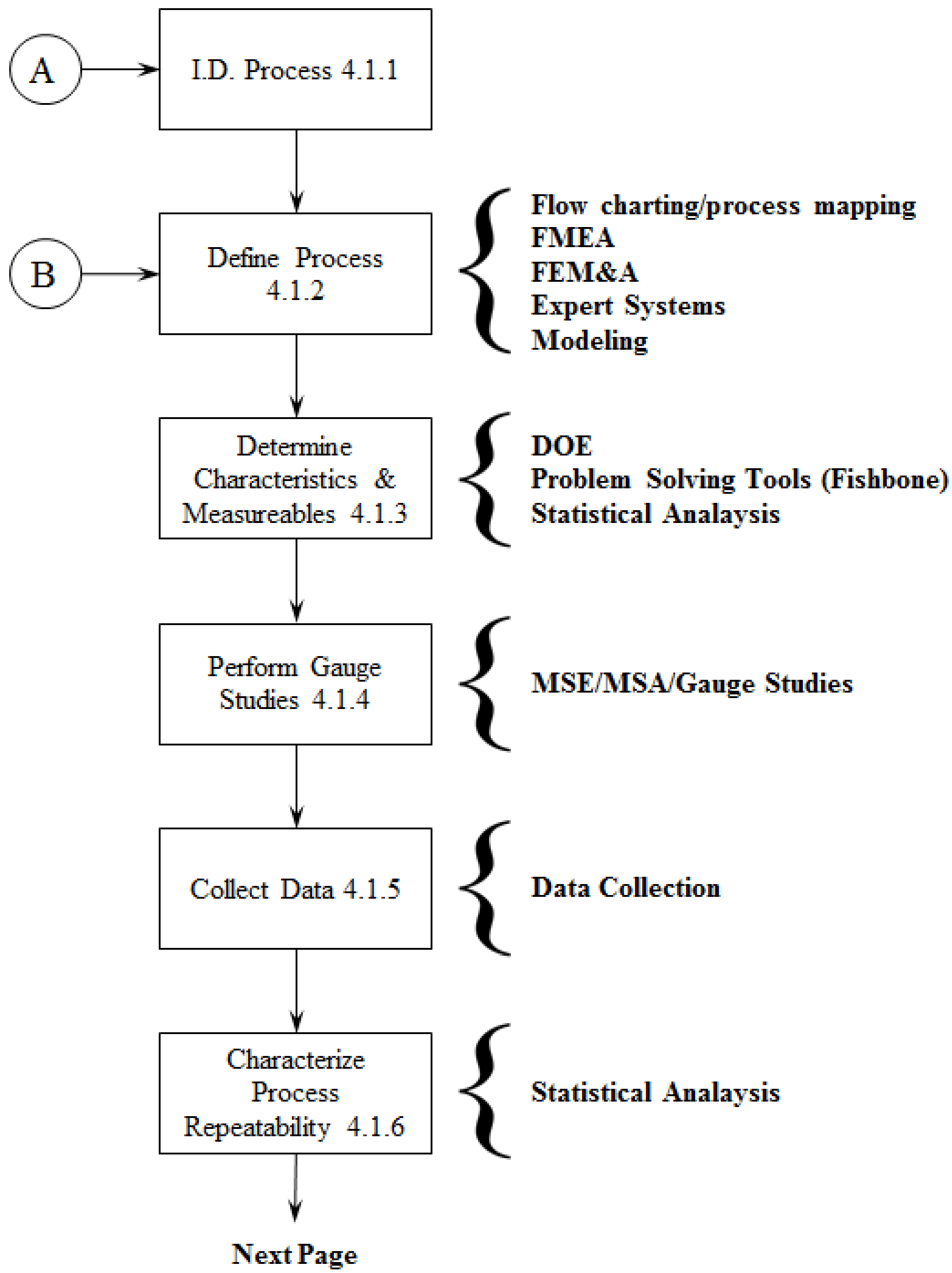
Any instrument used in the process characterization system shall be calibrated in accordance with industry standards or equivalent international standards (e.g., ANSI/NCSL Z540-1 or ISO/IEC 17025 standards or equivalent).

4.7 Self-Assessment

A self-assessment of the process characterization system shall be conducted at a frequency established by internal quality system requirements. An example of a process characterization self-assessment checklist is provided in Annex I.

Annex A Process Characterization Flow

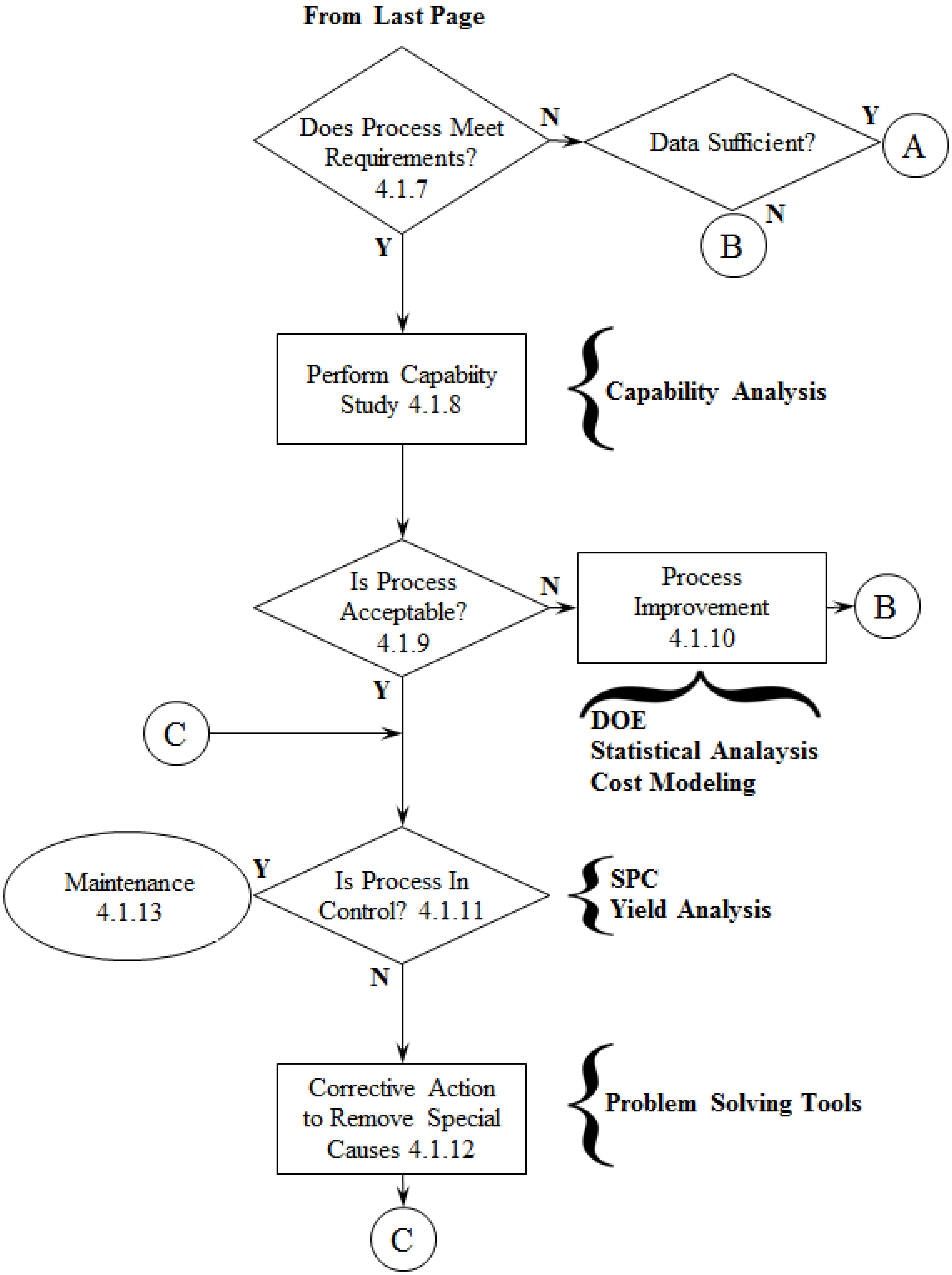
Process Characterization Flow (Clause 4.1)



NOTE Recommended tools, see Clause 4.2.

Figure 1 — Process Characterization Flow Chart for 4.1

Annex A **Figure 1 — Process Characterization Flow Chart for 4.1 (cont'd)**



Annex B Terms and Definitions

Accuracy - The difference between the sample estimate and the population parameter being estimated.

ANOVA (Analysis of Variance) - A statistical tool that allows for the comparison of more than two groups of data and provides valid assumptions. Computations of ANOVA involve partitioning total variation into two components, the variation from differences among group "means" and random variations within the groups known as "error", ANOVA provides for reliable results even when certain assumptions are violated.

Artificial Intelligence - A number of processes have highly non-linear or very complex input to output relationships. Modeling of these relationships may be done using computer hardware (neural networks) or software (expert systems, fuzzy logic). The development of the model involves the input of data, (based on human experience or experimental results), into the computer based system, and the implementation of training or learning process within that system, based on actual observed output.

Bias - The difference between the mean (or expectation) of an estimator, T, and the true value, θ, of a parameter: E(T) – θ.

Capability - The natural variation of the process due to common causes.

Capability Analysis - The study of a process to determine the probability that the characteristics of its output will fall within a previously defined set of constraints.

Cause and Effect Diagram - A tool for individual or group problem-solving that uses a graphic description of the various process elements to analyze potential sources of process variation. Also called a Fishbone Diagram (after its appearance) or Ishikawa Diagram (after its developer).

Characteristic - A distinguishing feature of a process or its output on which variables or attributes data can be collected.

Common Cause - A source of natural variation that affects all the individual values of the process output being studies. In control chart analysis it appears a s part of the random process variation.

Continuous Improvement - The methodology whereby quality improvement tools (e.g.; SPC, Ishikawa Diagram, DOE, etc.) are applied to a process to improve measurable attributes (e.g.; repeatability, efficiency, predictability, etc.).

Control Chart - A graphic representation of a process characteristic showing plotted values of some statistic gathered from that characteristic; a central line and one or two statistically derived control limits. Two basic uses are to determine whether a process has been operating in statistical control and to aid in maintaining statistical control.

Control Limits - The maximum allowable variation of a process characteristic due to common causes alone. Variation beyond a control limit may be evidence that special causes are affecting the process. Control limits are calculated from process data and are usually represented as a line (or lines) on a control chart. They are not to be confused with engineering specification limits.

Critical Process Node - A node in the process flow whose output has a significant impact on the process.

Annex B Terms and Definitions (cont'd)

Data Collection - Data is collected to verify if a problem exists, to determine the relative importance of the problem, to measure the importance of the cause, to communicate the problem to others, and to help solve the problem.

Data Points - Values that are either observed, measured or calculated.

Discrimination - The ability of the measuring equipment to differentiate between characteristic values. The equipment discrimination should be small (e.g., less than 10%) should be less compared to the process variability and/or control limits.

DOE (Design of Experiments) - DOE is a systematic approach to varying the input controllable variables in the process and analyzing the effects of these process variables on the outputs. When employed in conjunction with statistical process controls it can minimize process variability.

Efficiency - The measure of a process's ability to produce 100% of a desired output (through a common method), as a ratio of the required input (e.g.; time, materials, etc.)

Elimination of Non-Valued Activities - The deletion or elimination of costed steps within a prescribed process that do not measurably contribute to that process's ability to produce the defined output.

EWMA (Exponentially Weighted Moving Average) Chart - An SPC charting technique based on assigned weights to past observations.

Expert Systems - A computer -based form of artificial intelligence that provides decision-making capabilities within a system, based on a pre-programmed decision tree founded on knowledge of the process parameters and their interaction.

Failure Mode and Effect Analysis (FMEA) - A disciplined technique to identify and prevent potential failure modes. The FMEA provides a structured analysis in order to assess the probability of occurrence of a failure as well as the effect of the failure. A fully developed FMEA is continuously maintained and updated to reflect the latest actions and changes to the design or process.

Fishbone - See cause and effect diagram.

Flow Charting/Process Mapping - A flow chart is a chronological sequence of process steps that provides an opportunity to identify areas for improvement in efficiency and effectivity.

Input - Variables or steps that can alter, enhance, and/or validate a process.

Inputs for Modeling - The substantive and quantifiable attributes or input of a process model that when combined into a common process or methodology, can be utilized to simulate the desired output.

Linearity - The difference in the accuracy/bias values through the expected operating range of the gauge.

Modeling - Modeling is a methodology which attempts to describe characteristics of a process, or some aspect of a process. Once a satisfactory model is chosen, predictions about future output of the process can be made. Process variability, or error, is included to assess how well the model fits the true process and to bound future process predictions.

Annex B Terms and Definitions (cont'd)

Optimization - The methodology of making a process as efficient as possible.

Output - The end result of a process which is dependent on the input.

Predictability - The ability to determine in advance the quantifiable output of a process (e.g.; quantity, cycle time, etc.).

Performance Requirements - The critical process and end-product parameters.

Process - A systematic series of actions directed to some end and a part of that process that has some end.

Process Module/Node – A part of the process that has some end.

Process Analysis - Process analysis tools include histograms, scatter diagrams, time line charts, bar charts and control charts (for existing or modified processes).

Process Repeatability - A verification that the process output is consistent over time, that the product characteristics have the similar distribution parameters (i.e., mean, sigma, shape).

QFD (Quality Function Deployment) - QFD, typically applied in the development cycle, focuses on risk assessment based on customer requirements.

Repeatability - The ability of a process to consistently reproduce a given output. Repeatability involves the capabilities of an instrument, test, or process to produce the same output a multiple of times. Repeatability is considered interchangeable with the term “precision”. Statistical techniques in conjunction with data taken from repeatability studies can be used to determine the process capability of an instrument, test, or process.

Reproducibility - The variation in averages of measurements made by different operators using the same gauge when measuring identical characteristics on the same/set/sample of parts. Variation in measured averages may also be due to changes in the environment (temperature, humidity, etc.).

Response Surface Methods - A procedure using a sequential combination of DOE and regression analysis for determining factor settings that optimize a response.

Robust - A procedure that remains in control and capable within the expected variations of inputs.

Sensitivity - The degree to which a process metric or output responds to the stimulation of an input.

Stability - The measurable ability of an attribute or output of a process to remain constant within prescribed boundaries.

TQM - TQM is the management of company resources with the exclusive focus on customer satisfaction as the means of achieving sustained financial success. It combines the efforts of all employees to develop, implement, continually assess and improve the effectiveness of its processes and systems toward supporting customers' needs. Other equivalent organizations have the same responsibilities.

Variance Components Analysis/ANOVA - A DOE method of estimating the magnitude and contribution of each investigated source of variability to the total.

Yield Analysis - For existing and modified processes, is the determination of product yields and comparison to prior process performance.

Annex C Examples of Process Characterization Related Documents

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Annex C Examples of Process Characterization Related Documents (cont'd)

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"Quality Systems Terminology". ASQC, ANSI/ASQC A3-1978, Milwaukee, 1978.

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Annex D Failure Mode and Effects Analysis (FMEA)

Table 2 — Failure Mode and Effects Analysis (FMEA)

PROCESS	FAILURE MODE	POTENTIAL EFFECTS OF FAILURE	SEVERITY	POTENTIAL CAUSES OF FAILURE	OCCURRENCE	CURRENT PROCESS CONTROLS	DETECTION	RPN (S x O x D)
Inking	Smeared ink dots	Contaminate good die	6	Old ink	8	Verify at point of use	5	288
				Improper ink storage	5	Store in 40°F	4	120
		Assembly mis-process		Operator mishandling	5	Maintain certification	4	120
				Inker clogged	4	Periodic maintenance	6	144
				Too much thinner added	7	Hermetic ink capsule	7	294

NOTE RPN of 294 indicates that "Too much thinner added" is a critical potential cause of failure; it should be considered thoroughly if a failure occurs. Update the FMEA to reflect the latest design level, latest relevant actions, both preventative and reactive.

Annex E Example of MSE/MSA

Understanding the variability due to the equipment used will help to understand the total variability of a process. The following steps are an example of one method to approach a Measurement System Evaluation/Measurement System Analysis, given the following variables data:

Table 3 — Example to Approach a Measurement System Evaluation/Measurement System Analysis

Part #	Measurements 1	Measurements 2	x - bar	Range
1	11	10	10.5	1
2	14	13	13.5	1
3	10	11	10.5	1
4	17	17	17.0	0
5	9	8	8.5	1
6	13	11	12.0	2
7	12	11	11.5	1
8	9	7	8.0	2
9	14	13	13.5	1
10	15	13	14.0	2
11	11	10	10.5	1
12	8	9	8.5	1
13	13	15	14.0	2
14	14	14	14.0	0
15	19	20	19.5	1
16	16	16	16.0	0
17	10	10	10.0	0
18	9	11	10.0	2
19	15	16	15.5	1
20	19	19	19.0	0

NOTE See JESD557 for more in-depth information regarding Statistical Process Control calculations.

1) Given:

$$\sigma^2_{total} = \sigma^2_{part} + \sigma^2_{gauge}$$

2) Create an x-bar/R Chart and arrive at x-bar-bar and R-bar. In this example,

x-bar-bar = 12.8
R-bar = 1.0

It should be noted that x-bar values are typically indicative of the gauge’s ability to distinguish unit to unit, while the R values are indicative of the gauge’s magnitude of the measurement error. In-control R values would demonstrate that the gauge can measure consistently. Out-of-control x-bar values would indicate there is unit-to-unit variation.

Annex E Example of MSE/MSA (cont'd)

3) Calculate the standard deviation of the gauge. In this example,

$$\sigma_{gauge} = \frac{\text{R - bar}}{d_2} = \frac{1.0}{1.128} = 0.887$$

NOTE in the equation above, d_2 is considered to represent the mean of "range/standard deviation" or the "relative range". It is a range factor for constructing variables control charts. It is used when the mean or standard deviation is not known and they are estimated from a small preliminary sample size, assuming the distribution is normal. Values may be obtained from most statistical process control references.

4) A Precision-to-Tolerance ratio can now be calculated, one way of demonstrating gauge capability.

Precision is indicated by six standard deviations of the gauge, and Tolerance is indicated by the upper spec limit minus the lower spec limit (in this case 60 and 5, respectively)

$$\frac{P}{T} = \frac{\text{six } \sigma \text{ of the gauge}}{\text{USL} - \text{LSL}} = \frac{6\ (0.887)}{60 - 5} = 0.097$$

Values of P/T that are less than or equal to 0.1 typically imply adequate gauge capability, but that number may be adjusted for specific company preference.

5) To obtain total variability, calculate the standard deviation of the actual sample measurements and square it:

$$\sigma^2_{total} = s^2 = (3.40)^2 = 11.56$$

and therefore,

$$\sigma^2_{part} = \sigma^2_{total} - \sigma^2_{gauge}$$

$$= (11.56) - (0.887)^2$$

$$\sigma^2_{part} = 10.77$$

Therefore,

$$\sigma_{part} = 3.28$$

6) Another meaningful expression for gauge capability is determined from the following expression.

It may be more meaningful than the Precision-to-Tolerance ratio because it does not depend on the width of the specification limits. The following states that the measurement error is 27.03% of the part's characteristic variability:

$$\frac{\sigma_{gauge}}{\sigma_{part}} \times 100 = \frac{0.887}{3.28} \times 100 = 27.03\%$$

Annex E Example of MSE/MSA (cont'd)

7) To understand some of the components of the gauge variation, the following expression is used:

$$\sigma^2_{gauge} = \sigma^2_{repeatability} + \sigma^2_{reproducibility}$$

where the variation due to reproducibility may be due to different operators, shifts, or general environment. If Table 3 was representative of Operator 1, and additional data was added regarding Operator 2 and Operator 3:

Operator #	X-bar-bar	R-bar
Operator 1	12.80	1.00
Operator 2	12.28	1.25
Operator 3	12.60	1.20

8) Determine the R-bar-bar of the operators:

$$R - Bar - Bar = 1/3\ (R - Bar_{operator\ 1} + R - Bar_{operator\ 2} + R - Bar_{operator3})$$

$$= 1.15$$

9) Variation due to repeatability can now be calculated:

$$\sigma_{repeatability} = \frac{R - Bar - Bar}{d_2} = \frac{1.15}{1.128} = 1.02$$

10) Gauge reproducibility is ascertaining variability that arises because of differences among the three operators. If the x-bar-bar differs, the reason will be operator bias, since all three operators measure the same units.

$$X - Bar - Bar_{maximum} = maximum\ (X - Bar - Bar_{operator\ 1}, X - Bar - Bar_{operator\ 2}, X - Bar - Bar_{operator\ 3}) = 12.80$$

$$X - Bar - Bar_{minimum} = minimum\ (X - Bar - Bar_{operator\ 1}, X - Bar - Bar_{operator\ 2}, X - Bar - Bar_{operator\ 3}) = 12.28$$

and

$$\text{Range of } X - Bar - Bar = X - Bar - Bar_{maximum} - X - Bar - Bar_{mimimum} = 0.52$$

11) Variation due to reproducibility can now be calculated:

$$\sigma_{reproducibility} = \frac{\text{Range of } X - Bar - Bar}{d_2} = \frac{0.52}{1.693} = 0.307$$

12) The total variation of the gauge can now be calculated based on its repeatability and reproducibility:

$$\sigma^2_{gauge} = \sigma^2_{repeatability} + \sigma^2_{reproducibility}$$

$$= (1.02)^2 + (0.0307)^2 = 1.13$$

Therefore,

$$\sigma_{gauge} = 1.06$$

Annex E Example of MSE/MSA (cont'd)

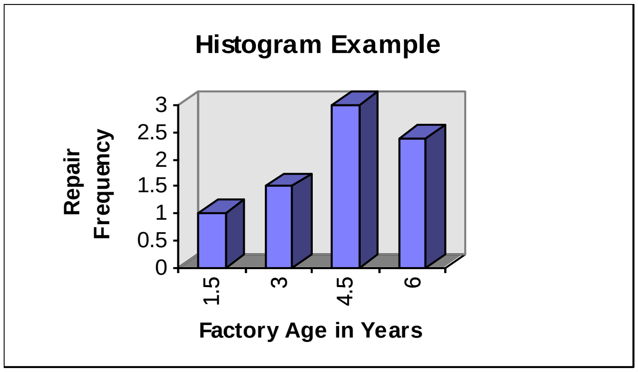
13) Note that when both reproducibility and repeatability are taken into account the standard deviation of measurement error increases:

$$\frac{P}{T} = \frac{6(\sigma_{gauge})}{USL - LSL} = \frac{6(1.06)}{60 - 5} = 0.12, \text{ and thus, too large.}$$

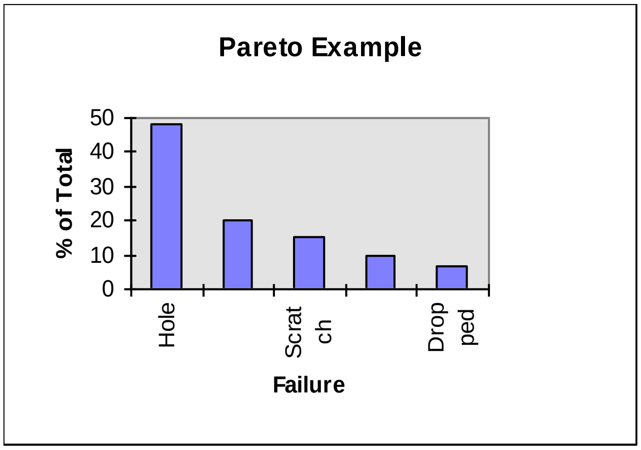
Training the operator to produce more uniform work in using the gauge would reduce the reproducibility variation, but since the repeatability variation is the largest component of the gauge variation, some effort should be devoted toward finding another piece of equipment. Note that in this example, the precision of the gauge has been analyzed, and not the accuracy. To examine accuracy would require a standard for which the value of the measured part was known.

Annex F Example of Problem Solving Tools

Fact Age	*Frequency*
1.5	1
3	1.5
4.5	3
6	2.4



Failure	*% Total*
Hole	48
Pit	20
Scratch	15
Rust	10
Dropped	7



Current	*Voltage*
2	14
5	18
1	22
7	24
2	8
4	19
5	11
10	10

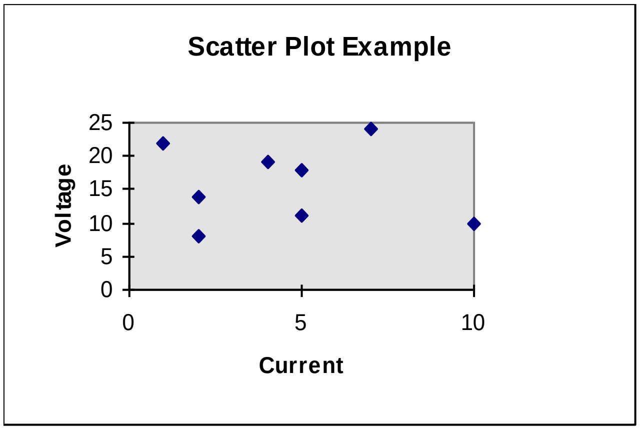
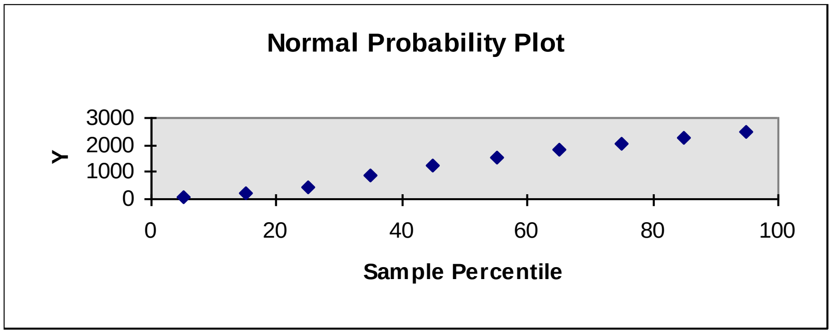


Figure 2 — Example of Problem Solving Tools

Annex G Example of Statistical Analysis

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.995843995
R Square	0.991705262
Adjusted R Square	0.99066842
Standard Error	83.87129389
Observations	10



ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	6728164.848	6728164.848	956.4669	1.29872E-09
Residual	8	56275.15152	7034.393939		
Total	9	6784440			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.000%*	*Upper 95.000%*
Intercept	-827.8181818	74.15940318	-11.16268668	3.71E-06	-998.8301828	-656.8061808	-998.8301828	-656.8061808
X Variable 1	571.1515152	18.4678511	30.92679879	1.3E-09	528.5645466	613.7384837	528.5645466	613.7384837

RESIDUAL OUTPUT

Observation	*Predicted Y*	*Residuals*	*Std. Residuals*
1	28.90909091	71.09090909	0.847619081
2	314.4848485	-64.48484848	-0.768854819
3	600.0606061	-140.0606061	-1.669946886
4	885.6363636	4.363636364	0.05202777
5	1171.212121	38.78787879	0.462469064
6	1456.787879	73.21212121	0.872910358
7	1742.363636	97.63636364	1.164121347
8	2027.939394	32.06060606	0.382259586
9	2313.515152	-13.51515152	-0.161141565
10	2599.090909	-99.09090909	-1.181463937

PROBABILITY OUTPUT

Percentile	*Y*
5	100
15	250
25	460
35	890
45	1210
55	1530
65	1840
75	2060
85	2300
95	2500

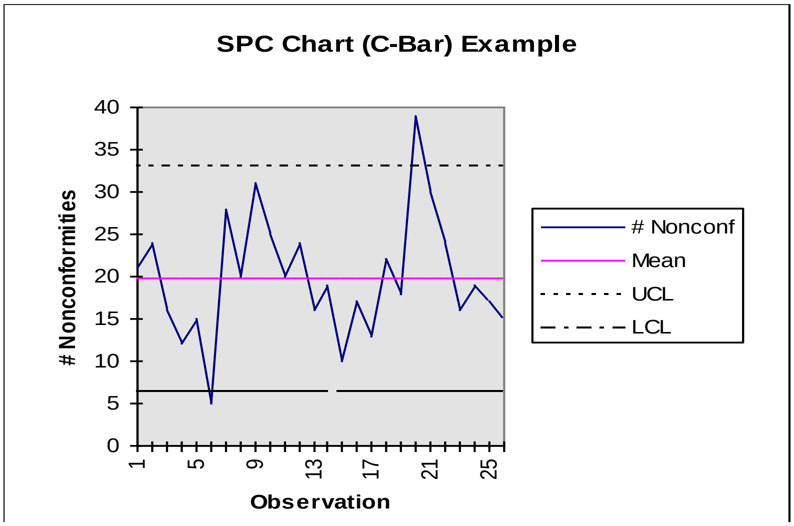
Actual Value	Actual Value
x	y
1.5	100
2	250
2.5	460
3	890
3.5	1210
4	1530
4.5	1840
5	2060
5.5	2300
6	2500

Figure 3 — Example of Statistical Analysis

Annex H Example of Statistical Process Control

Obs	# Nonconf	Mean	UCL	LCL
1	21	19.84615	33.21086	6.481447
2	24	19.84615	33.21086	6.481447
3	16	19.84615	33.21086	6.481447
4	12	19.84615	33.21086	6.481447
5	15	19.84615	33.21086	6.481447
6	5	19.84615	33.21086	6.481447
7	28	19.84615	33.21086	6.481447
8	20	19.84615	33.21086	6.481447
9	31	19.84615	33.21086	6.481447
10	25	19.84615	33.21086	6.481447
11	20	19.84615	33.21086	6.481447
12	24	19.84615	33.21086	6.481447
13	16	19.84615	33.21086	6.481447
14	19	19.84615	33.21086	6.481447
15	10	19.84615	33.21086	6.481447
16	17	19.84615	33.21086	6.481447
17	13	19.84615	33.21086	6.481447
18	22	19.84615	33.21086	6.481447
19	18	19.84615	33.21086	6.481447
20	39	19.84615	33.21086	6.481447
21	30	19.84615	33.21086	6.481447
22	24	19.84615	33.21086	6.481447
23	16	19.84615	33.21086	6.481447
24	19	19.84615	33.21086	6.481447
25	17	19.84615	33.21086	6.481447
26	15	19.84615	33.21086	6.481447

Total	516
Total/Obs	19.84615
UCL	33.21086
LCL	6.481447



NOTE Observation #6 and Observation #20 are out of control and the unnatural causes should be identified and corrected Documentation of the corrective action is also expected

Figure 4 — Example of Statistical Process Control

Annex I Self-Assessment

The following questions serve as a guideline for a self-assessment of process characterization. (If “yes/no” is not appropriate, please elaborate the answer in detail.)

Auditor: ____
Date: ____
Area: ____

ITEM	Y/N	QUESTIONS (TEXT REFERENCE)
1	___	Is there evidence of process characterization? (4.0)
2	___	Has process characterization been performed proactively, i.e., prior to equipment being brought in or a process being turned on? (4.0)
3	___	Has a flow of process characterization been planned and documented? (4.0)
4	___	What tools have been used throughout the process characterization? (4.2)
5	___	Have the performance requirements been determined at the beginning of process characterization? (4.1.1)
6	___	Have the inputs and desired outputs been identified in the process? (4.1.2)
7	___	Have the characteristics, including measurables, been defined and evaluated? (4.1.3)
8	___	If a DOE was performed, were all variables considered and were the results documented? (4.2)
9	___	Has GR&R been completed?
10	___	Have the process characteristics and/or product parameters been evaluated against short and long term requirements of the process and the business? (4.1.7)
11	___	Has and how ~~has~~ the process acceptability been determined? (4.1.9)
12	___	Have the improvements been defined and also evaluated for impact to other processes and product characteristics? (4.1.9)
13	___	Has the target been evaluated and optimized if needed?
14	___	Is the process in control? (4.1.11)
15	___	If the process indicates out-of-control situations, is there evidence of containment and corrective action? (4.1.12)
16	___	Has the process been checked in maintenance mode on a periodic basis? (4.1.13)
17	___	Has SPC been implemented without the process being characterized? (4.1.11)
18	___	Is there evidence of management commitment? (4.3)
24	___	What actions does management take to continuously improve the effectiveness of the process characterization system? (4.3.3)
26	___	Are the specific results of the various elements of the process characterization documented and in accordance with the manufacturer’s quality system? (4.4)
27	___	Is there evidence of adequate and appropriate training to support process characterization? (4.5)
29	___	Are the instruments used in process characterizations calibrated in accordance with industry standards or equivalent international standards? (4.6)

Annex I Self-Assessment (cont'd)

Table 4 — Qualitative Reference for Self-Assessment.

Assessment Status	Approach/Deployment	Results
Poor / No System	• No Documentation available	• Poor performance • No positive trends
Introductory	• Limited documentation • Major gaps exist in deployment that would inhibit progress in achieving the primary purposes of the item.	• Some good results • Early stages of developing positive trends
A good system	• Generally good documentation • No major gaps exist in deployment, though some areas or work units may be in the very early stages of deployment	• Positive trends in most areas • Good results in all areas
Excellent system	• Consistently good documentation • Approach is well-deployed, with no major gaps; deployment may vary in some areas or work units	• Current performance results are good to excellent in most areas • Most improvement trends and/or performance levels are sustained
World-class system	• Comprehensive documentation • Approach is fully deployed without any significant weaknesses or gaps	• Current performance results are excellent in all areas • Excellent improvement trends and/or sustained excellent performance levels in all areas

Table 5 — Example Assessment Checklist for Process Characterization

ASSESSMENT ELEMENT	VERIFICATION/EVIDENCE
1. Documentation: Process characterization flowchart & data is available.	Data from specific clauses within the characterization flow. Flowchart accessible.
2. Utilization: Characterization is done proactively & is performed routinely on new processes and equipment.	Evidence of characterization performed prior to usage of process or equipment.
3. Maintenance: Process characterization performed and process is reviewed periodically.	Cpk and UCL/LCLs updated periodically. Unnatural causes of variation identified quickly and documented.
4. Application: Tools are used correctly and at the appropriate step within the process characterization flow.	Specific data resulting from application of tools. Demonstration of effectiveness of tool utilization in the flow of process characterization.
5. Training: Personnel are trained in the concept of process characterization and the specific application of tools.	Training records.
6. Deployment: Use of process characterization to identify/prioritize process improvements.	Improvement plans, characterization results, meeting minutes, review board documentation.
7. Ownership: Management commitment and personnel empowered. Management review of characterization system.	Staff meeting minutes, personnel interviews and utilization of system, system reviews.
8. Self-assessment: Periodic audit of process characterization performed.	Assessment results, corrective actions, closure of open items in timely fashion.

Annex J (Informative) Differences Between Revisions

This annex briefly outlines the changes made to this publication, JEP132A.01, compared to its predecessor JEP132A

Clause	Description of Change
3.2	Updated references: added ANSI/NCSL Z540-1 and ISO/IEC 17025; removed revisions from references; moved references for ISO 9001, MIL-PRF-38534, MIL-PRF-38535 to Annex C.
4.2.11, 4.2.13, and Annex E	Removed revisions from referenced documents JESD557 and JESD671.
4.6	Corrected reference from ISO 9001 to ISO/IEC 17025.
Annex B	Updated definition of bias to remove offensive language and to match definition (2) for the term bias from JESD88.
Annex C	Added references for ISO 9001, MIL-PRF-38534, MIL-PRF-38535 to Annex C since they are not referenced in main body.

This annex briefly outlines the changes made to this publication, JEP132A, compared to its predecessor JEP132 (last reaffirmed in 2007)

Clause	Description of Change
3.2	Updated references.
4.1.3	KPI clarification.
4.1.12	NIST e-handbook reference.
4.2.11, 4.2.13	Updated references (JESD671, JESD557).
4.2.2	Updated cost model.
4.2.3	GR&R clarification.
4.2.8	FMEA reference and flow.
Annex A	Updated and aligned flow with clauses.
Annex B	Process node and module definitions added.
Annex C	NIST reference for statistical methods.
Annex E	Updated reference (JESD557).
Annex I	Updated checklist.

Standard Improvement Form **JEDEC JEP132A.01**

The purpose of this form is to provide the Technical Committees of JEDEC with input from the industry regarding usage of the subject standard. Individuals or companies are invited to submit comments to JEDEC. All comments will be collected and dispersed to the appropriate committee(s).

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1. I recommend changes to the following:
   - ☐ Requirement, clause number ________
   - ☐ Test method number ________ Clause number ________

   The referenced clause number has proven to be:
   - ☐ Unclear ☐ Too Rigid ☐ In Error
   - ☐ Other ____________________

2. Recommendations for correction:

   ____
   ____
   ____
   ____

3. Other suggestions for document improvement:

   ____
   ____
   ____
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