Build4Scale
U.S. Department of Energy

Regulation, Certification, and Industry Standards

Module 6B Identify Quality Needs

Motivation

Why is this module important?

- Your bankruptcy may be one big quality failure away!
- It is key to establish your quality plan early on during beta testing to avoid the unexpected during scaling
- How to get a product right the first time and every time depends upon a capable process

Example: 2014 General Motors ignition switch recall. The actual cost of the ignition switch was only a few cents, but its quality failure was responsible for millions of vehicle recalls costing billions of dollars to the company

Motivation

Why is this module important? (cont.)

- **Voice of the customer**: a market-research technique that produces a detailed set of customer wants and needs, organized into a hierarchical structure, and prioritized by relative importance and satisfaction with current alternatives
- You need to know what others are doing to stay competitive in the market place (That is called "**benchmarking**" or "**reverse engineering**" depending upon the context)

Module Outline

- Learning objectives
- What this module addresses
- Where does this fit in the overall Product Development (PD) process?
- Process capability analysis
  - —Determining capability of your process for scale-up
- **Six sigma** process-improvement methodology
  - —Nuts and bolts of *Define, Measure, Analyze, Improve and Control* (DMAIC) phases with some examples of quality tools
- Benchmarking quality
  - —Voice of the market and understanding your competition

Learning Objectives

- LO1. Analyze data to determine process capabilities
- LO2. Apply the Six Sigma process to quality problems
- LO3. Identify critical quality needs through use of benchmarking

What This Module Addresses

- Quality planning during beta testing to ensure that you have a capable process to produce your product when you do so at scale
- An extensive discussion of several ways to study and analyze the capability of a production process
- An explanation of the Six Sigma quality-improvement methodology and metrics
- What to benchmark and how benchmarking can help you compare your product quality with that of your competitors
- Business practices of your competitors, and what you can learn from their products and processes to improve your competitiveness in the marketplace

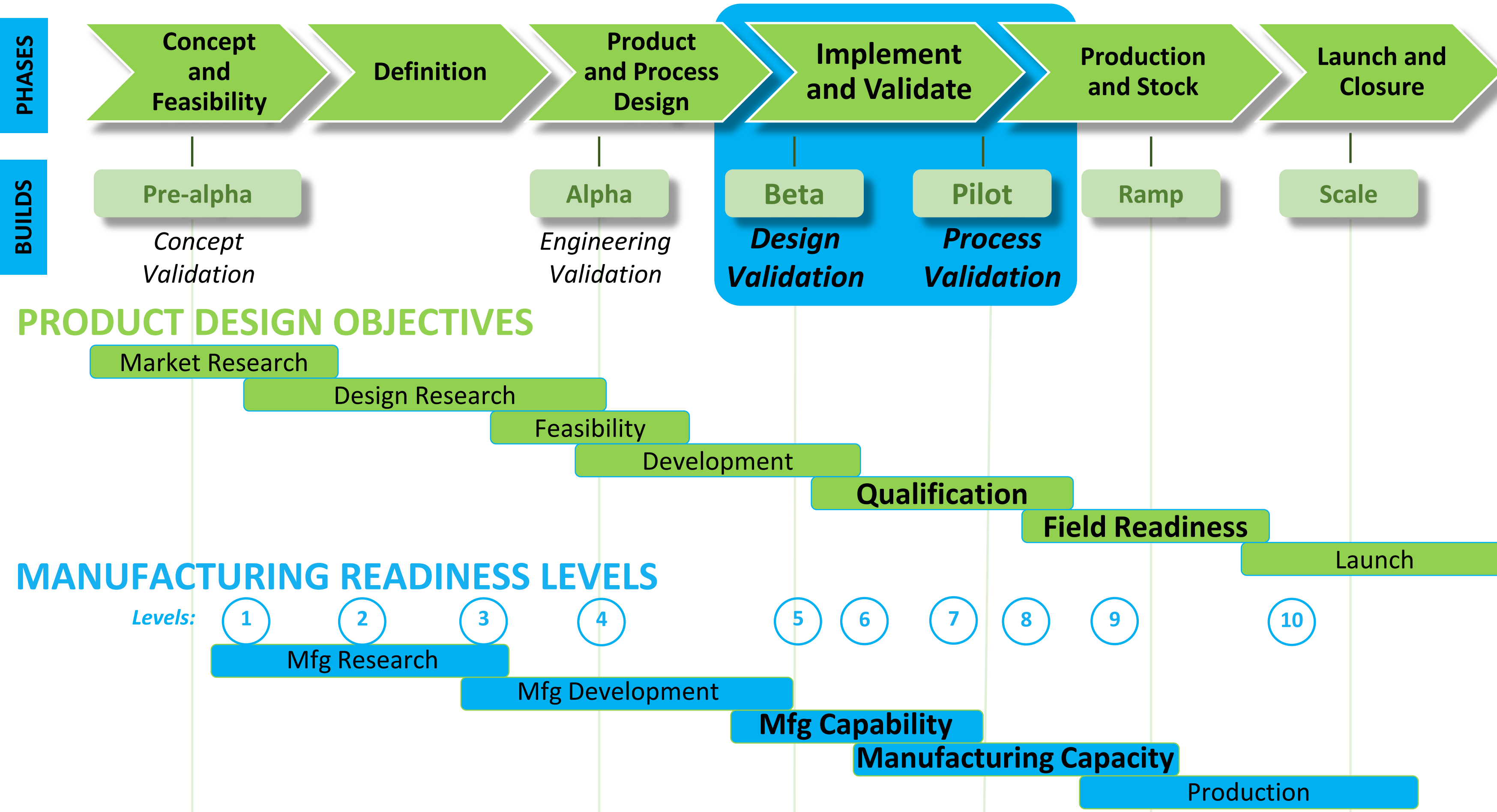
What This Module Addresses

(cont.)

- Process capability analysis can be helpful throughout the product-development cycle and during product-development activities conducted prior to manufacturing. It allows you to compare the variability of your selected process with respect to the design tolerances
- The Six Sigma quality-improvement methodology is a package of quality tools and philosophies. Its data-driven improvement cycle can be applied during any phase of the product-development cycle to improve product quality and reduce cost. It also reduces the variability of your manufacturing process, thereby improving its overall capabilities and efficiency
- Understanding your customers and the marketplace provides the data needed to make informed decisions about design and manufacturing strategies

Quality Planning

Where does this fit into the development cycle?



Identify Quality Needs

Process Capability

Basics

- Process capability refers to the ability of a process to produce a product that meets products requirements (also defined as design specifications)
- A highly capable process produces high volumes with few or no defects—world-class levels of process capability are measured by parts per million (ppm) defect levels
- A process is deemed “fully capable” if individual product units consistently meet design specifications

Process Capability Analysis Data

What it is and how to use it

Process capability analysis data uses include:

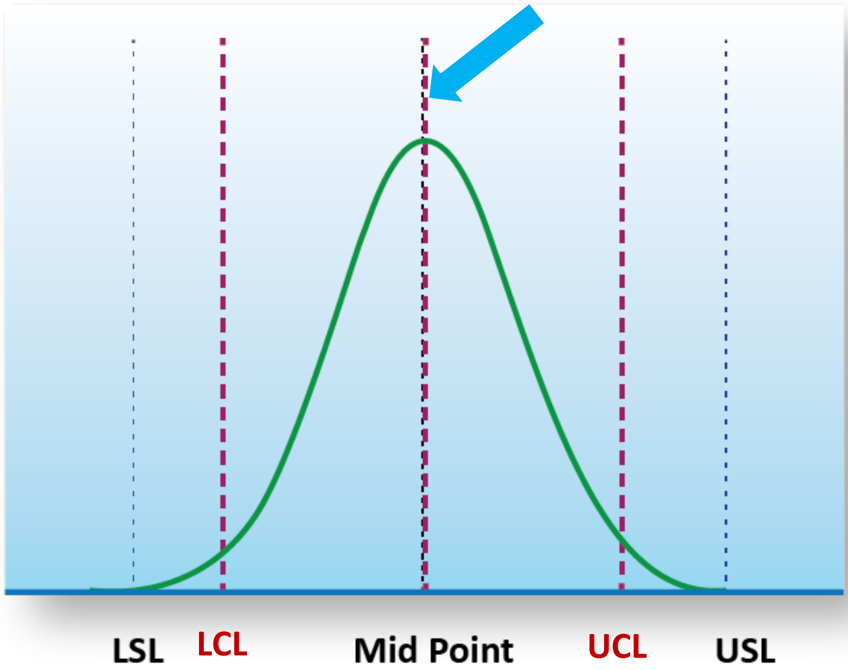
- Predicting how well the process will hold the designed tolerances
- Assisting product developers and designers in selecting or modifying a process
- Assisting in establishing an interval between sampling for process monitoring
- Specifying performance requirements for new equipment
- Selecting a vendor
- Planning the sequence of production processes when there is an interactive effect of processes on tolerances
- Reducing the variability in a manufacturing process

Process Capability Analysis Data

Basics

- **Process mean:** Defined as the average of the sample data collected from a process with respect to the quality characteristic in question
- The **lower control limit** (LCL) and the **upper control limit** (UCL) accounts for the process variability
- **Target mean:** It is an average of lower **specification limit** (LSL) and **upper specification limit** (USL) values specified in a bill of process

Process mean = Target mean



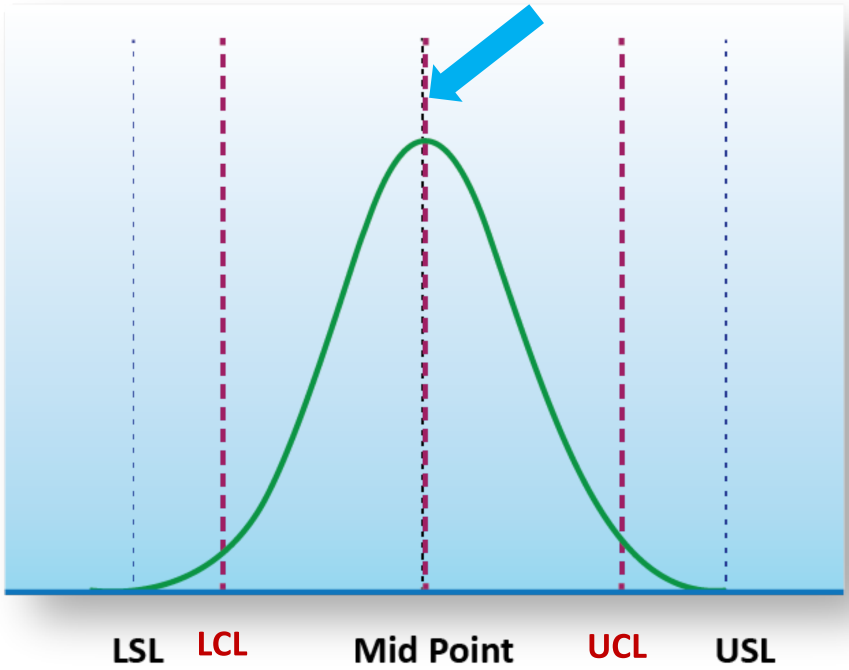
Process Capability Analysis Data

Centered processes

- The goal is to have both process mean and target mean to meet at the same point

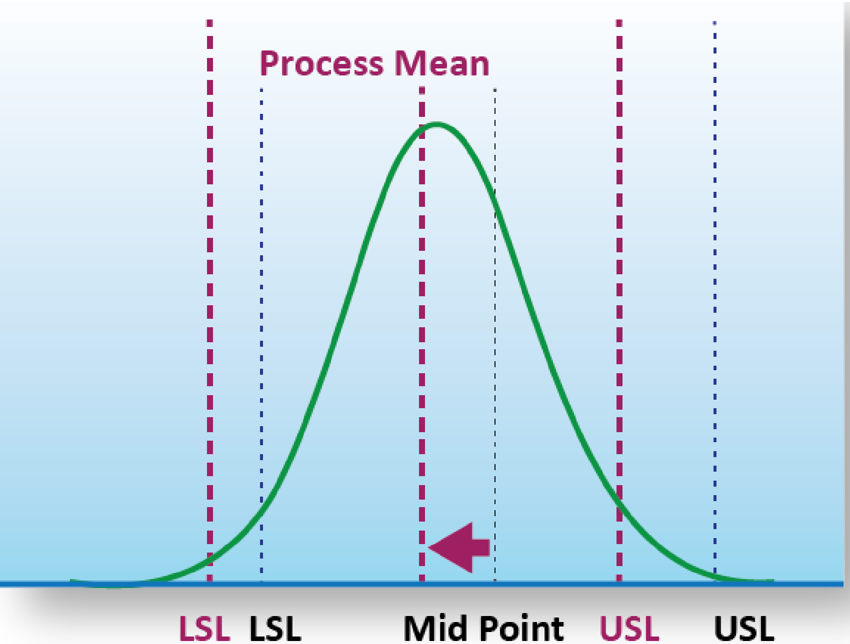
*In other words, a process is **centered** if both the process mean and*
the target mean coincide at the midpoint

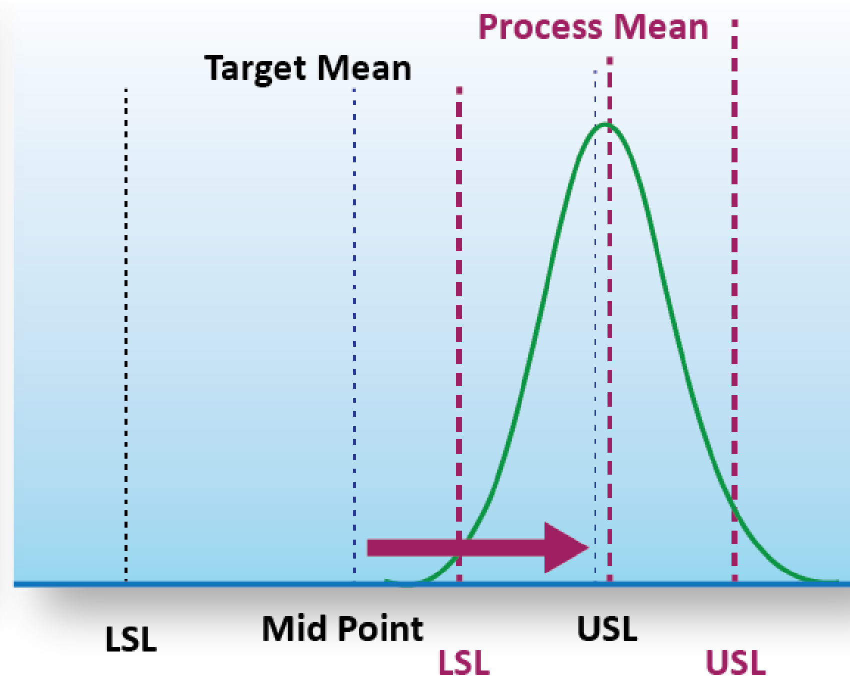
Process mean = Target mean



Process Capability Analysis Data

Off-centered processes





Left off-centered process:
Process mean is to the left of the target mean, so the process is likely to produce undersized parts

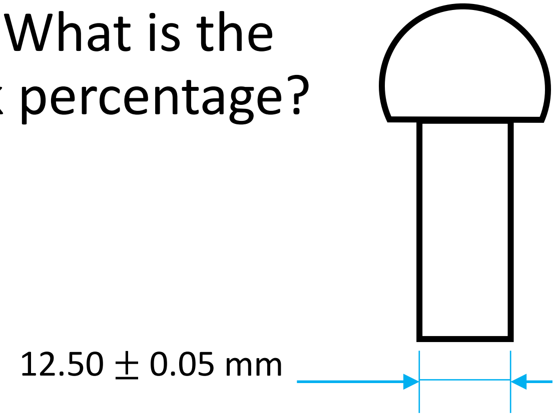
Right off-centered process:
Process mean is to the right of the target mean, so the process is likely to produce oversized parts

Process Capability Studies

Example

Problem background:

- Location pins for work-holding devices are ground to a diameter of 12.50 mm (approximately ½ in) with a tolerance of ± 0.05 mm
- The process is centered at mean 12.50 (μ) and the dispersion is 0.02 mm (σ)
  a) What percentage of the product must be scrapped, and what percentage can be reworked?
  b) How can the process center be changed to eliminate the scrap? What is the rework percentage?



Process Capability Studies

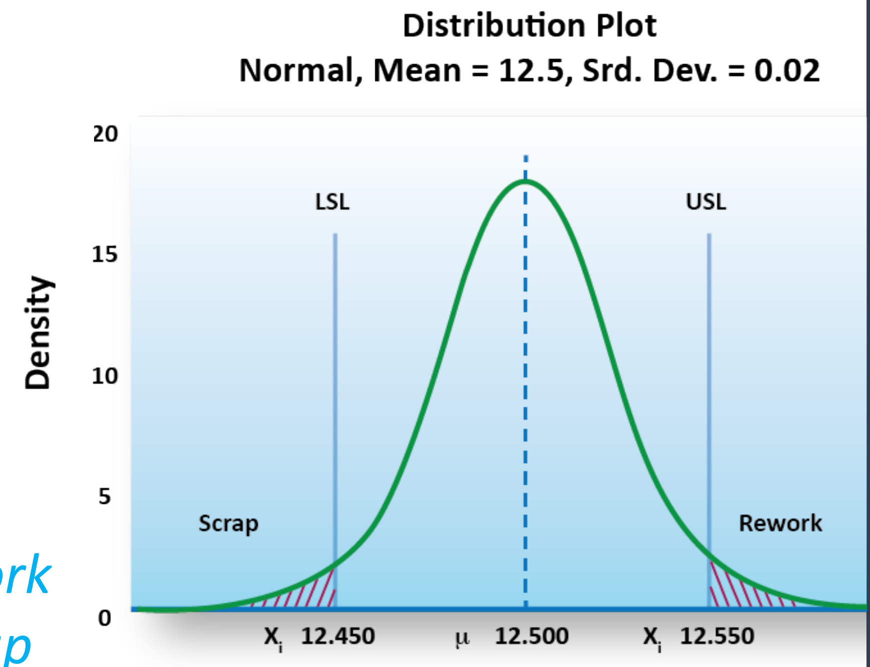
Solution A – Determine % scrap and rework

USL = μ + 0.05 = 12.50 + 0.05 = 12.55 mm
LSL = μ + 0.05 = 12.50 - 0.05 = 12.55 mm

$$Z = \frac{X_i - \mu}{\sigma} = \frac{12.45 - 12.50}{0.02} = -2.50$$

Now, for a Z-value of -2.50, $Area_1$ = 0.0062 = 0.62% scrap

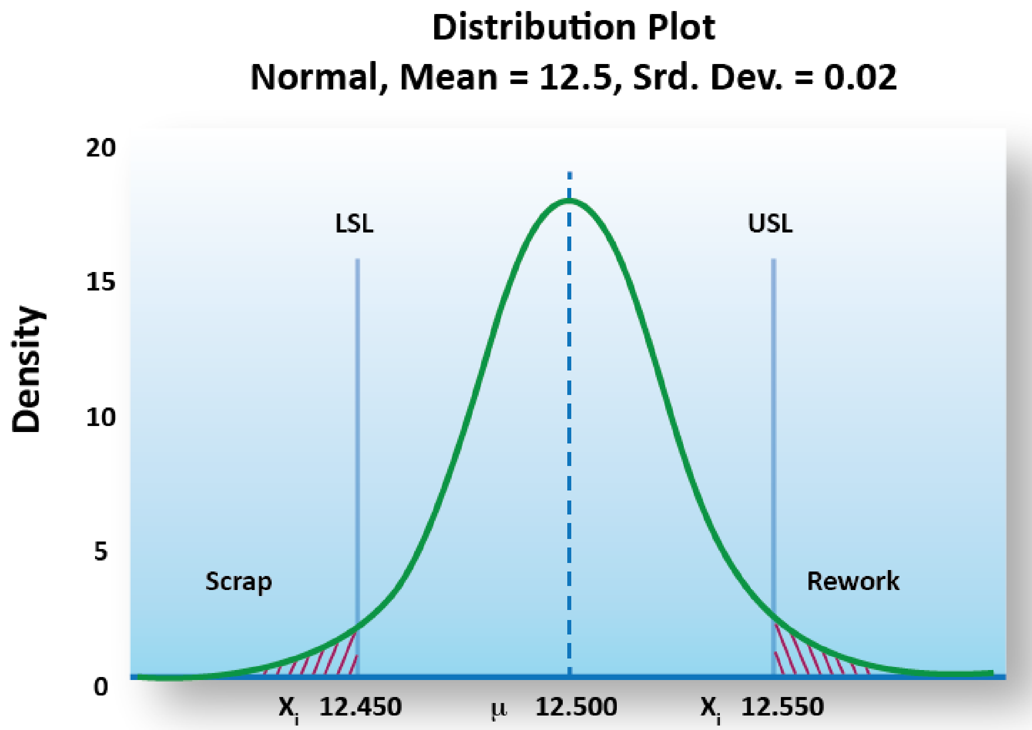
Since the process centered, the rework percentage will be the same as scrap percentage, i.e., 0.62%



Note: Using Excel to calculate the area under curve, you can calculate the area under the curve directly by using Excel function:
=norm.dist(x,mean,standard_dev, True)

Process Capability Studies

Solution A – Determine % scrap and rework (cont.)



Note: Usually, you need to calculate Z-score for LSL (12.450 mm) and USL (12.550) and then determine the probability separately. However, since this process is centered, you can calculate the probability for LSL, and then using symmetry, calculate the probability for USL.

Process Capability Studies

Solution B – Eliminate scrap/change process center

Note: Scrap a part only when it is undersized because if it is oversized you can rework it to the specification. That means area on the left outside of LSL should be zero. If we use 0 (or near zero) value for area and calculate Z-score, we get z= –3.59. Now, plug this new Z-value in to get the new mean.

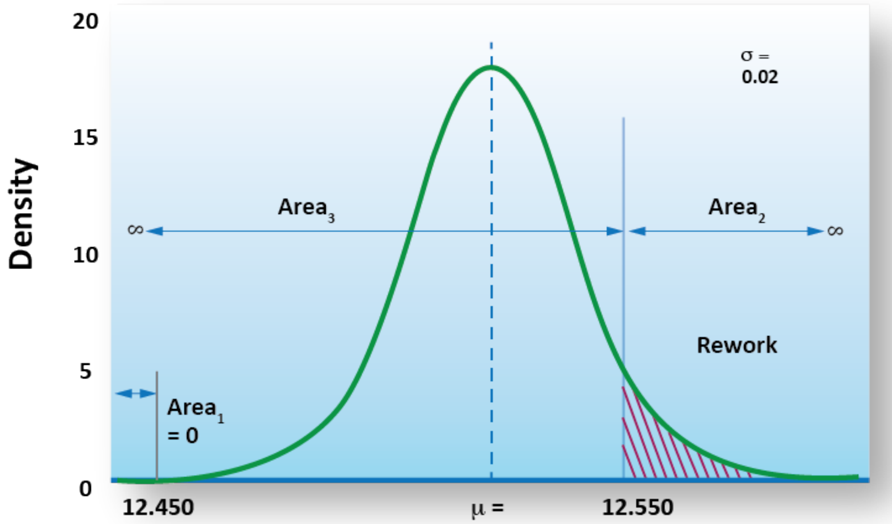
-3.59 = i.e. **= 12.52 mm**

Percentage of rework: Z = =

So, $Area_3$ =0.9332

$Area_2 = Area_T - Area_3 =$
1.0000 – 0.9332 =
0.0668 = 6.68 %

Thus, the amount of rework is **6.68%**



Note: the percentage of rework is significantly higher for an off-centered process than for that of the centered case in solution A

Process Capability Index

Basics

- Mathematically, the process capability is measured by its process capability index (C_p), which is defined as follows:

$$C_p = \frac{USL - LSL}{6\sigma}$$

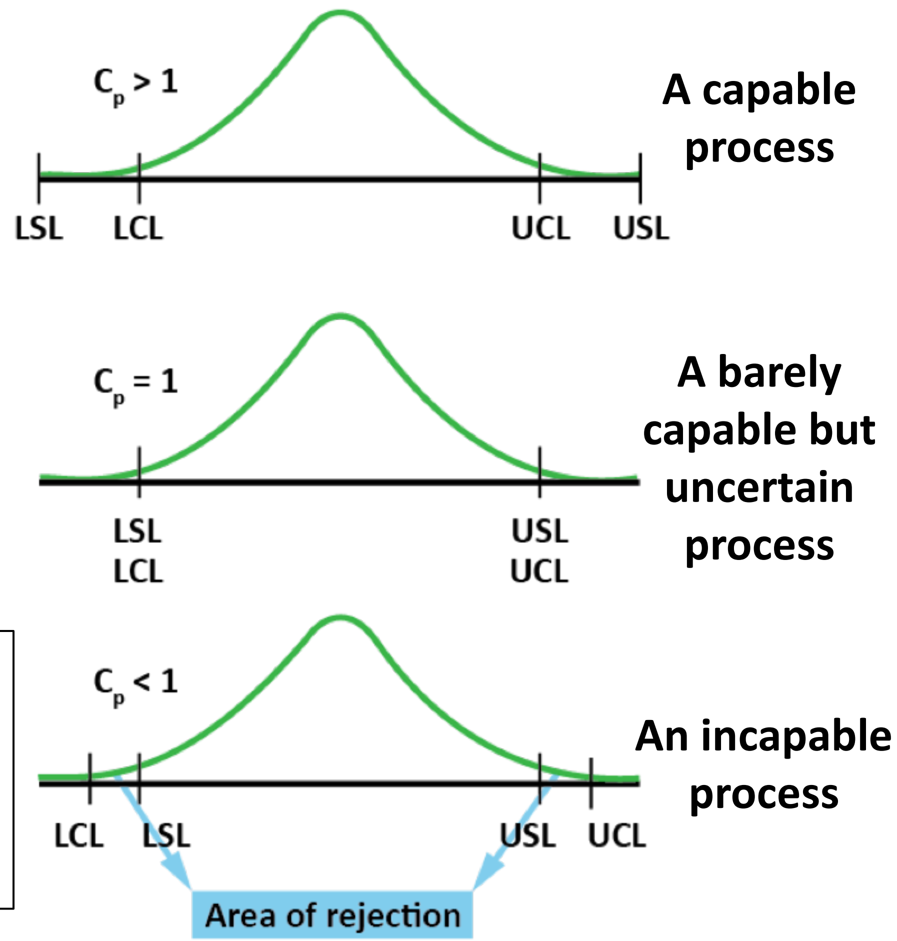
  —LSL and USL are the lower and upper specification limits, respectively

  —The 6σ spread is the natural tolerance interval of the process

Different Capability Processes

Examples

- Control limits represent the process spread (variability), whereas specification limits represent the design tolerance defined in the BOP
- For a process to be capable, control limits should be well inside the specification limits



LCL = Lower Control Limit
UCL = Upper Control Limit
LSL = Lower Specification Limit
USL = Upper Specification Limit

C_p Calculations

Key assumptions

- The quality characteristic (the design specification in question) has a normal distribution
- The process is in statistical control
- In case of two-sided specifications, the process mean is centered between the LSL and USL
- If any of the above assumptions are not valid, C_p would not be a reliable measure to determine the capability of a process

Process Capability Index

Off-centered process

- As stated earlier, if a process is not centered then C_p should not be used
- The appropriate process capability index for an off-centered process is C_{pk}, which is defined as follows:

$$C_{pk} = \min(C_{pl}, C_{pu})$$

$$C_{pl} = \frac{\mu - LSL}{3\sigma}$$

$$C_{pu} = \frac{USL - \mu}{3\sigma}$$

Process Capability Index

Example

- Consider two types of processes that can machine the same part
  - Process A produces parts with a mean length of 100 mm and standard deviation of 3 mm
  - Process B produces parts that have a mean length of 105 mm and a standard deviation 1 mm (the design specifications for the parts are 100 ± 10 mm)
- Calculate the C_p and C_{pk} values for each of the two processes and check whether they differ from one another

Process Capability Index

Solution

- We have USL = 110 mm and LSL = 90 mm

$$C_p = \frac{USL - LSL}{6\sigma},$$

$$C_{pk} = \min\left(\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\right)$$

	Process A ($\mu = 100, \sigma = 3$)	Process B ($\mu = 105, \sigma = 1$)
C_p	1.111	3.333
C_{pk}	1.111	1.667

- Process A is centered between the specification limits, so the C_p and C_{pk} values are the same for it
- Process B is not centered between the specification limits because the process mean (μ) = 105 > 100 (the center of the specification limits), so for B, the C_p and C_{pk} values are different

Process Capability Index

Summary

- The C_p and C_{pk} are both process capability indices that predict the potential capability of the process to meet the required specifications
- The C_p compares the total predicted process variation (defined as ± 3 standard deviations) to the allowable process variation (specification limits)
- The C_{pk} compares the actual process center and spread to the nominal or target process center and spread
  - —C_{pk} is based on the distance from the process mean to the nearest, and therefore the riskiest limit, so the smallest value is always selected

Six Sigma

Methodology

Six Phases (each has a specific purpose and is deliverable):

- ☐ **D**efine
- ☐ **M**easure
- ☐ **A**nalyze
- ☐ **I**mprove
- ☐ **C**ontrol

Six Sigma process improvement methodology

=

DMAIC methodology

Six Sigma

Basics

Six Sigma metrics:

- **Defect**: anything outside of customer specifications that is passed on to a customer
- **Defects per unit** (DPU): number of defects discovered divided by number of units produced
- **Defects per million opportunities** (DPMO): DPU × 1,000,000 ÷ opportunities for error
- Use of DPMO allows us to broadly define quality

Example: in the airline industry, it covers every opportunity for a failure to meet customer expectations right from initial ticketing until bags are received after completing the journey

- Six sigma methodology represents a quality level of at most 3.4 DPMO

Six Sigma

Define phase

Purpose:

- Establish a clear and compelling reason for improving the process or product based on the following:
  - —Voice of customer
  - —Stakeholder requirements
  - —Gap in current process capability

Deliverable:

- Charge that includes the current observable problems, goals for the project, and information that will guide the team
- Outline of customer expectation/failure data, performance gap; clear statement of the perceived problem written using *SMART*

***S**pecific, **M**easurable, **A**ttainable, **R**esults-oriented, **T**imely*

Six Sigma

Measure phase

Purpose:

- To factually understand the problem
- Collection of data will narrow the range of potential causes
- Use later in the "Analyze" step

Deliverable—An amended business case that includes:

- **Flowchart**: an "as-is" process check sheet for data collection
- **Data collection**: completed and displayed
- Costs of the current process
- **Key metrics**: the measurable quality standards
- **Performance matrix**: current process details

Examples: process step, inputs, outputs, key success factors, performance measurement, and standards/goals

Aerospace Tank Quality Defects

Example – Check sheet for identifying defects

CHECK SHEET

DEFECT DATA FOR 2002-2003 YTD

Part No: TAX-41
Location: Bellevue
Study Date: 6/5/03
Analyst: TCB

List of Defects

	2002												2003					
Defect	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	Total
Incorrect dimensions											13	7	13	1		1	1	36
Parts damaged		1		3	1	2		1		10	3		2	2	7	2		34
Machining problems			3	3				1	8		3		8	3				29
Masking insufficient		3	6	4	3	1												17
Supplied parts rusted			1	1		2	9											13
Adhesive failure				1							1		2			1	1	6
Salt-spray failure													4			2		6
Film on parts						3		1	1									5
Processing out of order	2															2		4
Wrong part issued		1						2										3
Unfinished fairing			3															3
Misaligned weld	2																	2
Paint out of limits						1								1				2
Voids in casting									1	1								2
Delaminated composite										2								2
Powdery alodine					1													1
Paint damaged by etching			1															1
Primer cans damaged								1										1
Improper test procedure										1								1
TOTAL	4	5	14	12	5	9	9	6	10	14	20	7	29	7	7	8	2	168

Number of Occurrences

Six Sigma

Analyze phase

Purpose:

- To make sense of all the data gathered in the "Measure" phase; and to use that data to discover areas of delay, waste, poor quality, and high costs
- To identify and verify the root cause of a problem

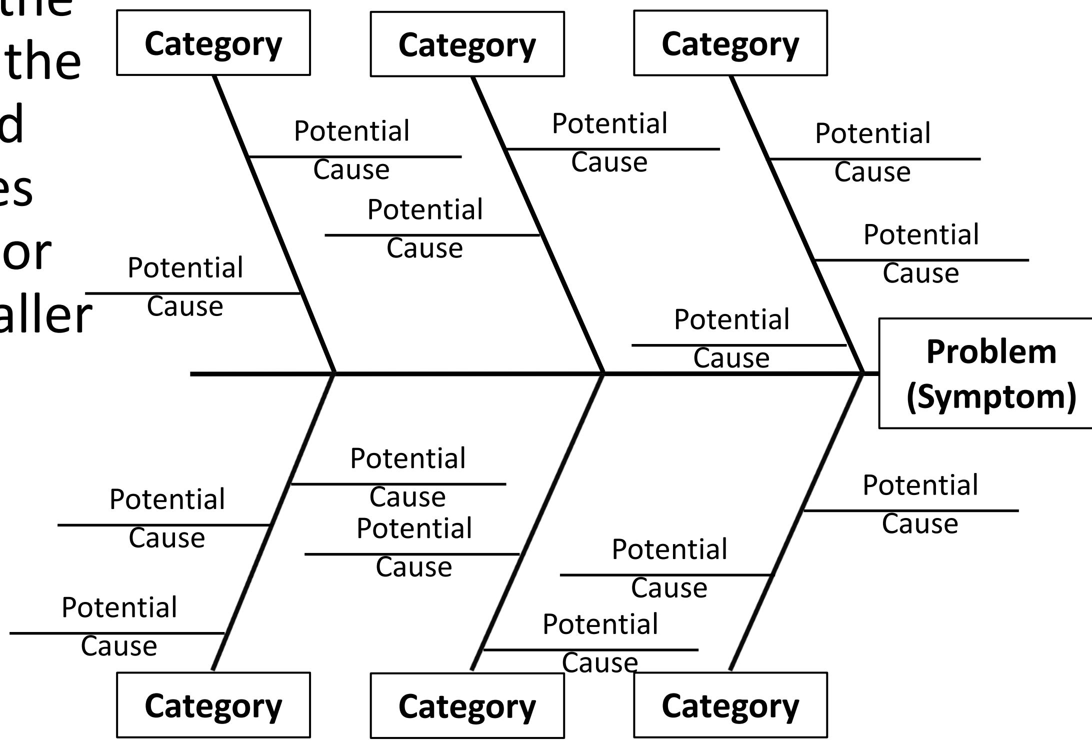
Deliverable—An amended business case that includes:

- List of problems that are responsible for the defects occurring in the system/process in an Ishikawa "fishbone" diagram
- Root cause analysis (or cause and effect analysis)
- **Pareto chart** (chart of frequency) of root causes

Analysis Tools

Cause and effect diagram basics

- A cause and effect diagram is designed to help workers focus on the causes of a problem rather than the symptoms
- The diagram looks like the skeleton of a fish, with the problem being the head of the fish, major causes being the ribs, and minor causes forming the smaller bones of the ribs (Therefore, it is also known as “fishbone” diagram)



- Fishbone diagrams are created during brainstorming sessions

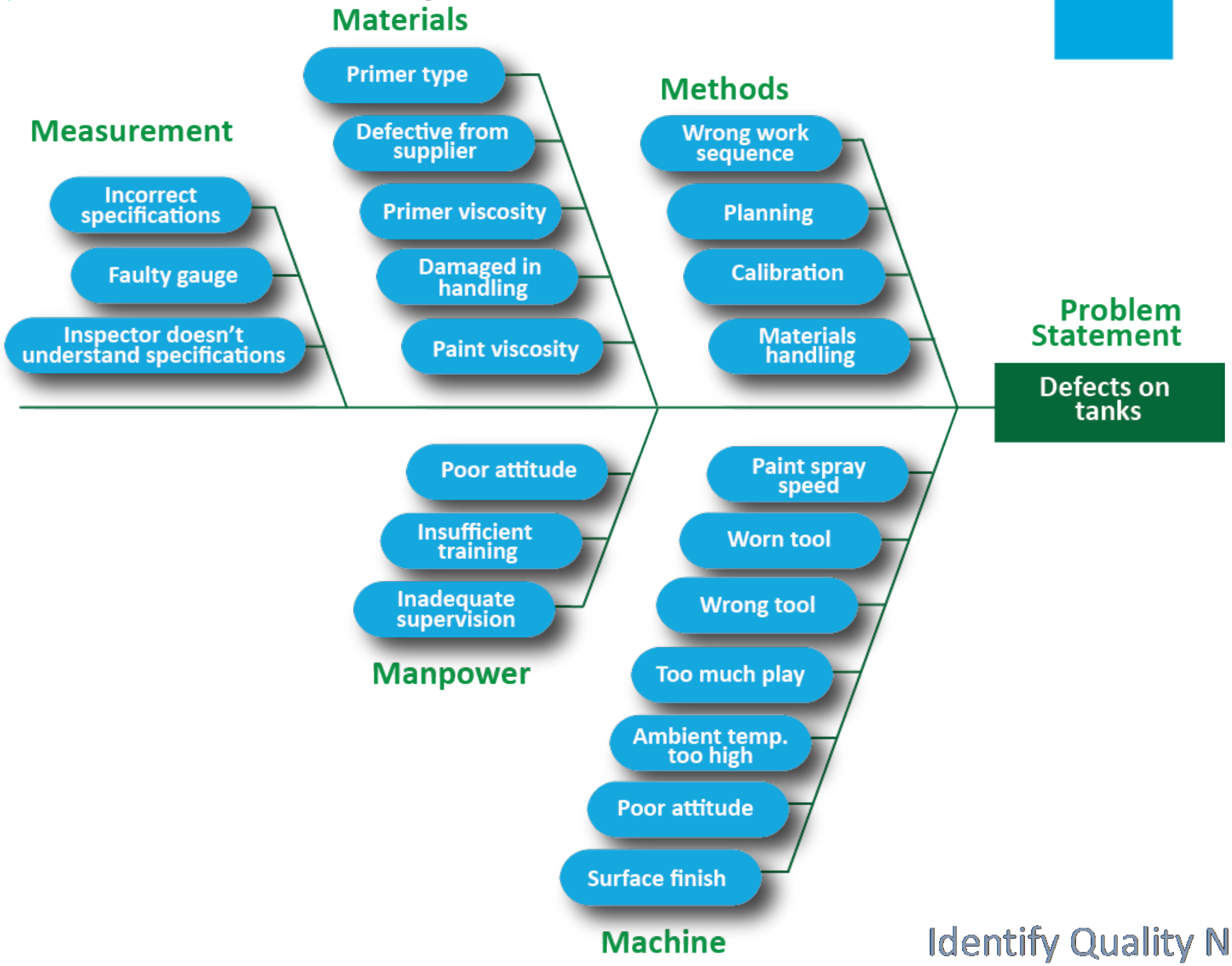
Cause/Effect (Fishbone) Diagram

Step-by-step

1. State the problem clearly in the "head of the fish"
2. Draw the backbone and ribs
   —Ask the participants in the brainstorming session to identify major causes of the problem labeled in the head of the diagram (If participants have trouble identifying major problem categories, it may be helpful to use materials, machines, people, and methods as possible bones)
3. Continue to fill out the fishbone diagram, asking "Why?" about each problem or cause of a problem until the diagram is filled out—*Usually, it takes no more than five levels of questioning to get to root causes; hence, the "Five whys"*
4. View the diagram and identify root causes
5. Set goals to address the root causes

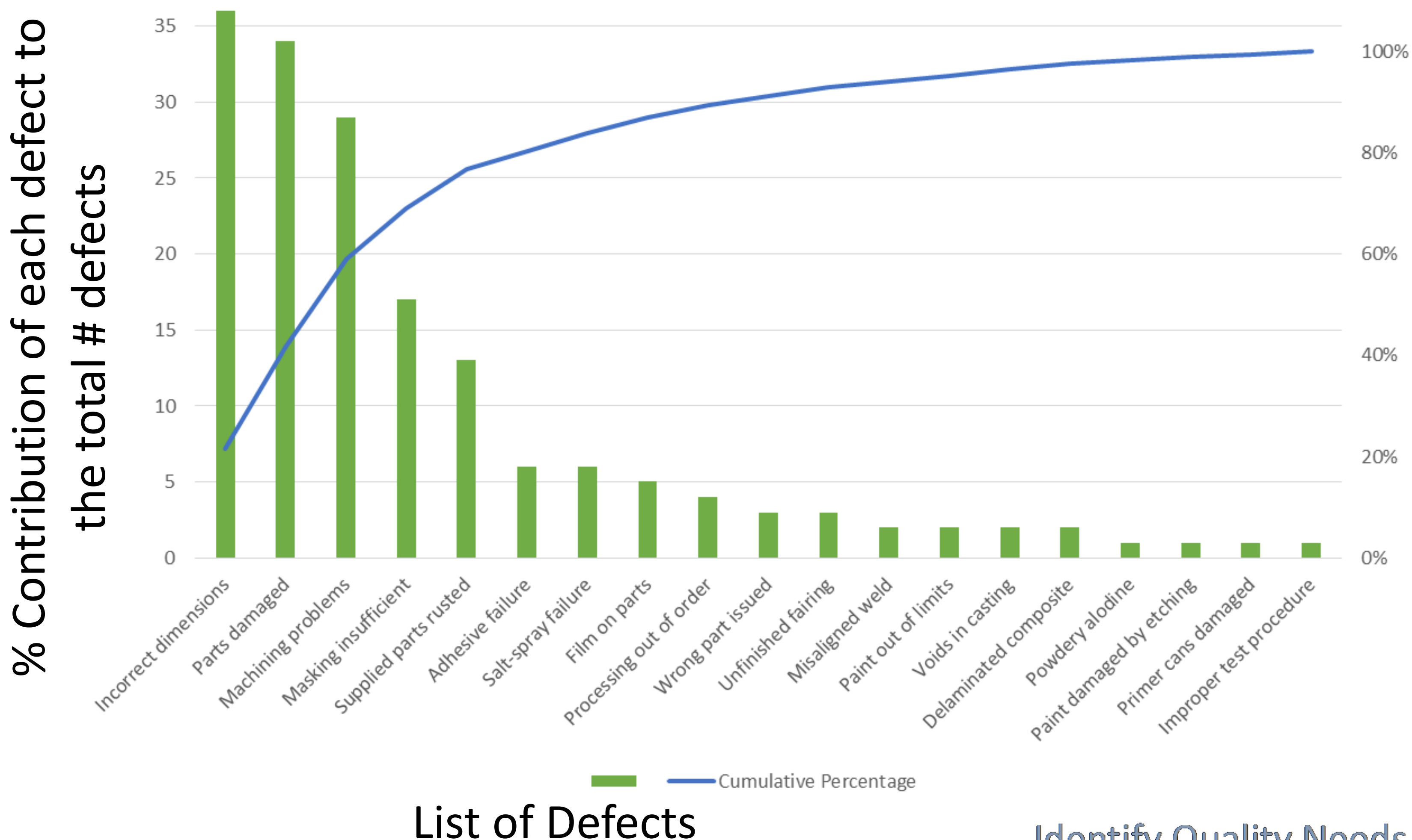
Aerospace Tank Quality Defects

Example – Fishbone diagram



Aerospace Tank Quality Defects

Example – Pareto chart



Six Sigma

Improve phase

Purpose:

- To generate, pilot, and implement viable solutions that address the root causes—the solution(s) should have the following characteristics:
  - —Effective in performing corrective action
  - —Financially feasible to create a favorable cost/benefit position
  - —Acceptable by other parts of the organization.

Deliverable—An amended business case that includes:

- Alternative solutions and their related cost-benefit analysis (CBA)
- Pilot testing of high-impact, cost-efficient solutions
- A "should be" process map/flowchart and cost model based on a pilot

Types of Improvements

Examples - Generic

- Simplification of process
- Changes in staffing schedules
- Improved training
- Changes in level of staffing
- System upgrades and reprogramming
- Upgraded equipment
- New management techniques

Six Sigma

Control phase

Purpose:

- To sustain and control future process performance

Deliverable—An amended business case that includes:

- A documented measuring and monitoring plan for maintaining standardized processes and procedures, and reduced costs
- A documented transfer of ownership to the process owner and management team
- Why customers can expect reliability and how the improvement will be sustained over time

Control Hand-Offs

Document the following:

- New quality standards
- Responsibility and timeline for full implementation
- Methods to measure customer satisfaction
- Methods to measure process control and capability
- Expectations for progress reports

Benchmarking

Quality

Voice of the market:

- Customers are not the only source of information about the market
- One of the best sources of information can be other companies
- By understanding our competitors, we begin to understand the marketplace better and what it takes to compete successfully in the marketplace

Benchmarking

Process

- Benchmarking is sharing of information between companies so that both can improve
- Benchmarking process involves multiple organizations, including a benchmark that you are trying to follow for improvement of your product or process
- A benchmark is an organization recognized for its exemplary operational performance
- There are many benchmarks in the world including Toyota for processes, Intel for design, Motorola for training, Scandinavian Airlines for service, and Honda for rapid product development
- Parties to benchmarking relationships:
  —The initiator firm (you)

  —The target firm (benchmark)

Benchmarking

Types

Process benchmarking:

- The goal is to identify and observe best practices on business processes

Financial benchmarking:

- The goal is to perform financial analysis and compare the results in an effort to assess your overall competitiveness

Performance benchmarking:

- Allows initiator firms to assess their competitive position by comparing products and services with target firms

Benchmarking

Types (cont.)

Product benchmarking:

- Many firms perform product benchmarking when designing new products or upgrades to current products (often includes reverse engineering)

Strategic benchmarking:

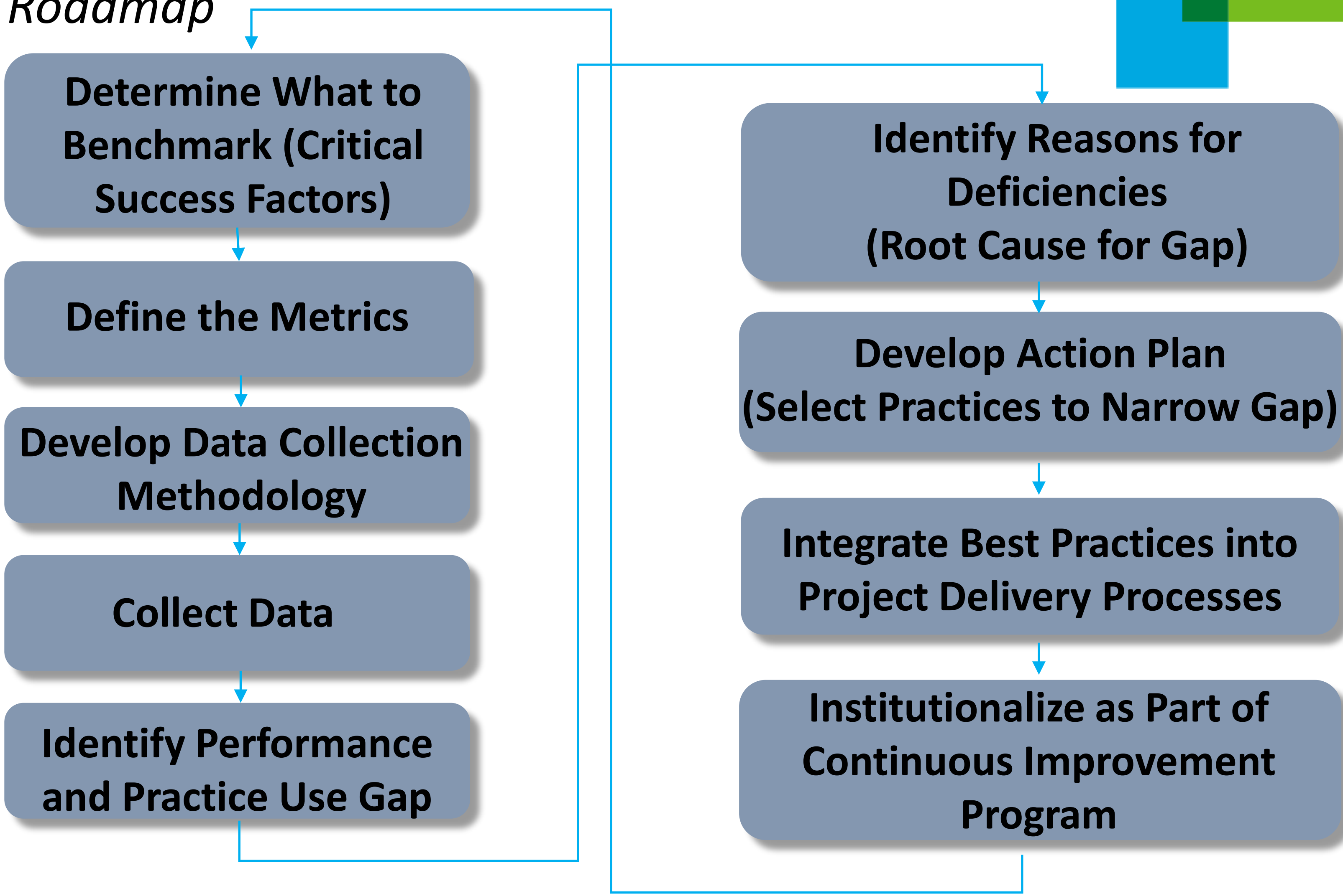
- Involves observing how others compete (the focus is to identify the mix of strategies that make firms successful competitors)

Functional benchmarking:

- Involves a company focusing its benchmarking efforts on a single function to improve the operation of that function

Benchmarking

Roadmap



Source: National Academies of Sciences https://www.nap.edu/read/11344/chapter/5

Benchmarking

Partners

Selection criteria:

- Once we determine what to benchmark, the next step is to identify the benchmarks
- The selection criteria for a benchmarking partner primarily depends upon the purpose of benchmarking
- For product quality and service performance, usually you benchmark against direct competitors

Benchmarking

Partners (cont.)

For process benchmarking, you can benchmark the following organizations:

- Internal benchmarking (different departments or business units within the same company)
- Competitors
- Companies in the same industry sector with similar product and business characteristics
- Companies in different industry sectors but with similar processes (order placement, lead time management, customer support systems, etc.)

References

- Foster, S.T., *Quality Management*. Fifth edition, Pearson Publications, 2013
- Besterfield, D.H., *Quality Improvement*. Ninth Edition, Pearson Publications, 2013
- Montgomery, D.C., *Introduction to Statistical Quality Control*. Seventh edition, Wiley Publications, 2013

List of Acronyms

- DMAIC – Define-Measure-Analyze-Improve-Control
- MRL – Manufacturing Readiness Level
- PPM – Parts Per Million
- CL – Control Limit
- LCL – Lower Control Limit
- UCL – Upper Control Limit
- SL – Specification Limit
- LSL – Lower Specification Limit
- USL – Upper Specification Limit

List of Acronyms

- DPU – Defects Per Unit
- DPMO – Defects Per Million Opportunities
- SMART – Specific-Measurable-Attainable-Results-oriented-Timely
- BOP – Bill Of Process

List Of Terms

In glossary

- **Voice of the Customer** is a term used in business and Information Technology (through ITIL, for example) to describe the in-depth process of capturing customer's expectations, preferences and aversions.
- **Benchmarking** is comparing one's business processes and performance metrics to industry bests and best practices from other companies.
- **Process Benchmarking** is when the initiating firm focuses its observation and investigation of business processes with a goal of identifying and observing the best practices from one or more benchmark firms. Activity analysis will be required where the objective is to benchmark cost and efficiency; increasingly applied to back-office processes where outsourcing may be a consideration.
- **Financial Benchmarking** is performing a financial analysis and comparing the results in an effort to assess your overall competitiveness and productivity.
- **Performance Benchmarking** allows the initiator firm to assess their competitive position by comparing products and services with those of target firms.
- **Product Benchmarking** is the process of designing new products or upgrades to current ones. This process can sometimes involve reverse engineering which is taking apart competitors products to find strengths and weaknesses.
- **Strategic Benchmarking** involves observing how others compete. This type is usually not industry specific, meaning it is best to look at other industries.
- **Functional Benchmarking** is when a company will focus its benchmarking on a single function to improve the operation of that particular function.
- **Six-Sigma** is a set of techniques and tools for process improvement.
- **Pareto Chart** is a type of chart that contains both bars and a line graph, where individual values are represented in descending order by bars, and the cumulative total is represented by the line.
- **Defects Per Million Oopportunities (DPMO)** is a measure of process performance.

List Of Terms

In glossary (cont.)

- **Process Validation** is the analysis of data gathered throughout the design and manufacturing of a product in order to confirm that the process can reliably output products of a determined standard.
- **Design Validation** is testing aimed at ensuring that a product or system fulfills the defined user needs and specified requirements, under specified operating conditions.
- **Process Mean** is the average of the sample data collected from a process with respect to the quality characteristic in question
- **Lower Control Limit (LCL)** is the bottom limit in quality control for data points below the control (average) line in a control chart. Opposite of upper control limit.
- **Specification Limit** are boundaries or parameters that define acceptable performance for a process expressed as a target limit as well as an upper and lower limit.
- **Upper Specification Limit (USL)** is a value that represents the highest range of a variable. The upper specification limit is the benchmark below which a product or service performs.
- **Target Mean** is an average of lower specification limit (LSL) and upper specification limit (USL) values specified in a bill of process.
- **Qualification** is either the process of qualifying for an achievement, or a credential attesting to that achievement.
- **Field Readiness** is the stage of development just prior to final launch. It is time to review the Pilot run and determine if there are any “game stopper” issues.
- **Manufacturing Capacity** is the volume of products or services that can be produced by an enterprise using current resources. Three commonly used definitions of capacity are as follows: design capacity, effective capacity & actual output. (Repeat from 2B)
- **Left Off-Centered Process** mean is to the left of the target mean, so the process is likely to produce undersized parts.
- **Right Off-Centered Process** mean is to the right of the target mean, so the process is likely to produce oversized parts.

List Of Terms

In glossary (cont.)

- **Defect** is a physical, aesthetic, or functional attribute of a product or service that exhibits that the product or service failed to meet one of the desired specification.
- **Defects Per Unit (DPU)** is a metric used in Six Sigma and other process improvement methodologies. The observed defects per unit value is used to calculate the Defects per Million Opportunities value for a process, which in turn is used to assess the overall quality of the process output and to determine areas in which the process can be improved.
- **Deliverable** is a tangible or intangible good or service produced as a result of a project that is intended to be delivered to a customer (either internal or external)
- **Flowchart** is a type of diagram that represents an algorithm, workflow or process, showing the steps as boxes of various kinds, and their order by connecting them with arrows.
- **Data Collection** is the process of gathering and measuring information on targeted variables in an established systematic fashion, which then enables one to answer relevant questions and evaluate outcomes.
- **Key metric** are the measurable quality standards according to six sigma standards.
- **Performance Metric** also called KPI's (Key Performance Indicators) focuses on how the task is being performed by measuring performance and if individual goals are being achieved. A widely used tool to assist in determining these goals is the Balanced Scorecard re the current process details.
- **Pareto Chart** is a type of chart that contains both bars and a line graph, where individual values are represented in descending order by bars, and the cumulative total is represented by the line.
- **DMAIC – Define-Measure-Analyze-Improve-Control** refers to a data-driven improvement cycle used for improving, optimizing and stabilizing business processes and designs.
- **MRL – Manufacturing Readiness Level** is a measure developed by the United States Department of Defense (DOD) to assess the maturity of manufacturing readiness, similar to how technology readiness levels (TRL) are used for technology readiness.

List Of Terms

In glossary (cont.)

- **PPM – Parts Per Million** is the concentration by volume of one part of a gas (or vapor), or by weight of a liquid or solid, per million parts of air or liquid.
- **CL – Control Limit** also known as natural process limits, are horizontal lines drawn on a statistical process control chart, usually at a distance of ±3 standard deviations of the plotted statistic from the statistic's mean. Control limits are used to detect signals in process data that indicate that a process is not in control and, therefore, not operating predictably.
- **LCL – Lower Control Limit** is the bottom limit in quality control for data points below the control (average) line in a control chart. Opposite of upper control limit.
- **UCL – Upper Control Limit** is a value that indicates the highest level of quality acceptable for a product or service. The upper control limit is used in conjunction with the lower control limit to create the range of variability for quality specifications, enabling those within the organization to provide an optimal level of excellence by adhering to the established guidelines.
- **SL – Specification Limit** boundaries or parameters that define acceptable performance for a process expressed as a target limit as well as an upper and lower limit.
- **LSL – Lower Specification Limit** is the lowest level of process performance or product quality that is within the acceptable range defined by customer standards and measurements of defects in the process or product itself.
- **USL – Upper Specification Limit** is a value that represents the highest range of a variable. The upper specification limit is the benchmark below which a product or service performs.
- **SMART** (specific, measurable, action oriented, reasonable, timely) goal is a written statement that describes what needs to be done to work toward a specific change, ultimately creating success and improvement. Specific – Specific goals are more likely to be achieved than nonspecific goals…
- **BOP – Bill of Process** is a best practices template for production comprised of detailed plans explaining the manufacturing processes for a particular product. Within these plans resides in-depth information on machinery, plant resources, equipment layout, configurations, tools, and instructions. (Repeat from 2A)