Managing Product and Process Variations in Support of 9103

“Variation Management of Key Characteristics”

Education Package – Based on 9103:2001 Version
Contents & Document Structure

- Introduction: Why manage variation?
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  - Why manage variation?

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  - Identifying Key Characteristics
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- 9103 presentation – cont.
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    - Summary of actions
    - 9103 stages in relation to First Article Inspection, Process Reproducibility and PDCA cycle
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What is variation?

- No two products or processes are exactly alike
- Variation exists because any process contains many sources of variation
- The differences may be large or immeasurably small, but always present
- Problems occur when the variation exceeds what the customer expects

Why manage variation?
Why manage variations?

- Variation of some sort is responsible for all non-conformances / customer dissatisfaction
- All non-conformances cost money, which reduces investment, money available for pay rises, potential to retain business
- By reducing variation it reduces the risk of non-conformances and improves ease of assembly
- Process Control helps to identify:
  - Different types of variation
  - The amount of variation
  - How well the process will meet customer requirements
- Once we know how much variation exists and the source, we can take steps to reduce it
Why do we need to minimise product and process variations?

- To enhance confidence that all your true stakeholder expectations are met
- To continuously improve the overall business results
  - To drive the continuous improvement of manufacturing processes
  - To reduce costs by eliminating wastes and unnecessary efforts
    - Levels of non conformance
    - Fitting/adjustment/selective assembly
    - Scraps and rework
    - Inspection and verification
    - Warranty claims
- To improve product performances and reliability
Why manage variations?

Why do we need to minimise product and process variations?

- Reducing Variation allows to lower total cost of acquisition while improving stakeholder satisfaction
For a country like USA, 99.9% equates to:

- 1 hour of unsafe drinking water every month
- 2 unsafe plane landings per day at O'Hare International Airport in Chicago
- 16,000 pieces of mail lost by the U.S. Postal Service every hour
- 20,000 incorrect drug prescriptions per year
- 500 incorrect surgical operations each week
- 50 newborn babies dropped at birth by doctors every day
- 22,000 checks deducted from the wrong bank accounts each hour
- 32,000 missed heartbeats per person per year
- 76 newborn babies each month would be given to the wrong parents

People generally believe that 99.9% is very good but…

Do you still believe that 99.9% is good enough everywhere?
Why manage variations?

Quality Planning Lever

- Customer takes possession (Loss of control for Producer)
- Inspection
- Potential for non-conformance
- non-conformance

Inspection is necessary but not sufficient

- Receipt
- Reject
- Customer Complaint
- Recall Warranty Investigation
Why manage variations?

**Quality Planning Lever**

Control of Product and Process Variation-----

- Understand Customer requirements
- Plan a method to achieve minimum variation
- Run and analyze the process
- Review and improve the process
- Customer takes possession (Loss of control for Producer)
- Inspection

Reducing process variation will reduce cost of inspection

**QUALITY**

non-conformance
Why manage variations?
Impact of Product and Process Variation on Total costs of acquisition

Increasing quality costs

Failure costs
Inspection costs
Prevention costs

Do you know where your business is?

Effective variation management
Why manage variations?
Managing product and process variations

On Target with minimum variation
Why manage variations?

Example: Wall thickness

Why minimal variation?

- 'Wall thickness' process variation
- Possibility of weight reduction

Reduced Tolerance

time

casing

Possibility of
Why manage variations?

**Why minimal variation?**

- **Example: Tensile Strength**

- **time**
  - Reduce variation of mechanical properties
  - LSL increase

- **disc**
  - Increase in mechanical props. for design utilisation and possibility of,
    - Increased life
    - Weight reduction

**LSL = Lower Spec Limit**
Why manage variations?

Why minimal variation?

Less likelihood of scrap or rework

Greater tolerance to nominal shift

Example: Reduce number of Quality issues
Why manage variations?

Process Capability versus Customer Satisfaction

- Awareness! +

Process Capability ➡ Product ➡ Performance ➡ Customer Satisfaction

<table>
<thead>
<tr>
<th>Process Capability</th>
<th>Product</th>
<th>Performance</th>
<th>Customer Satisfaction</th>
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</thead>
<tbody>
<tr>
<td>Development</td>
<td>Production</td>
<td>Engine</td>
<td>Aircraft</td>
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</tbody>
</table>

Cost of unstable process &/or excess variation
- concession
- scrap
- rework
- poor performance
- surprises

Awareness

- Warranty claims
- Financial losses
- Poor reliability
- High cost of ownership
- Business growth
- Enhanced reputation
- Customer delight

In-service

Development ➡ Production ➡ In-service

Key Characteristic: VOC

VOP: Value of Process

Engine

Aircraft
Do you know what Key Characteristics are?

Which ones were missed?
What are Key Characteristics (KCs)?

- 9103 Definition: The feature of a material or part whose variation has a significant influence on product fit, performance, service life or manufacturability
  - Key characteristic for a part, sub-assembly or system: selected geometrical, material properties, functional and cosmetic features which are measurable and whose variation is necessary in meeting Customer requirements
  - Key characteristic for a process: selected measurable parameters of a process whose control is essential
  - Substitute Key characteristic: when Customer defined key characteristic is not readily measurable and other characteristic may need to be controlled
What are Key Characteristics (KCs)?

- KCs are the variables whose attributes have the greatest impact on the Customer Perspective.

![Key Characteristics (Product or Process)]
What are Key Characteristics (KCs)?

- Key Characteristics are the critical features at every level of a product’s design, assembly and manufacture necessary to satisfy the customer’s requirements.
What are Key Characteristics (KCs)?

- **Product Characteristics**
  - Example: Aerodynamic gap

- **Assembly Characteristics**
  - Example: Defined gap between two panels

- **Manufacturing Characteristics**
  - Example: Wing skin thickness
What are Key Characteristics (KCs)?

- Example 1

![Figure 1.4.3 Clock Assembly](image)

- Clock
  - Readability
  - Accuracy
- Power supply
  - Voltage
  - Key: Current
- Display assembly
  - Key: Illumination
- Photo diode
  - Key: Light transmission
- Filter glass
  - Key: Component failure
- LCD
- Backlight lamp
  - Illumination
- Panel lamp
  - Key: Illumination
What are Key Characteristics (KCs)?

- Example 2 – Service-Life Characteristics

- A KC of a cargo-door actuator is its expected time to failure (MTBF)
- This KC flows down to several part-level KCs, including the case depth and case hardness of a nitralloy gear within the actuator
- Case depth and hardness are then flowed down to the KCs in the nitriding process, which produces the case depth and hardness
- The KCs in this process are the nitriding temperature, the time at temperature and the disassociation rate of ammonia during the nitriding process
Benefits of Identifying KCs

- If KCs are properly identified and correctly controlled
  - Products will have higher quality
  - Losses will be reduced
  - Costs will be cut
  - Customers will be more satisfied

- Typically, around 4-5 KCs is usual for an individual component

- A larger number of KCs may be identified for a more complex component or process
Who, Why and How to determine KCs?

- **The Customer (or the designer):**
  - **What?:** Key characteristic for:
    - a part
    - a sub-assembly
    - a system
  - **Why?:** He knows:
    - the final Customer expectations
    - the functional requirements for the part
    - the sub-assembly on which it will be installed
    - the historic data of similar parts in service, etc …
  - **How?:** Mainly based on risk analysis methodology:
    - Safety
    - Performances
    - Maintainability
    - Reliability
Who, Why and How to determine KCs?

- The supplier (or the manufacturer):
  - What?: Key characteristic for a process
  - Why?: He understands
    - his processes
    - his tools
    - his manufacturing capabilities,
    - where he failed in the past
    - where he is loosing money
    - where his scrap rate is high
    - where his Customer return rate is high, etc…
  - How?: Mainly based on risk analysis methodology
    - Reproducibility
    - Variability

Introduces Business improvement and cost savings
Who, Why and How to determine KCs?

Key characteristics may be defined by the producer even when the customer or the designer has not defined them.

Use of 9103 should not be limited to cases where Key Characteristics exist in drawing.
Drivers, actors involved, selection methods, process and KC selected may vary depending on the product and should be fixed by each company.
Approaches & Tools used to identify KCs

- From Customer Needs to Key Characteristics: Existing Advanced methods to determine KCs
  - Voice of Customer (VOC)
  - Critical to Quality (CTQ)
  - Affinity Diagram
  - QFD – Quality Function Deployment
  - Functional analysis
  - Risk analysis (FMEA Failure Modes and Effects Analysis)
  - Etc
Approaches & Tools used to identify KCs

- Need to flow down KC for each package

Customer

Supplier

Suppliers N-1

Suppliers N-2

Part CA
Part B
Part C
Part D
Final Assembly
Finished Product
Part CA Product
Part B Product
Part C Product
Part D Product
Part A Process
Part B Process
Part C Process
Part D Process
Part CA Process
Part CB Process
Part CA Input
Part CA
Part CB
Part D
Part A
Part B
Part C
Part D
Part CA
Part CB
Part D
Part A
Part B
Part C
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Part CA
Part CB
Part D
Approaches & Tools used to identify KCs

- Different methods exist to identify Key Characteristics

FMEA

Historical Data Analysis

Statistical Variation Analysis

Loss Function

Product, Process and Problem Analysis

Design of Experiments

Flow Down
Scope of 9103

- Establishes requirements for management of key characteristics variation
  - Specifies general requirements
  - Provides a process

- Primarily intended to apply to new parts but should also be applied throughout the life of the programme to ensure that changes are taken into consideration
KC and 9103 applicability

- KCs clearly given by your Customer (drawing and specifications)
  - Use of 9103 is a Requirement

- KC’s not identified by your Customer:
  - To identify Product KCs:
    - Working group involving Customer
    - In service experience (e.g. non quality analysis)
  - To identify Process KCs
    - In service experience (e.g. non quality analysis)
    - Internal issues (scrap rate, rework rate, etc…)
    - Cost and lead time reduction
    - Risk analysis
  - Use of 9103 is a General Recommendation but may become mandatory for some critical products or some contracts
9103 : A seven stages process

- 9103 - Variation Management of KCs

Stage 1: Understand KCs and required performance
Stage 2: Plan a process that will produce acceptable performance
Stage 3: Operate the process to generate Data
Stage 4: Analyse data to identify appropriate action
Stage 5: Take action from study (operate, re-design and improve)
Stage 6: Continue to monitor the performance
Stage 7: Is a process change required?

Yes

No
Stage 1 - Understand KCs and Required Performance

- **Stage 1**: Understand KCs and required performance
- **Stage 2**: Plan a process that will produce acceptable performance
- **Stage 3**: Operate the process to generate Data
- **Stage 4**: Analyse data to identify appropriate action
- **Stage 5**: Take action from study (operate, re-design and improve)
- **Stage 6**: Continue to monitor the performance
- **Stage 7**: Is a process change required?

Decision:
- **Yes**: Proceed to Stage 7
- **No**: Continue to Stage 6
Stage 1 - Understand KCs and Required Performance

- Ownership of the process
  - Establish an appropriate cross-functional team:
    - Design Engineering
    - Manufacturing Engineering
    - Process Operators
    - Customers
    - Component Definition
    - Quality
    - Laboratory
    - Inspectors
    - Anyone else who is involved...

Whoever has an input or is affected by your process

The primary owner of the process is that group, department or function that holds prime accountability for the development and production of manufacturing methods (this is not only Quality)
Stage 1 - Understand KCs and Required Performance

- An appropriate cross-functional team will allow identifying all parameters and constraints

- Design Engineer: Potential design failure modes, causes and effects
- Manufacturing Engineer: Process issues, potential failures, causes and effects
- Inspection Department: Definition of inspection methods and criteria
- Buyer (Purchasing): Feedback from Supply Chain and flow down of requirements
- Quality Engineer (Facilitator): Feedback from similar product, customer returns, guarantee that process is adequately followed
- Etc... It shall look at product, process & Customer requirements: What does he want and how we can do it?
Stage 1 - Understand KCs and Required Performance

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It shall look at product, process & Customer requirements: What does he want and how we can do it?
Stage 2 - Plan Manufacturing Processes

Stage 1: Understand KCs and required performance

Stage 2: Plan a process that will produce acceptable performance

Stage 3: Operate the process to generate Data

Stage 4: Analyse data to identify appropriate action

Stage 5: Take action from study (operate, re-design and improve)

Stage 6: Continue to monitor the performance

Stage 7: Is a process change required?

Yes → Stage 1

No → Continue
Stage 2 - Plan Manufacturing Processes

- Identify key manufacturing processes impacting key characteristics
- Ensure process owner exist for each key characteristic
- Establish a minimum acceptable capability ratio (Cp, Cpk, ...) for each key characteristic
- Identify sources of variation and potential risks… and mitigate them
- Relate process data back to what designers want…
- … and designers: Also understand capability of manufacturing Processes
Stage 2 - Plan Manufacturing Processes

- Process Control Document (PCD)

A written description of manufacturing plan developed to control variation in KCs. It is a living document and is updated to reflect the addition/deletion of any KCs.
**Stage 2 - Plan Manufacturing Processes**

**Process Control Document (PCD)**

- Used to record characteristics and progress of process
Stage 2 - Plan Manufacturing Processes

SIPOC = Supplier - Inputs - Process - Outputs - Customer

Identification of most contributing process steps

Identification of process KCs

Reduction of process KC variation

Efficient product KCs management is based on efficient Process KCs management
Stage 3 - Operate on Trial Basis to Generate Data

Stage 1: Understand KCs and required performance
Stage 2: Plan a process that will produce acceptable performance
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Stage 5: Take action from study (operate, re-design and improve)
Stage 6: Continue to monitor the performance
Stage 7: Is a process change required?

45
Stage 3 - Operate on Trial Basis to generate Data

- Create Data collection plan for all key characteristics (who, what, where, frequency, conditions,...) and ensure you have a capable measurement system

- Produce parts/components to specified work instructions in a representative environment

- Perform First Article Inspection (9102 Refers)

- Measure key characteristics on a sufficient number of parts and collect data to document any deviations
Stage 3 - Operate on Trial Basis to Generate Data

Capable Measurement System

“If it say’s 10 how do we know if it’s 10 and not 9.99 or 10.01”

Measurement Variation
Repeatability & Reproducibility
Gauge R&R
Why Worry About Measurement Variation?

Consider the reasons why we measure:

- Verify product/process conformity to specifications
- Assist in continuous improvement activities

How might measurement variation affect these decisions?
What if the amount of measurement variation is unknown?

Measurement variation can make our processes LOOK worse than they are.

* LSL and USL: Lower and Upper Specification Limits
Stage 3 - Operate on Trial Basis to Generate Data

- Measurement Unit Discrimination

- The technological ability of the measurement systems units to adequately identify variation in a measured parameter

<table>
<thead>
<tr>
<th>Measurement Unit</th>
<th>Discrimination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruler</td>
<td>.28 .279 .2794</td>
</tr>
<tr>
<td>Caliper</td>
<td>.28 .282 .2822</td>
</tr>
<tr>
<td>Micrometer</td>
<td>.28 .279 .2791</td>
</tr>
</tbody>
</table>

- Operate on Trial Basis to Generate Data
Stage 3 - Operate on Trial Basis to Generate Data

- **Measurement Accuracy**
  - Instrument accuracy is the difference between the observed average value of measurements and the master value. The master value is an accepted, traceable reference standard.

Master Value
(Reference Standard)

Average Value

Calibration of gauges!
Stage 3 - Operate on Trial Basis to Generate Data

- **Measurement Linearity**
  - A measure of the difference in accuracy (bias) over the range of instrument capability
    - Over what range of values for a given characteristic can the device be used?
    - When the measurement equipment is used to measure a wide range of values, linearity is a concern

```
<table>
<thead>
<tr>
<th>Gauge 1</th>
<th>Gauge 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linearity is an issue here</td>
<td>Linearity is not an issue here</td>
</tr>
</tbody>
</table>
```

Accuracy

![Accuracy Graph](image1)

Measurement Range

Accurate Data

![Accuracy Graph](image2)

Measurement Range
Stage 3 - Operate on Trial Basis to Generate Data

- Measurement Repeatability
  - The variation between successive measurements of the same part, same characteristic, by the same person using the same instrument

Also known as **test - retest error**

Master Value
Stage 3 - Operate on Trial Basis to Generate Data

- Measurement Reproducibility

- The difference in the average of the measurements made by different persons using the same or different instrument when measuring the identical characteristic
Stage 3 - Operate on Trial Basis to Generate Data

- Gauge Reproducibility & Repeatability (R&R) test
  - Everybody measure the part using the Vernier
  - Record the measurement (without letting anybody see it)
  - Pass the part and Vernier to the next person
  - Repeat?

Reproducibility Causes

Repeatability Causes
Stage 3 - Operate on Trial Basis to Generate Data

- Understanding Gauge R&R
  - Repeatability and Reproducibility can be expressed as a percentage of the drawing tolerance used
  - There are set of methods and formulas that work this out! It doesn’t take long to do
  - Ideally, we should not use more than 10% of the available tolerance with measurement errors
Stage 3 - Operate on Trial Basis to Generate Data

- First Article Review (Ref 9102) in relation to Key characteristics (Stage 3)
  - Adequate identification of Product and Process KCs and Capability of processes and tools used to achieve KC’s shall be demonstrated at First Article Inspection (FAI) review
  - At New Product Introduction (NPI) producer shall ensure that FAI is performed on a part that has been produced:
    - According to specified work instructions that will be used in serial production
    - In a representative environment, using scheduled Production means:
      “9102 §5.1 Note 2 : The organisation shall not use prototype parts, or parts manufactured using different methods from those intended, for the normal process for the FAI”
Stage 3 - Operate on Trial Basis to Generate Data

- Process Reproducibility review (End of Stage 4)
  - According to 9102, FAI is performed at very beginning of production, when full attention is given to this first product, but before full production rate is attained
  - However, staff learning curve, adaptation of people and tools to the production reality, natural tendency to deviate from what is really written in working instructions, production rate increase between first parts and few weeks or months later, etc leads to some hidden changes, with more or less impacts on the process and the product
Stage 3 - Operate on Trial Basis to Generate Data

- Process Reproducibility review (End of Stage 4) Cont.
  - It is highly recommended to conduct a second review some time later, based on the FAI report, when production is stabilised (rate, production means, staff, tooling, etc,..). This should take form of a product and process review or audit aiming at:
    - Ensuring that key characteristics are properly managed
    - Identifying what has possibly changed since first FAI and what are the possible impacts of these changes and. Every change compared to FAI, corresponding action and justification shall be carefully documented
    - Verifying that the collection of processes and tools in place will always reproduce a satisfactory result (sustained Customer satisfaction)
Stage 3 - Operate on Trial Basis to Generate Data

- **Impact of change on FAI and Process Reproducibility review (stage 7)**

  - “9102, §5.3”: The organisation shall perform a full FAI or a partial FAI for affected characteristics, when any of the following events occurs:
    - A change in the design affecting fit, form or function of the part
    - A change in manufacturing sources, process(es), inspection methods, location of manufacture, tooling or materials, that can potentially affect fit, form or function
    - A change in numerical control program or translation to another media that can potentially affect fit, form or function
    - A natural or man-made event, which may adversely affect the manufacturing process
    - A lapse in production for 2 years or as specified by the customer
Stage 3 - Operate on Trial Basis to Generate Data

- Impact of change on FAI and Product/and Process Reproducibility review (stage 7) – Cont.

- In this case, it is highly recommended to conduct a second full or partial Process Reproducibility review for affected characteristics as stated in stage 4

Product life (from development to series production)
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

Warning: Stages 4 and 5 need iterative actions but actors are different
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

"just carry on, that does happen occasionally"

Open the curtain to review the process

Costs / non-conformances / complaints

No learning ..............no progress
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

"Eureka!... now we know what's happening"

Open the curtain to review the process

Know learning ...........know progress
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Review control charts to determine if process is stable
  - Process not stable: Perform root cause analysis with proper tools and document it
  - Identify, classify (special or common causes, prioritise (Pareto approach, risk analysis), then remove or minimise causes... and verify effectiveness of corrective actions
  - When process is stable and only when it is stable, calculate process capability and compare with what is required to meet Customer needs
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- If process stable but not capable
  - Prioritise causes of variation
  - Identify most influential root causes
  - Investigate if centering of the process is the best answer to the problem (e.g. could decide to be closer to LSL to save weight)
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- If process stable but not capable

- Prioritise causes of variation
- Investigate if centering of the process is the best answer to the problem (e.g. could decide to be closer to LSL to save weight)

- Change the Plan
- If manufacturing processes are taken that change the process starting at Stage 2, repeat the action from study

- LCL (Lower Control Limit)
- UCL (Upper Control Limit)
- LSL (Lower Spec Limit)
- USL (Upper Spec Limit)

- Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- What should our improvement strategy look like now?

If we assume the hose pipe to be optimally positioned, then would all the water land in the bucket?

Do we need to re-position the hose pipe?

Variation reduction

.........this?

Process centering

.........or this?
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

Process Variation

- Common Causes (Environmental)
  - 85% of Variation (Many Small Problems)
  - Predictable
  - Difficult to Eliminate

- Special Causes (Assignable)
  - 15% of Variation (Few Large Problems)
  - Unpredictable
  - Easily Detected & Corrected

- Common cause or special cause? : a real life example
Although we park our car in the garage every day, we have never hit the garage wall so far.

To prevent such an accident in the future, we have to make sure that the following effects/interference factors will never cause problems:

- **Common causes:** Weather, time of day (light), cars of different sizes, ...
- **Special cause:** Drunken driver, defective brakes, ...

This can be achieved only when process capability is adequate, that means when a minimum distance is maintained between the garage wall and the car.

With increasing distance (higher process capability), less corrections are required when parking the car and getting out of the car will become easier.
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Examples of Process Variation
  - Common Causes (Environmental)
    - Poor maintenance of machines
    - Normal wear and tear
    - Insufficient training
    - Not one way of working
    - Poor working conditions
    - Measurement error
    - Ambient temperature / humidity
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Examples of Process Variation
  - Special Causes (Assignable)
    - Poor Batch of Material
    - Inexperienced Operator
    - Out of Date Drawings
    - Tool Damage
    - Maintenance Check Overlooked
    - Misread Drawing / Planning Instruction
    - Machine Breakdown
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Root cause analysis
  - In general, root cause analysis must be performed step by step
    - Process not stable: Identify and Eliminate Special causes
    - Process stable but not capable: Identify and eliminate or reduce common (systemic) causes
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Action Plan
  - Eliminate Special Cause Variation
    - Identify when it happens
    - Identify root causes
    - Eliminate root causes
  - Reduce Common Cause Variation
    - Identify amount of variation
    - Establish if it is excessive
    - Identify root causes
  - How......?

Stabilize Process

Control variations
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

How….? SPC

- Statistical Process Control (SPC) is a methodology that uses statistical techniques to make continuous improvements in quality and productivity by reducing variation in all processes

- But SPC is a tool that is highly effective for a variety of problems, but not necessarily for every one
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

How….? SPC

- SPC uses basic statistical methods
  - Histograms - to summarise process data
  - Mean - to measure process average
  - Range - to measure process variation
  - Standard deviation - another way to identify process variation
  - Control charts – to display time ordered data
  - Capability analysis – to identify process’ ability to meet design intent

- Goal of SPC: Be on target with the least amount of variation
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Normal Distribution
  - 6 Standard Deviations = $6 \sigma$
  - $6 \sigma = 99.97\%$ of the distribution

- The Normal Curve describes the distribution that will be present in most cases

- Characteristics:
  - Single Peaked
  - Bell Shaped
  - Average is Centred
  - 50\% Above & Below The Average
  - Extends To Infinity

Examples:

Shoe Sizes | Hours of Sunshine | Height of People
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Control Chart

A Control Chart is simply a Run Chart with Upper Control Limit and Lower Control Limit lines drawn on either side of the process average

- When you want to eliminate Special Cause Variations, it helps you
  - to identify when it happens
- When you want to Reduce Common Cause Variations, it helps you
  - to Identify amount
  - to establish if it is excessive

Then

- Identify root causes
- Eliminate root causes

Then

- Identify root causes
- Control if possible
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- **Control Chart Analysis**
  - Any Point Outside Control Limits
  - A Run of 7 Points Above or Below The Average Line
  - A Run of 7 Points Increasing or Decreasing
  - Any Non-Random Patterns
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Benefits of Variable Control Charts
  - Demonstrates how much common cause variation there is
  - Identifies when special causes happen
  - Allows us to establish whether the process is good enough to meet the customer needs
  - Helps to pinpoint the sources of variation
  - Shows whether a process is improving or not
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Process Capability

A Means of Establishing the Extent a Process is Likely to Produce Items Acceptable to the Design

And can be useful for:
- Measuring continual improvement over time
- Prioritising processes to improve
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Process Capability for Variable Data

Compares the spread of process data with the spread of the tolerance

It is expressed as a ratio of:

\[
\text{Drawing Tolerance} \div \text{Variation of the process}
\]

The smaller the variation, the better!
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- *Cp*

**Calculation of Cp**

\[
C_p = \frac{\text{Drawing Tolerance}}{\text{Variation of the process}} = \frac{\pm 3 \text{ mm}}{6 \times \sigma} = \frac{6 \text{ mm}}{9 \text{ mm}} = 0.67
\]

*Cp* is just a measure of how the variation of the process compares with the total tolerance.

*LSL* and *USL*: Lower and Upper Specification Limits
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

**Cpk**

Cpk is a measure of how the variation and average of the process compares with each side of the tolerance.

It is taken as the smaller value of Cpk “upper” and Cpk “lower”

Assessment against upper spec limit:

$$Cpk_u = \frac{\text{Available tolerance}}{3 \times \sigma} = \frac{\text{USL} - \text{Avg}}{3 \times \sigma} = \frac{131 - 128.4 \text{mm}}{3 \times 4.5 \text{ mm}} = 0.58$$

Assessment against lower spec limit:

$$Cpk_l = \frac{\text{Available Tolerance}}{3 \times \sigma} = \frac{\text{Avg} - \text{LSL}}{3 \times \sigma} = \frac{-128.4 - 125 \text{ mm}}{3 \times 4.5 \text{ mm}} = 0.75$$

Cpk = 0.58
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

Cp is the capability index used to measure process spread.

Cpk is the capability index used to measure process location and spread.

<table>
<thead>
<tr>
<th>LSL</th>
<th>USL</th>
<th>CP</th>
<th>Cpk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.33</td>
<td>1.33</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.00</td>
<td>2.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>
### Interpretation of Indices

<table>
<thead>
<tr>
<th>Cp</th>
<th>Cpk</th>
<th>%Defects</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7</td>
<td>0.2</td>
<td>27% (274,000ppm)</td>
<td>Not capable:</td>
</tr>
<tr>
<td>1.00</td>
<td>0.50</td>
<td>6.7% (66800ppm)</td>
<td>Barely Capable:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Part of process distribution outside of specification</td>
</tr>
<tr>
<td>1.33</td>
<td>0.83</td>
<td>0.6% (6210ppm)</td>
<td>Minimum Acceptable Process:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Process distribution barely within specification.</td>
</tr>
<tr>
<td>1.67</td>
<td>1.17</td>
<td>0.02% (233ppm)</td>
<td>Acceptable Process:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Process distribution within specification</td>
</tr>
<tr>
<td>2.00</td>
<td>1.50</td>
<td>0.0003% (3ppm)</td>
<td>World Class Process:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Process exhibits reasonable margin for error</td>
</tr>
</tbody>
</table>

### Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- **Real World Definition**

- **Interpretation of Indices**
  - Evaluation:
    - Not capable:
    - Barely Capable:
    - Minimum Acceptable Process:
    - Acceptable Process:
    - World Class Process:
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- Stabilise the process, then control variation

Simulating and gripping but dissatisfied customers...

1. Process for this production lot Unstable & unpredictable over time

2. Process for this Production lot remaining stable & predictable over time

3. Variation between lots

4. Component proving phase

...hard work but happy customers

predictable process and consistent product over time
Stage 4 - Analyse data to identify appropriate Action and Stage 5 - Take action from study

- 9103 – Monitoring and Control of KCs
  - Other Variation Control methods may be used to ensure process stability and capability
    - Tooling
    - Control of Process Settings
    - Standard Processes
    - Mistake Proofing
  - Measurable evidence must demonstrate that the controls are effective
Stage 6 - Continue to Monitor the Performance

Stage 1: Understand KCs and required performance
Stage 2: Plan a process that will produce acceptable performance
Stage 3: Operate the process to generate Data
Stage 4: Analyse data to identify appropriate action
Stage 5: Take action from study (operate, re-design and improve)
Stage 6: Continue to monitor the performance

Stage 7: Is a process change required?

- Yes
- No
Stage 6 - Continue to Monitor the Performance

• When characteristics are meeting customer requirements:
  ▪ Continue to measure periodically to detect possible long term variation
  ▪ Optimise process monitoring (reduce or increase frequency as required)
  ▪ Identify opportunity for improvement
  ▪ Record all checks and changes
### Stage 6 - Continue to Monitor the Performance

- **Process Control Document (PCD)**

---

**Stage 1**
- **Conformance Control Feature**
- **CCF No.**
- **CCF Name**
- **Process ID**
- **Operation Number**
- **Work Instruction No. /Change Level**
- **Minimum Requirement**
- **Origin of CCF**
- **Are Sources of Variation Identified?**
- **Yes/No**
- **Is Risks Mitigation Specified?**
- **Yes/No**

**Stage 2**
- **Flowchart Created?**
- **Yes/No**

**Stage 3**
- **Preliminary Process Capability Study**
- **Type of Control Chart**
- **Stable Y/N**
- **Calculations**
- **Action from Study, Y/N**

**Stage 4**
- **Ongoing Monitoring Methods**
- **Control Chart/Other**
- **Capability Review Freq.**

**Stage 5**
- **Process Control Document Number**
- **Part Number / Latest Change Level**
- **Date (Original)**
- **Date (Rev)**

**Stage 6**
- **Process Owner**
- **Date (Original)**
- **Date (Rev)**
- **Flowchart Created?**
- **Yes/No**

---

**Must be permanently updated and reason for change recorded**
Stage 7 - Is a process change required?

Stage 1: Understand KCs and required performance
Stage 2: Plan a process that will produce acceptable performance
Stage 3: Operate the process to generate Data
Stage 4: Analyse data to identify appropriate action
Stage 5: Take action from study (operate, re-design and improve)
Stage 6: Continue to monitor the performance
Stage 7: Is a process change required?

Yes
No
Stage 7 - Is a process change required?

- If no change is required
  - Continue to monitor and optimise process performance and monitoring per Stage 6

- If a change occurs (required or unexpected)
  - Assess if you need to return to stage 1
  - Otherwise, return to stage 2 and repeat all stages whatever the nature and reason for change,
  - Document any planned manufacturing process change, including reasons for change
  - Perform a Last Article Inspection (LAI) of the last part or component produced with current production process (“knowledge capture”).
  - Perform a full or partial First Article Inspection (FAI) review when new production process (representative of the new serial production) is in place .../...
Stage 7 - Is a process change required?

• If a change occurs (continued):
  • If change is generated by - or associated with - a location change (e.g. work transfer) perform a full FAI where the new production takes place
  • Compare new production process (tools, process steps, inspection methods, etc...) to old production process and ensure all possible changes are analysed together with their impact on final product
  • Compare last article and first article for quality
  • Then, do not forget to perform the associated Process Reproducibility Review

“To know more about relation between FAI and 9103, go to stage 3”
9103: Summary & Key Factors of Success

- 9103 - Variation Management of Key Characteristics

Stage 1: Understand KCs and required performance
Stage 2: Plan a process that will produce acceptable performance
Stage 3: Operate the process to generate Data
Stage 4: Analyse data to identify appropriate action
Stage 5: Take action from study (operate, re-design and improve)
Stage 6: Continue to monitor the performance
Stage 7: Is a process change required?

9103 Summary and Key factors of success
## 9103 - Variation Management of Key characteristics - Summary of actions

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4</th>
<th>Stage 5</th>
<th>Stage 6</th>
<th>Stage 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understand KCs and required performance</td>
<td>Plan a process that will produce acceptable performance</td>
<td>Operate the process to generate Data</td>
<td>Analyse data to identify appropriate action</td>
<td>Take action from study (operate, re-design and improve)</td>
<td>Continue to monitor the performance</td>
<td>Is a process change required?</td>
</tr>
</tbody>
</table>

### Stage 1 - Understand KCs and required performance
- Use a cross-functional team to look at product, process and customer requirements
- Process must be capable of meeting today's needs and future aspirations
- Speak with your Customer

### Stage 2 - Plan a process that will produce acceptable performance
- Data collection method planned to provide process parameters and product variation relevant to the KCs
- Perform FAI and Process Reproducibility review

### Stage 3 - Operate the process to generate Data
- Skilled interpretation of data to give evidence of process performance and product variation
- Make informed decisions based on objective information

### Stage 4 - Analyse data to identify appropriate action
- Information acted upon in a controlled and appropriate manner
- Avoid process tampering

### Stage 5 - Take action from study (operate, re-design and improve)
- Monitor product or process KCs critical to satisfying customer expectations
- Vital to know where variation may occur before it is detrimental to the customer

### Stage 6 - Continue to monitor the performance
- Any decision must be substantiated with data to enable implementation of an effective action plan
- Document any planned change, including reasons for change
- Perform LAI and repeat FAI then Process Reproducibility review

### Stage 7 - Is a process change required?
- Yes
- No
9103 stages in relation to FAI (9102), Process Reproducibility and PDCA cycle

9103 Stage 4

9103 Stage 5

9103 Stages 6 & 7

Partial or full FAI & PR (Product or Process Change)

9103 Stages 1 & 2

FAI First Article Inspection (new product introduction)

PR Process Reproducibility Review (Serial Production)

9103 Stage 3

Act
Implement or reassess

Check
Measure and analyze the effects

Plan
Specify theory or conjecture: Study, analyze and plan the process

Do
Carry out test or run an experiment

Improve

9103 key factors of success...

Effective variation Management of Key Characteristics requires permanent Communication and Data Exchange between all Actors

* VOC = Voice of Customer   VOP = Voice of the Process
9103 key factors of success...

- Manage Keys characteristics during all life of the program, in particular when introducing a change
- Involve all concerned functions
- Focus on key characteristics and associated processes… but don’t forget the others!
- Feedback from manufacturing & supply chain to engineering: “Close the loop of information”
- Record all what you do… and keep history (knowledge capture):
  - Potential loss of experience during the program life
  - When KCs are selected (at start of the program or when KCs change), reasons for their selection should be recorded
  - If certain KCs are thought to be no longer a priority, they can be removed. In that case, the reasons for their deletion must be recorded

To be flown down internally and within Sub-Tiers