L4 improvement Practitioner

End Point Assessment

Knowledge criteria and Multiple-Choice Question Exam

Candidate Reference Document

Introduction

Welcome to the Knowledge criteria and Multiple Choice Question Exam (MCQE) Candidate Reference. This document has been produced to provide you with an easy and accessible reference for use during the MCQE and, if undertaking the exam through our TestReach portal, a copy of this document will be available to you within the application during the exam. We advise you to become familiar with this reference so that you can easily find a specific topic during the exam itself.

The MCQE

The MCQE will present you with 40 questions to be completed within the time limit of 40 minutes. Each correct answer will contribute 1 mark to your overall score for the MCQE, missed or incorrect answers contribute 0 marks. The MCQE contributes 10% weighting toward your overall EPA grade, and the MCQE itself is graded as follows:-

Fail: -	Less than 25 marks
Pass: -	25 marks or more
Merit: -	31 marks or more
Distinction: -	35 marks or more

The MCQE tests the Knowledge (K) criteria of the standard across 15 K criteria, questions for your exam will be chosen at random from a large question bank but selected in such a manner that each K criteria will be allocated a minimum of 2 questions relating to that criteria. The 15 K criteria measured in the MCQE are as follows shown in bold below, K02 and K04 not being assessed in the MCQE -

K01 Compliance
K02 Team formation and Leadership
K03 Project Management
K04 Presentation and reporting
K05 Change Management
K06 Principles and Methods
K07 Project Selection and Scope
K08 Problem definition
K09 Process mapping and Analysis
K10 Data Analysis
K11 Measurement systems
K12 Basic Statistics and measures
K13 Data analysis – statistical methods
K14 Process capability and Performance
K15 Root cause analysis
K16 Experimentation
K17 Identification and prioritisation

INDEX

Compliance (K01)

Compliance affects everyone in work – you need to comply with relevant legislation and company systems for the particular job you do. Obviously, it is not possible to cover every potential compliance issue, so the MCQE questions for this section mainly focus on those compliance issues common to everyone – Health and Safety.

The key legislation for Health and Safety is the Health and Safety at Work Act 1974 – Known as HASAW or HASAWA. In summary, HASAW places duties on employers and employees which can be summarised as follows:

Duties of employers:

- It shall be the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees.
- This is further defined as:
    - The provision and maintenance of safe plant and safe systems of work.
    - Arrangements for ensuring health and safety in connection with the use, storage, handling and transport of articles and substances.
    - The provision of such information, instruction, training and supervision as is necessary.
    - The provision of a safe place of work and safe means of access to and egress from it.
    - The provision and maintenance of a safe and healthy working environment.

Duties of employees:

- To take reasonable care of his own health and safety at work and that of other people who may be affected by what he does, or does not do, whilst carrying out his duties
- To co-operate with his employer or any other person so far as is necessary to enable his employer or any other person to comply with any statutory duties imposed on him.

The Management of Health and Safety at Work Regulations have extended these duties. They require that employees: -

- carry out any work in accordance with any training or instruction given
- inform the employer of any health and safety problems.

HASAW is 'enabling' legislation which allows other laws (Regulations) to be made without the need to pass another Act. Some of these other regulations are:-

The Management of Health and Safety at Work Regulations 1999

The main employer duties under these Regulations include:

- making 'assessments of risk' to the health and safety of its workforce, and to act upon risks they identify, so as to reduce them
- appointing competent persons to oversee workplace health and safety
- providing workers with information and training on occupational health and safety
- operating a written health and safety policy.

The Workplace (Health, Safety and Welfare) Regulations 1992

The main provisions of these Regulations require employers to provide:

- adequate lighting, heating, ventilation and workspace (and keep them in a clean condition);
- staff facilities, including toilets, washing facilities and refreshment
- safe passageways, i.e. to prevent slipping and tripping hazards.

The Health and Safety (Display Screen Equipment) Regulations 1992

The main provisions here apply to display screen equipment (DSE) 'users', defined as workers who 'habitually' use a computer as a significant part of their normal work. This includes people who are regular users of DSE equipment, or rely on it as part of their job. Employers are required to:

- make a risk assessment of workstation use by DSE users, and reduce the risks identified
- ensure DSE users take 'adequate breaks'
- provide regular eyesight tests
- provide health and safety information
- provide adjustable furniture (e.g. desk, chair, etc.)
- demonstrate that they have adequate procedures designed to reduce risks associated with DSE work, such as repetitive strain injury (RSI).

The Personal Protective Equipment at Work Regulations 1992

The main provisions of these regulations require employers to:

- ensure that suitable personal protective equipment (PPE) is provided free of charge
- provide information, training and instruction on the use of this equipment.

The Manual Handling Operations Regulations 1992

The main provisions of these Regulations require employers to:

- avoid (so far as is reasonably practicable) the need for employees to undertake any manual handling activities involving risk of injury
- make assessments of manual handling risks, and try to reduce the risk of injury.
- provide workers with information on the weight of each load.

The Provision and Use of Work Equipment Regulations 1998

The main provisions of these regulations require employers to:

- ensure the safety and suitability of work equipment for the purpose for which it is provided
- properly maintain the equipment, irrespective of how old it is
- provide information, instruction and training on the use of equipment
- protect employees from dangerous parts of machinery.

The Control of Substances Hazardous to Health (COSHH) 2002

The main provisions of these regulations require employers to:

- Prevent or control exposure to hazardous substances.
- Implement control measures around hazardous substances and ensure these are maintained
- Provide employees with information, instruction and training
- Have procedures to deal with accidents and emergencies relating to hazardous substances
- Ensure employees exposed to hazardous substances are under adequate surveillance
- Carry out COSHH risk assessments.
- Ensure the use of hazardous substances doesn't exceed the Workplace Exposure Limit
- Check employees are carrying out tasks as they are supposed to.

Team Formation and Leadership (K02)

- We don't know everything about a problem/process – there are customers, suppliers and process experts who all have a valid and important contribution to make
- Improvements are likely to be implemented by other people and they should be involved from the beginning (if only to secure their buy-in)
- People who know nothing about a problem/process can bring a 'fresh-eyes' perspective
- Involving others enables the methodology and tools of robust problem resolution/process improvement to be shared with more people
- There are 3 types of Decision making that you need to be aware of:
  1. Consensus decision making: Proposals agreed by all team members
  2. Authority rule: Proposals or decisions pre-set
  3. Majority rule: Democratic decision making

Project Management (K03)

- What is project Management?
  - Project management is the term used to describe the application of Methods, Processes, Knowledge and experience to achieve project objectives.
- What are the success criteria for a project? Projects are deemed to be a success if they achieve the following criteria: -
  - Scope. Has the project achieved the acceptance criteria?
  - Cost. Is project within or on budget target.
  - Time. Completed within timescale.
- Why is Project Management important?
  - Tracks benefits against the Customer requirements in a controlled manner
  - Defines expected resource and timeframes for completion
  - Will assist in understanding potential risks and problems projects may encounter
  - Promotes efficient and effective communication between the team
  - Clarifies the Roles and Responsibilities of the team whilst ensuring the objectives are clearly understood
- What Tools are available that you might use?
  - Project tracker - Provides an Overview of the Project and tracks benefits
  - Gantt Charts – Breaks down the Project schedule into its terminal and summary element
  - Project Responsibility – Communicates who is doing what and when they are doing it
  - Risk Management – Understanding what can go wrong, What's the impact, what can we do and how can we control the risk
  - Communication plan – A tool to communicate improvement activities to a wider audience. Promotes awareness of improvement initiatives
- What Leadership style is required?
  - Proactive in approach, Coaches, manages, builds rapport with teams and facilitates

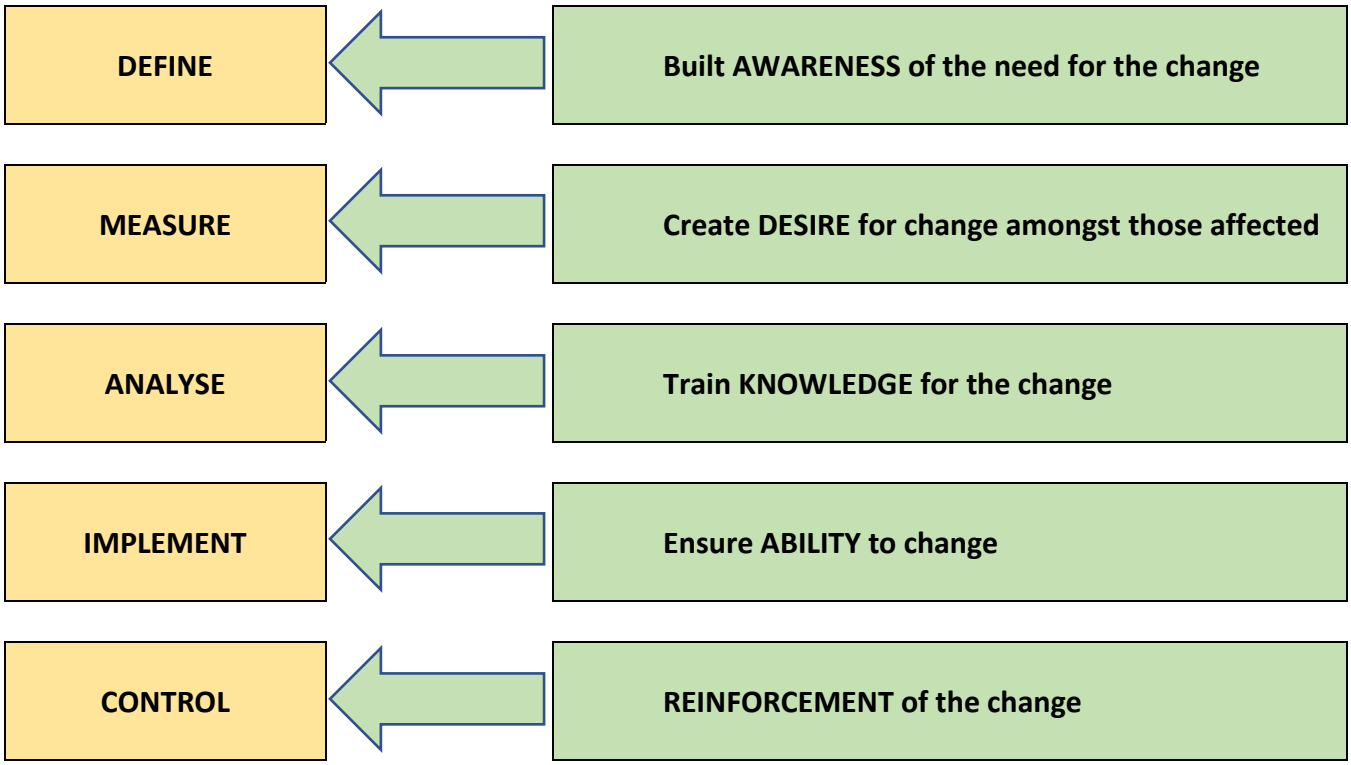
Presentation and reporting (K04)

- Presentation and reporting are an important skill set amongst CI technicians.
- Implementation of Continuous improvement will often involve a change in human behaviour; therefore, it is vital that a clear message is communicated to the organisation.
- In order to do this the use of reporting templates and dashboard reports are widely used to communicate the status of projects.
- By using such tools, you're able to clearly and concisely update key stakeholders, thus providing the management team with early escalation of any potential risks.

Change Management (K05)

Change management is the process that:

- Builds awareness in an Organisation
- Creates a desire for change
- Trains knowledge for change
- Ensures we can change
- Reinforces Change



Role of a CI Leader

- Build awareness and desire for change management competency within your team of CI professionals
- Develop your knowledge of change leadership and change management6
- Become proficient at the practical application of tools and processes for managing change
- Reinforce change management competency with your team

Change Management tools

- A team approach - Engage the "Process Expert" people who do the job day in day out, a cross functional team is vital to success Stakeholder Analysis
- Conduct stakeholder analysis; Understand who is for and against change, develop strategies to combat resistance to change.
- Communicate the "Shared win", develop detailed communication plans to influence and drive positive change.

It is important to note that anyone directly or indirectly impacted by the change process can be considered a stakeholder

Communication strategies

- Let the organisation see early and ongoing leadership support
- Generate awareness and enthusiasm among members – be realistic
- Seek and share early wins
- Provide periodic financial reports and dashboards
- Recognise and communicate successful team efforts

Managing Change

The use of a Project Responsibility Matrix or RACI chart links activities to resources, it ensures that each task is completed by someone. RACI stands for: -

- **Responsible**
  - The person/Team/Person who own the work.
  - Every sub task in the project needs to have someone shown as responsible
- **Accountable**
  - The Person who ultimately approves the work/project
  - Only one person can be Accountable
- **Consulted**
  - Persons/groups who are asked to deliver input into the work/project
- **Informed**
  - Persons/Groups who are kept informed of the progress of the work/project/deliverable

In addition, you may find 'S, V, F' used in a RACI Matrix and these stand for:-

- **Supportive** – provides work in addition to the responsible parties
- **Verifies** – The person/group who approve the work meets standards
- **Final Authority** – the person who may have to 'sign off' on the project

The roles of the various people/persons/groups involved in or stakeholders in a project can be summarised visually in a 'RACI' Matrix (sometimes called a Project Responsibility Matrix)

There are many variants on the look and layout of a RACI Matrix - Your training provider may have provided you with an example as part of your training.

Principles and Methods (K06)

- Continuous improvement methods are a set of structured methodologies and tools for improving processes, resolving problems and designing new products and services.
- They encourage data driven decision making, focus on the customer requirements, drive an understanding of key characteristics, root cause identification and elimination.
- They can be applied to any process, aiming to eliminate waste (Lean) and reduce variation (Six Sigma).
- CI Processes operate at near perfection and striving for this across organisations can have a profound effect on culture in the following ways
    - Attitude towards data
    - Approach to questioning
    - Demand for rigour
    - Cross functional teamwork
    - Best Practice Sharing ('Yokoten')

All CI methods are team orientated methods to solving problems within processes and systems. Methods include: -

- **Design for Six Sigma (DMADV)** - Design, Measure, Analyse, Design, Verify.
    - Used when a non-existent product/process needs to be developed at a company and when an existing product/process exists but still needs to meet a CI level or the customer requirement

- **DMAICR** – Design, Measure, Analyse, Improve, Control, Replicate.
    - Used when improving a process that has deep rooted, systemic problem that is complex.

  This method requires: -
    - Definition of the customer and the Voice of the Customer (Who they are and what they need)
    - Development of a detailed understanding of the process
    - Creation of a clear operational definition to fully understand how to exercise measurement activities
    - Calculation of the baseline performance
    - Creation and testing of Hypothesis
    - Isolation of potential root causes
    - Analysis and prioritisation of potential solutions, creating strategies and plans for sustaining improvements.

- **Theory of Constraints (TOC)**
    - A method for identifying the most important limiting factor that stands in the way of achieving a goal, often referred to as the bottleneck.
    - A scientific approach to improvement that hypothesises that every complex system contains multiple inked activities that act as constraints on the entire system.

- **8D ('Ford 8D')**
  - A method for reacting to customer problems, frequently used in Manufacturing environments.
  - Often applied to simple problems and less frequently to complex problems.
  - Use immediately when product concerns are identified. Key tools include:
    - D1- Team formation
    - D2- Problem definition
    - D3- Containment
    - D4- Root cause analysis
    - D5- Improvement selection
    - D6- Implementation
    - D7- Prevention occurrence
    - D8- Team recognition and congratulation

- **PPS - Practical Problem Solving ('Toyota A3')**
  - A method for reacting to product concerns that is logical and visual, projects can be completed in two days.
  - Requires Toyota style team empowerment and team working conditions.
  - Key concepts include Containment and deeper understanding of the problem.
  - Key tools: Clarify and grasp the problem, Root cause analysis, Countermeasures, Standardisation and Yokoten (Sharing).

- **The 7 Wastes and the goal of waste reduction.**
  - The goal of identifying the 7 Wastes is to seek out their existence and eliminate them.
  - The 7 wastes ('7 types of Muda') can be recalled by the acronym 'TIMWOOD' and are as follows (no priority order is implied): -
    - Transportation – moving parts from A to B
    - Inventory – Holding excess stock or buffers
    - Motion – Human movement when making the product
    - Waiting – waiting to do the next process step
    - Over processing – doing more than is required
    - Over Production - making too many
    - Defects – Faults or scrap arising from the process
      (Some sources add an 8th waste, 'Skills')
  - By eliminating the waste from the Work, we are able to improve Productivity in the work place.
  - The goal is to improve Value Added (Any work that changes the nature or characteristics of the product, in line with customer requirements) whilst reducing Non-Value Added (Any work carried out, which is necessary under current conditions but does not increase product value) and removing all waste.

<u>Process Before Improvement: -</u>

<u>Process After Improvement: -</u>

Project Selection and Scope (K07)

It is important to select a project where the root cause is not known. An appropriate project may come from the following: -

- System or business objectives
- Management directive
- Issues highlighted through problem resolution
- Customer requests
- Improvement suggestions from within the Organisation

It is important that a potential project includes: -

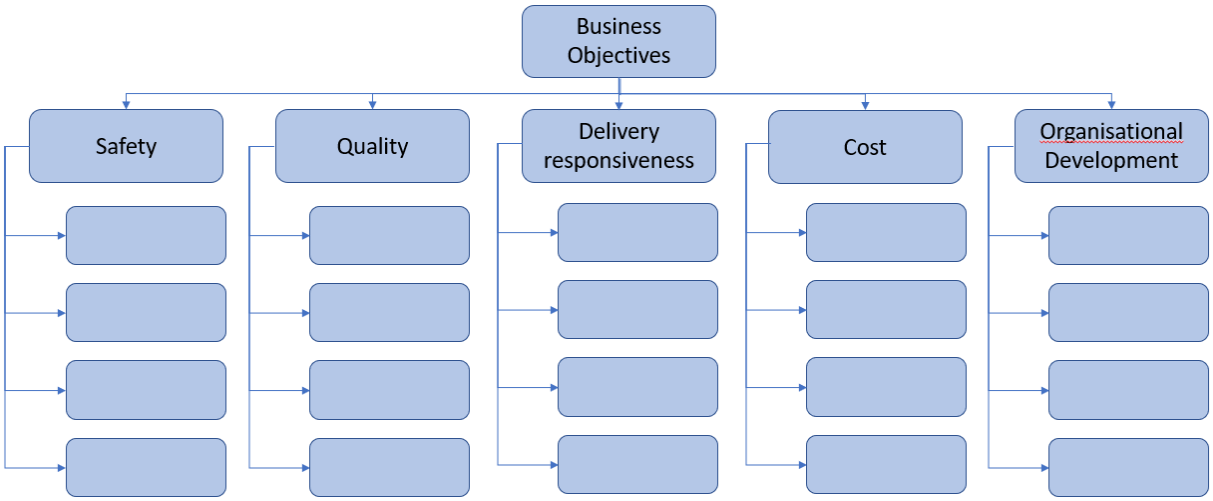
- The Problem or Process is recurring (Not a one- off)
- Data is available or can be collected
- Has support from the Manager
- Can be completed within 4 – 6 months
- Is within your area of control
- Will have significant impact on the bottom line
- Fits in the business strategy

It is important to remember the 3 Ms when selecting a project: -

1. Meaningful - Projects must be tied to the overall objectives of the business and must tackle a problem that is affecting the team and process owners
2. Manageable - Projects must not be too complex or large in scope, the process must be stable, and results must be achievable within a reasonable timescale
3. Measurable - The team must be able to collect data that is Measurable at key intervals.

Useful tools for deciding a project include:

1. A Scoping tree:



Use your scoping tree to: -

- Help identify potential projects
- Ensure your project ideas align with business objectives

2. A Project selection matrix: -

		Project FILTERS (Y/N)?					Selection Criteria							
		Best solution/ root cause known?	Problem addressed elsewhere?	Solution outside team member control?	Potential Contradictions w/ Other Projects?		Improves company image	Improves Company Profitability	May be completed within Timing Goals	Relatively Low Investment Cost	Project Priority	Rank	Estimated Annual Savings, $$	
#	Project Name	Y/N	Y/N	Y/N	List #	Rating (1..5)	5	4	2	2			Hard Savings	Soft Savings
1	Reduce CFC emissions by 10%	N	Y	N	7,8	Selection Criteria Ratings (Low=1; Medium=3; High=9)	9	1	3	1	57	2	$XX	$XX
2	Reduce power consumption by 15%	N	Y	N	8		9	3	3	3	69	1	$XX	$XX
3	Eliminate electric shock	Y	Y	N			9	1	1	1	53	4	$XX	$XX
4	Reduce EMF to less than 50 v/m	N	N	Y			1	1	3	1	17	8	$XX	$XX
5	Improve reliability (no of hours before repair)	N	Y	N			3	3	3	3	39	5		$XX
6	Reduce warranty claims by 15%	N	Y	N	5		3	3	3	3	39	5	$XX	$XX
7	Reduce cost by 15%	N	Y	N	1,2,5,6,8		3	9	1	1	55	3		
8	Increase storage capacity by 20%	N	Y	N	7		1	3	1	1	21	7		$XX

The project selection matrix allows you to measure the potential impact and viability of various project ideas. Again, your training provider may have issued you with a suggested format.

Understanding Scope

- All outputs are the result of inputs and process interaction, we focus on understanding the Customer requirements (Outputs) and the Inputs / Process required to deliver these.
- Another way of thinking of this is:

  $$Y = f(X)$$

  Where Y is the output of the process and X is the input to the process, therefore the outputs are a function of the inputs.
- The importance of a correctly scoped project will remove the risk of scope creep and potentially higher costs due to a large scope project.
- The risks of a large scoped project include
  - Higher material costs
  - Higher labour costs
  - Frustration due to lack of progress
  - Diversion of manpower away from other activities
  - Delay in realisation of project benefits
  - Team member turnover
  - Low project success rate
  - Decline in the confidence of the problem solver

Business Scorecard Cascade

A business scorecard is considered to be a way of showing those things that are of high importance to the performance of that organisation. This may, therefore, be the key performance indicators of the organisation.

It is important when using a business scorecard that these key metrics and objectives can be cascaded to everyone within the organisation. This means that everyone's objective will then support those of the organisation, and all will understand the main objectives of the organisation.

Is / Is not tool

The IS/IS NOT gathers facts about the key problem definition questions……What, Where, When and How Big? – and helps to focus as to the scope of the problem.

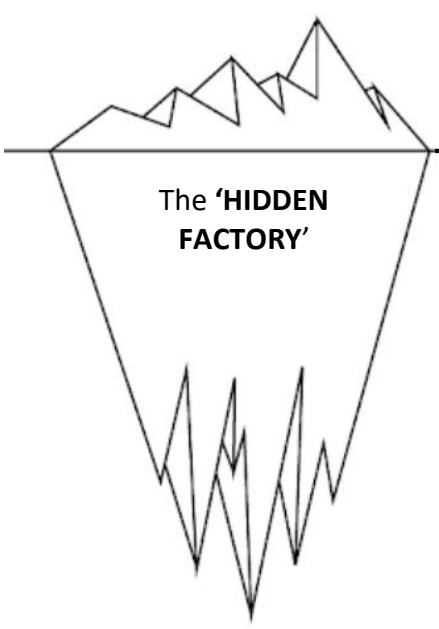
- The is/is not tool is a comparative analysis tool to determine where the problem IS and IS NOT
- It drives further investigation to properly answer key questions using evidenced data and reveals contrasts which help in several ways:-
    - The search for contrasts leads to clearer problem definition
    - Reduces the scope of further investigation to the IS's
    - An aid to logical deduction - why is the problem not present in the IS NOT's?

Problem definition (K08)

What is a Problem?

- Traditionally a problem is defined as the gap between the current situation and the business target or objective.
- However, with respect to the Practitioner standard, problem definition is focused on the Cost of Poor Quality (COPQ) and problem analysis models such as Is/Is Not.

Cost of poor quality (COPQ) model



Traditional Costs of Quality
(easy to count)

- Admin
- Chasing/Follow up
- Concessions
- Inspection
- Warranty
- Scrap / rework
- Rejects
- Transport

Hidden Costs of Quality
(difficult to count)

- Lost Customers / lost sales
- Lost opportunity
- Late delivery
- Expediting costs
- Excess stock
- Long cycle times
- More set-ups
- Design changes
- Specification changes

Impact to business and how to reduce.

- The costs that would disappear if systems, processes, and products were perfect
- Taking corrective actions as early as possible improves cost saving chances

Why do we use COPQ?
Cost of Poor Quality is used to understand the financial impact to an organization, it is used when creating a problem statement at the Define stage, however it can be used throughout the improvement cycle with the relevant analysis tools.

All problem statements should include the following details: -

- A clear and narrow description of what the problem is, and how this will impact on the customer's expectations
- Metrics indicating the size of the problem plus the timeframe and source of the data – data should be transformed to allow datasets to be compared on a common scale without distorting differences in the ranges of values.
- An aim/goal
- Any boundaries of the improvement project (the scope of what is and is not to be included in any investigations)
- A problem statement should NEVER include Potential causes or Possible solutions

Process mapping and Analysis (K09)

- Process mapping is a tool that visually represents the flow of information, material and products through a system.
- By doing so we can identify bottlenecks and wasteful elements within the process.
- Before any improvement we must understand Process purpose by reviewing the following questions and assessing understanding: -

Why does this process exist?	*Who are the customers of the process?*	*What are the intended process outputs?*
Explains WHAT is done, not how it is done	*Allows evaluation of which tasks add value*	*Must be constant throughout the improvement cycle*
Must be understood by everyone in the process and those working to improve it	*Changes with changes in customer requirements*	*Important to identify who is the 'process owner' (if not you)*

Go Study Understand (GSU) – Key Steps to understanding your Process.
Also called 'Genchi Gembutsu' – Go to the source of the problem.

- The only way to understand a process
- Don't rely on reports or hearsay – any information about a process will be simplified when reported
- There is no substitute for seeing the process yourself
- This is not to 'visit' but to 'know'
- Essential for defining problems and opportunities and designing solutions – if these tasks are completed away from the process and by people who are not involved, they will most likely fail

Collect relevant data about the:

- Process Flow - include all main activities and material movements
- Information Flow - show orders, scheduling and tracking plus communication with customers and suppliers
- Timings of the Process.

When Do we use a Process Map?
Use a Process map to gain an understanding of the Process and its boundaries during the Define stage.

- SIPOC is a key tool during this phase.
- Conduct GSU to create a detailed Process map

Tips for Process Mapping

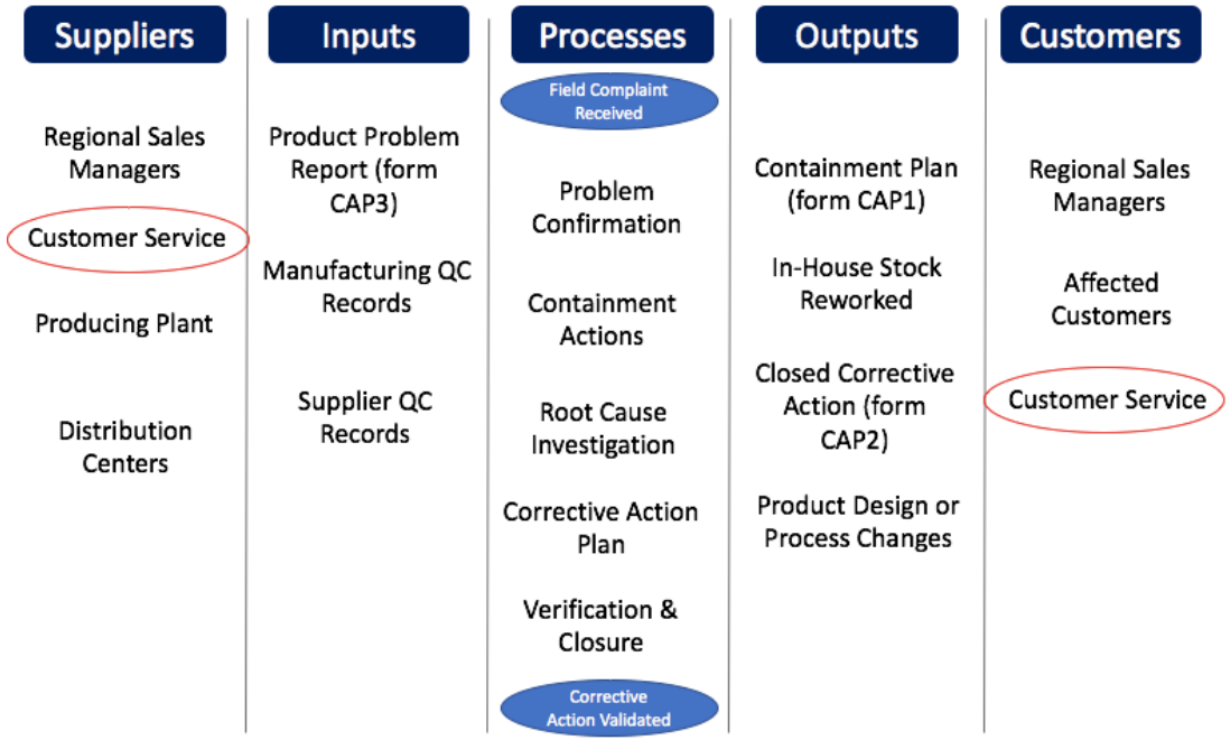
- Map the process as a team
- Walk the Process
- Identify Value Added (VA) steps, Non-Value Added (NVA) steps and potentially Necessary / business required Non-Value Added steps as you walk to process
- Start at the highest levels and add detail when required
- Use standard symbols
- Use Post-It notes, and move them around as necessary
- Draw arrows in at the end
- Capture Quality concerns alongside your map

If you see a problem that can be resolved as you work through your project, write it down!

SIPOC
(suppliers, inputs, processes, outputs, customers)

- A top-level process diagram
- Defines the purpose and boundary, highlights major activities
- Customers and Suppliers can be either External to the business (the 'final' customer), or Internal (the person within the business who your Outputs go to)
- SIPOC gives high level process steps and identifies what happens upstream and downstream of each step. It does not show volume, decisions, quality, etc.

Example of a SIPOC Diagram



Your training provider may have provided you with their own template which may appear somewhat different to the example above

SIPOC Outputs

- When collating the Outputs column for the SIPOC ensure that you take into consideration
    - What should your process be delivering (Primary Outputs)?

What other undesired elements are being output from your process (Secondary Outputs)

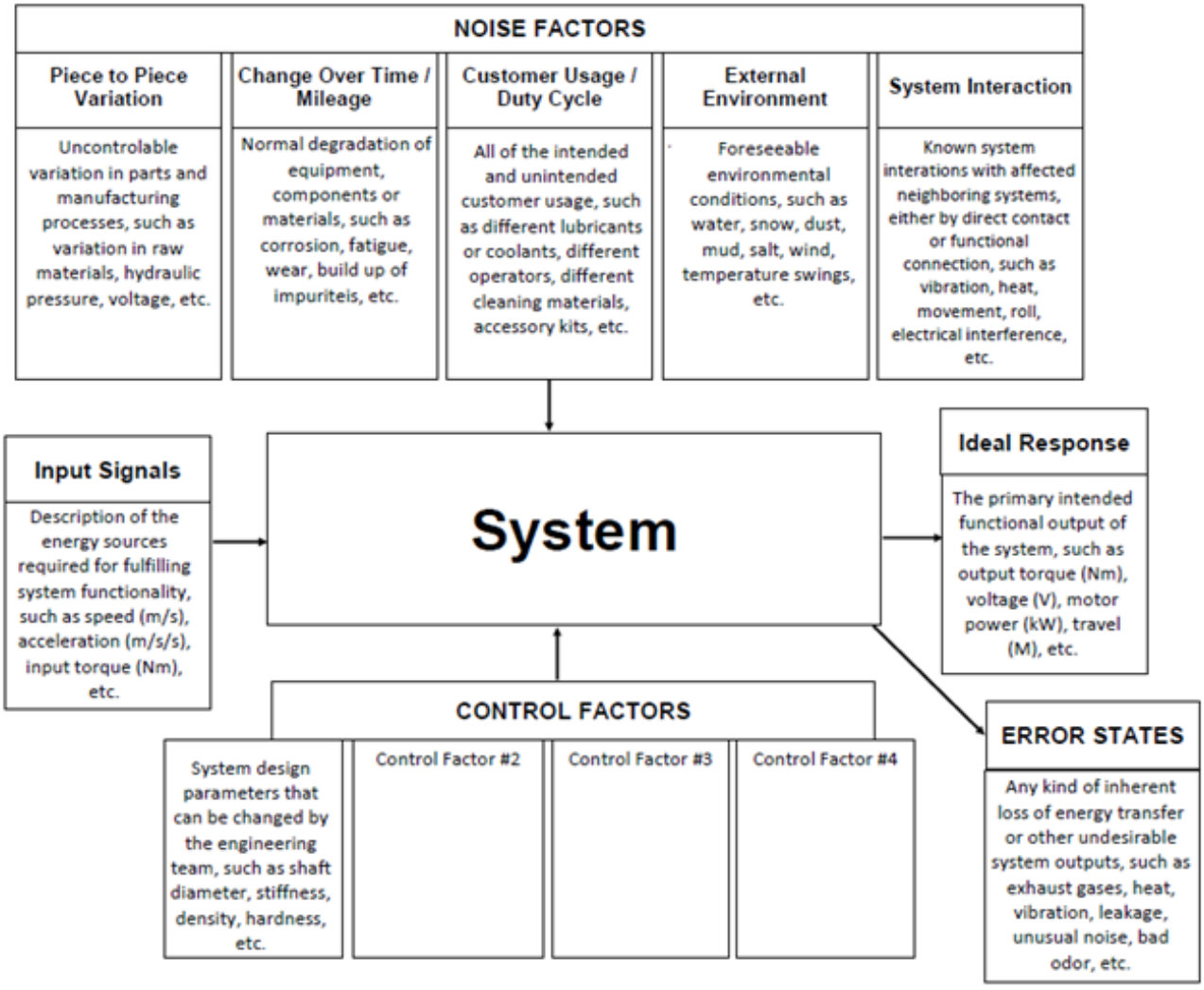
Takt time.

- The Frequency at which ONE unit should be produced in order to match customer demand
- Takt time takes into account: -
    - Time available to manufacture and deliver (defined by the producer)
    - Number required (defined by the customer)
- The calculation of takt time therefore is: -
    - **Time available/Number required**

Parameter Diagram (P diagram)

- A P-Diagram is a tool most often associated with 'Design Robustness', but also suitable for use in the formulation of an FMEA
- It considers the system in question, the inputs, ideal outputs, 'error states', 'noise factors', and 'control factors'
- Amongst the 'Error states' should be the 'failure mode' of concern for this project
- 'Noise factors' are identified in 5 different categories – amongst them should be your root cause, or 'critical X's'
- 'Control factors' are the things that can be influenced to obtain the 'Ideal Function' in the presence of 'Noise'.

Example P Diagram



Kanban

- A tool used to connect Information (customer demand) and Material flow (How we build demand).
- It is used to eliminate/minimise the waste Overproduction as the Kanban instructs areas to produce in relation to the demand of the customer thus improving flow and minimising waste.
- Kanban can also be used to signal material movement

OEE (Overall equipment effectiveness)
(Availability %) * (Performance %) * (Quality %)

- OEE is a measure of how well a manufacturing operation is utilised (facilities, time and material) compared to its full potential, during the periods when it is scheduled to run. It identifies the percentage of manufacturing time that is truly productive. An OEE of 100% means that only good parts are produced (100% *quality*), at the maximum speed (100% *performance*), and without interruption (100% *availability*).
- OEE is expressed as a percentage
- Data required to calculate OEE includes: -
    - Right first time %
    - Total available time
    - Planned and unplanned stoppages
    - Actual operating time taken to produce the parts in the period
    - Number of parts produced
    - Ideal cycle time for the part in the process

Data Analysis (K10)

Is the use of the relevant Spreadsheets, Pivot tables and other software tools to analyse data. Your training provider will have recommended a suitable package for you to use during your training, such as minitab or an excel add-in.

For the MCQE, questions in this area will be related to definitions, facts and general understanding of the various Data Analysis tools required - questions regarding Sampling, common and special cause, purpose of various charts, and similar.

Measurement systems (K11)

Key concepts of measurement systems:-

Repeatability

- Does the Measurement system return the same measured value when being measured more than once by the same person?
    - DOES HE/SHE DO IT THE SAME EVERY TIME?
    - Repeatability assesses variation due to the gauge and is also known as Equipment Variation (EV)

Reproducibility

- Reproducibility is the degree of agreement when multiple operators measure the same characteristics on the same part
    - DO THEY ALL DO IT THE SAME?
    - Reproducibility assesses variation due to the Operator also known as Assessor Variation (AV)

Linearity

- The measure of consistency of accuracy of measurement equipment over the operating range of the measurement system is known as Linearity

Stability

- The measure of variation in measurement over time is known as Stability

Discrimination

- Measure in increments that are 1/10th of the specification / tolerance OR process variation, whichever is the smallest. Known as the 10% rule

Bias

- The difference between the standard value and observed value is known as Bias (or Accuracy)

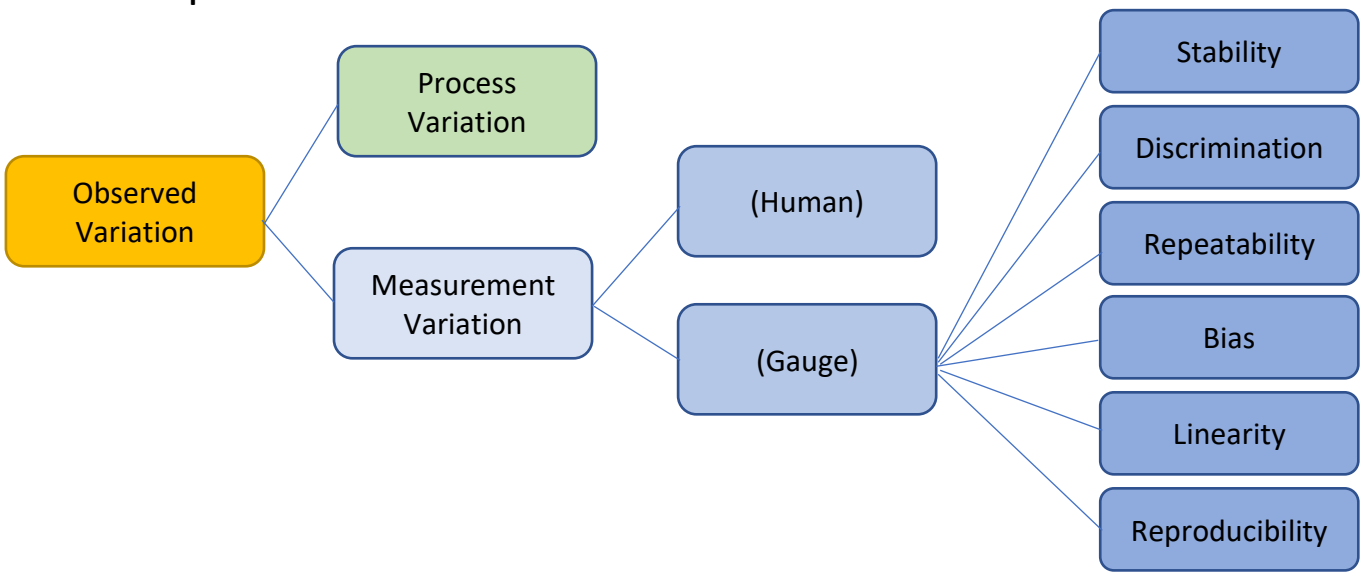
Measurement Systems Analysis

- Measurement Systems Analysis is the evaluation of the tools and processes used to collect data
- If your Measurement system does not function correctly it can be a source of Variation.
- It shows whether or not that the variation observed is from the process or the measurement system
- By conducting MSA an Organisation can accurately accept whether good parts are good and bad parts are bad. Components of Variation
- An MSA helps to minimise Measurement Variation, allowing process variation to be clearly measured.
- It is impossible to eliminate all measurement variation; therefore we must limit its impact
- The objective of an MSA is to ensure that the measurement variation is acceptably smaller than the observed variance.

Types of MSA

- Dependant on the data there are 2 types of MSA
  - Attribute MSA (Minimum data point 50 – 100)
  - Variable MSA (Minimum data points 30)
- Each type of MSA will identify the source of Variation

What makes up observed variation?



Aims of MSA

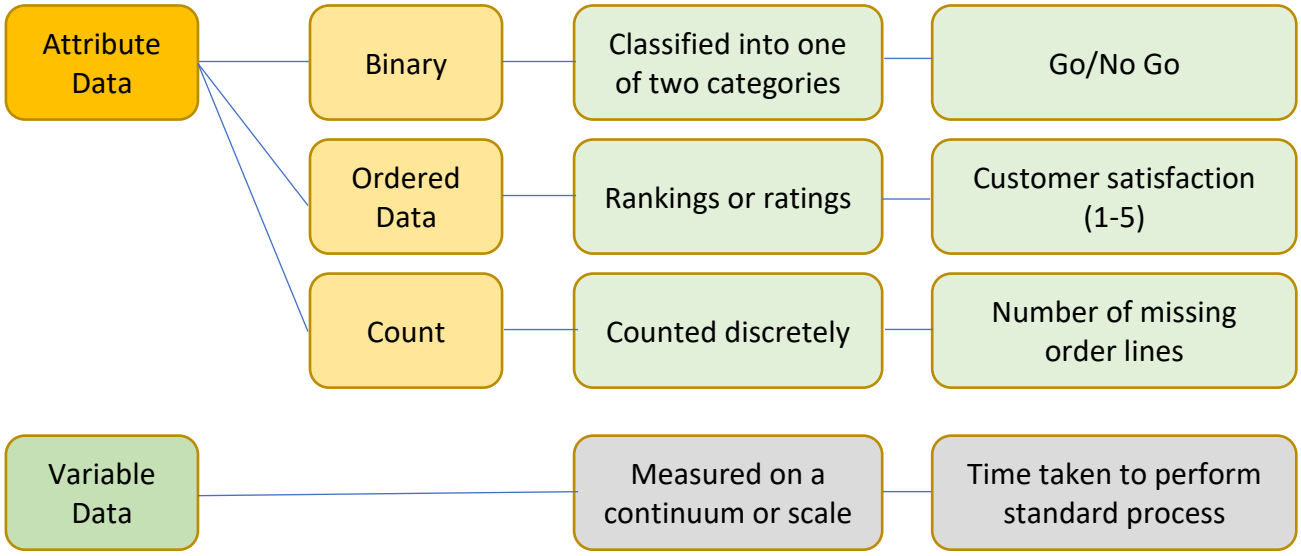
The aim of an MSA is to help minimise the variation due to the measurement process. A full MSA should answer the following key questions:

1. What could go wrong with the measurement system?
2. Are the measurement units small enough to detect the variation present?
3. Is the measurement system accurate?
4. Is the measurement device accurate over the operating range?
5. Is the measurement system stable over time?
6. How much of the observed variation is a true reflection of the process variation?

Basic Statistics and measures (K12)

Data is information we can collect from the process or information that is provided via an external input.

Types of Data



The Value of Measurement

Measurement provides data that enables an Improvement Team to:

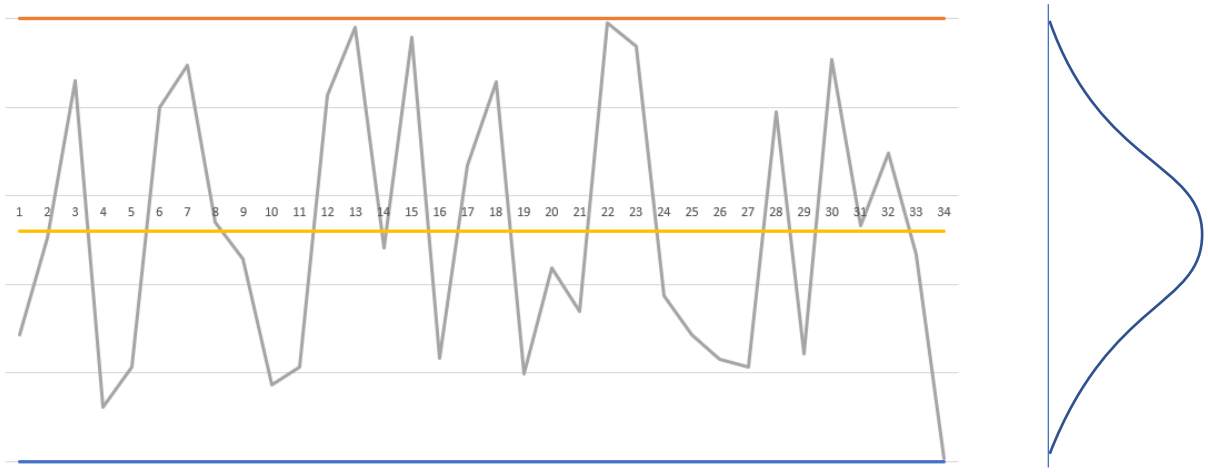
- Establish a baseline process performance
- Understand a process in detail Identify areas where improvements can be made
- Verify that improvements have been made and sustained

We can collect a population of data or a sample of the population and from that data make inferences about the population by calculating a Process sigma value. From this data you can analyse, optimise and control the process.

Control Charts
Control charts are related to data distributions

Data points in chronological (or time sequence) order

‘Added up’ values

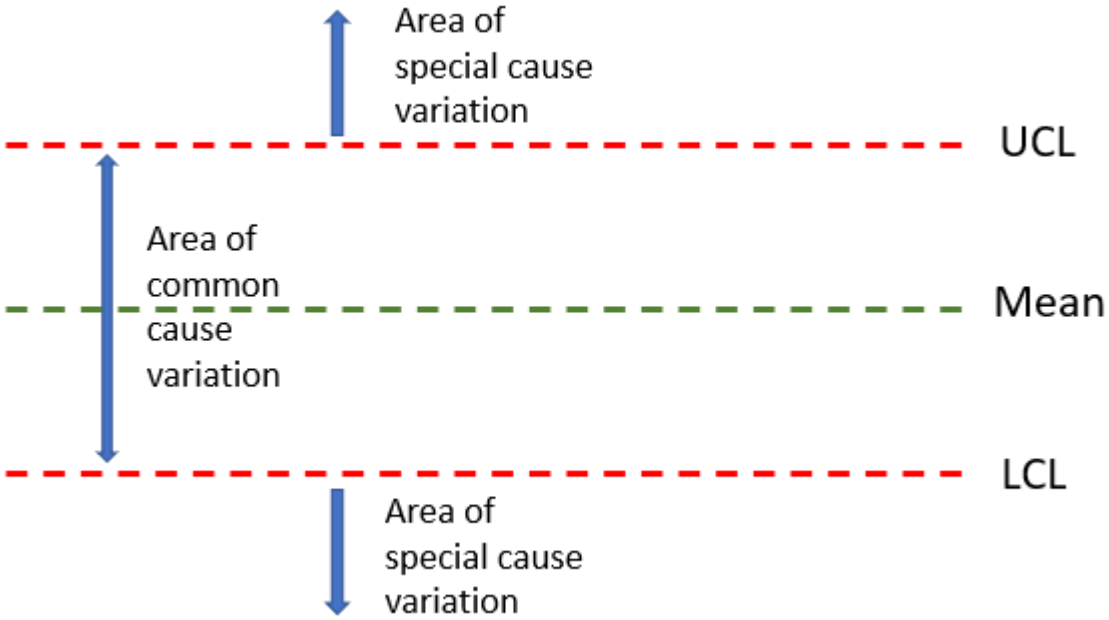


Control Charts

- There are Variable and Attribute control charts that enable swift assessment of process variation
- Control limits are usually set at ±3 standard deviation
- Control limits are the Voice of the Process (Process & Capability)
- They represent what is happening at the Process, if the process is stable it will continue to fall within the parameters of the control limits.
- They are not Specification Limits. (Voice of the Customer)
- Data should be collected over appropriate durations and displayed in time order
- There are 2 type of variation. Special Cause and Common cause: -

Type of Variation	Definition	Characteristics
Common Cause	The **natural** variation in a process	Expected. Natural Random Always Present
Special Cause	Variation generated through **special circumstances**	Unexpected Not normal/natural Non-random Result of an action/event

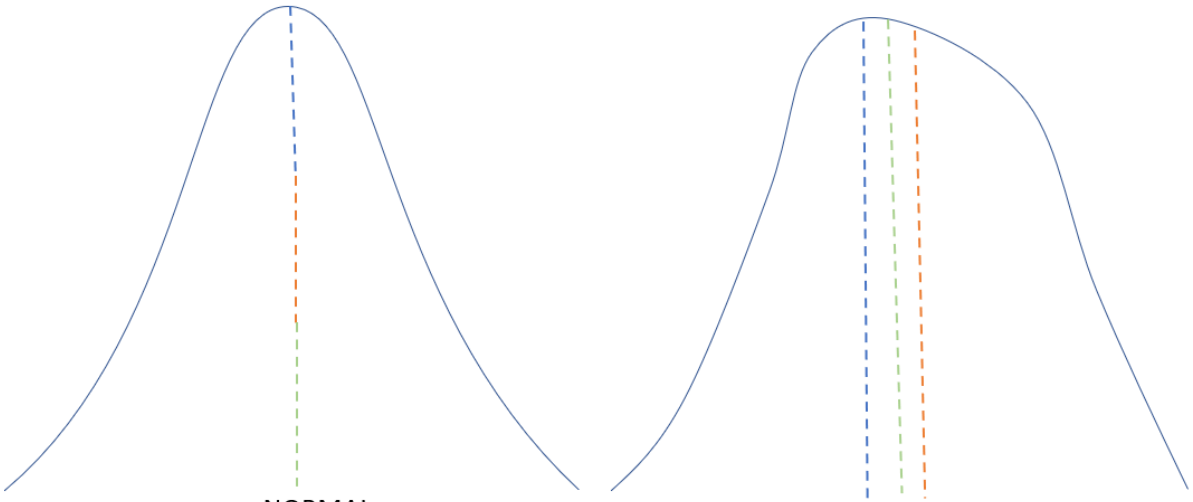
Location of variation



Types of Control Charts

Data Type	Data Characteristic	Sample Quantity	Control Chart	Ideal sample size	Chart shows:-
Attribute	Defect	Variable	U	Any	Proportion (DPU)
		Constant	C	Any	Number (Defects)
	Defective	Variable	P	>50	Proportion (Defects/sample)
		Constant	N_P	>50	Number (Defectives)
Continuous			X-MR	1	Individual data points and moving range
			Xbar-R	<10	Mean and range

The Principles of normality



Data analysis - statistical methods (K13)

Measures of Central Tendency and Spread

This relates to data sets. A measure of central tendency is a single value that attempts to describe a set of data by identifying the central position within that set of data. As such, measures of central tendency are sometimes called measures of central location.

Three important measures of central tendency are more generally referred to as 'averages'. These are the Mean, the Mode and the Median

Mean ('Arithmetic mean')

- The sum of all values in the data sample divided by the number of data points.
- The symbol for the sample mean is 'X Bar', written as $\bar{x}$.

$$\bar{x} = \frac{x_1 + x_2 + \ldots + x_n}{n} = \frac{\sum x}{n}$$

x_1	x_2	x_3	x_4	x_5	x_6	x_7	x_8	x_9	$\bar{x}$
27	30	19	22	34	31	27	29	33	28

- A different symbol, μ, (lower case mu) is used if the mean is of the total population.

- One problem with the mean is that the value can be skewed by outlier values:-

x_1	x_2	x_3	x_4	x_5	x_6	x_7	x_8	x_9	$\bar{x}$
27	30	73	22	34	31	27	29	33	34

Mode

The mode is the most commonly occurring value in the dataset – i.e. the most frequently occurring, the most popular.

x_1	x_2	x_3	x_4	x_5	x_6	x_7	x_8	x_9	Mode
27	30	19	22	34	31	27	27	35	27

- A problem with the mode is that is it possible to have multiple Modes:-

x_1	x_2	x_3	x_4	x_5	x_6	x_7	x_8	x_9	Mode
27	30	30	22	34	31	27	27	30	27 or 30?

- In this case the mode(s) are 'a measure of central tendency'.
- Also, the mode cannot be used with continuous data as it is likely that all values in the dataset could be different.

Median

The median is the middle value if the data set was ordered.

x_3	x_4	x_1	x_7	x_8	x_2	x_6	x_5	x_9	Median
19	22	27	27	**27**	30	31	34	35	27

- A data set with an even number of data points will have two 'middle values'. In this case the median is the mid-point of the two centre data points. (i.e. average the two)

x_3	x_4	x_1	x_7	x_8	x_2	x_{10}	x_6	x_5	x_9	Median
19	22	27	27	**27**	**30**	31	31	34	35	28.5

Standard Deviation (SD)

Is the measure of the variability or dispersion of data from the mean.

Calculating SD:-

1. **Calculate** the average of all of the data points to find the mean.
2. For each data point, **find** the square of its distance to the mean.
3. Sum these values.
4. Divide the sum by the number of data points.
5. Find the square root

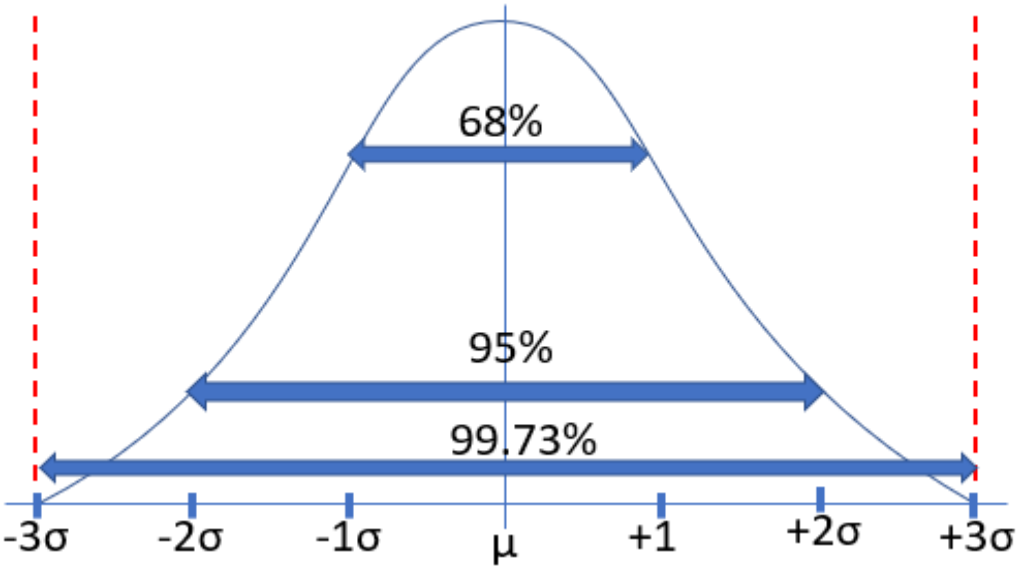
Excel and most stats packages will do this calculation for you.

Standard deviation describes the degree of variation from the mean in a data set.

- High SD indicates data is spread out from the mean.
- Low SD indicates data is close to the mean.

The symbol for standard deviation is the Greek symbol for lower case Sigma, shown as σ

In a normal distribution ('bell curve') the distribution of data points in relation to standard deviation is as shown below – i.e. 99.73% of the data points will be inside of 3 SD either side of the mean.

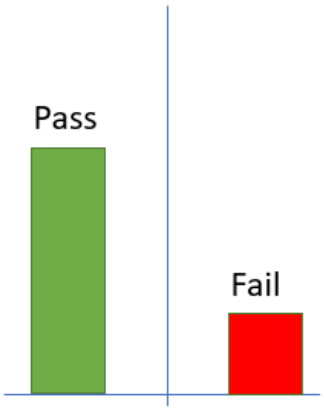


Process capability and performance (K14)

Process capability: -

- is a measure of how well a process can perform against defined specifications
- is determined by comparing the process spread of data against the specification spread
- can be calculated for both Attribute and Variable data: -

ATTRIBUTE DATA

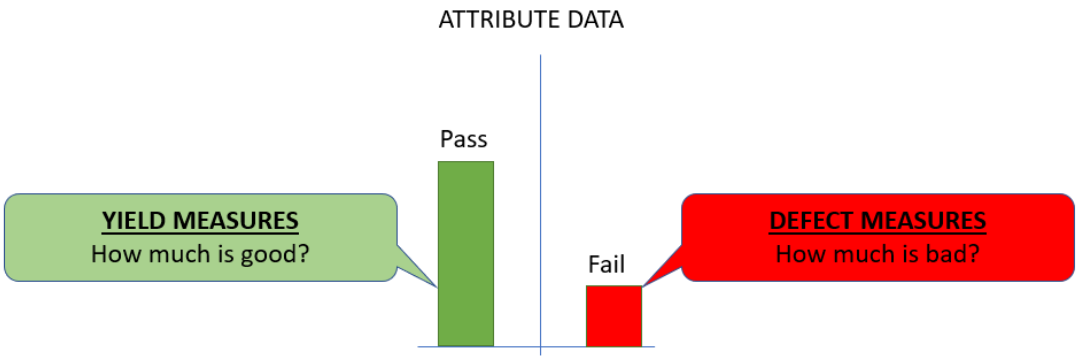


VARIABLE DATA

A defect is an output which does not reach customer requirements

Attribute Capability

Capability for Attribute data is defined in the terms of Good or Bad, Pass or Fail.



Traditional Attribute measures include the following.

- Traditional Yield (YT = Parts out / Parts in)
- First Time Through Yield (YFTT)
- Rolled Throughput Yield (YRT)

Attribute Capability (Binomial)

- Use Capability Analysis to produce a process capability report when your data is from a binomial distribution
    - Binomial distributions are usually associated with recording the number of defective items out of the total number sampled
    - For example, you might have a pass/fail gage that determines whether an item is defective or not. You could then record the total number of parts inspected and the number failed by the gauge

- Use Capability Analysis (Binomial) if your data meet the following conditions:
    - each item is the result of identical conditions
    - each item can result in one or two possible outcomes (success/failure, go/no-go)
    - the probability of a success (or failure) is constant for each item
    - the outcomes of the items are independent of each other Attribute Capability (Poisson)

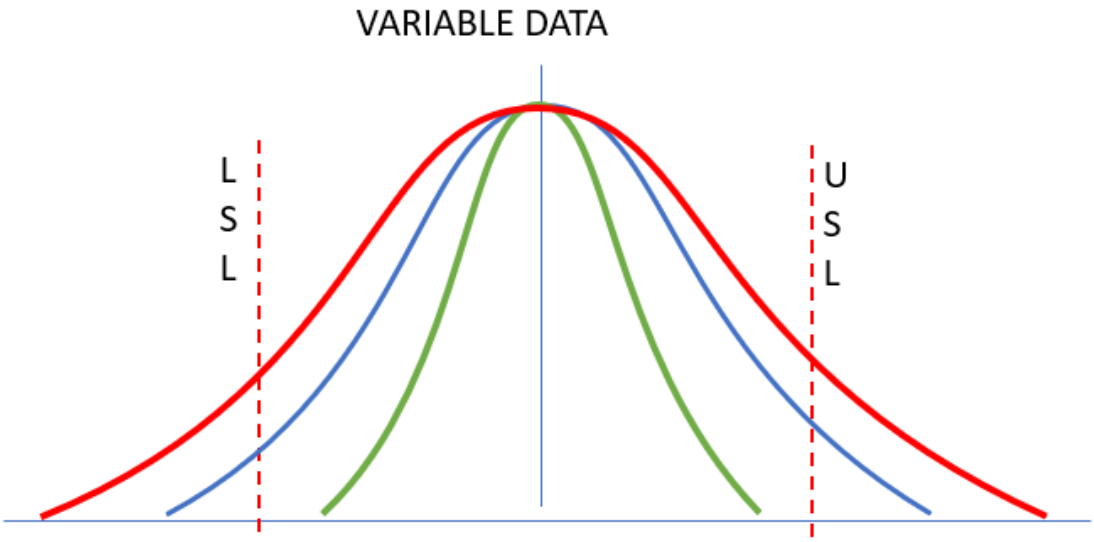
Attribute Capability (Poisson)

- Use Capability Analysis (Poisson) to produce a process capability report when your data is from a Poisson distribution.
    - Poisson data is usually associated with the number of defects observed in an item, where the item occupies a specified amount of time or specified space. The size of the item may vary, so you may also keep track of the size.
    - For example, if you manufacture electrical wiring, you may want to record the number of breaks in a piece of wire. If the lengths of the wire vary, you will have to record the size of each piece sampled

- Use Capability Analysis (Poisson) when your data meet the following conditions:
    - The rate of defects per unit of space or time is the same for each item
    - The number of defects observed in the items are independent of each other

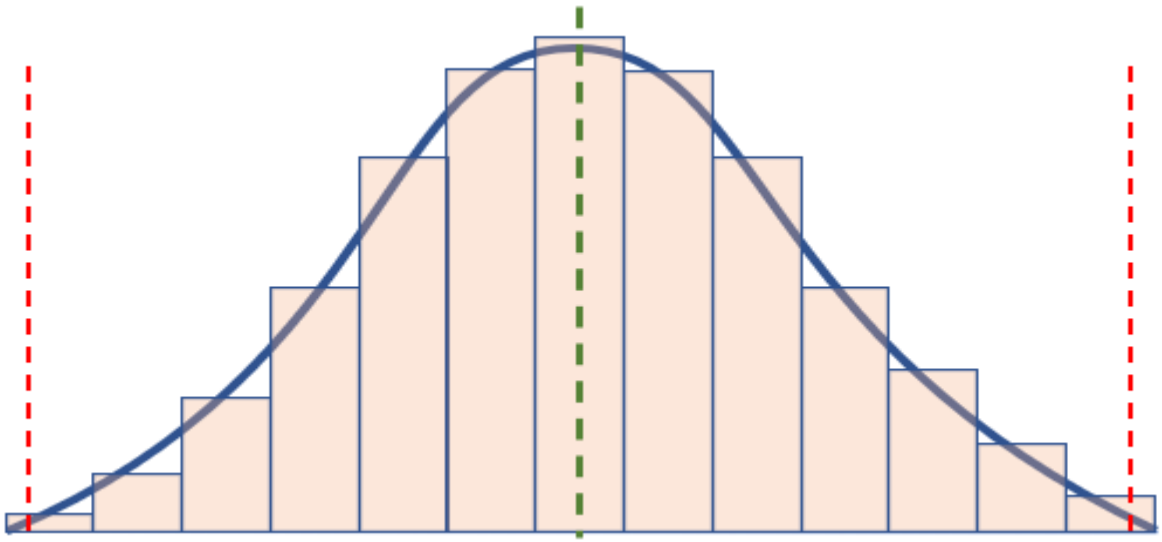
Variable Capability

- Capability for Variable data is determined by the spread of process data in relation to the Process specifications



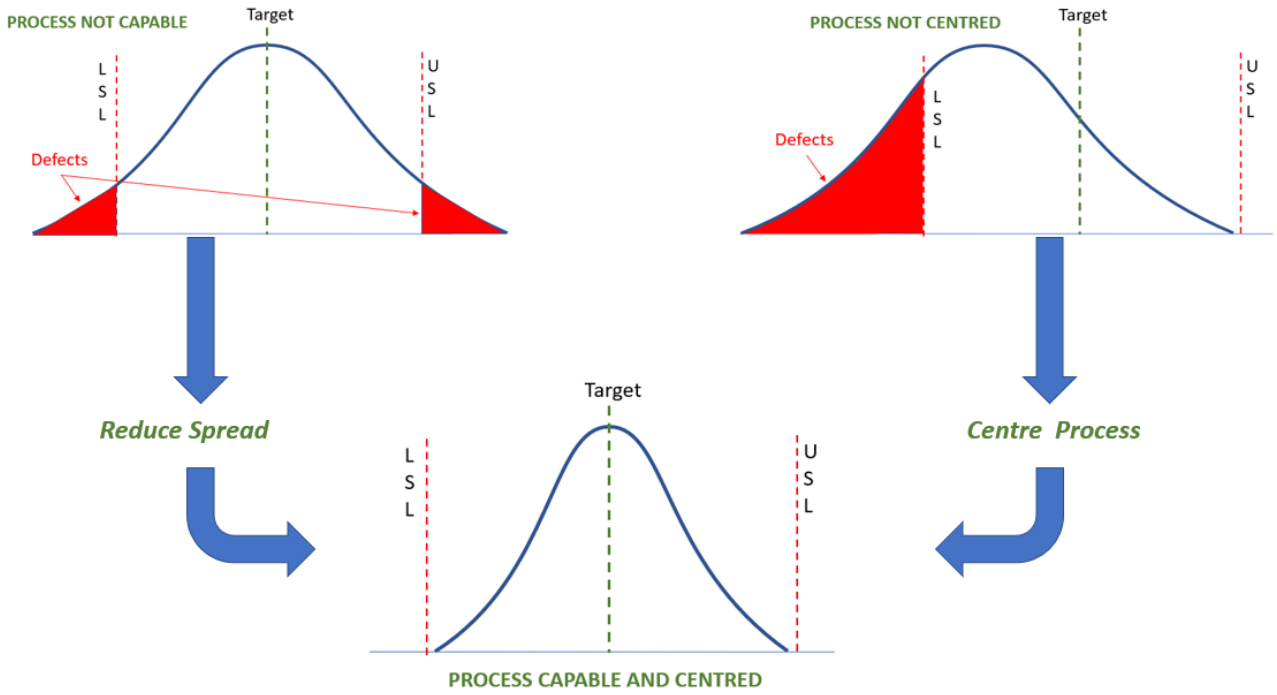
As the spread or Standard Deviation increases, the defect level increases

- By adding the target and specification limits, we can see how well the process is performing:



The idea is to have the centre of the data aligned with the target and all data points within the specification limits

The relationship between Variation and Process Capability:

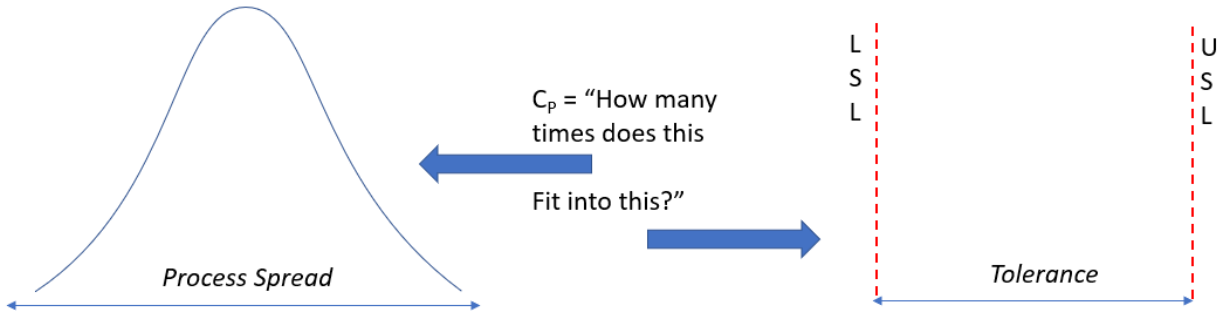


Variable process capability is the ability of a process output to 'fit' between the maximum and minimum specification limits which have been defined by the customer/engineer.

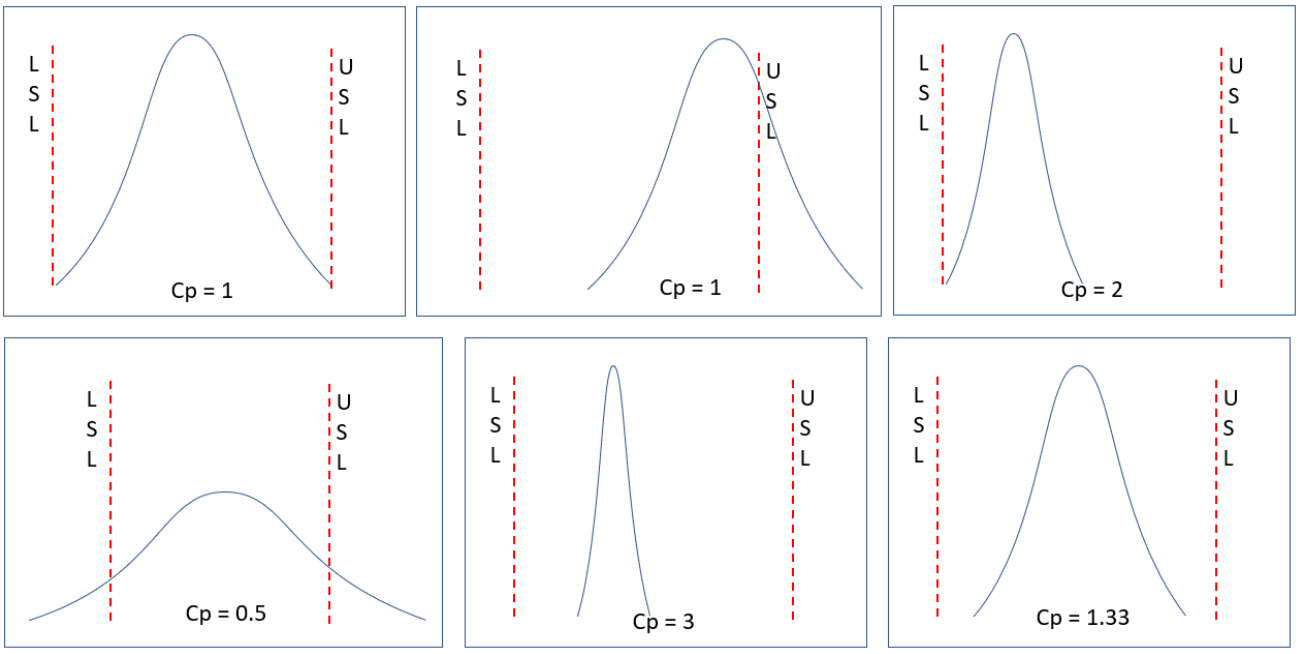
Cp & Cpk Capability Analysis

Cp and Cpk are numerical measures which together give values for the centering and degree of spread of the process. It gives a 'common language' which allows easy communication of the process capability and allows comparisons between processes or between a previous process state and a current process state.

Cp relates to the SPREAD of the process and is the ratio of the spread of the process to the 'available width' between the specification limits. Cp is completely independent of where the process is centred – for this reason Cp is referred to as 'Process Potential' – potentially can the spread fit within the specification?



Cp examples



Cp formula

$$Cpk = (USL - LSL) / 6\sigma$$

- Note that Cp can never be negative.
- A Cp of value 1 or greater is deemed as potentially capable

- Usually a Cp of at least 1.33 is desirable for a capable process (and see Cpk also)
- The higher the Cp, the narrower or tighter the spread.

Cpk.

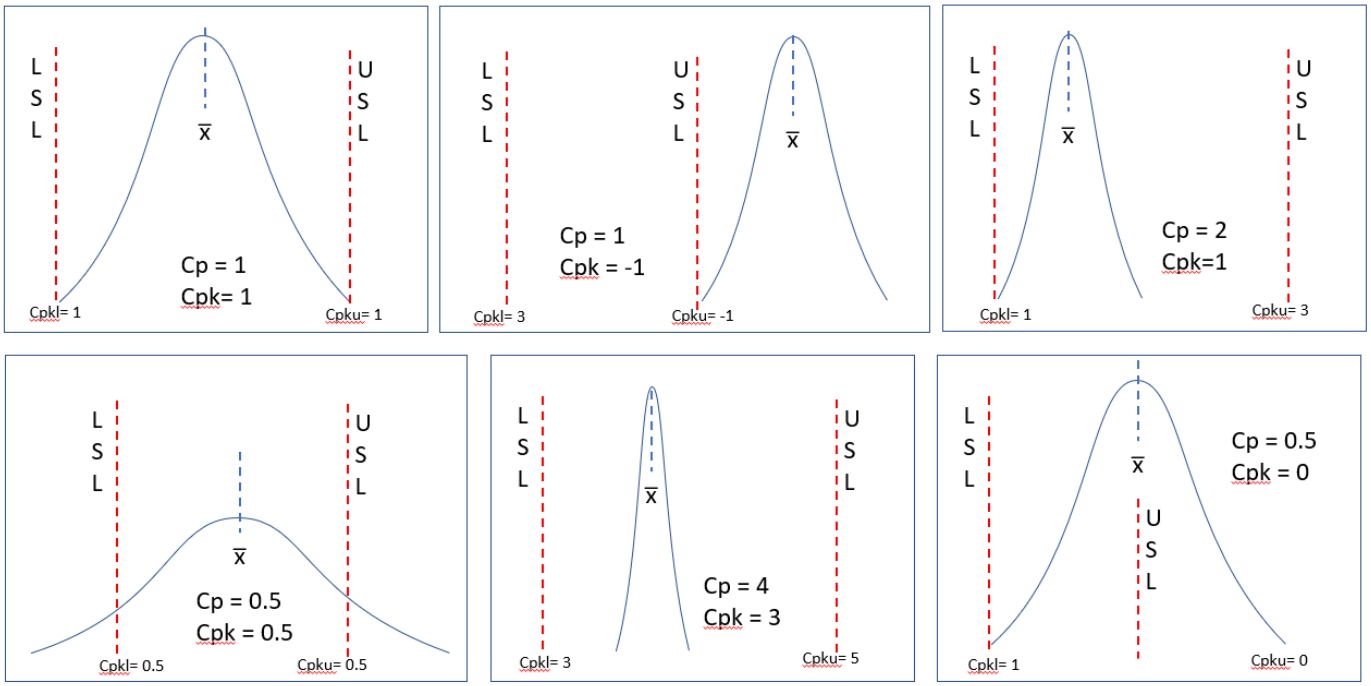
Cp give us information about the spread but not about the centering – conversely Cpk gives us information about the centering but NOT about the spread!

- Cpk compares the position of the data in relation to the Specification Limits: How many times does half the total process spread (3 SD) fit between the mean and the upper or lower specification limit? (whichever is the closest)
- So Cpk is the lower value of:

$$Cpku = \frac{\text{USL} - \bar{\text{x}}}{3\sigma} \quad \text{OR} \quad Cpkl = \frac{\bar{\text{x}} - LSL}{3\sigma}$$

- Note that if Cpku = Cpkl, the process is centred
- Cpk can be negative. (Occurs when the process mean is outside of the specification limits)
- Cpk can be Zero – this occurs when the mean is equivalent to the USL or to the LSL
- Cpk cannot be greater than Cp
- Cpk should be > 1.33 to be fully acceptable

Cpk and Cpk Examples



Root cause analysis (K15)

What is a root cause? (terminology):-

SYMPTOM	A quantifiable event or effect, experienced by customers, that may indicate the existence of one or more problems
FAILURE MODE	A way in which a part or process fails to meet its intended function
ROOT CAUSE(S)	The verified reason(s) that account for the problem; verified passively and/or actively, by making the problem come and go.

Why do we determine a Root cause?

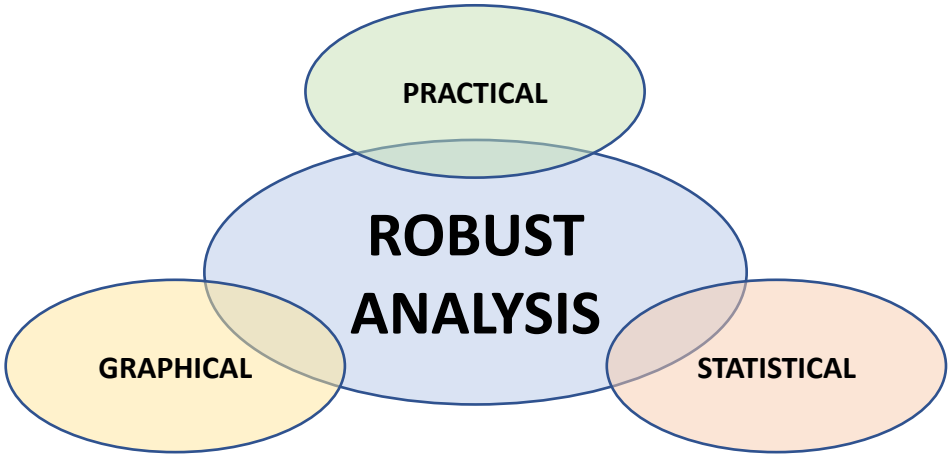
- Prevent problems from recurring
- Reduce possible injury to personnel
- Reduce rework and scrap
- Increase competitiveness
- Promote happy customers and stakeholders
- Ultimately, reduce cost and save money

When should Root cause Analysis be performed?

- Significant or consequential events
- Repetitive human errors are occurring during a specific process
- Repetitive equipment failures associated with a specific process
- Performance is generally below desired standard

How to determine the real Root cause?

1. Develop possible solutions
2. Define and implement an action plan (e.g., improve communication, revise processes or procedures or work instructions, perform additional training, etc.)
3. Monitor and assess results of the action plan for appropriateness and effectiveness
4. Repeat analysis if problem persists- if it persists, did we get to the root cause?
5. Perform robust Analysis



Graphical tools used to conduct Robust Analysis

The key tools are:

- ***Check Sheet***: A check sheet is a structured, prepared form for collecting and analysing data
- **Measles Chart**: Similar to a check sheet, identifies occurrences and defect location
- ***Dot Plot***: Used to display distributions when there are multiple sub-groups.
- ***Pareto Chart***: A bar graph that shows which factors are more significant.
- ***Run / Trend Chart***
- ***Histogram***: The most used graph for showing frequency distributions, or how often each different value in a set of data occurs.
- ***Box & Whisker Plot***: Graphical tool that enables multiple data sets to be analysed. Similar to a histogram.
- ***Scatter Plot***: Graphs pairs of numerical data, one variable on each axis, to look for a relationship

Additional Root Cause Analysis tools

Cause and Effect diagram

- Tool for capturing and prioritising all potential causes of the problem outlined in the Problem Statement
- Help the improvement team consolidate all they've learned about the process (including output from SIPOC, Process Map, VA/NVA analysis and FMEA)
- Alternative names commonly used include:
    - Fish Bone Diagram
    - Ishikawa Diagram

Cause and Effects Matrix

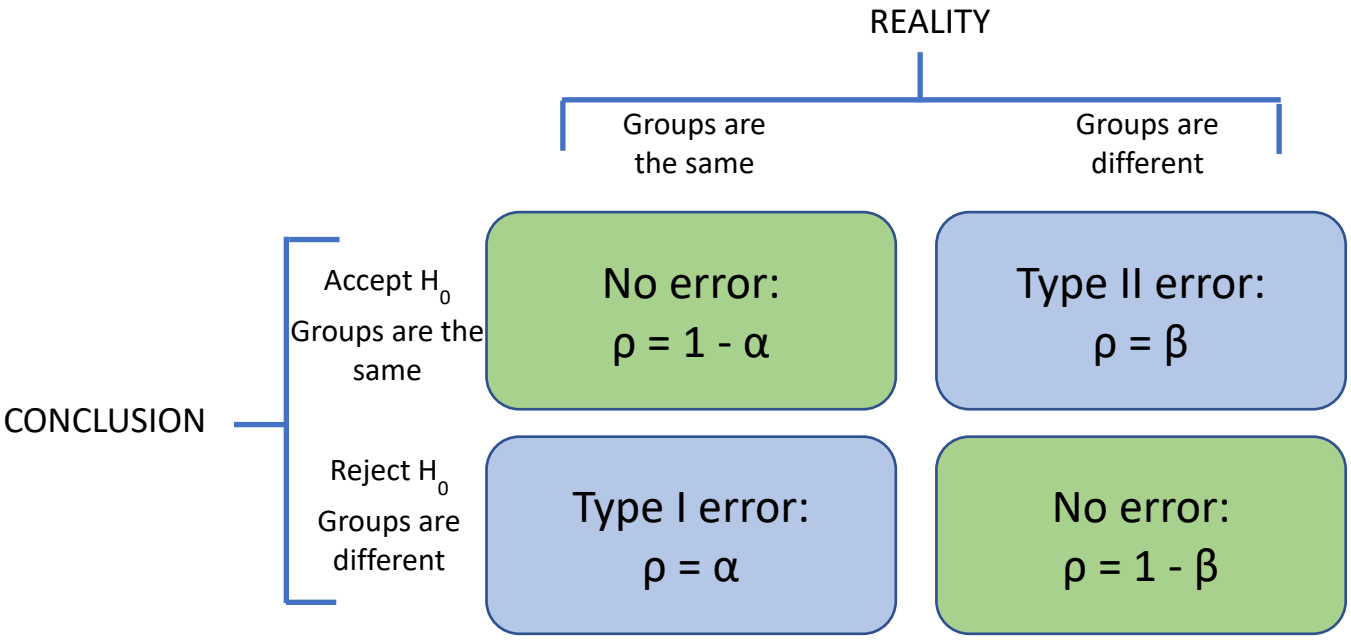
- A useful tool for prioritising the potential causes identified on the Cause & Effect Diagram
- Helps answer the question 'Which of these potential causes have the biggest effect?
- Enables the team to focus on a smaller number of potential causes
- Can be used for prioritising:
    - Potential root causes
    - Process steps (those having the biggest effect on customer requirements)
    - Potential solutions (known as a Solution Effect Matrix)

Hypothesis testing

Hypothesis testing is the use of statistics to determine the probability that a given hypothesis is true. It has four stages

1. Formulate the Null Hypothesis Ho, (commonly, that the observations are the result of pure chance) and the alternative hypothesis H1 (commonly, that the observations show a real effect combined with a component of chance variation)
2. Identify a test statistic that can be used to assess the truth of the Null Hypothesis
3. Calculate the P-value, which is the probability that a test statistic at least as significant as the one observed would be obtained assuming that the Null Hypothesis were true. The smaller the p-value, the stronger the evidence against the Null Hypothesis (ie. p-value is 0.05 or less)
4. Compare the p-value to an acceptable significance value (sometimes called an alpha value). If, that the observed effect is statistically significant, the Null Hypothesis is ruled out, and the alternative hypothesis is valid.

Error states in Hypothesis testing



Experimentation (K16)

Design of Experiments

- A methodology / tool that is used during the Improve Phase
- Also has good applications during both Measure and Analyse phases
- A technique for helping to identify those critical inputs – X's (factors) that are the potential root causes of our problem and for testing out our ideas for improvements
- Allows a number of inputs to be considered simultaneously so interactions between factors can be identified
- Prior to conducting a DOE it is important to confirm the output metric which will be used to confirm optimisation.

DOE Vocabulary

- Experimental Design: The formal plan for conducting the experiment.
- test Run: A single combination of factor levels.
- Factors: A factor (or input) is one of the controlled or uncontrolled variables whose influence on a response (output) is being studied in the experiment. E.g. Temperature in °C, Time in secs, operator etc.
- Level: The levels of a factor are the values of the factor being studied in the experiment.

e.g. The experiment is conducted at two levels (high and low temperature) and with 3 factors

$$\text{Level}^{\text{Factors}} \text{ or } 2^3$$

- Replication: A duplication of the entire experiment including set-up

- Repetition: A repeat run at the same settings. I.e. making two panels with no adjustment to the press settings.
- Inference Space: The Operating range of the factors under study– The difference between the Low & High settings for a factor.
- Main Effect: The change in the average response (output) observed during a change from one level to another for a single factor (input)
- Interaction: The combined effect of two or more factors observed over and above the main effect of each factor
- Active Analytics: is described as running a set of tests where input variables are forced to be in specific ranges, i.e. completing a Design of Experiments
- Passive Analytics: is described as analysing a process where the Xs and Ys are allowed to fluctuate in their normal range, i.e. leaving a process to run as usual and continuing to observe what is going on

Philosophy of DOE

- Accounts for all sources of variation
- Minimises or eliminates effects of uncontrolled (noise) factors
- Focuses on factors having the greatest effect
- Reduces costs associated with experimentation

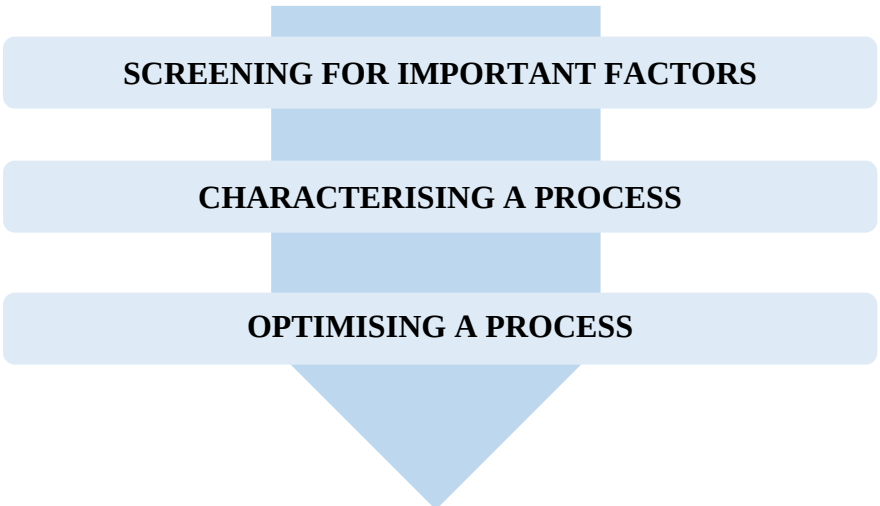
Benefits of DOE

- Allows multiple factors to be studied simultaneously
- Outputs can be controlled even when noise factors cannot
- Interactions are detected and measured
- Fewer experiments are necessary, cost effective
- Experimentation is based on statistical analysis rather than judgement
- Quicker than one factor at a time

DOE involves adjusting Inputs in a controlled way and observing the Outputs

DOE can be used for:

- Screening – Identify the 'vital few' sources of variation (most often used in the Analyse phase)
- Characterisation – Quantify the effects of the important Inputs, including their interactions
- Optimisation – Determine optimum settings (most often used in the Improve phase)



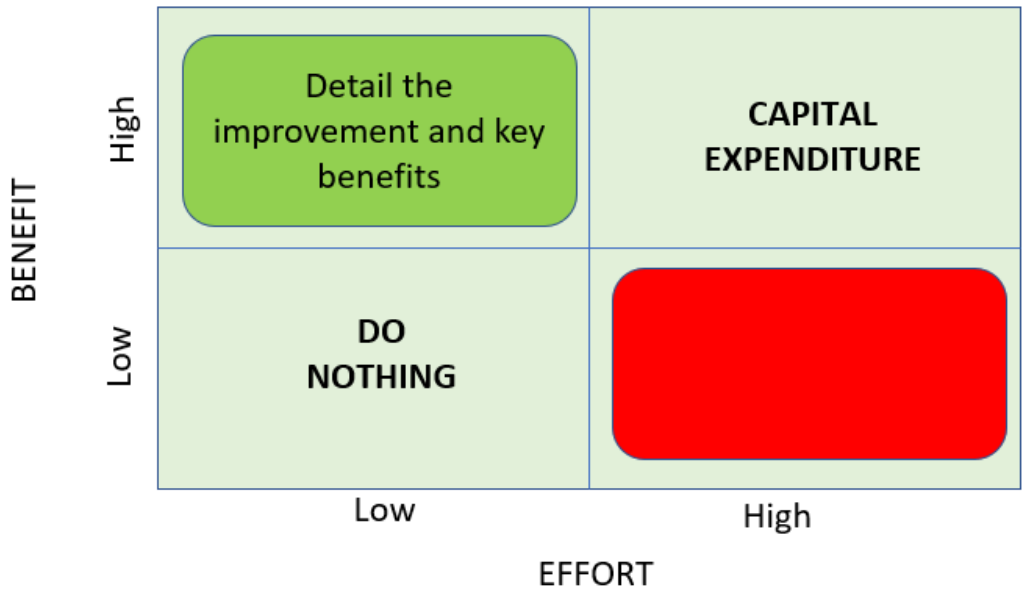
Identification and prioritisation (K17)

Once the Selection Criteria have been developed, benchmarking completed and DOE (where applicable) carried out, a Selection Matrix can be used to assess each improvement alternative: (Your criteria may be different to the below to suit your own needs)

Selection Criteria - weighting		9	5	3	10	6	
Selection Criteria		*Quality*	*Cost*	*Delivery*	*Safety*	*Env'ment*	**TOTAL:**
Improvement options:	**Option a**	8	5	2	8	5	**213**
	Option b	7	3	5	8	5	**203**
	Option c	9	8	2	9	5	**247**

Warning – eliminate any options which do not meet identified 'must have' criteria

An additional tool for analysing alternatives is the pay-off matrix, which provides a useful idea of how ideas compare:-



Process Failure Modes Effects Analysis (PFMEA)

A PFMEA can be described as a group of activities intended to:
Recognise & evaluate the potential failure of a product/process & it's effects
Identify actions which could eliminate or reduce the chance of the potential failure occurring
Document a process
Risk assessment of associated processes during the virtual series

A PFMEA complements the Process by positively defining what a Process must achieve to satisfy the customer.

Benefits of PFMEA

- To assist in the improvement of product/process safety, quality & reliability
- Documents all activity
- Helps develop Plans
- Assists in methods and focus on concerns and problem prevention
- Improves customer/consumer satisfaction
- Enables failure modes to be anticipated and prevented

Why do we need PFMEA?

- The complexity of business processes means that potential failure modes are inevitable
- Identify potential failures early enough in the process to rectify by the introduction of process controls

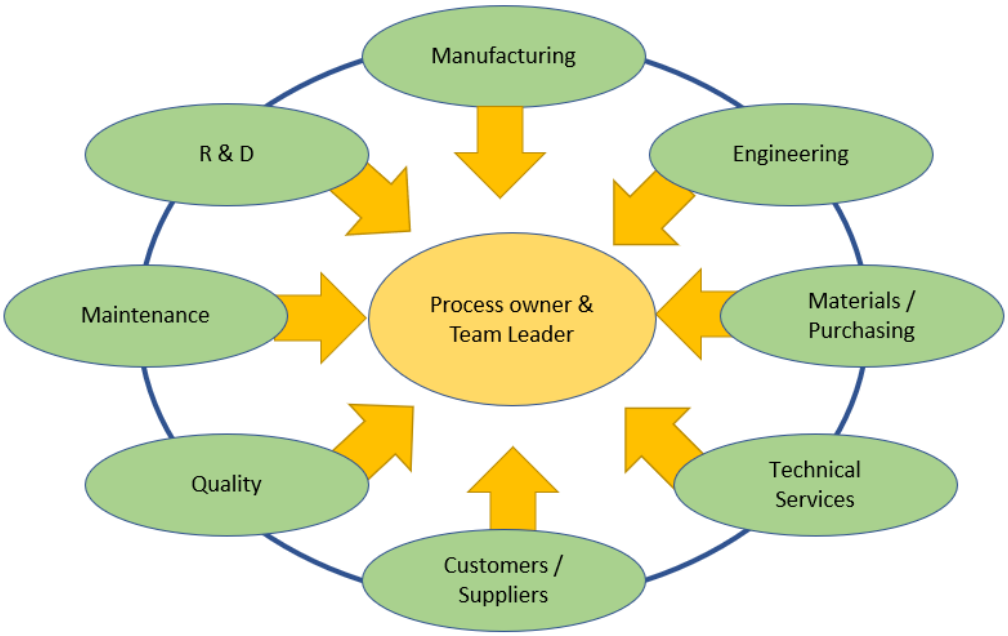
Practicalities

- PFMEA views processes from the point of counter-measure development, & focus the attention on measuring the effectiveness of the countermeasures applied to prevent a failure mode from escaping

PFMEA Timing
PFMEA's are meant to be a 'before-the-event' set of activities not an 'after-the-fact'

- Three basic cases that trigger PFMEA generation or review:
    - A new process
    - Modifications to existing design or process
    - Use of existing design or process in a new environment, location or application

Roles and Responsibilities



Potential Team Members selected based on the contribution that they can make and to ensure team is cross-functional

Why do PFMEA?

- To understand what can go wrong with a process during the virtual series engineering events.
- To create controls that prevent process failures
- To make recommended actions
- To reduce reworking of products/units/services
- To reduce warranty & campaign actions
- To Improve the process to the level where failure is eliminated, or its effect minimised

Risk Priority Number (RPN)

- The RPN is a measure of Process risk
- The RPN will be between 1 and 1000
- The Risk Priority Number (RPN) is the product of:

Severity (S) times Occurrence (O) times Detection (D) rankings.

- Severity, Occurrence and Detection ratings are scored 1 – 10.
- High Severity i.e. 8, 9 and 10, will attract immediate action
- High RPNs are then investigated and remedied
    - This threshold value will depend upon process and environment and would be expected to be reduced year upon year as the process matures.

PFMEA as an activity

- Ensure an appropriate cross functional team has been identified that will create the PFMEA document.
- Define the scope of the activity as a team.
- Complete the FMEA document in sequential steps:-

1. Review the Process
2. Identify potential failure modes
3. List potential effects of failure
4. Assign Severity Ratings
5. Assign Occurrence Ratings
6. Assign Detection Ratings
7. Calculate the RPN's
8. Develop the Action Plan
9. Take Action
10. Calculate the resulting RPN's

Example Header row for PFMEA Document table

Process Step / Function	Requirements	Potential Failure Mode	Potential cause of Failure	Severity	Current Prevention Controls	Occurance	Current Detection Controls	Detection	Current RPN	Recommended Actions	Resp. and Target Date	Revised Severity	Revised Occurrence	Revised Detection	Revised PRN

SMART targets

Ensure throughout the project that targets are:

- Specific
- Measurable
- Attainable
- Realistic
- Time bound

(end of document)