Oregon Life Sciences
Virtual Classroom

BioPro

Workforce Training

Class Workbook

Statistical Process Control

For more information

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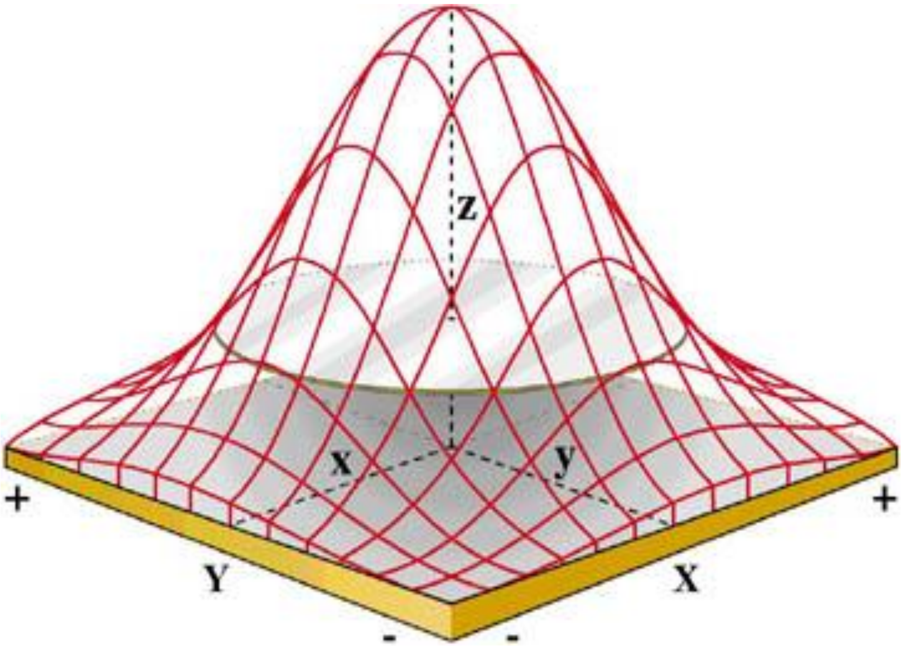
OREGON
Life Sciences

Table of Contents

Working With Statistical Process Control



Presented by:

ETI GROUP

Course Overview

The key to improving process performance is the ability to understand, control and reduce variation. In this workshop, participants will learn how the monitoring and analysis tools of SPC can be used to achieve that goal. Going beyond the mere mechanics of SPC, this workshop will also guide participants through the steps needed to define a process and determine proper measurement techniques so that the right control chart is used in the right place at the right time.

Learning Objectives

By the end of the course, you will be able to:

- Understand the role of SPC in the quality improvement process
- Identify key process and product characteristics
- Establish key characteristics for process monitoring
- Distinguish between variable and attribute data
- Create a meaningful data collection plan
- Use statistics to separate common and assignable causes of variation
- Perform a process capability study
- Decide when a particular SPC tool is appropriate to use
- Collect data for that tool and convert the data into charts
- Interpret patterns and signals on the charts
- Use Cause and Effect diagrams and Pareto charts to diagnose process problems
- Use Excel for basic statistical analysis and capability studies.

Course Outline:

Day 1

- Why Use SPC?
- Defining the Process
- Measuring the Process
- Using Statistics

Day 2

- Determining Process Capability
- Control Charts for Variables
- Control Charts for Attributes
- Identifying Patterns and Trends
- Diagnosing the Process

Who Should Attend:

Individuals and teams requiring a thorough understanding of the philosophy and tools of Statistical Process Control (SPC) in order to plan and implement successful SPC efforts their workplace.

Prerequisites:

Participants in this training course should have:

A laptop computer loaded with MS Excel (version 2003 or later). They will also need to add in the **Analysis ToolPak, a statistical package that comes with MS Excel.**

An SPC project in mind from their workplace.

Experience using personal computers, especially using the Windows operating system

Basic math skills and be able to follow the order of operations for basic algebraic functions.

Why Use SPC?

Just starting out, how much do you know about Statistical Process Control and why it is used?

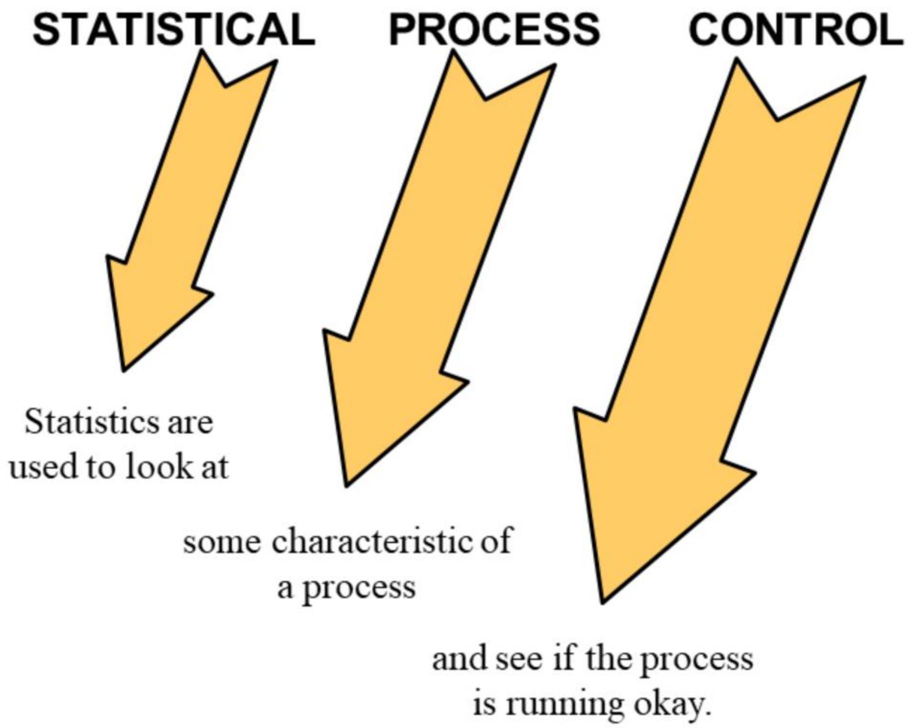
Nothing A little A lot

Learning Objectives

By the end of this section, participants will be able to:

- ☑ State the reasons for and benefits of implementing Statistical Process Control.
- ☑ Explain how the use of SPC will further the organization's mission.
- ☑ Describe how SPC will be utilized in daily work life.

What Is SPC?



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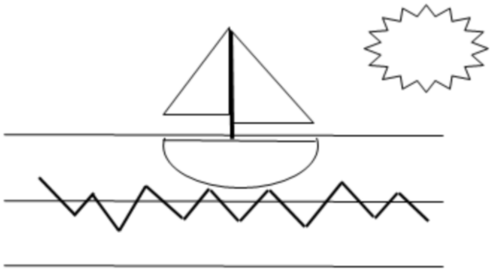
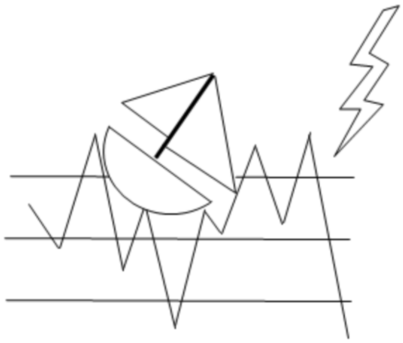
What are some examples of processes in your area?

SPC Tells You

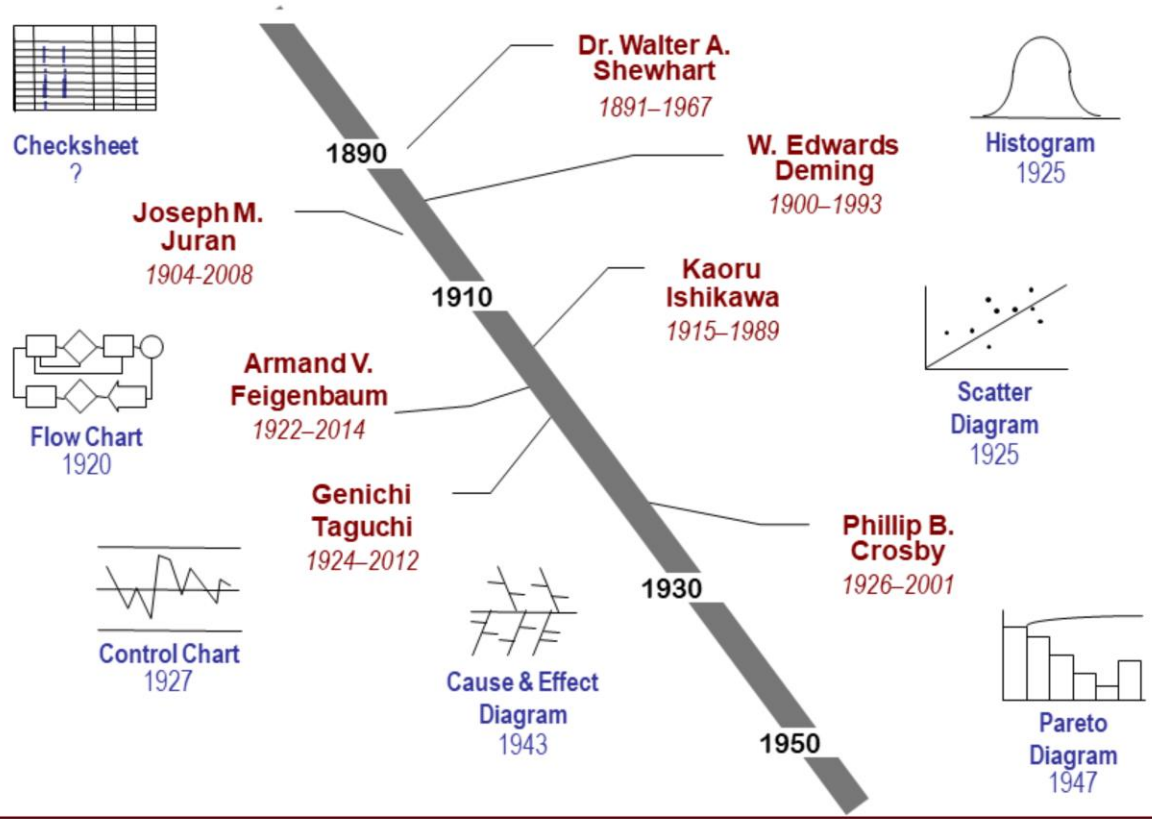
- when there is smooth sailing



- when the process may be in trouble



SPC History



Dr. Walter A. Shewhart
1891–1967
W. Edwards Deming
1900–1993
Joseph M. Juran
1904-2008
Kaoru Ishikawa
1915–1989
Armand V. Feigenbaum
1922–2014
Genichi Taguchi
1924–2012
Phillip B. Crosby
1926–2001
1890
1910
1930
1950
Checksheet
?
Histogram
1925
Scatter Diagram
1925
Flow Chart
1920
Control Chart
1927
Cause & Effect Diagram
1943
Pareto Diagram
1947

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Signature Exercise

Sign your name five times on the lines provided, just as you would when signing a check or autograph.

Then, sign your name one time using the opposite hand.

What are the differences?

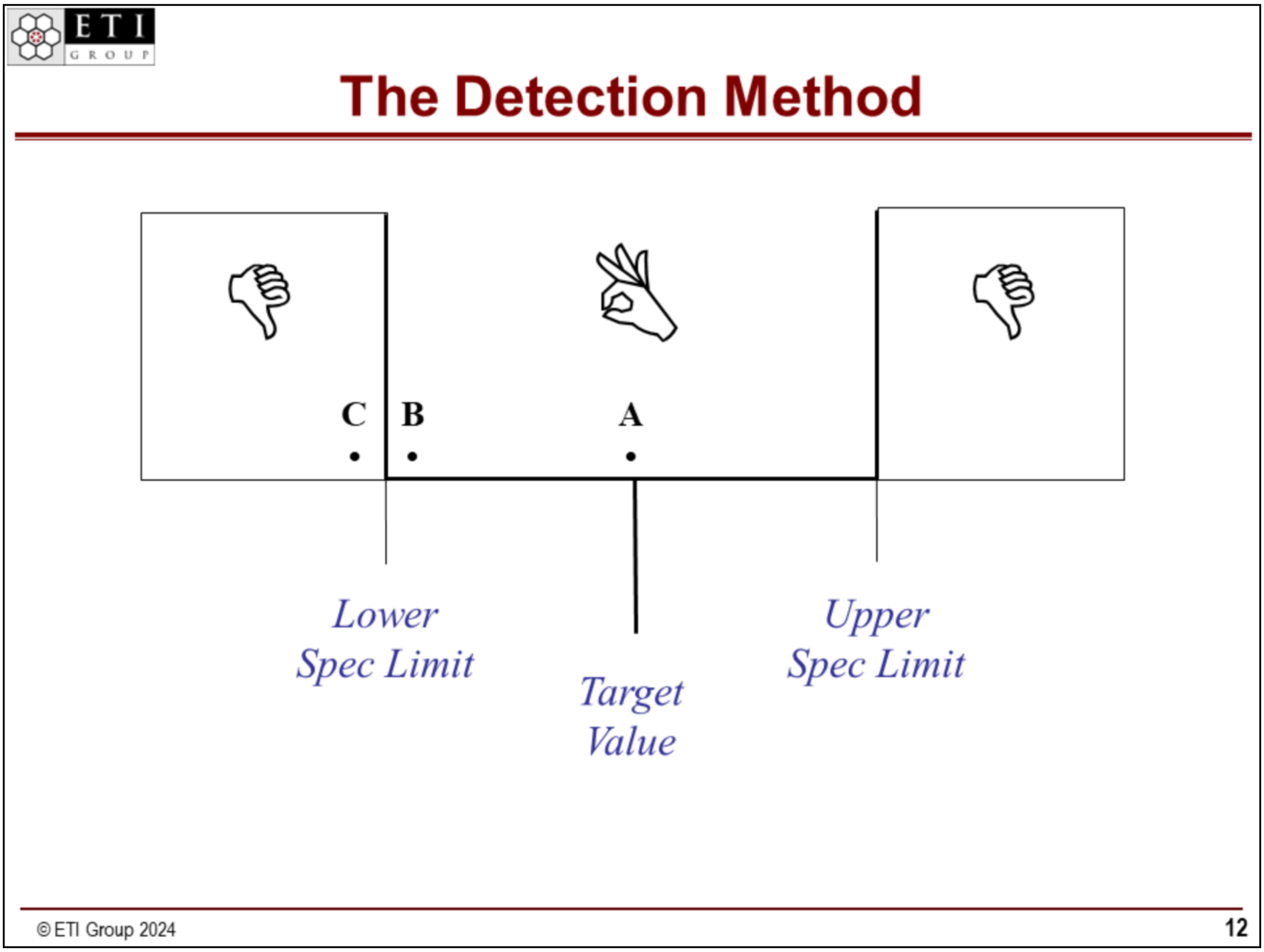
Assignable Cause Variation

- Is unexpected.
- Shows that something is obviously different with the process.
- The process is *not* operating normally.

Assignable cause variation is also referred to as "special" cause variation.

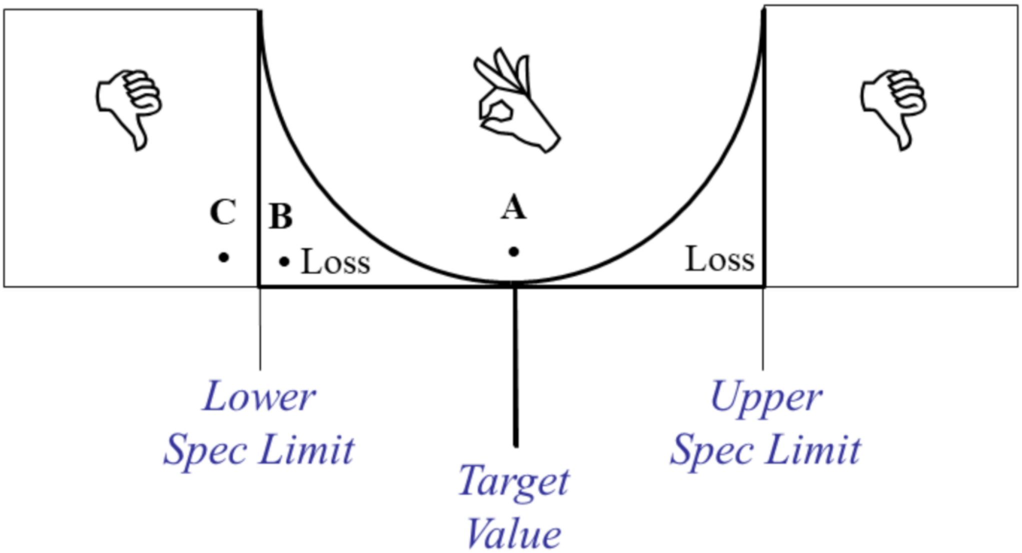
Common Cause Variation

- Is expected.
- Found in all normally operating processes.



When we “screen” parts during testing and inspection, the goal is to detect defects in a product, often well after the defect was introduced.

The Prevention Method



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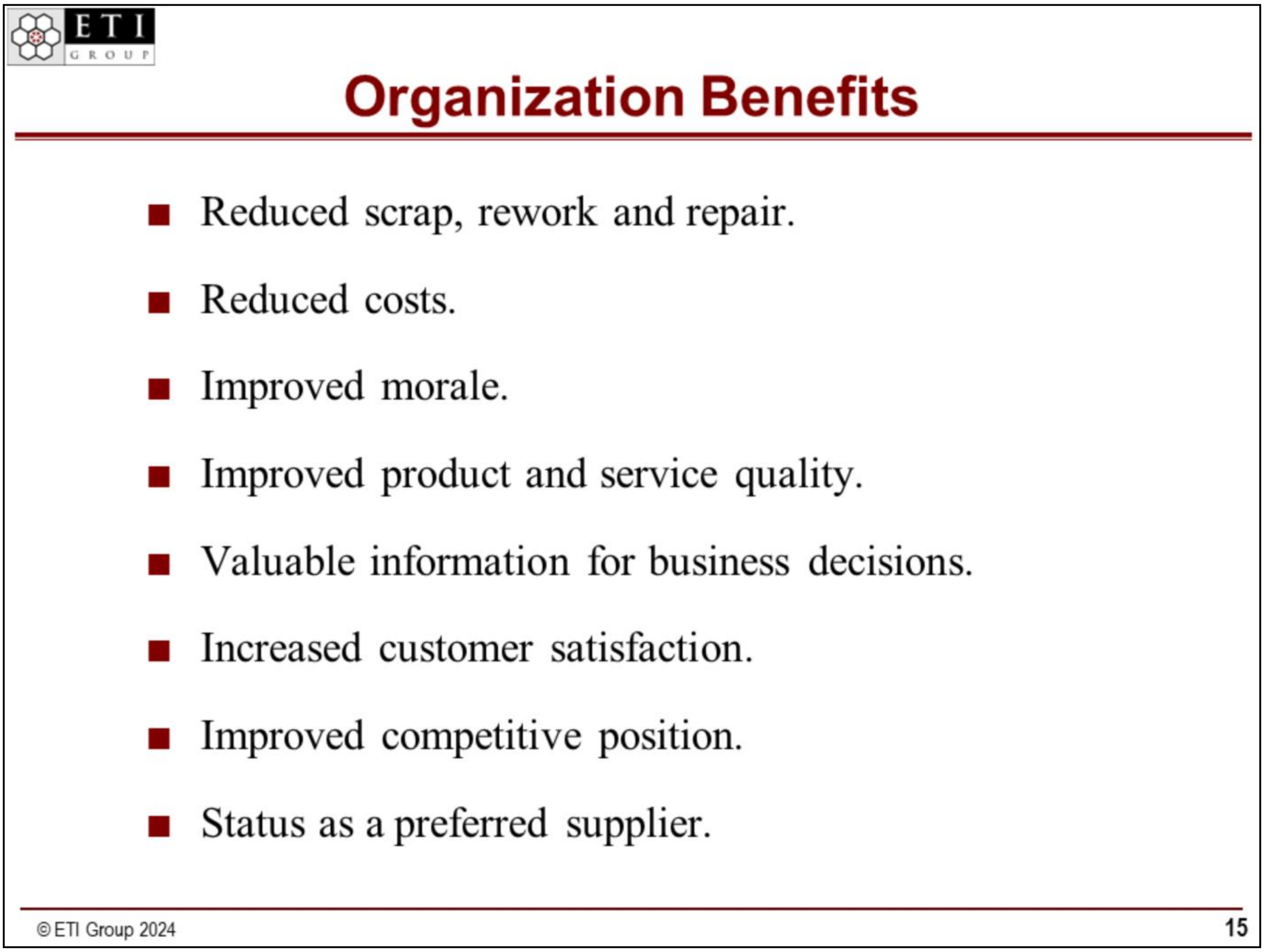
The prevention method recognizes that values close to the spec may lead to defects further down the line and/or decreased quality and reliability for the end customer, and that it's better to reduce variation around the specification target. SPC helps to achieve this goal.

Process Benefits

- Eliminates unneeded (and possibly harmful) process adjustments.
- Focuses on preventing problems, instead of detecting them later.
- Helps create consistent products and services.
- Provides proof of process capability.

What are some other process benefits?



Which of the benefits above would be most valuable for your organization?

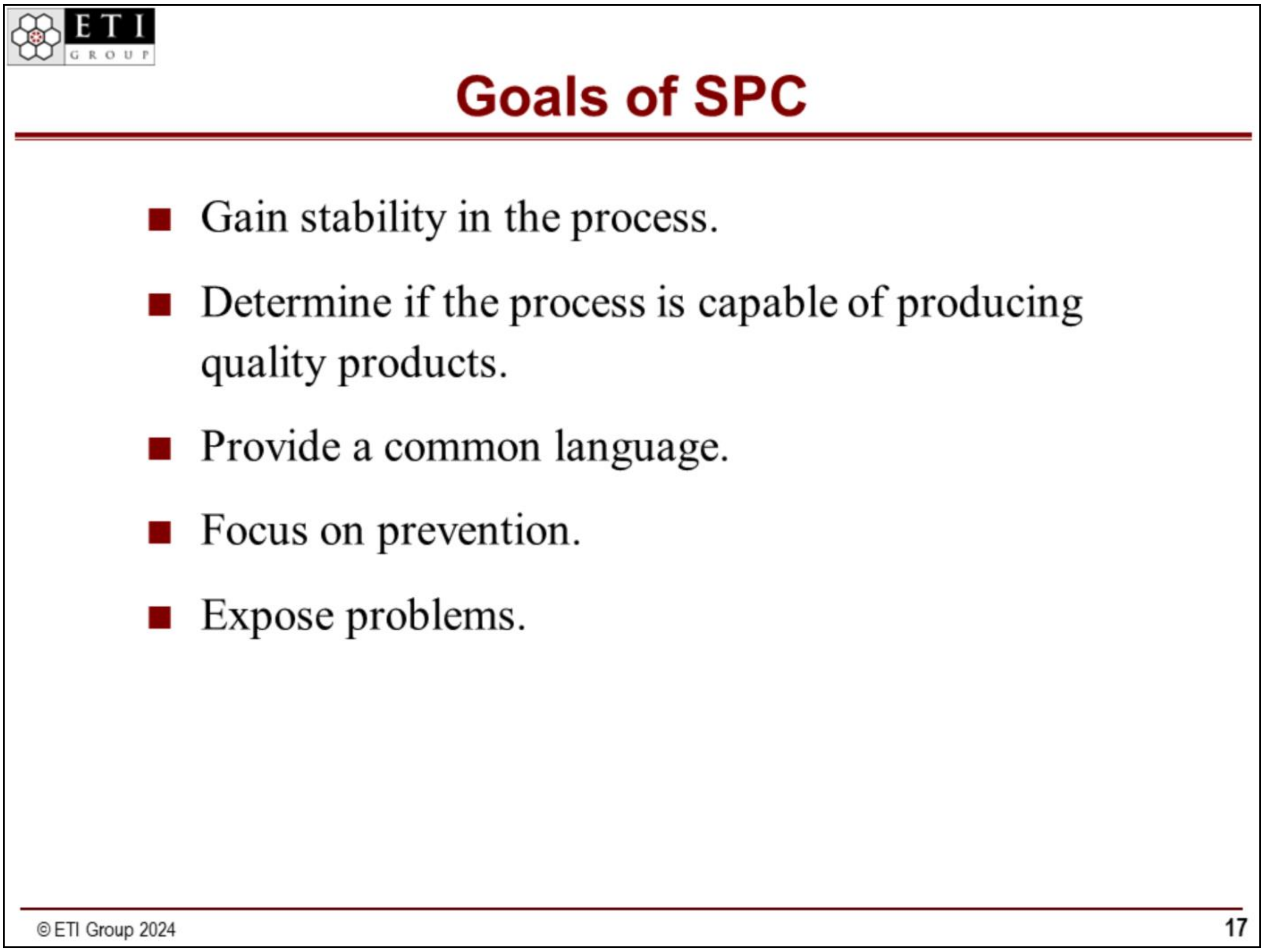
What are some other organizational benefits?

Personal Benefits

- Provides a helpful tool for understanding the process.
- Promotes pride in the process and in workmanship.
- Helps maintain employability.

Which benefits above are most important for you?

What might some other benefits be?



We must eliminate ________________ _____________ variation in order to gain stability.

We compare process data to __________ ____________ to determine if the process is capable.

It is important to have a common language for communicating about quality issues because:

____

When we focus on preventing problems, we can spend less time on ______________ing problems.

We want to expose problems so that we can...

____

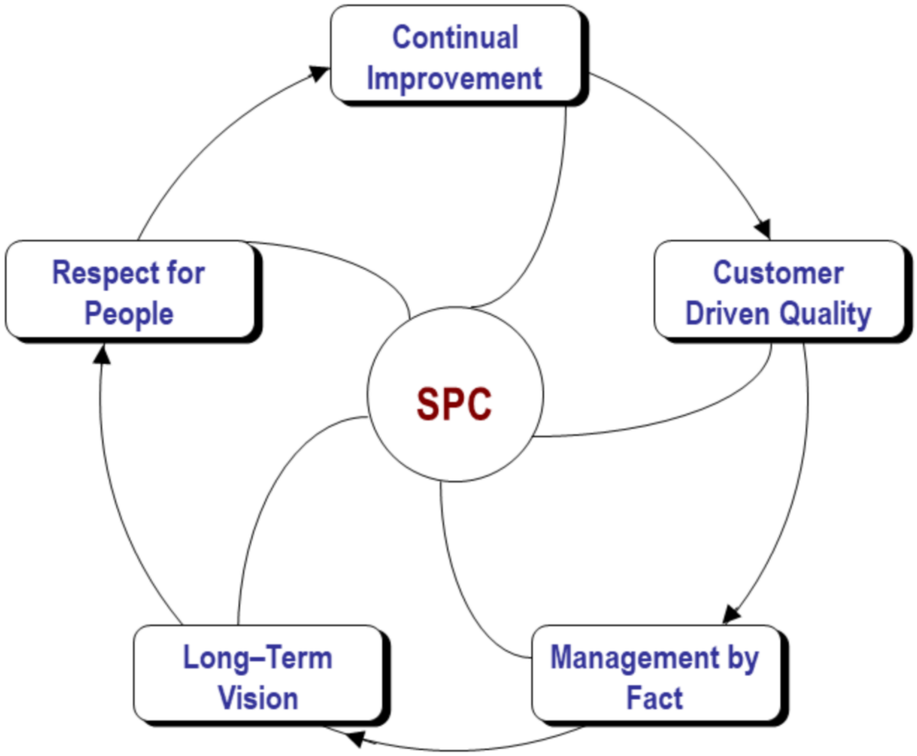
____

____

____

____

Role of SPC in Continual Improvement



SPC is one of the key tools for continual improvement. It can help to identify problems, solve problems and determine whether an implemented solution is effective.

Roles and Responsibilities for SPC

Process operators are typically responsible for:

- Collecting data from the process.
- Plotting points on the control charts.
- Interpreting whether the process is in or out of control.
- Notifying the lead/supervisor of out of control situations.
- Helping to determine causes of variation in the process.
- Giving suggestions for solutions to process problems.
- Implementing process solutions.

Roles and Responsibilities for SPC

Leads and supervisors are typically responsible for:

- Deciding on the appropriate control chart.
- Creating the data collection plan.
- Calculating control limits.
- Taking appropriate action when the process is out of control.
- Finding solutions to process problems.
- Ensuring that solutions are implemented and the charting system is maintained.
- Communicating needs for assistance and resources to Engineering and Management.

Roles and Responsibilities for SPC

Support engineers are usually expected to:

- Assist leads and supervisors in their responsibilities.
- Provide technical support for identifying and solving process problems.
- Document changes to process procedures.

Roles and Responsibilities for SPC

Management members are usually expected to:

- Review SPC status to ensure continuing use.
- Provide resources needed for process improvement.
- Demonstrate their commitment and support for SPC and continual improvement through their daily actions.

Defining the Process

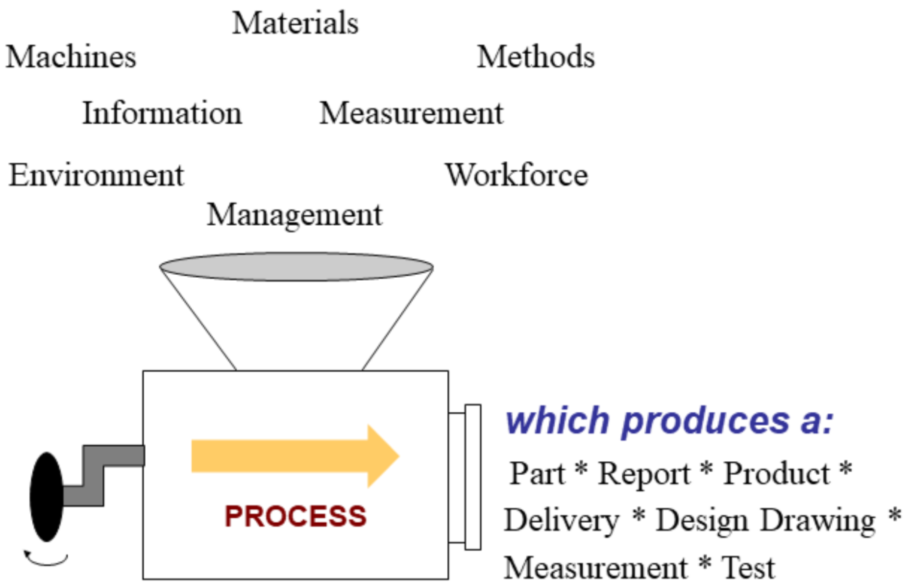
Learning Objectives

By the end of this section, participants will be able to:

- ☑ State a definition of a process.
- ☑ Create a process model showing inputs, process, and outputs.
- ☑ Describe internal and external suppliers and customers of a process.
- ☑ Describe process boundaries.
- ☑ State the reasons for defining a process.
- ☑ Explain when it is helpful to define a process.
- ☑ Identify process and product characteristics, and environmental factors.
- ☑ Establish key characteristics for process monitoring.

What Is a Process?

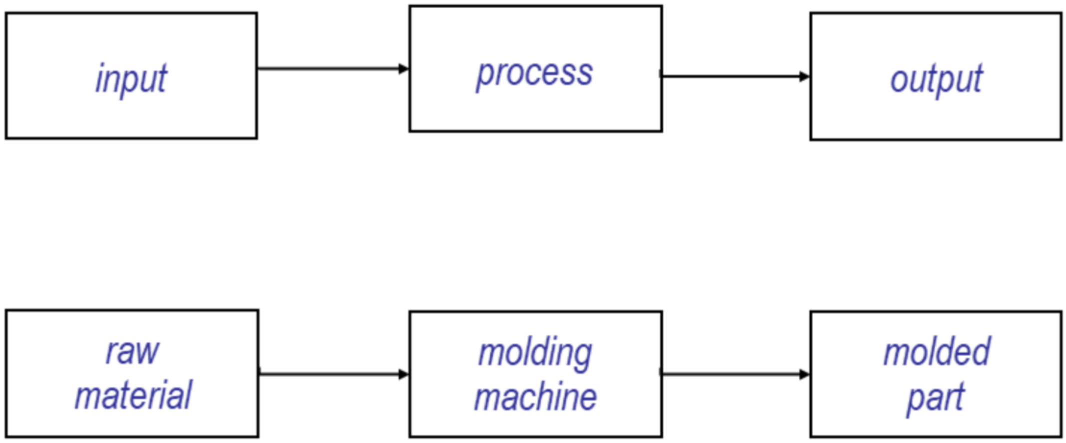
A process is some combination of:



A general definition of a process is that it takes an input and transforms it into an output.

Think about how a process in your area fits this description.

A Basic Process Model



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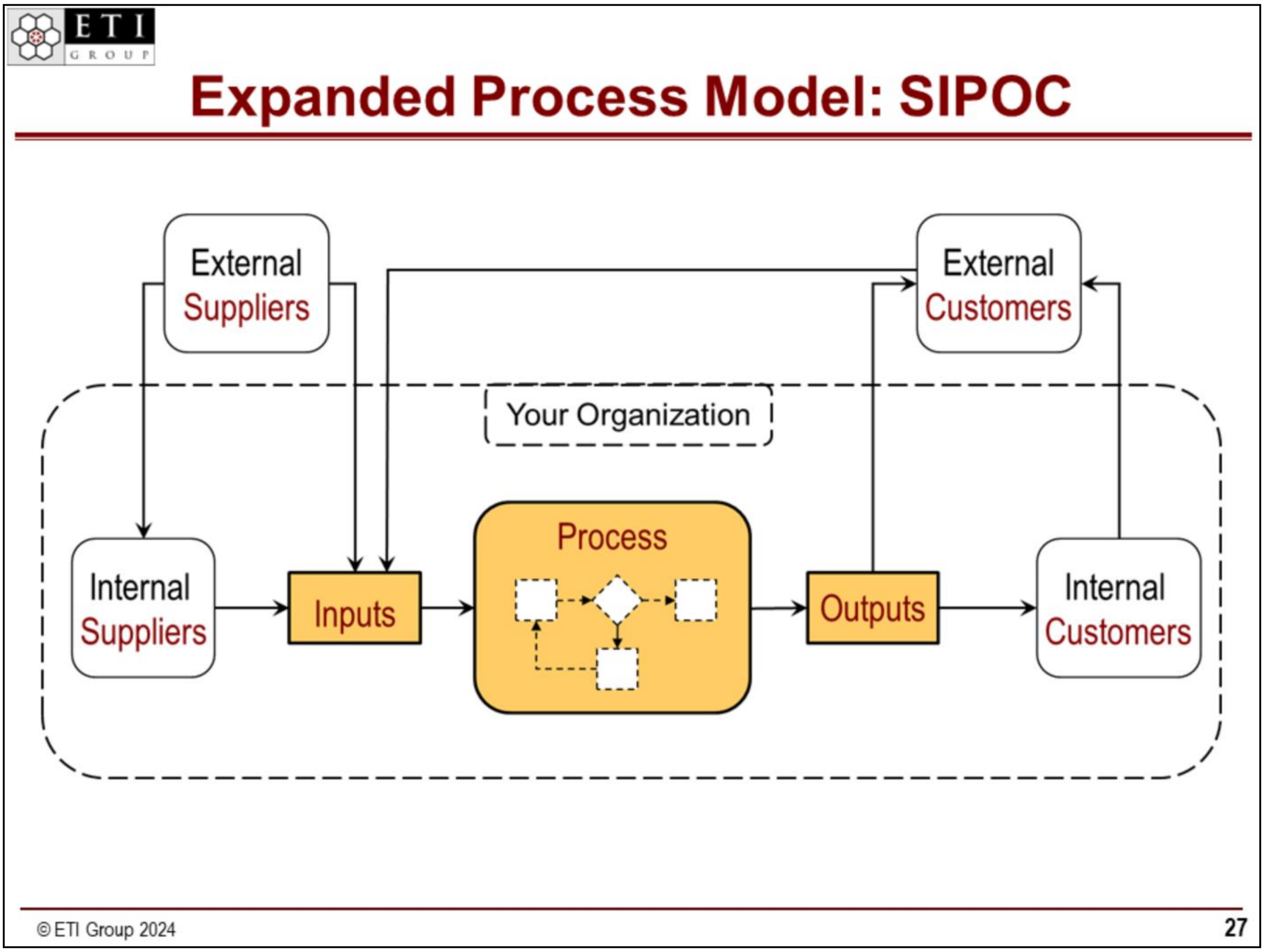
Another way to model a process is to show it in blocks, as above.



External customers are the people who buy products and/or services from your organization; they also play a supplier role.

Internal Suppliers:

- Stockroom
- Tool Crib
- Upstream area/workstation
- Planner, Supervisor, Engineer, etc.

External Suppliers:

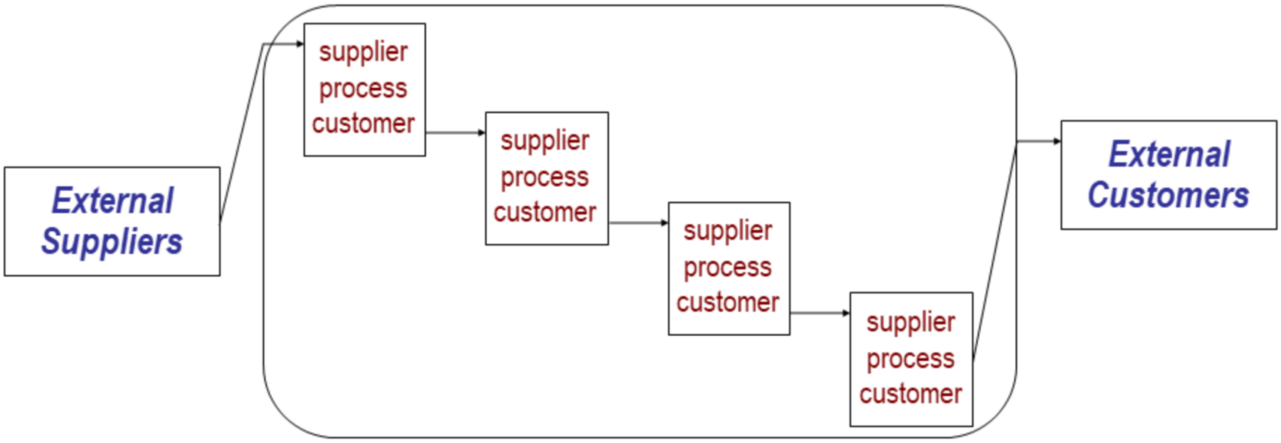
- Raw material supplier.
- Components manufacturer.
- Outsourced processing
- Service provider

Internal Customers:

- Downstream area/workstation
- Test/Inspection area
- Finished Goods warehouse

External customers are the people who buy products and/or services from your organization; they also play a supplier role.

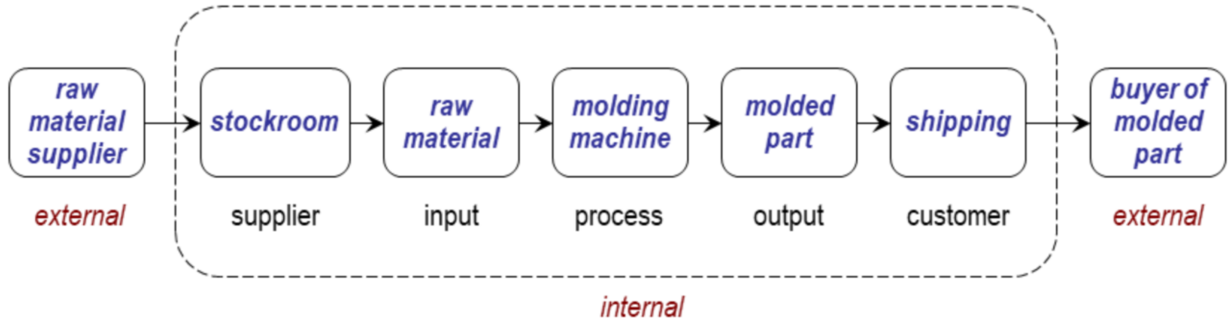
Supplier–Process–Customer Chain



It's important to remember that the organization is made up of many chains of suppliers, processes, and customers. All of these chains must link to meet the external customers' needs, and process control efforts need to support this goal.

In general, SPC should be used as early as possible in the overall flow, rather than at the "end of the line."

Process Boundaries



When planning for SPC implementation, we need to understand the process under study in terms of its relationship to the whole and well as its immediate interfaces, and whether they are internal or external to the organization.

SPC efforts may involve a process which:

- is solely within the control of a single department,
- crosses several work areas inside the organization, &/or
- involves external suppliers/customers.

Why Define the Process?

- Get everyone to agree on how the process is performed.
- Understand what is most important in the process.
- Decide what to monitor in the process.

Having a clear picture of the process is an important step in preparing for SPC. What are some other reasons for defining the process, in addition to the benefits listed above?

When to Define the Process

- Before implementing SPC.
- When the process changes.
- When a new process is introduced.

What are some other times when a process should be defined or redefined?

We'll continue to build on our process model, by defining the process in more detail in the following pages.

Product Characteristics

Observable features of the **output** of a process that contribute to its fit, form or function.

These characteristics may or may not impact the fit, form, function or service life of a product in its final use.

Some examples are:

- Hole diameter
- Thickness
- Tensile Strength
- Voltage Output
- Part Marking

Product characteristics are a direct indicator of how well a process is performing.

For service processes, "product" characteristics are those aspects of the service that can be observed &/or experienced, such as speed of service delivery, responsiveness of the provider, etc.

Process Characteristics

Characteristics of material and information **inputs** to the process.

Process parameters/settings that impact the product characteristics and may be held constant or adjusted during the process.

Some examples are:

- Speed
- Temperature
- Viscosity
- Machine programming
- Tooling offsets

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Environmental Characteristics

Factors like vibration or humidity, which can influence the quality of the process output.

They are usually not within the control of the process operator.

Environmental factors are also called “noise” or “nuisance” factors. They are aspects of the process that are present but cannot be completely controlled or eliminated.

Process Scenario Exercise

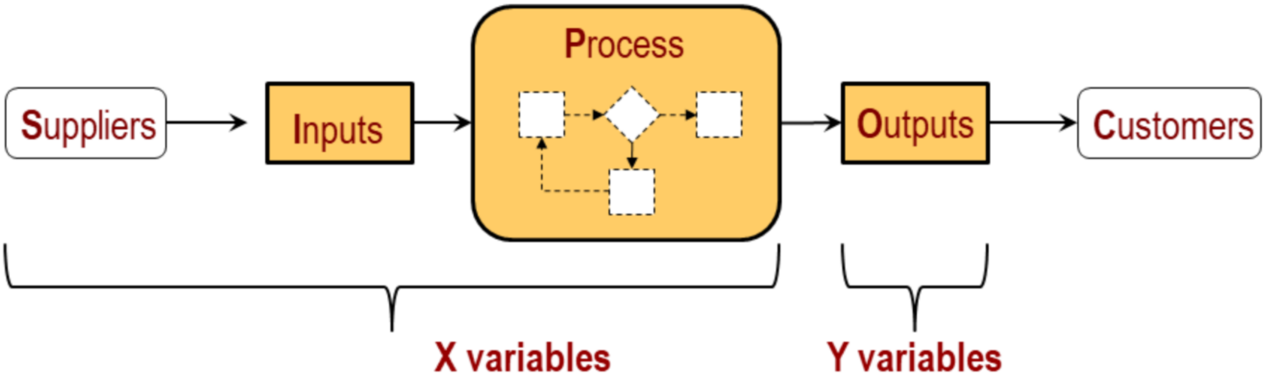
	PRODUCT CHARACTERISTIC	PROCESS CHARACTERISTIC	ENVIRONMENTAL FACTOR
Making Popcorn			
Temperature of oil	❑	❑	❑
Type of popcorn	❑	❑	❑
Taste of popcorn	❑	❑	❑
Type of popper used	❑	❑	❑
Un-popped kernels	❑	❑	❑
Injection Molding			
Injection speed	❑	❑	❑
Temperature of mold	❑	❑	❑
Flash (excess material)	❑	❑	❑
Humidity of room	❑	❑	❑
Finished material hardness	❑	❑	❑

SIPOC with a Quantitative Process Model

A common way to represent a process quantitatively is

$$y = f(x)$$

where the output is a function of the input and process variables.



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Outputs — the Y variables, are associated with product characteristics.

Process and Environmental/Noise characteristics are the X variables.

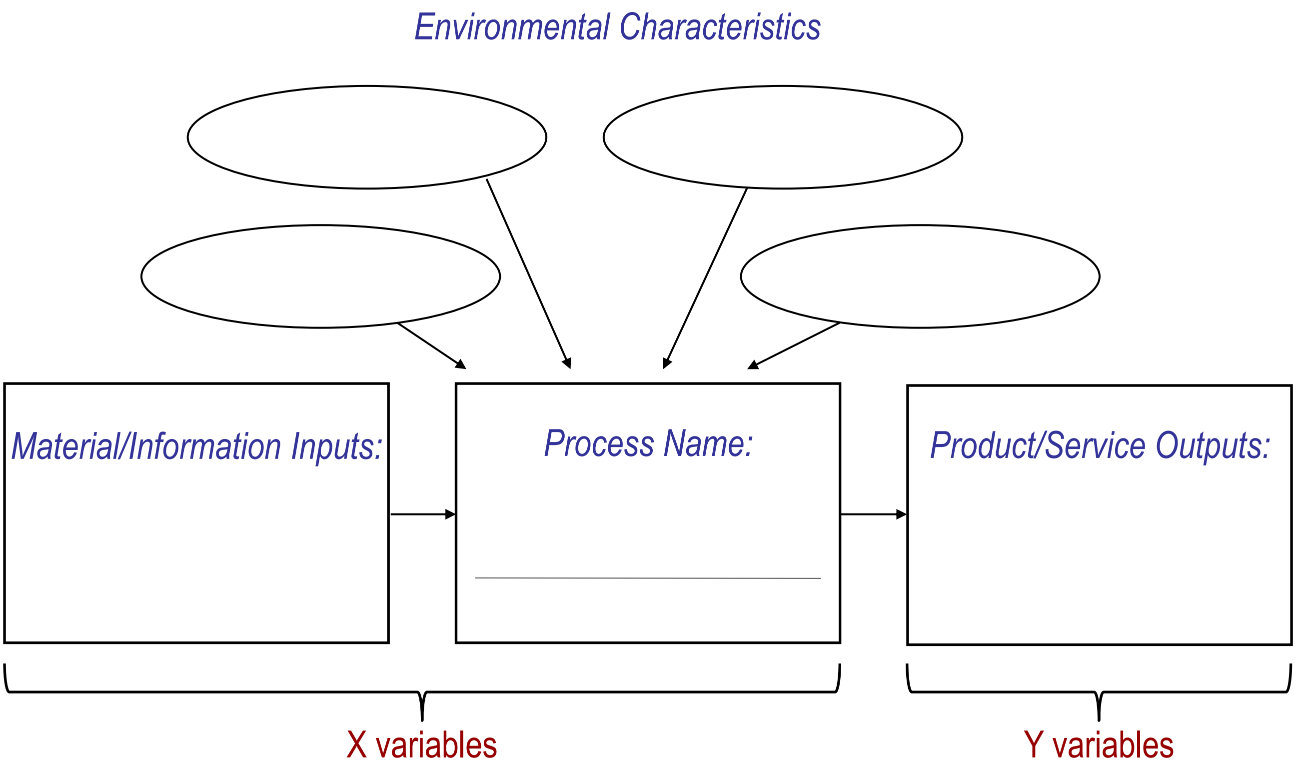
Note: Depending on the situation, X variables may be controllable or not. If the Environmental/Noise factors are controllable, e.g., temperature, humidity, particle count inside a Clean Room, then these parameters should be considered Process Characteristics. There will always be "unknown" X variables.

To summarize, what a process can produce is a function of what goes into the process and the performance of the process itself.

BUILDING A PROCESS MODEL
Worksheet

Instructions:

1. Fill in the information below for a process in your area.
2. Put a star by key process, product and environmental characteristics.



Process Characteristics	UOM

Product Characteristics	UOM

UOM = Unit of Measure

Key Characteristics

Physical or functional product features whose variation has a significant effect on the product's:

- Fit, form, function
- Performance
- Usability and service life
- Manufacturability

Specific actions are needed to control this variation.

Determining Key Characteristics

- Choose one to five features per part.
- Have a good understanding of the final use or application of the part.
- Preferably, determine them during production planning and/or engineering.
- Use historical data including repairs, rejections, or returns.
- Think about risks of product failure, or safety problems.
- Consider characteristics which are difficult to produce within tolerance requirements.
- Think about how easy it is to detect problems in these features.
- Get agreement from your customer!

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Looking back at your examples of product characteristics, which might be key characteristics?

Traditionally, customers speak of key characteristics for products only. It is just as important to identify key process and environmental characteristics that can impact product quality.

Looking back at your examples of process and environmental characteristics, which would you consider to be key?

Process Flow Charting

Once the overall process is modeled, a detailed flow chart of the process itself will be a helpful aid for SPC planning.

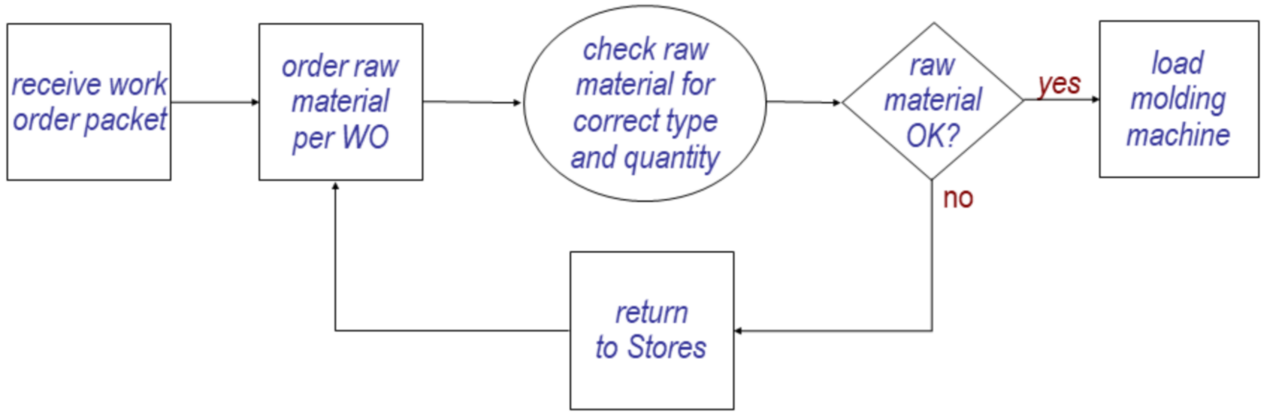
- A Context Diagram of 3–6 blocks is a good place to start.
- Each block can then be broken out into a detailed flow chart.

Context Diagram: Molding Machine Process

Creating or accessing a detailed flow chart of the process is suggested for the same reasons we listed earlier under defining the process.

Process Flow Chart Example

Molding Area: Work Order Preparation



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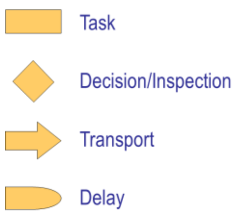
When creating a flow chart, decide where the process boundary is going to be drawn. In the example above, the boundary was Work Order (WO) Preparation.

Flow Chart Symbols

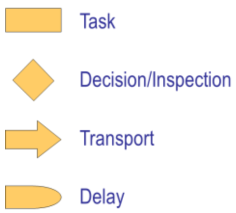


BUILDING A PROCESS FLOW CHART
Worksheet

Instructions

1. Draw a context diagram of your selected process.
2. Draw the flow chart. Be descriptive: use at least two words to describe what is being done (verb) to what (noun).

Flow Chart Symbols



Measuring the Process

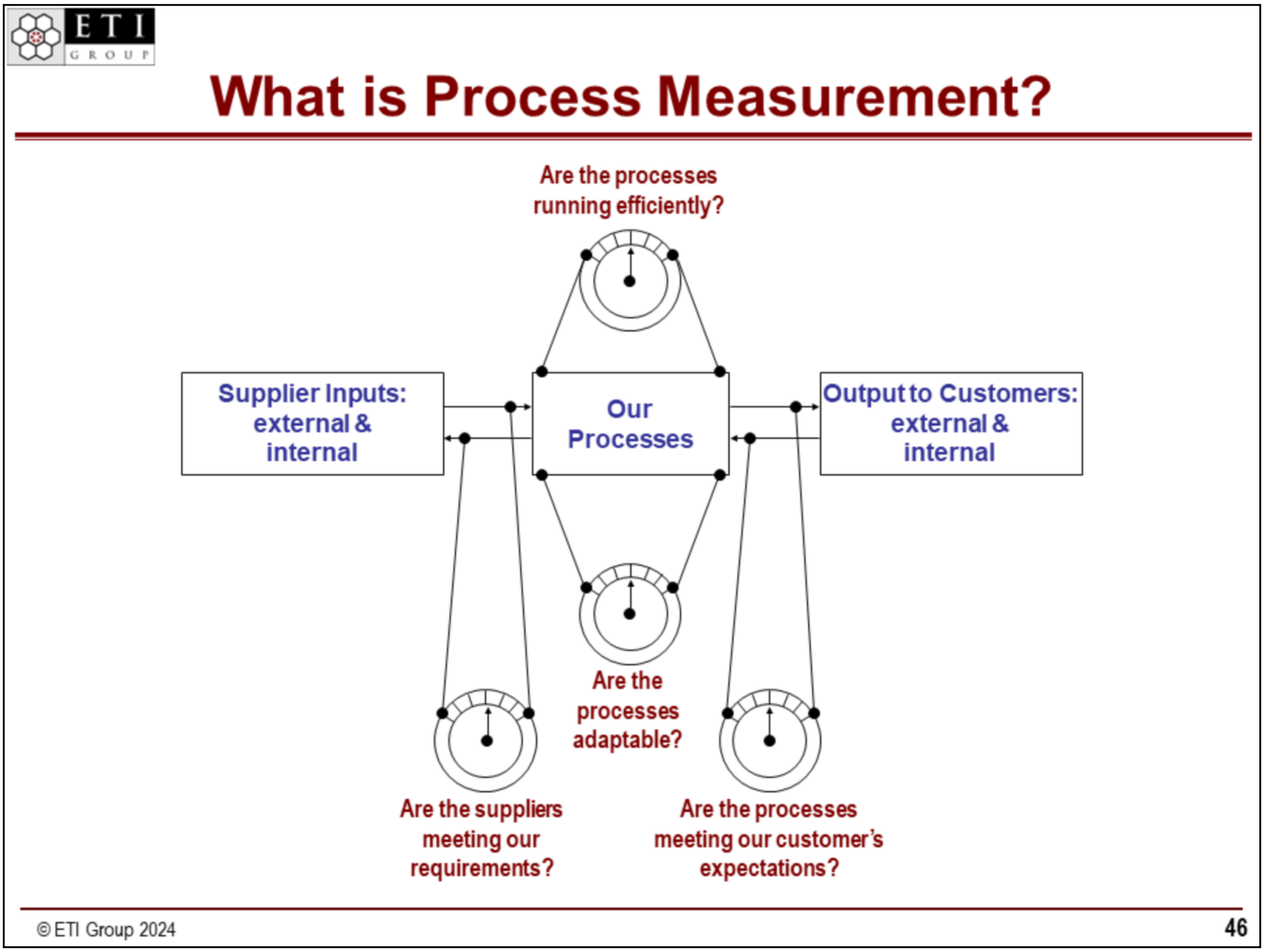
Learning Objectives

By the end of this section, participants will be able to:

- ☑ Describe process measurements in terms of effectiveness, efficiency, and adaptability.
- ☑ State the reasons for measuring a process.
- ☑ State definitions for variable and attribute data.
- ☑ Collect meaningful data through the use of clear purpose statements, Juran's Theory of Dominance, and consideration of all sources of process variation.
- ☑ State characteristics of good measurements.

Learning Objectives continued

- ☑ Describe measurement accuracy and precision.
- ☑ Utilize appropriate gauging for data collection.
- ☑ Create operational definitions.
- ☑ Take a sample from a process.
- ☑ Decide when to measure process/product characteristics.
- ☑ Design a data collection plan.



Think of process measurement as setting gauges at different places in our processes and reading the dials to see how the key characteristics are performing.

The three categories being measured are:

- Effectiveness
- Efficiency
- Adaptability

How might these measurement categories relate to X and Y Variables? Remember the formula:

$$y = f(x)$$

Process Measurement Examples

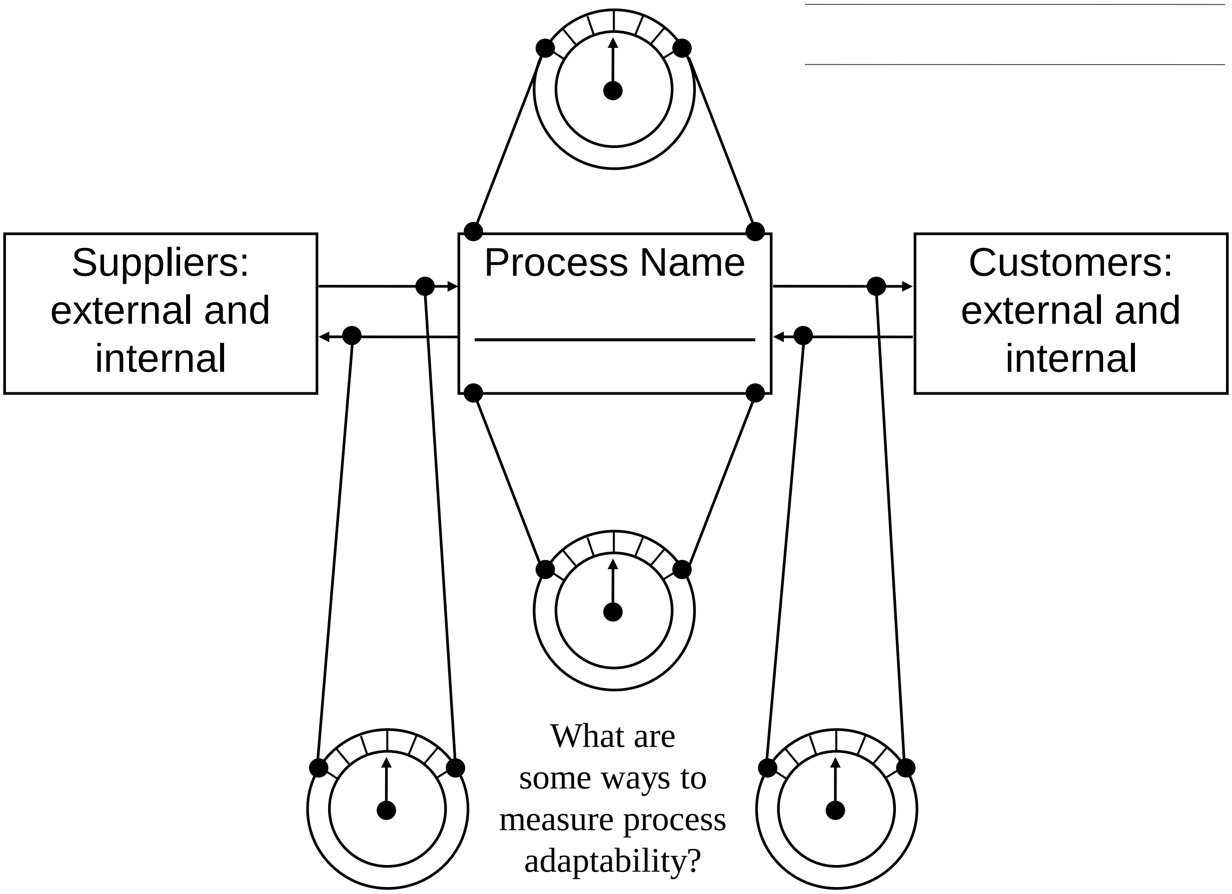
Measurement	Question Asked	Dimensions	Examples
Effectiveness	Are the outputs of the process meeting the customer's expectations?	Accuracy	Number of change orders per drawing. Number of qualification failures.
		Responsiveness	Percent of parts delivered on time.
Efficiency	How well does the process utilize resources to provide output meeting customer expectations? Are the resources minimized and waste eliminated?	Throughput	Product or process cycle time.
		Resource Utilization	Time spent correcting bills of material.
Adaptability	How well does the process respond to special customer requests or a changing environment?	Frequency of requests made that deviate from standard policy and procedure.	Number of special requests per time period (week, month, etc.) Number of special requests granted.
		Percentage of time requests are granted.	Percentage of special requests granted by direct contact employees.

Defining Process Measurements
Worksheet

Instructions:

1. Answer the questions below for a process in your area.
2. Hint: Look back at your key characteristics from the module "Defining the Process."

What are some ways to measure process efficiency?



What are some ways to measure process adaptability?

What are some ways to measure whether suppliers are meeting our expectations?

What are some ways to measure whether our process meets customer expectations?

Why Measure?

In order to control and improve processes, we have to be able to measure them.

Measuring a process allows us to:

- Establish a process baseline.
- Gather data on process performance (effectiveness, efficiency, adaptability of key characteristics).
- Show progress.

"What gets measured gets done." — Tom Peters

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As we have seen, there are a variety of measurements that can be taken. It is important to measure the right things, in the right combination, to get the best possible information about a process.

For example, a process may be effective (parts meet specifications), but it might not be efficient (the process takes too long to run, or relies too much on inspection to get good parts). Or, a process may have a very good throughput (parts per hour), but is not effective because the reject rate is too high.

What Gets Measured?

To measure process performance, we need to gather *data*.

- Data are concrete facts that give us information on our processes and their key characteristics.
- Data can answer questions that start with what, where, when and/or how.
- There are only two kinds of process data.

Variable Data

Data that are measured, using a continuous numbered scale with units. Examples are:

- Length in inches.
- Weight in grams.
- Temperature in degrees Celsius.

Variable data are also referred to as Continuous or Quantitative data.

What are some other examples of variable data?

Attribute Data

Either/or in nature. For example:

- Pass/Fail
- Go/No go.
- Presence/Absence.
- Yes/No.

Or, attribute data can come from counting things like:

- Number of defects.
- How many times something happens.

Attribute data are also referred to as Categorical data.

What are some other examples of attribute data?

Look back at your Process Measurements Worksheet and think about what kind of data would be generated by each of the measurements.

Label each measurement as “V” for variable or “A” for attribute.

What did you find?

How to Measure

- Collect meaningful data.
- Use good measurement methods.
- Sample the process.
- Plan for data collection.

Collecting Meaningful Data

Most important is having data that tells you what you want to know.

Having a clear measurement purpose statement will help:

- Do you need information on effectiveness, efficiency, and/or adaptability?
- Are you measuring a product or process characteristic (or an environmental factor)?
- What part of the overall process is being measured? (The input–process interface, the process itself, or the process–output interface?)
- What are the most important sources of variation?
- What information are you being asked (by management, customers, suppliers, etc.) to provide?
- What decision do you need to make (specification vs. process)?

Answer the measurement purpose questions above for a process in your area.

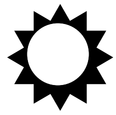
Sources of Variation

MACHINE

- Set up
- Tool wear
- Fixturing

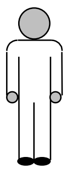
MOTHER NATURE

- Temperature
- Humidity
- Vibration



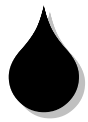
MEMBERS

- Experience vs. Inexperience
- Training



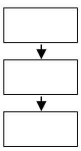
MATERIAL

- Thickness
- Availability
- Shelf Life



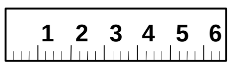
METHOD

- Procedures
- Maintenance Programs



MEASUREMENT

- Inaccurate Measurement System



What are some additional ways the "6 M's" above can vary for the process(es) in your area? Think about quantity as well as the nature of the variation — how many machines, members, measurement devices, etc. exist in the process?

The 6 M's of a process are all sources for X variables. The design and procurement/resource provision choices made for each "M" and the resulting effects (including interactions among the M's), are what determine the Y variables, i.e., the output from the process. As before: $y = f(x)$

Juran's Theory of Dominance

Collecting meaningful data also means choosing *appropriate* data.

Dr. Juran created a guideline for controlling processes based on the underlying factors that have the biggest influence on quality. These are:

- Setup
- Time
- Operator
- Component
- Information

What is the dominant factor for the process(es) in your area?

Juran's Theory of Dominance

Adapted from: Juran's *Quality Control Handbook*, 4th edition, McGraw Hill.

Dominance Factor	Biggest Influence on Quality	Process Examples	Suggested Areas for Process Control	Ability of Operator to Control Process
Setup	accuracy of setup	drilling die cutting screen printing press work molding labeling	• know where to center the setup • measure whether the setup is actually centered • be able to adjust the setup with precision • pay attention to process and product characteristics	operator can adjust the setup
Time	progressive process changes over time (tool wear, heating up of machine, depletion of chemical reagent)	screw machining volume filling paper making chemical processes automated machining	• have a schedule of process checks with feedback • adjust process only when necessary • measure product defects or process characteristics	operator can adjust the process (machine, tools, materials, etc.)
Operator	skill and talent of the person	welding painting order picking manual operations-soldering, grinding, die attach	• use training and certification for operators • use process audits • measure defects	operator has the most control over her/his ability
Component	input materials and components defects can be epidemic or random	assembly operations food formulation	• use supplier partnerships • monitor incoming material	operator has limited control, can report problems
Information	accuracy and up-to-dateness of information provided to operators	order editing lot travelers in job shops	• actively check documentation • use computer generated info • use barcodes and electronic entry	operator has limited control, can report problems

Separating Data

To get the best process information, data from different populations should be separated.

For example, if there are two or three machines performing the same process, data should be recorded by machine number.

If data is mixed, it will be unclear which machine is having a problem.

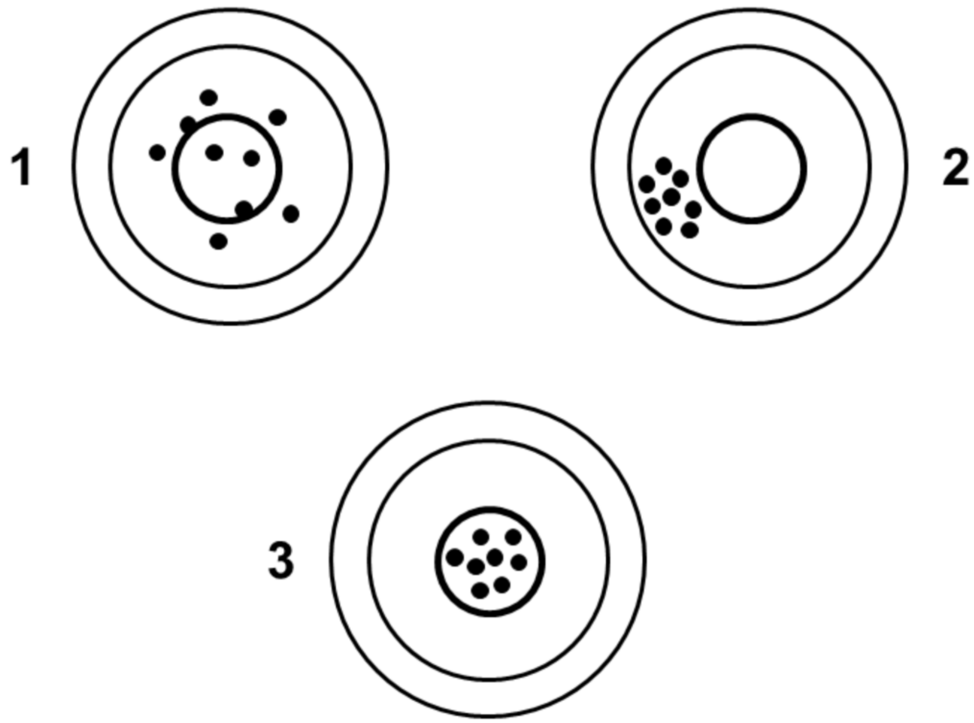
Using Good Measurement Methods

Process data will only be as good as the measurement method used to collect it.

Good measurements:

- Leave no opening for debate in terms of accuracy.
- Can be broadly applied.
- Will have uniform interpretation.
- Have an identified owner.
- Drive appropriate corrective action.

Measurement Methods



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How would you describe the measurement scenarios above?

1.

2.

3.

Measurement Terms

Accuracy

Precision

Gauge Resolution

The equipment used to measure product and process characteristics must be both accurate and precise.

Statistical Process Control *also* requires a gauge resolution fine enough to break the total process variation into at least ten divisions.

A starting point for estimating total process variation is to look at the tolerance limits.

Resolution is *not* the same thing as accuracy!

Gauge Resolution

For example:

- a part length must be: 1.0 inch ± 0.1 inch
- the tolerance range is: 0.9 to 1.1 inches
- which is a spread of: 1.1 – 0.9 = 0.2 inches

If we divide 0.2 by 10 divisions, we get:

- 0.2 ÷ 10 = 0.02 inches

So, our gauge for measuring length must be able to measure as small as 0.02 inch.

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What types of gauges (and resolution) are available/needed for measuring your process and product characteristics?

Typical resolution values for various measurement devices:

Calipers: 0.0005 inches

Micrometer: 0.0001 inches

Vision System: 0.00001 inches

CMM (Coordinate Measuring Machine): 0.000001 inches

Measurement Instructions

Whenever a measurement is made for variable type data (length, weight, temperature), the method for taking the measurement needs to be defined.

Instructions should be clear on:

- Where to measure.
- When to measure.
- How to measure.
- How many measurements to take.
- How to read and record results.

Operational Definitions

Measuring attributes requires a good operational definition for defects or pass/fail criteria. Establishing this definition can be difficult, especially when personal judgment is involved.

A good operational definition has 3 elements:

1. Defined criteria which must
   - be understandable and simple;
   - have agreement among all people involved, including the customer &/or supplier.
2. A test against the criteria which must
   - have a clearly defined method of inspection;
   - yield a yes or no answer with no gray areas.
3. A decision based on the criteria which must
   - be consistent.

Practice writing an operational definition for a product or process attribute.

THE F TEST
Worksheet

Instructions

Read through the paragraph shown by the instructor and keep a running tally in your head of the number of times you see the letter “f.”

How many “f’s” did you count?

Sample vs. Population

The population is the complete collection of objects, and a sample is a sub-set, or smaller part of the population.

For example, the population of an organization is made up of all employees.

A sample of an organization would be the Purchasing department, or all supervisors, or the swing-shift employees.

What are some examples of populations and samples in the process(es) in your area?

Reasons for Sampling

When collecting data, we will often *sample* the process. There are two reasons for sampling:

1. Cost
   - 100% inspection may take too much time.
   - Taking the measurement may destroy the part.
2. Accuracy
   - As we saw in the "f" exercise, 100% inspection is never 100% correct.
   - Sampling can be more accurate because the operator can concentrate on a small number of parts.

What would be the primary reasons for using sampling in your process?

How to Sample

To detect process shifts, we need to take a *reasonable* sample of the process.

- Samples should estimate, or try to represent, the population.
- Samples need to be taken in the order of production and as soon as possible in an operation to get an early warning of defects.
- The chance of variation from assignable causes should be minimized within an individual sample set (pull parts for a sample close together in time).
- The chance of variation from assignable causes should be maximized between samples (time separation between samples).

An understanding of the interplay of the 6M's for a process is critical to designing a representative sampling strategy for SPC charting.

How to Sample

Pulling subgroups of parts at a predetermined interval works best.

- Do not pre-identify which parts will form the SPC sample before they are manufactured (avoid bias).
- Do not adjust the process during sampling.

A sampling plan might be to pull 5 parts in a row from a machine every hour, or every 100 parts, or some other interval. For non-production processes, a monitoring frequency could be daily, weekly, monthly, quarterly, etc.

What methods might you use to gather a nonbiased sample from the process(es) in your area?

Note: samples pulled for ongoing monitoring of a process have a different purpose from a "set-up" part/sample used for machine/process buy-off.

Sample Size

Sample size will depend on the particular process and product, and the type of control chart used.

- Typical sample sizes for variable data may range from 1 to 15.
- Typical sample sizes for attribute data may be 30 or more.

While a statistical sample size calculation could be performed, it is not necessary. The most important aspect of sampling for SPC charting is to make the samples representative of the day-to-day process.

Planning for Data Collection

Up-front planning should take place to make sure that the best possible data is gathered.

Collecting data can be time consuming, so important points to remember are to:

- Consider the sampling technique.
- Collect only relevant data.
- Keep forms simple.
- Utilize historical data.

Relevant data refers to the information that helps trace a data point back to when and where it was collected.

Planning for Data Collection

When selecting process measurements, think about:

- The availability of the data. (How easy is it to measure?)
- How much it will cost to collect the data.
- Needs of the user (process operator).
- Customer requirements for data reporting.

When to Measure

Typical times to measure a process are:

- Before a process step begins.
- After a process step ends.
- At the end of a specific time period.
- After a process change.

When does it make sense to measure the process(es) in your area?

SPC DATA COLLECTION FORM

Part Name/Class:	Gauge Used:	Gauge Resolution:
Part Number:	Sampling Frequency:	USL= Target=
Material Type:	Characteristic Measured:	LSL=

Date/Time	Changes to the Process	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10

SPC DATA COLLECTION PLAN
Worksheet

Purpose Statement: *(What information is needed? By whom?)*
Process Dominance Factor: *(Setup, time, operator, component, information)*
Major Sources of Variation: *(More than one machine, tool, operator, etc.?)*
Process/Product Characteristic to be Measured or Inspected:
Specification/Tolerance for Variable Data: *(List measurement and units.)*
Gauge(s) to be Used: *(List gauge and required resolution, note whether new gauges, fixtures, S/W, etc. are needed. Could also list Gauge Capability index, reference to work instructions for measurement, calibration, etc.)*
Measurement Instructions for Variables Data: *(measurement location, method of measurement, how to read gauge and record data; could reference a work instruction.)*
Sampling Method: *(How will sample be pulled? By whom? When?)*
Operational Definition for Attribute Data: *(Inspection method, pass/fail criteria, inspection aids, etc. Could reference a work instruction.)*
Traceability Information Needed: *(Time, machine, tool, material lot #, job #, etc.)*
Notes:

Example: SPC DATA COLLECTION PLAN
Worksheet

Purpose Statement: *(What information is needed? By whom?)* Information is needed on the effectiveness of the widget making process in meeting the customer's specification for length. Process operators will use the SPC chart information to monitor in real-time the accuracy and consistency of the production process.
Process Dominance Factor: *(Setup, time, operator, component, information)* The widget process is time dominant. The cutting tool can wear and cause material to go outside specifications.
Major Sources of Variation: *(More than one machine, tool, operator, etc.?)* The three stamping machines and their cutting tools.
Process/Product Characteristic to be Measured or Inspected: Widget length.
Specification/Tolerance for Variable Data: *(List measurement and units.)* Widget length = 1.0 ± 0.1 inch.
Gauge(s) to be Used: **Gauge(s) to be Used**: *(List gauge and required resolution, note whether new gauges, fixtures, S/W, etc. are needed. Could also list Gauge Capability index, reference to work instructions for measurement, calibration, etc.)* Digital micrometer with resolution of 0.01 inch or better.
Measurement Instructions for Variables Data: *(measurement location, method of measurement, how to read gauge and record data.)* Take one length measurement for each part in sample. Use fixture S/N 335 per work instruction WI-001. Enter data in SPC S/W program per WI-002.
Sampling Method: *(How will sample be pulled? By whom? When?)* A sample of 3 parts will be pulled from every 20 parts built (after setup approval) by the operators on each machine, and also after any machine adjustments and/or tool changes. A second operator will select the 3 sample parts from the twenty parts.
Operational Definition for Attribute Data: *(Inspection method, pass/fail criteria, inspection aids, etc.)* Not applicable.
Traceability Information Needed: *(Time, machine, tool, material lot #, job #, etc.)* Date, time, machine #, tool #, job #.
Notes:

Using Statistics

Learning Objectives

By the end of this section, participants will be able to:

- ☑ State the reasons for using statistics.
- ☑ Chart a frequency distribution.
- ☑ Build a histogram.
- ☑ Use histograms to describe the center, range, and shape of a distribution.
- ☑ Calculate an average, range, and standard deviation.
- ☑ Describe the characteristics of a Normal Distribution.
- ☑ Relate common and assignable cause variation to the Normal Distribution.

ETI GROUP

Why Use Statistics?

In Statistical Process Control, *statistical* methods are used to interpret data collected from a *process*, in order to "*control*" it.

The term "control" in SPC is a bit of a misnomer; a more accurate word would be "monitoring."

Raw Data

.54	.54	.56	.53	.57
.57	.55	.58	.56	.54
.53	.55	.53	.56	.53
.54	.57	.54	.56	.54
.57	.55	.55	.56	.54
.54	.56	.54	.54	.55
.55	.56	.56	.53	.56
.55	.56	.56	.56	.52
.57	.57	.55	.56	.56
.54	.55	.57	.57	.53
.55	.55	.54	.54	.55
.56	.55	.55	.54	.53
.56	.56	.55	.54	.56
.54	.53	.55	.58	.52
.57	.57	.54	.54	.56
.55	.57	.54	.55	.53
.57	.55	.55	.54	.55
.55	.56	.54	.56	.54
.55	.58	.56	.55	.53
.56	.53	.55	.56	.55

A typical collection of raw data is shown above.

How quickly can you find the highest and lowest values in this set of data?

What number would fall in the middle of this data set?

Trying to interpret a set of data by looking at the raw numbers can be difficult. By using a few simple statistical charts and calculations, we can organize our data and make it easier to understand.

What Are Frequency Distributions?

Statistical tools are used to help us describe process variation.

- Frequency is the number of times something happens; for example, how often we get a measurement of 0.53 inches.
- Distribution describes how the data is distributed, or spread out.

M & M DISTRIBUTION
Worksheet

Yellow	**Red**	**Blue**	**Green**	**Orange**	**Brown**

What are some characteristics of this distribution?

Frequency Table

Title: *Example* Comments: *Sample Study*

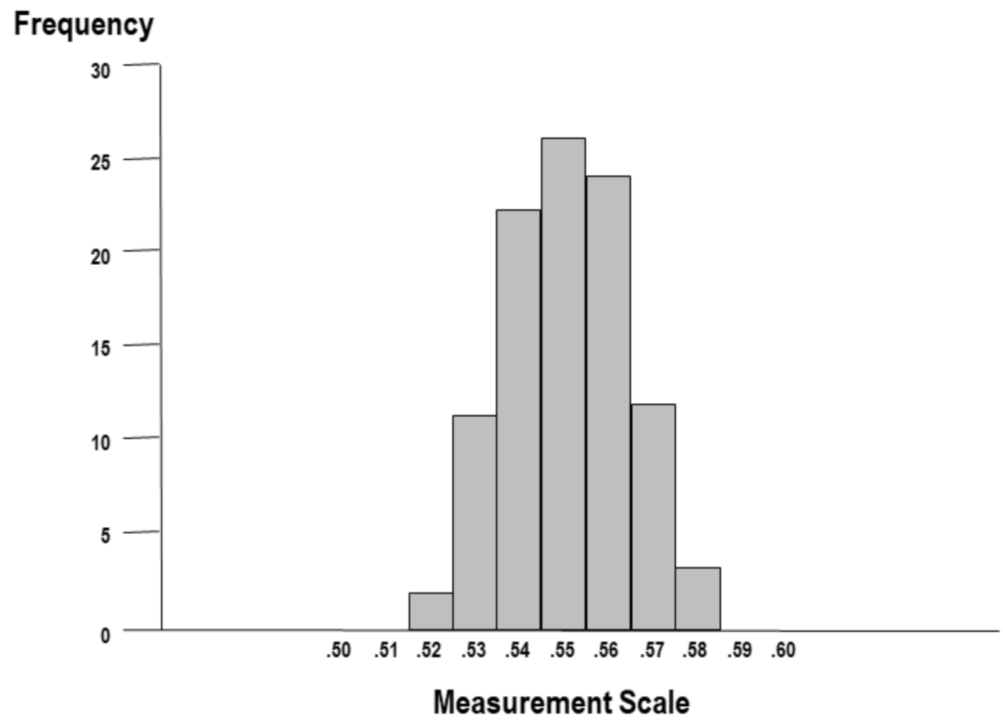
Unit of Measure: *inches* Upper Spec: .59 Lower Spec: *.50*

Measurements	Tally	Frequency
.50		0
.51		0
.52	II	2
.53	~~IIII~~ ~~IIII~~ I	11
.54	~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ II	22
.55	~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ I	26
.56	~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ IIII	24
.57	~~IIII~~ ~~IIII~~ II	12
.58	III	3
.59		0
.60		0

An easy way to chart a frequency distribution is to tally the numbers in a table format.

- The first column lists the possible measurement values.
- The second column is used to keep a tally.
- The last column shows the totals (frequencies).

What Are Histograms?



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What are you noticing about the frequency distributions we've seen so far?

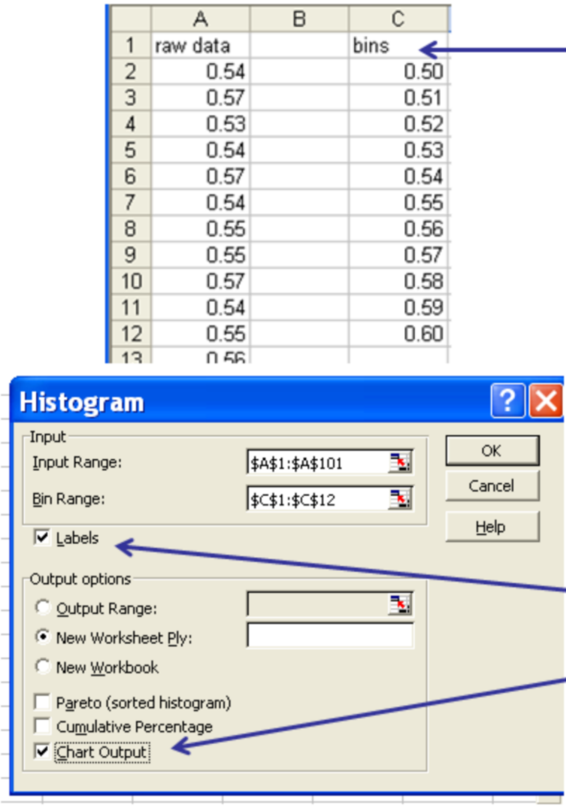
We can take the Frequency Table one step further by charting a Histogram. Think of this chart as showing the "history" of the process.

The histogram shows both the frequency and distribution of the data, except this time the measurement scale is shown on the bottom of the chart, and a frequency scale is drawn up the side.

As before, the individual data values are used. Instead
of a tally mark for each number, the data is broken into "classes." A class can be an individual number (as shown), or if there is a greater spread of data, classes may be ranges of numbers. For example, 0.50 – 0.51, 0.52 – 0.53, 0.53 – 0.54, etc.

Each class is shown with a bar; the height of the bar (on the Frequency Scale) shows how many measurements fell into this range.

Using Excel: Frequency Distribution & Histogram

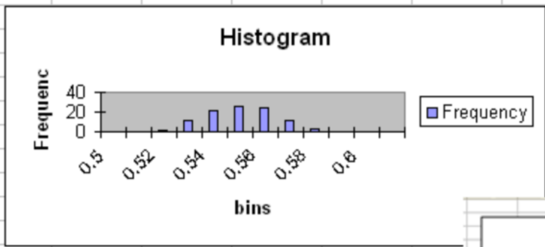


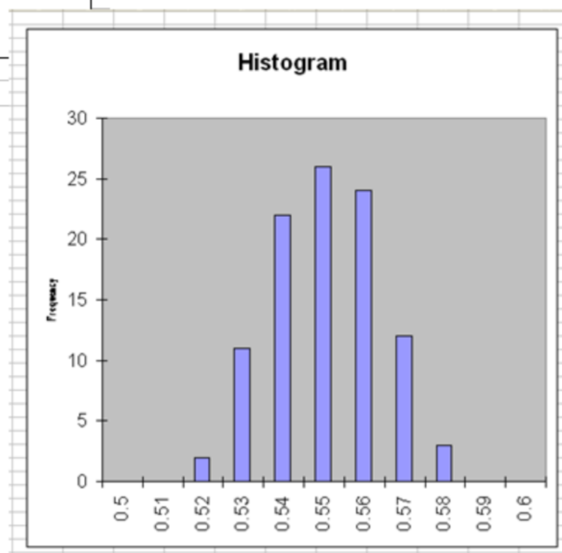
Use file: *Data sets for exercises\ raw data*

1. Manually enter bin values (class intervals) shown
2. Select *Data*
3. Select *Data Analysis*
4. Select *Histogram*
5. Click OK
6. For *Input Range* select data in column A
7. For *Bin Range* select data in column C
8. Select *Labels*
9. Select *Chart Output*
10. Click OK

Using Excel: Frequency Distribution & Histogram

bins	Frequency
0.5	0
0.51	0
0.52	2
0.53	11
0.54	22
0.55	26
0.56	24
0.57	12
0.58	3
0.59	0
0.6	0
More	0





This is the frequency distribution.

delete row: "More"

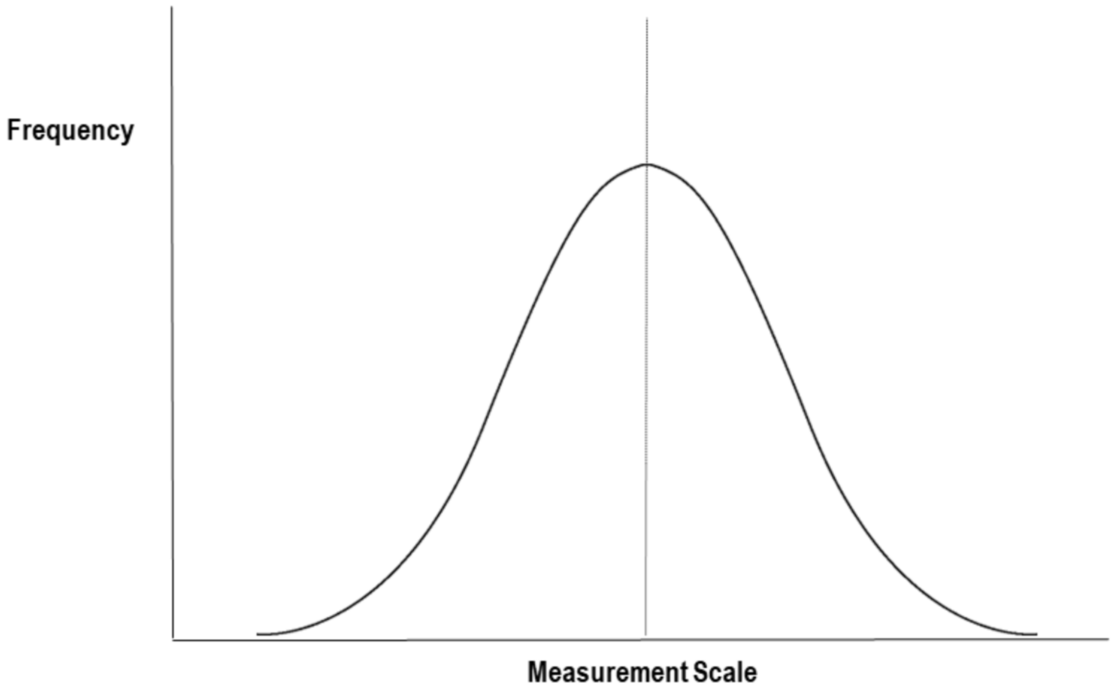
Do some editing, as shown above, to make the chart a little better looking.

Applying Statistics

Histograms help to show three important characteristics of a data set:

- The center of the data.
- The spread of the data.
- The shape of the data.

The Normal Distribution



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The frequency distributions we have looked at are called *Normal* distributions. These types of distributions happen regularly in nature, and tend to be normal for manufacturing processes too.

The Normal Distribution

Characteristics of the Normal Distribution:

- It has one peak.
- It has a bell shape, with most of the measurements around the center, dropping rapidly toward zero at the edges.
- It is symmetrical—if you divide it down the center, the right and left sides will be mirror images.

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What might be some examples of Normal distributions?

What would the distribution shape look like if we plotted heights of both NBA basketball players and horse racing jockeys on the same histogram?

This shape would be similar to what a distribution might look if data from two different sources (like machines) were mixed.

Average

Besides shape, the other two characteristics shown by a histogram are the center of the data, and its spread, or distribution.

The center of the data is most often referred to as the *Average*. We saw from the "Bull's Eye" pictures in the last module that averages are used to measure accuracy.

Knowing the average will tell you where your process is centered and whether or not it is on target.

Average

To get the average, we add up all the measurement values, then divide by how many measurements we took.

To save time, statisticians use mathematical formulas to represent different terms.

- Data points are symbolized as x's.
- When data is averaged this is shown by drawing a line over the data: $\bar{x}$

This symbol for average is also called "x-bar."

If we had the following measurements, what would the average be?

2, 5, 3, 6, 4

$\bar{x}$ =

Range

Data will always be scattered around both sides of the average. This spread is the amount of variation in the data/process, and can also be represented with numbers.

- The Range (R) is often calculated; this number is just the difference between the highest and lowest values.
- Range = highest value - lowest value

Thinking back to the Bull's Eye pictures in the Measurement module, what is another term used for describing measurement scatter?

Standard Deviation

Another number often used for spread is the Standard Deviation. This number gives more information about the distribution because it shows how much the individual measurements differ (deviate) from the average.

- Instead of using only the highest and lowest values, the standard deviation is calculated using *all* of the data values.
- As the sample sizes get large (more than 10), Standard Deviation is a better measure than Range.

The Standard Deviation for that last data set of five numbers is s = 1.58

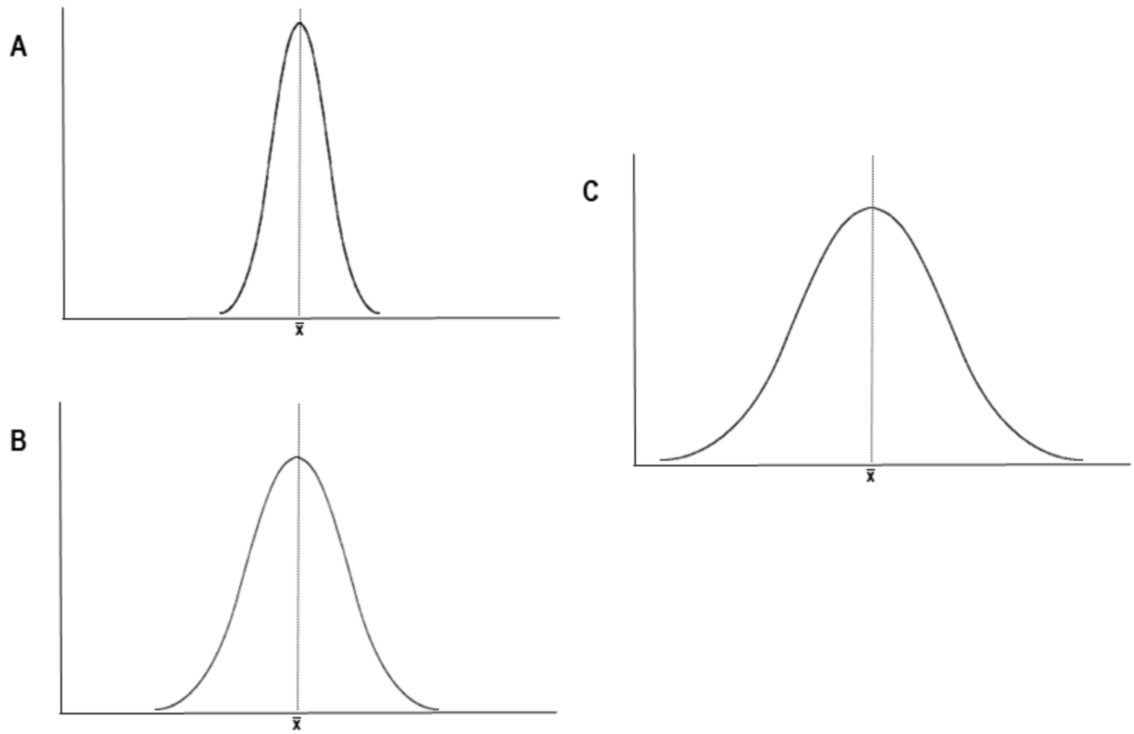
What would the Range be?

Notes on Symbols

Depending on the application, we may work with data that represents the *population* of a process (all possible parts) and at other times use a sample from a process (a subset of all possible parts).

- When statisticians talk about a sample, they use English symbols: "$\overline{X}$" for average, "s" for standard deviation.
- For populations, they use Greek symbols: mu, μ, for average and the Greek letter for "s", which is sigma, written as "σ."

Distribution Comparison



Which distribution would have the smallest range and standard deviation?

Which distribution would have the highest range and standard deviation?

Looking at Range or Standard Deviation will tell you how much spread there is in a process; therefore, how *consistent* it is.

If you were able to make five parts with lengths exactly the same—say 6.000 inches—what would the average be? Range? Standard deviation?

Which of the processes—A, B, or C—is the most consistent?

CALCULATING STATISTICS
Worksheet

Instructions

Generate a set of data using the method described by the instructor.

________	________	________	________	________
________	________	________	________	________
________	________	________	________	________

Compute:

Average ($\bar{x}$) =

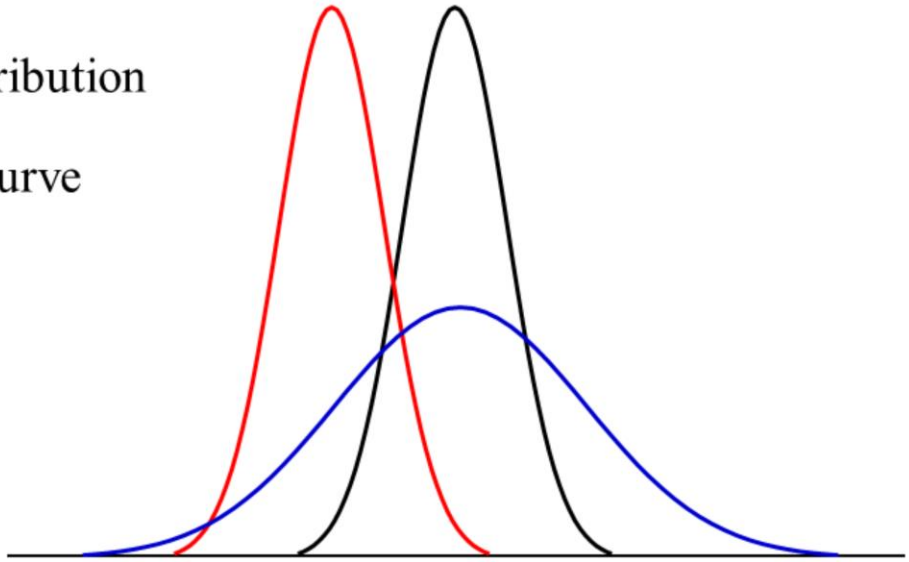
Range (R) =

Standard Deviation (s) =

More on The Normal Distribution

Also known as

- Gaussian distribution
- Bell-shaped curve



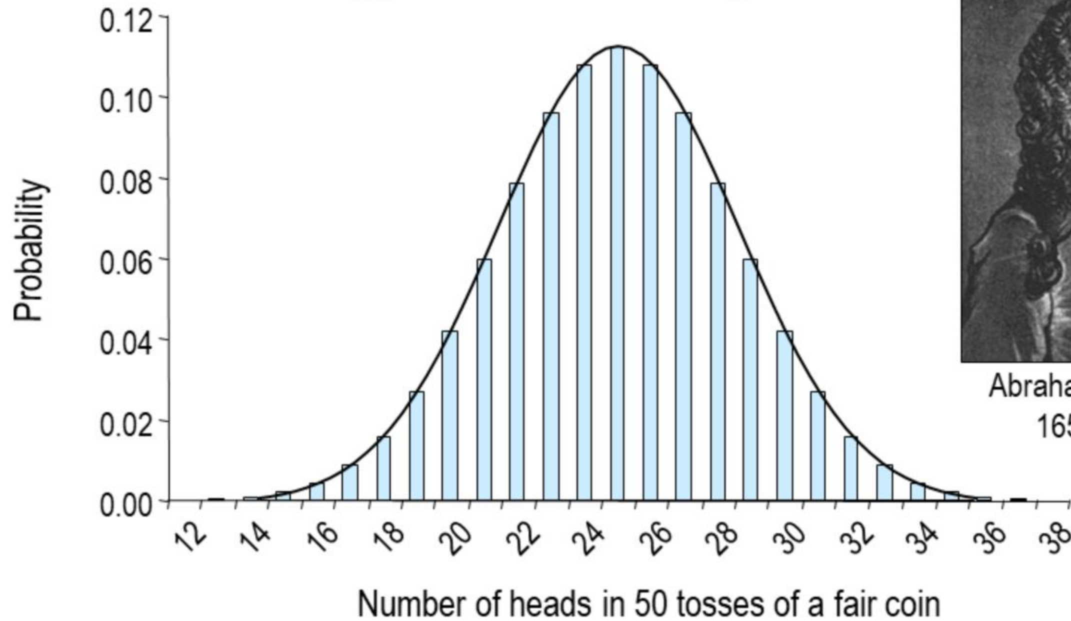
Everyone believes in the Normal curve: experimenters think it is a mathematical theorem, mathematicians think it is an experimental fact. —G. Lippman

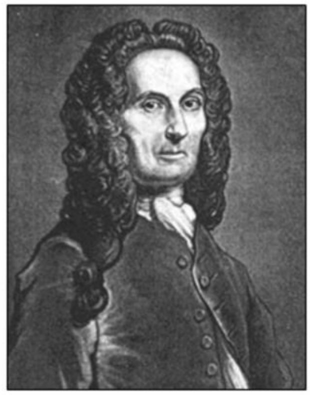
The Normal distribution is an abstraction, an idealization, a mathematical construct. At the same time it has been, overwhelmingly, the device of greatest practical value in the toolkit of Statistics.

It’s called the Gaussian distribution because the German mathematician Carl Friedrich Gauss made important early applications to astronomy in the 1820’s. As we will see, it was actually discovered a century earlier by the French mathematician Abraham de Moivre. Life really isn’t fair.

From whence The Normal Distribution?

As the number of tosses of a fair coin increases, the probability distribution of the number of heads approaches a bell-shaped curve.



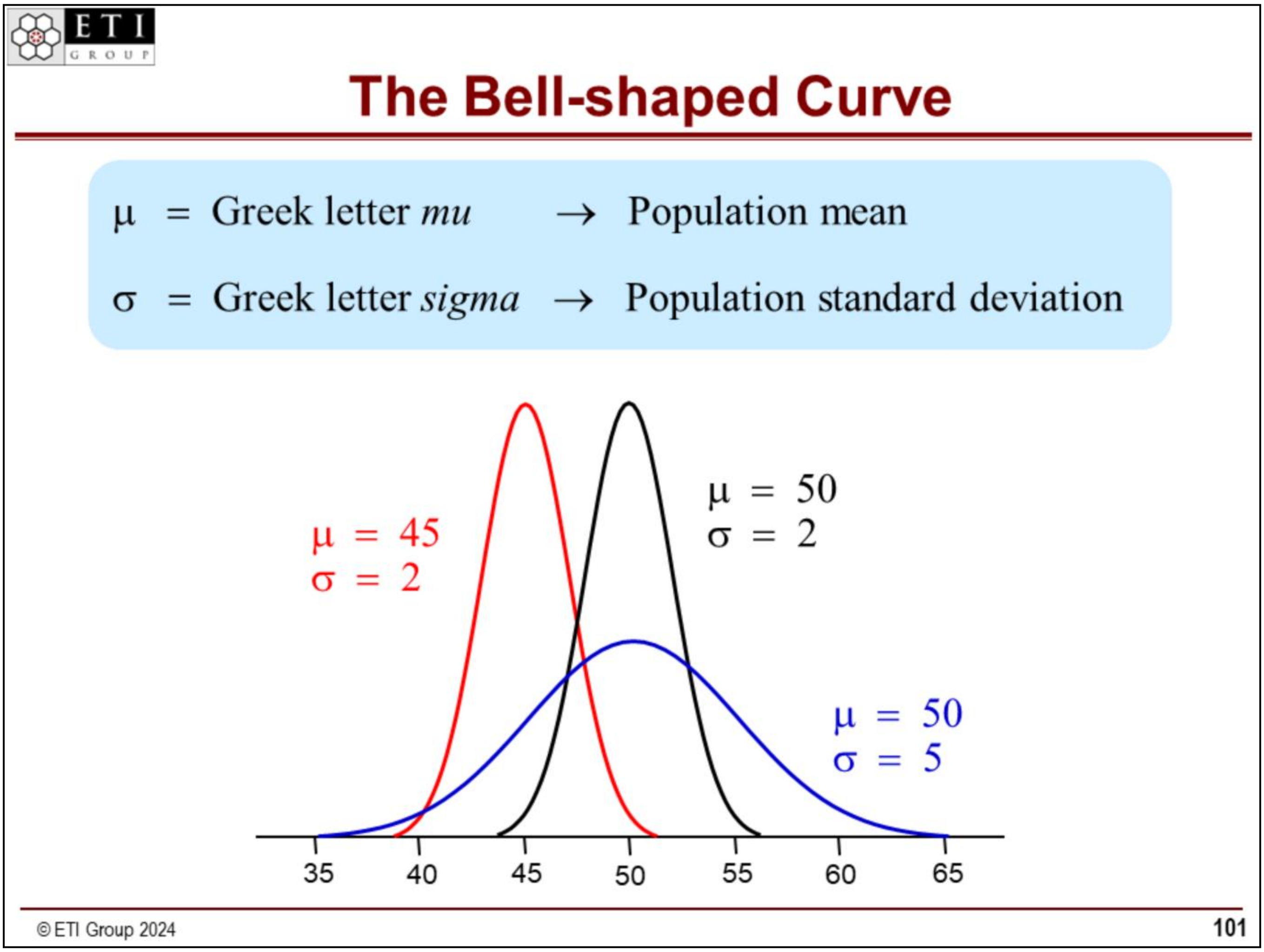


Abraham de Moivre
1657 - 1754

The statistical model for the number of heads in N tosses of a coin is called the *Binomial distribution*. In 1730, the French mathematician Abraham de Moivre discovered the bell-shaped curve as the limiting form approached by the Binomial distribution as the sample size N increases without bound. He never made any money on his discovery of the Normal distribution, and in fact died a pauper. To add insult to injury, it was eventually named after someone else (Gauss).

Over the next 200 years, de Moivre’s discovery was extended far beyond coin tossing. Today, we know that most continuous measurements are sums of large numbers of small, independent, possibly unobservable contributing factors. Measurements of this type in a stable population will follow the Normal distribution, at least as a good approximation. Statisticians call this phenomenon the Central Limit Theorem.

For this reason, the Normal distribution is the default population model for continuous data.



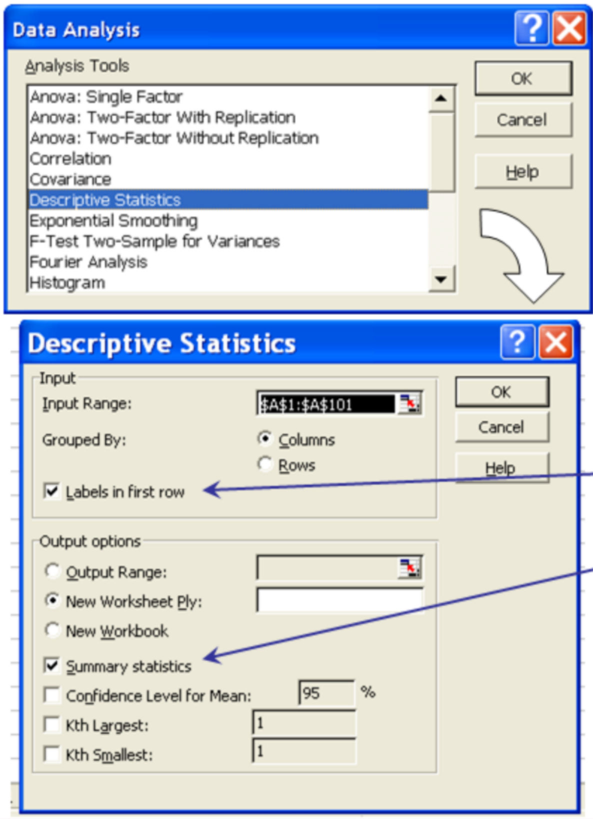
A population model is an equation that can be used to make predictions about a population. When we represent the mean and standard deviation by Greek letters, as above, we are thinking of the mean and standard deviation of the entire population, not just the numbers in our data set. It means we are thinking of the Normal distribution as a population model. When English letters are used for statistics, they represent a sample from a population.

You may have been graded "on the curve" at some point in your academic career. Well, this is the curve, and here is the formula (i.e., the probability density function):

$$f(y) = \frac{1}{\sqrt{2\pi}}\frac{1}{\sigma}e^{-\frac{1}{2}\left(\frac{y-\mu}{\sigma}\right)^2}$$

In this equation, f (y) is the height of the curve above the value y on the horizontal axis.

Using Excel: Summary Statistics



Use file: *Data sets for exercises \ raw data*

1. Select *Data*
2. Select *Data Analysis*
3. Select *Descriptive Statistics*
4. Click OK
5. For *Input Range* select data in column A
6. Select *Labels in first row*
7. Select *Summary statistics*
8. Click OK

Using Excel: Summary Statistics

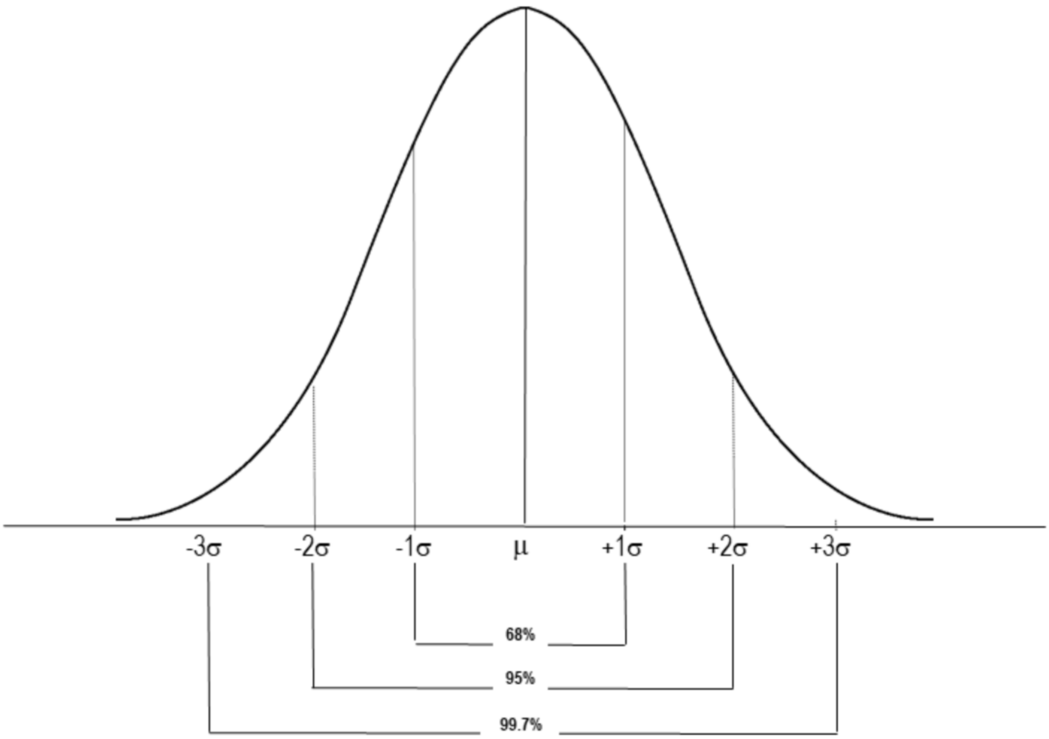
	A	B
1	*raw data*	
2		
3	Mean	0.5507
4	Standard Error	0.001357769
5	Median	0.55
6	Mode	0.55
7	Standard Deviation	0.013577685
8	Sample Variance	0.000184354
9	Kurtosis	-0.522604072
10	Skewness	-0.005605925
11	Range	0.06
12	Minimum	0.52
13	Maximum	0.58
14	Sum	55.07
15	Count	100

Edit down to the “vital few”

40		
41	*raw data*	
42		
43	Mean	0.5507
44	Median	0.55
45	Standard Deviation	0.013577685
46	Range	0.06
47	Minimum	0.52
48	Maximum	0.58
49	Count	100

Basic statistical summary for quantitative data

Using the Normal Distribution



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The Normal Distribution has some very unique characteristics, which are the key to SPC. Its bell curve is like a crystal ball—it can be used to make predictions.

- Using the Average and Standard Deviation, we can predict where the data will fall if it has a Normal distribution.
- The numbers show what we can see from the curve: most of the data (68%) falls fairly close to the center peak, and then it drops off from there.
- What is most significant, is that 99.7% of the data in a Normal distribution will fall in between the three standard deviations on either side of the average.

Common Cause Variation

Remember common cause variation?

- This is the variation that happens *normally* in a process.
- If a process is operating *normally*, all of the data (99.7%) should be inside the *Normal* distribution.
- The outcomes of the process are statistically predictable.

Common cause variation will be random, with many small fluctuations. Causes for these individual fluctuations cannot be determined, they are an inherent part of the process as designed (the combination of the "6M's").

Assignable Cause Variation

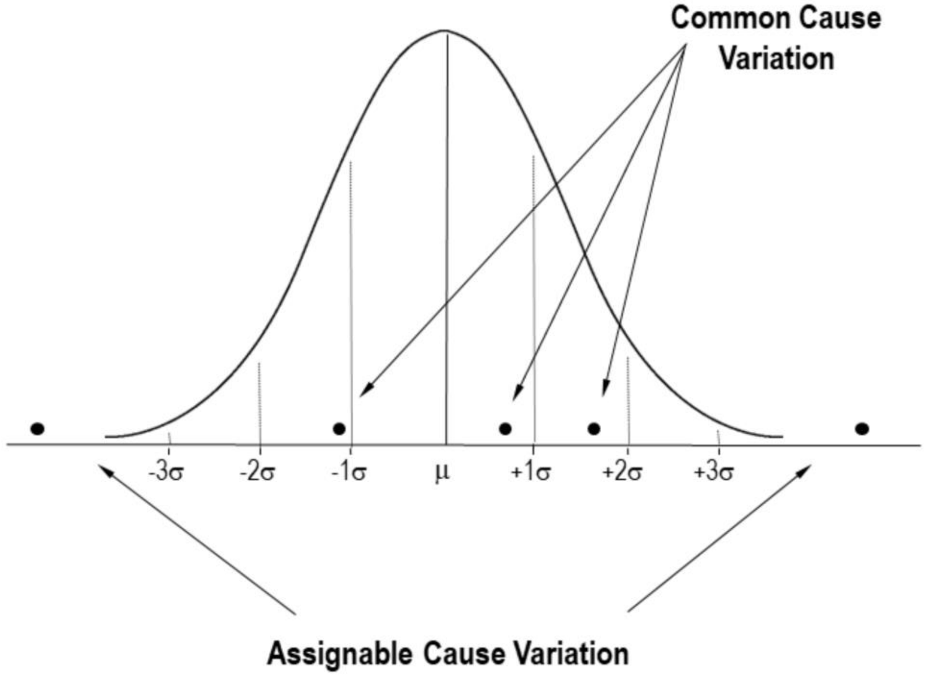
We said that assignable causes of variation are unexpected, or *not normal*.

- Assignable causes happen when data falls outside of the Normal distribution.
- This situation is not normal, because 99.7% of the data should fall randomly between ±3 standard deviations.
- We know that something obviously different is happening in the process and outcomes are *not* statistically predictable.

The term "assignable" describes the case where the causes of individual fluctuations *can* be determined (sometimes easily, sometimes not). Again, the source of this assignable variation will come from one or more of the 6M's.

Variation that is not normal will be *systematic*, which means there is an underlying pattern. We will discuss these different types of patterns in a later section.

Variation in the Normal Distribution



Variation

With SPC use over the years, it has been found that about 85% of the variation typically seen in a process comes from common causes.

- Common cause variation is just the normal amount of variation expected from the interplay of the "6 M's."
- To reduce common cause variation, the design of the process must be changed. For example, improving machines, materials, methods, etc.
- These types of fixes are usually the responsibility of Engineering and Management.

W. Edwards Deming was well-known for saying "Blame the process, not the people!"

Variation

The rest of the variation (about 15%), comes from assignable causes.

- These causes are usually things that the process operator can recognize and fix.

Knowing whether variation is coming from common causes or assignable causes will help in solving process problems.

Determining Process Capability

Learning Objectives

By the end of this section, participants will be able to:

- ☑ Explain the difference between the natural variation of a process, and the defined specification limits.
- ☑ Calculate process potential (C_p) and process capability (C_{pk}) indices.
- ☑ Determine whether or not a process is capable.
- ☑ Design machine and process capability studies.
- ☑ Estimate the percent defective output of a process.
- ☑ State the benefits of a highly capable process.

What is Process Capability?

A process operating in statistical control means that assignable causes of variation have been eliminated, and the only variation seen is due to common causes.

The process is consistent over time and the distribution of measurements is predictable.

We can look at this prediction of natural variation and compare it to the specifications for the process.

We want to know if the process is *capable* of producing parts that meet the specifications.

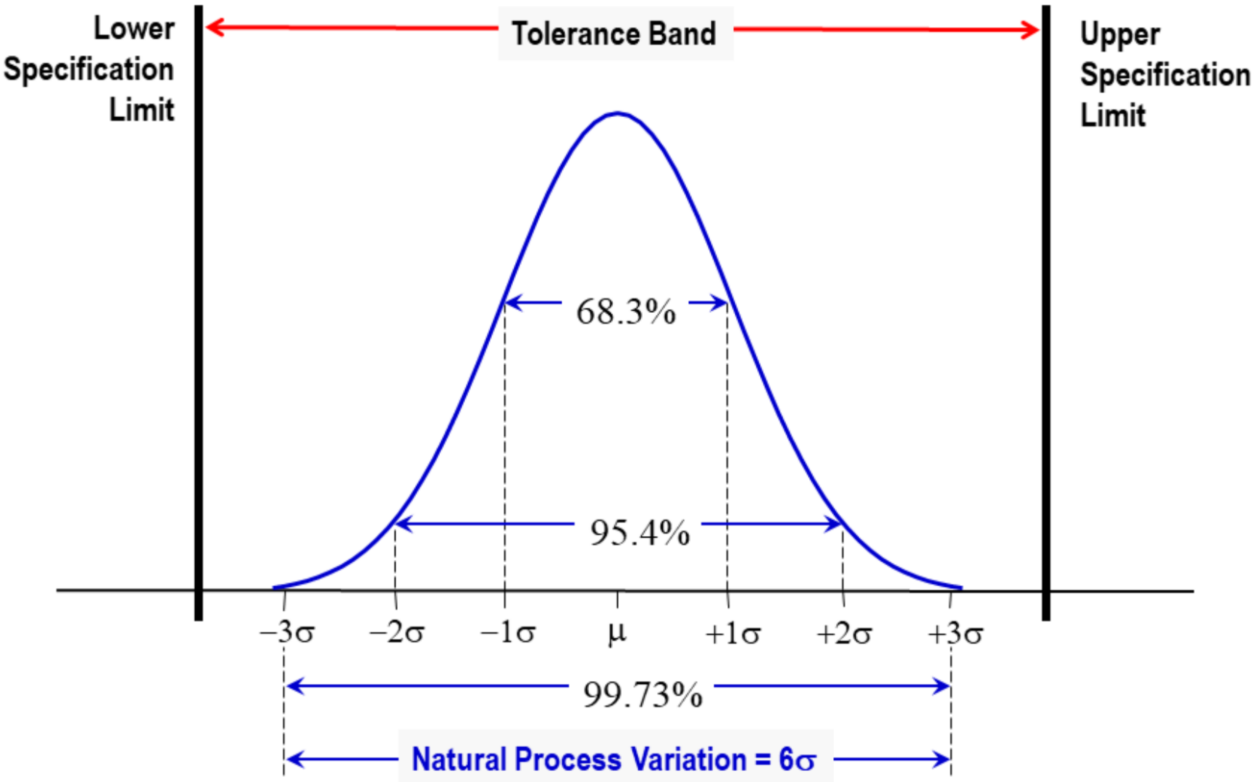
Histograms vs. Specification Limits

We know that a histogram is built from actual process measurements; it shows the history of the process.

- When these measurements form a Normal distribution, we know that 99.7% of the data will fall inside ±3 standard deviations.
- Another way of saying this is that the total natural variation of the process covers 6 standard deviations.

Specification limits, on the other hand, do not typically come from actual process data, but are set by design engineers. Blueprints will usually give a nominal value and an acceptable tolerance band.

Process Capability



Process Potential Index, C_p

The potential of a process to meet specifications is calculated by dividing the specification range, or tolerance band, by the natural variation of the process. This ratio of process potential is symbolized as "C_p." In mathematical terms, this can be shown as:

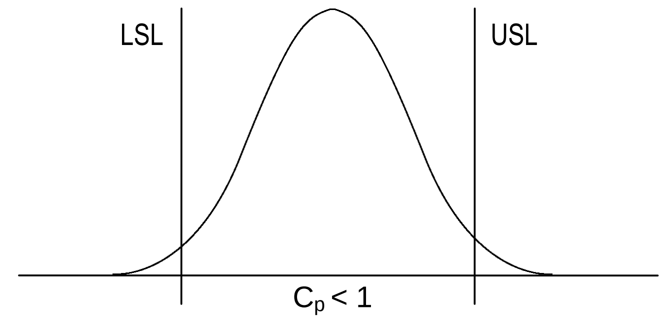
$$\text{Process Potential, } C_p = \frac{\text{Tolerance Band}}{\text{Natural Variation}} = \frac{USL - LSL}{6\sigma}$$

The process *must* be operating in statistical control before a true measure of process potential can be given.

The process potential "index" using attributes data such as fraction of units defective (p chart) or defects per unit (u chart) is simply the mean of the distribution — the center line of the control chart. (In plain English: "on average we expect the yield of this process to be ____%."

Process Potential Scenarios

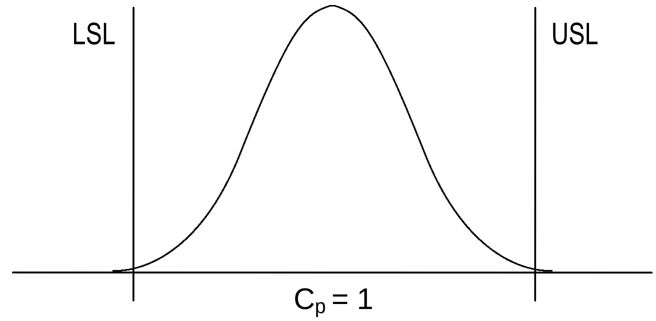
NOT CAPABLE



If the specification limits fall inside the distribution, the Cp index will be less than 1.

The process is not capable because it is producing parts outside the specification limits.

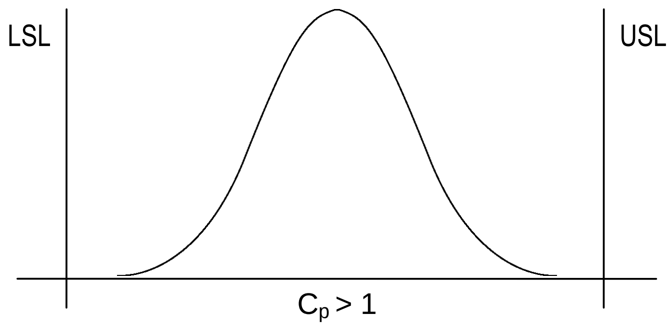
BARELY CAPABLE



If the specification limits fall right on ±3 standard deviations of the distribution, the Cp index will be equal to 1.

The process is barely capable because there’s a good chance some parts will fall outside the specification limits.

CAPABLE



If the specification limits fall outside the distribution, the Cp index will be greater than 1.

The process is capable because there is virtually no chance of parts falling outside the specification limits.

A Cp = 1.33 is usually the minimum number required to have a capable process.

C_p vs. C_{pk}

The C_p index assumes that the process is centered inside the specification limits, with the average being close to the nominal specification.

- A process average may not always fall in the middle of the specification limits, but the C_p won't show this off-centering.
- We need to use a different index, called "C_{pk}," to show where exactly the distribution is located in relation to the specification limits. Where C_p stood for Process Potential, C_{pk} is defined as Process Capability.

When the process is off-center the C_p shows what the potential improvement would be if the process mean were centered between the USL and LSL.

Process Capability Index, C_{pk}

Instead of using the whole tolerance band, C_{pk} measures centering by comparing the average to the nearest specification limit.

To match this, only half of the distribution, 3σ, is used.

In mathematical terms, this can be shown as:

$$\text{Process Capability, } C_{pk} = \frac{\text{Nearest Spec. Limit} - \mu}{3\sigma}$$

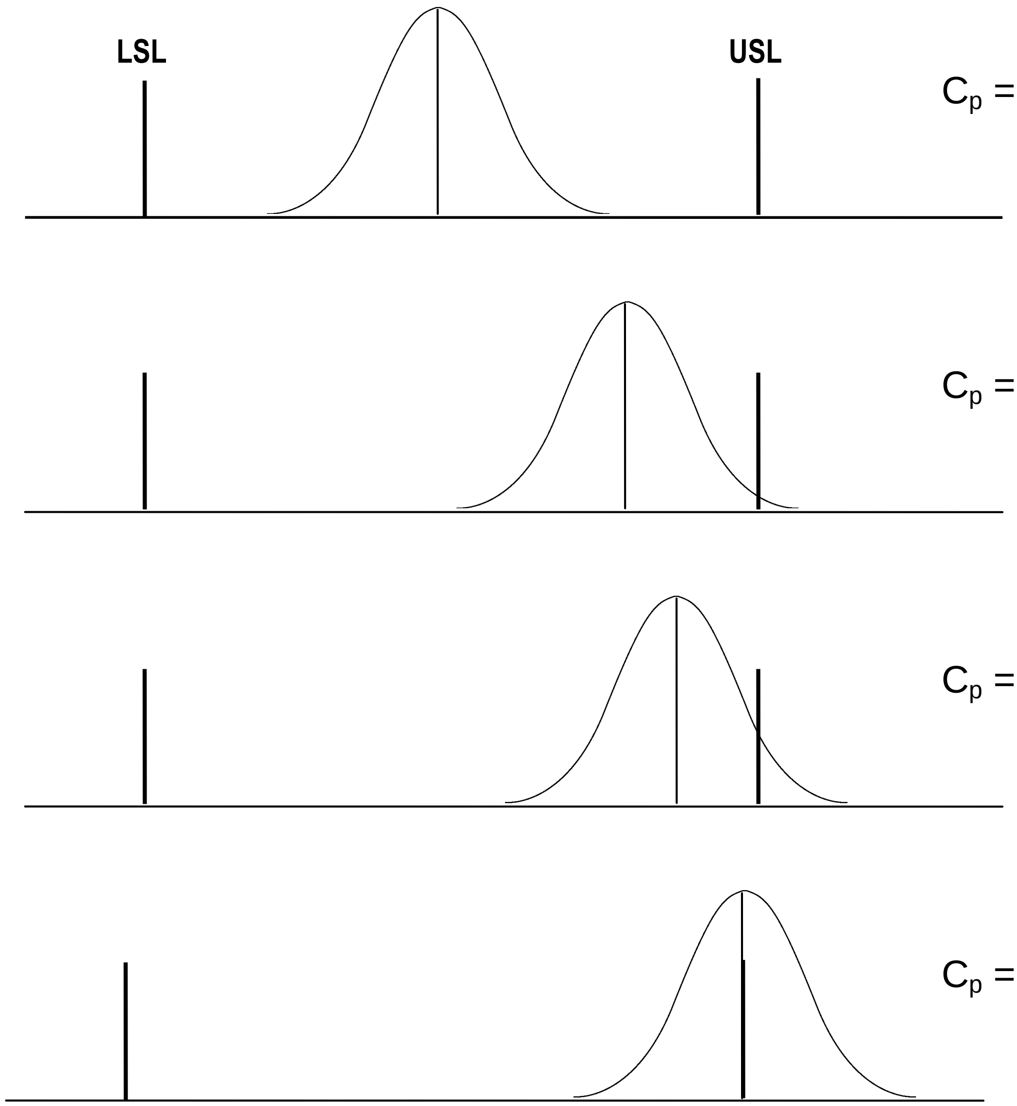
Process Capability Index, C_{pk}

The closest specification limit can usually be determined by looking at the histogram. If not, calculations are performed for both specification limits, and the smaller of the two is used for C_{pk}. These equations look like this:

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

C_{pk} = minimum of C_{pl} and C_{pu}

C_p vs. C_{pk}



POTENTIAL	ACTUAL
$C_p = 1.5$	$C_{pk} = 1.5$
$C_p = 1.5$	$C_{pk} = 1$
$C_p = 1.5$	$C_{pk} < 1$
$C_p = 1.5$	$C_{pk} = 0$

Other Applications of C_{pk}

C_{pk} is also used when:

- The process is not targeted to run in the middle of the upper and lower specifications.
- There is only one specification limit.

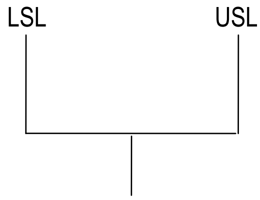
The definitions of capability are the same as for C_p. Again, a $C_{pk} = 1.33$ is generally the minimum number required to claim a process is capable.

DESCRIBING PROCESS CAPABILITY
Worksheet

Instructions

Draw the process distribution described in each scenario below. Decide if C_{pk} is >1, <1, or =1.

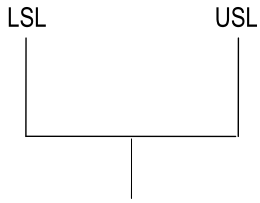
A.



Process is very consistent, but parts are falling outside the upper specification limit.

C_{pk} __________

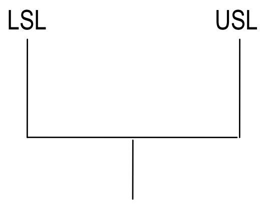
B.



Process is very consistent, yield =100% (no defects), and parts are right on target.

C_{pk} __________

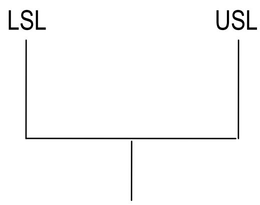
C.



On average, the parts are on target, but consistency is very poor and parts are falling outside both the upper and lower specifications.

C_{pk} __________

D.

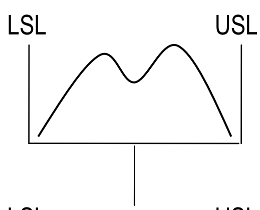


Consistency is poor. Parts are falling outside the lower specification, but staying inside the upper specification.

C_{pk} __________

For scenarios E and F, a process capability study would be invalid—C_{pk} would not really be accurate. Why?

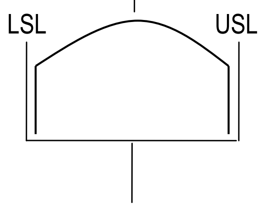
E.



____

____

F.



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____

CALCULATING C_p and C_{pk}

Worksheet

Instructions Using the data provided, calculate C_p and C_{pk}.

Data

USL = 0.60

LSL = 0.54

μ= 0.56

σ = .01

Formulas

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

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

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

C_{pk} = minimum of C_{pu} and C_{pl} = ________________

Designing a Capability Study

Minimum sample size is 30. More is better.

Consider the purpose of the capability study.

- A machine study will attempt to look only at variation coming from the machine to assess whether the equipment itself can meet specifications.
- A process capability study will look at all sources of variation (the "6 M's") to see if the overall process is capable.

As with control charting measurements, gauges used for the in a capability study should be capable.

Machine Capability Study

Performed on a single "machine."

Data collection is short–term to minimize variation from other sources.

- Machine is set up and parts are run consecutively without any adjustment.
- Set up should be static (same raw material lot, operator, environmental conditions, etc.)

For equipment with multiple heads/spindles/tools etc., each "option" must be considered a separate machine for the study.

Length of time for the study will depend on the process. Running for just a couple minutes wouldn't be long enough but running too long would allow other sources of variation to affect the process. Ideally, run as many parts as possible (with consideration of cost) before the machine would need more material, lubricant, etc.

Most important, do not adjust or "tweak" the machine during the study.

Process Capability Study

Also performed on a single "machine."

Data collection is long-term to capture typical variation in the "6 M's."

- Sampling is typically periodic over time, as with control charts.
- Different set–ups, operators, lots, environmental conditions, etc. should be represented.

Using Process Capability

Using the principles of the Normal Distribution and the Process Potential or Process Capability index, we can predict the amount of defects or "fallout" from a process.

- Again, for defect predictions to be valid, the process must be in statistical control—the distribution has to be consistent over time.
- There are times when we want to calculate process capability before the process is under control, for example to set an initial baseline or make a rough prediction.
- The purpose of a process capability study should always be communicated along with the numbers.

Designing a Capability Study
Worksheet

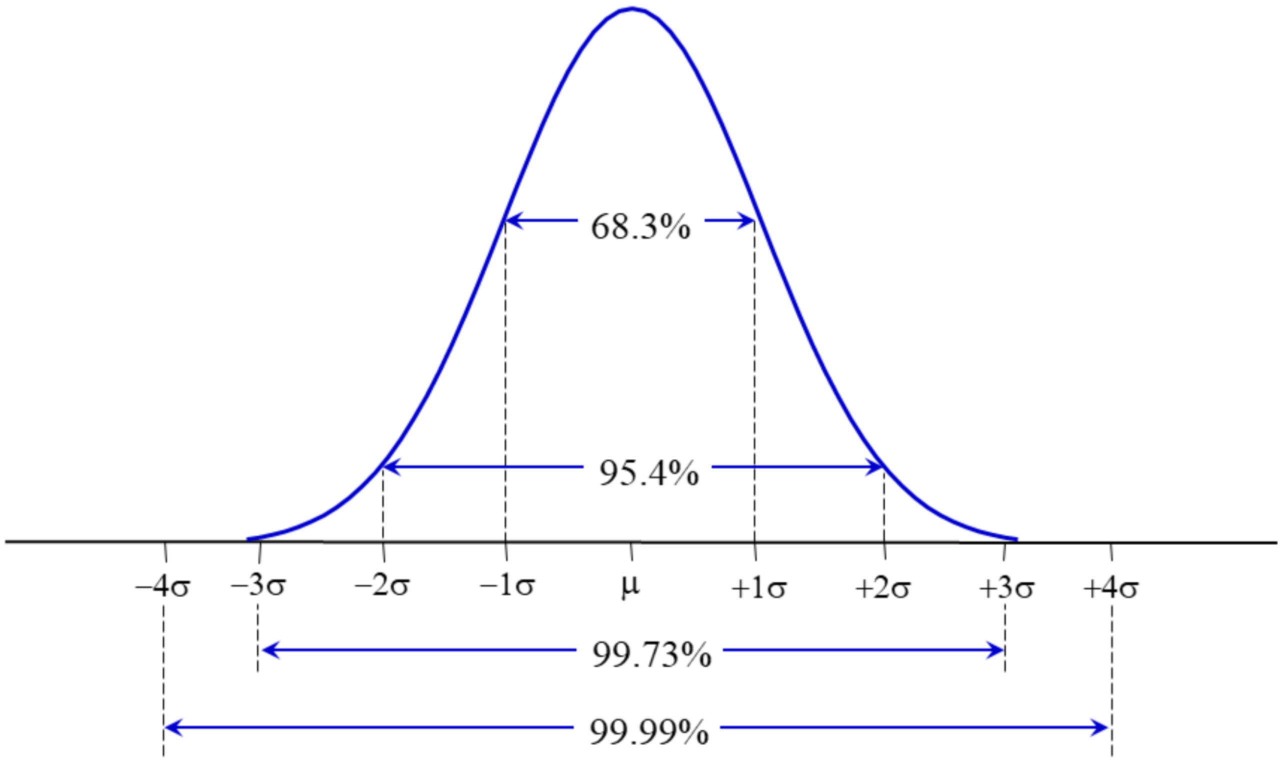
Instructions

Design a Capability Study for a process in your area of responsibility; choose a focus of either Machine or Process.

Address the following Elements

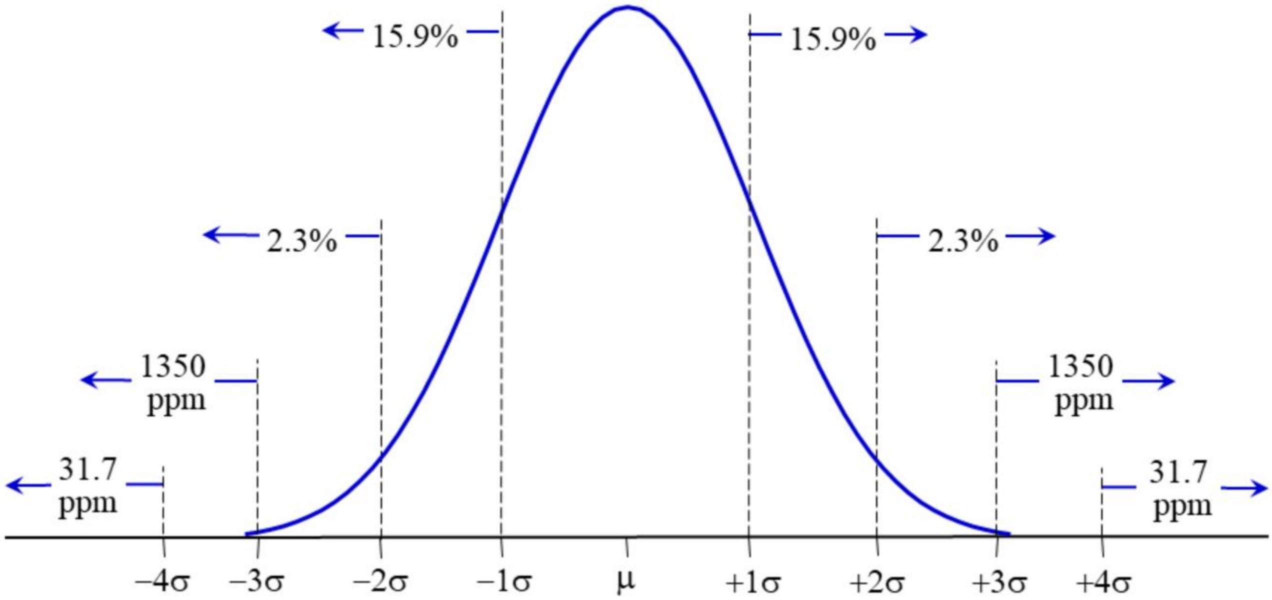
Purpose of Study:	☐ Machine Capability ☐ Process Capability
Name of Machine or Process:	
Variation Sources:	Consider the 6M's of variation and describe key factors of concern related to each source during the Capability Study:
MACHINE:	
MOTHER NATURE (ENVIRONMENT):	
MEMBERS:	
MATERIAL:	
MEMBERS:	
MEASUREMENT:	
Sampling & Set-up:	Given the considerations above, describe a sampling and set-up strategy appropriate to the purpose of the study, include the time duration needed in order to collect at least 30 data points, as appropriate to the study purpose:

Area under curve = % of population



Area under curve = % of population

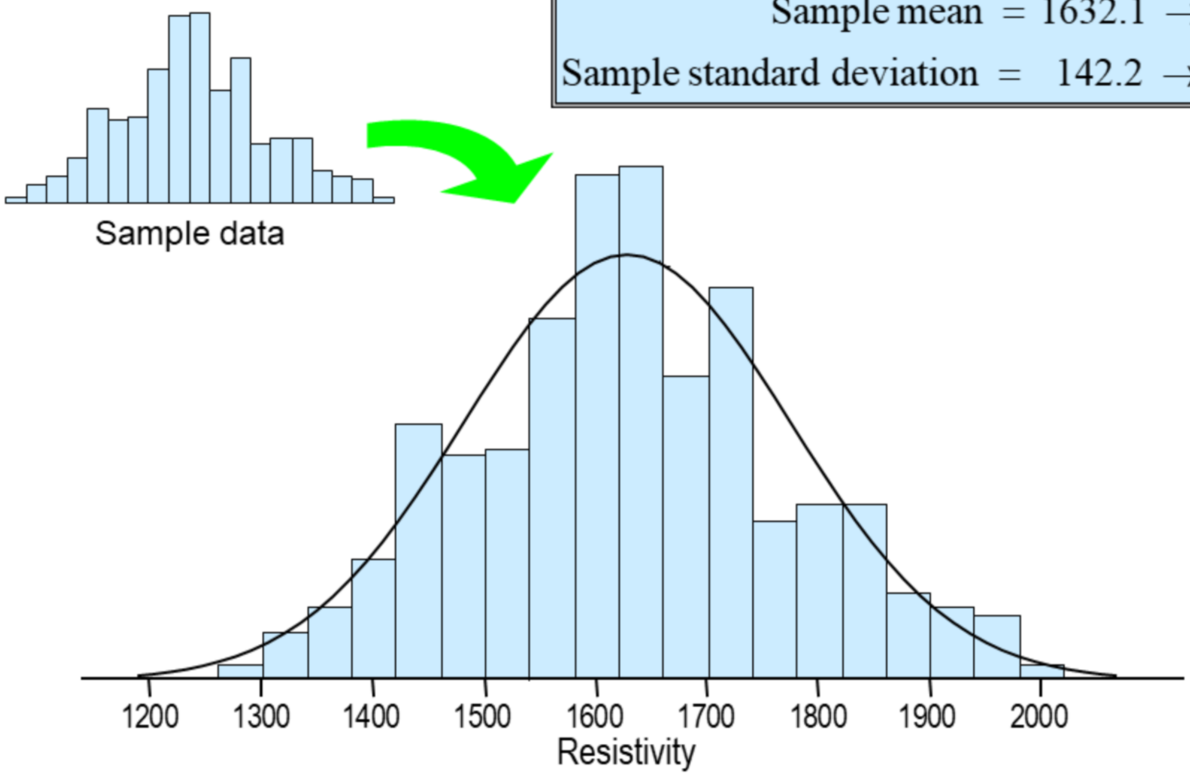
Usually we care mostly about % *beyond* certain points



Fitting the bell curve to data

$$\text{Sample mean} = 1632.1 \rightarrow \mu$$

$$\text{Sample standard deviation} = 142.2 \rightarrow \sigma$$



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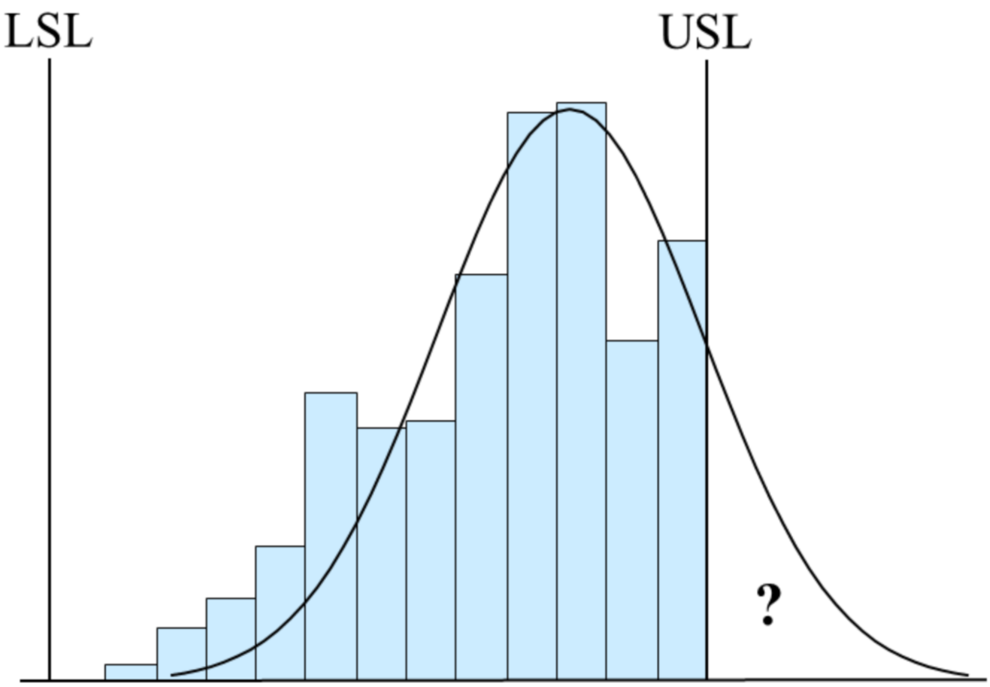
The three–sigma limits contain 99.73% of a Normal population. The three–sigma limits based on a sample mean and standard deviation are predicted to contain 99.73% of future outcomes from the same process. This assumes (a) the variable in question follows a Normal distribution, at least approximately, and (b) there are no significant changes to the process.

The three–sigma limits for the data set shown above contain all the data values. This will not always be the case, even for data on a variable known to follow a Normal distribution. What is true, for most real data sets, is that the percent of values contained by the sample three–sigma limits will be in the high 90's. The theoretical minimum coverage for arbitrary data sets is 89%, but this minimum is approached only in artificially constructed examples.

Why use fitted distributions?



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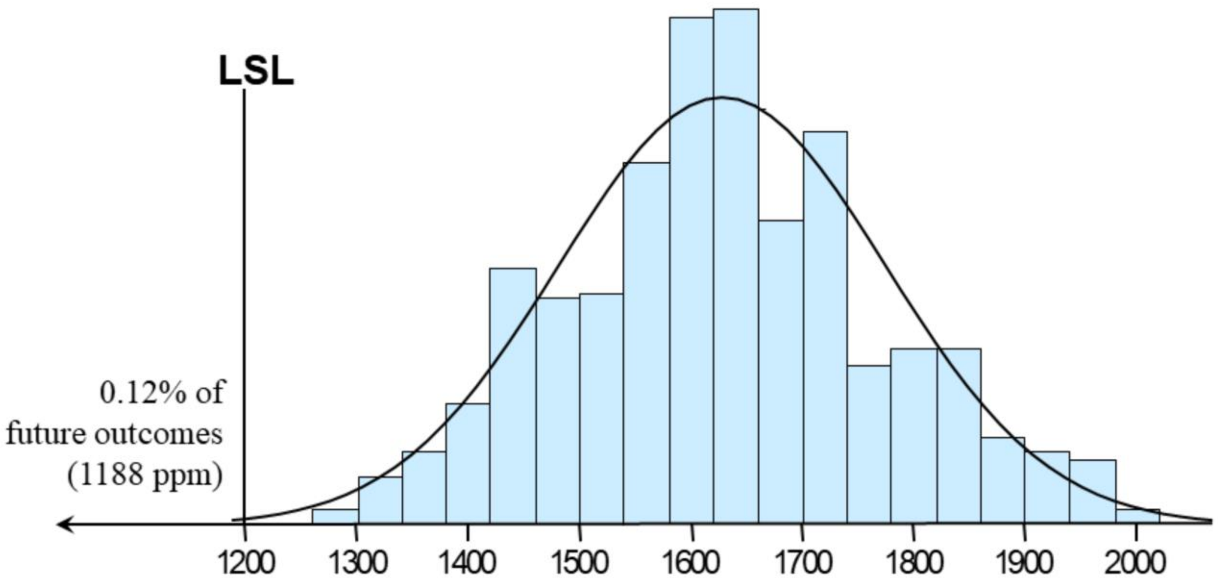
The practice of calculating % or PPM defective by means of fitted distributions instead of raw data came about historically as a crude but effective way for customers in the aerospace and automotive supply chains to expose the "hidden factories" of their suppliers. Suppliers would present final inspection data to customers to document their process capability. In the example shown above, the supplier claims 100% yield. When plotted as a histogram, the data mysteriously disappears right at the upper spec limit. This is because parts exceeding the upper limit are either scrapped or reworked to the limit. Often the rework is done by the inspector and not recorded as rework. In either case, the first–pass data is not recorded.

A distribution curve pays no attention to spec limits and will always produce a positive value for % or PPM defective. This gives a crude estimate of the supplier's first–pass yield. In the example shown above, it is obvious that the first–pass yield is far below 100%.

Process capability using the Normal curve

Allows extrapolation ( )



The problem with extrapolating defect predictions from a fitted curve occurs when the curve does not represent the actual distribution. A few possible scenarios:

- The sampling used to gather the data did not take into account all typical sources of variation (e.g., not a long enough time span, data from only one lot/operator/shift, etc.) .
- The process is not stable.
- The true distribution is Non–Normal, as may be found when a characteristic has a physical boundary. (Some statistical software allows a user to choose a different distribution model, such as Weibull, on which to base the capability predictions.)

Predicting Defects

C_p, C_{pk} Value	C_p Fallout (centered)	C_{pk} Fallout* (not centered)
.5	133,620 PPM	66,810 PPM
.6	71,860	35,930
.7	35,720	17,860
.8	16,400	8,200
.9	6,940	3,470
1.0	2,700	1,350
1.1	966	483
1.2	318	159
1.3	96	48
1.33	66	33
1.4	26	13
1.5	7	3
1.6	2	800 PPB
1.7	340 PPB	170
1.8	60	30
1.9	12	6
2.0	2	1

PPM = Parts Per Million
PPB = Parts Per Billion
Note: 1% = 10,000 PPM

*C_{pk} fallout is just for the closest specification limit (i.e., worst case scenario)

Using Excel: % below 1200

calculator - Normal distribution

1. Enter the quantities in the YELLOW cells.
2. The other values are calculated for you.

LSL	1200
Mean	1632.1
Standard deviation	142.2
Population % below LSL	0.119
Population PPM below LSL	1188.1

USL	
Mean	
Standard deviation	
Population % above USL	#VALUE!
Population PPM above USL	#VALUE!

Using Excel: % above 2000

1. Enter the quantities in the YELLOW cells.
2. The other values are calculated for you.

LSL	
Mean	
Standard deviation	
Population % below LSL	#VALUE!
Population PPM below LSL	#VALUE!

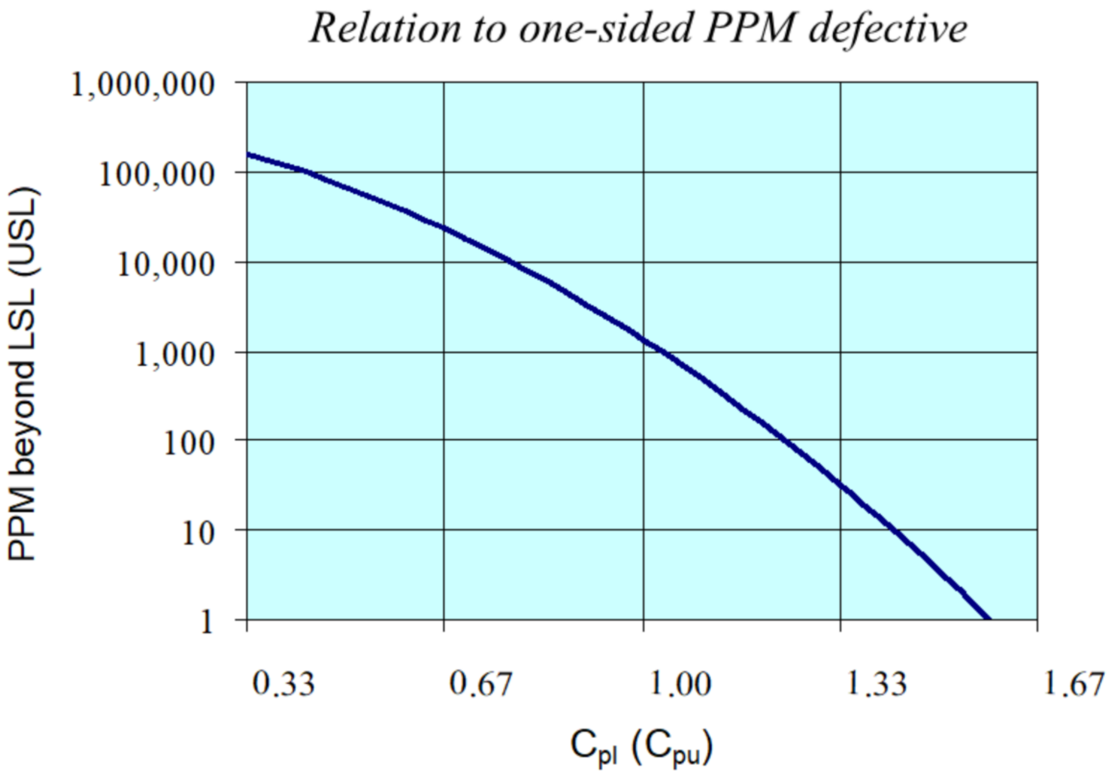
USL	2000
Mean	1632.1
Standard deviation	142.2
Population % above USL	0.484
Population PPM above USL	4838.0

These calculations can be sensitive to round-off error. Don't round off the mean and standard deviation when you enter them into the calculator. The best thing to do is copy them from a basic statistical summary, then use *Paste Special* → *Values*.

1. Open *Data sets for exercises \ solution properties*. Find the mean and standard deviation of *Spec grav*, then use the Normal distribution calculator to find the % or PPM for which *Spec grav* is greater than 0.925. Save your work.

2. Open *Data sets for exercises \ ER patient visits*. Find the mean and standard deviation of *Visits*, then use the Normal distribution calculator to find the % or PPM for which *Visits* is either less than 2700 or greater than 3300. Save your work

Alternative calculation of Cpl and Cpu



Using Excel: *calculator* - C_{pk}

1. Enter the known quantity in one of the yellow cells.
2. The other two equivalent values are calculated for you.

% Below LSL	PPM below LSL	C_{pl}
	#VALUE!	#VALUE!
#VALUE!		#VALUE!
#VALUE!	#VALUE!	

% Above USL	PPM above USL	C_{pu}
	#VALUE!	#VALUE!
#VALUE!		#VALUE!
#VALUE!	#VALUE!	

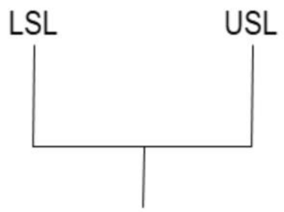
3. C_{pk} is the smaller of C_{pl} and C_{pu}.

Try this calculator with numbers from the previous exercises.

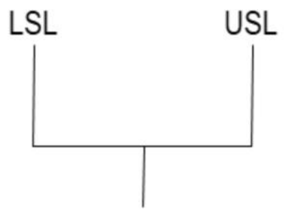
When data is not normally distributed (for example, when a characteristic has a physical boundary like zero), some statistical software packages will offer the choice of other distributions (e.g., the Weibull distribution) to use for Process Capability calculations.

Taking Action

Once we have a number for process capability, we need to take appropriate action.



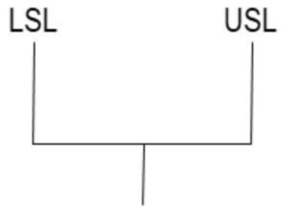
1. If the process is *in control* and *in specification*, no further action is required unless we want to increase the capability. An ideal goal is a capability of 2, since two defective parts per billion is essentially the same as zero defects.



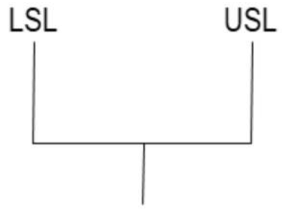
2. If the process is *in control* but *out of specification*, further work is required (usually by Engineering and Management). The design of the product and/or process needs to change. For example, an older machine may be consistent, but cannot hold tight enough tolerances.

For each scenario above, sketch what the distribution vs. the specification "goalposts" would look like.

Taking Action



3. If the process is *out of control* and *out of specification*, assignable causes of variation need to be eliminated. Once the process is in control, another capability study needs to be performed.



4. There may be a case when a process is *out of statistical control* but *in specification*—this can happen when the tolerance band is unusually wide.

In all cases, the costs, risks, and benefits of possible actions must be considered. The goal of a SPC program is to establish a controlled and capable process, at a cost which allows the organization to stay in business!

For each scenario above, sketch what the distribution vs. the specification "goalposts" would look like.

Benefits of a Capable Process

Highly capable processes give an organization many advantages. Having a guarantee of zero defects means:

- Automated assembly processes will run smoothly.
- Tolerance stack–up is minimized.
- Final inspections can be reduced or eliminated.
- Just–In–Time production methods can be used.
- Scrap and rework costs are minimized.
- Throughput is improved.
- Customers are satisfied!

What would be the advantages if your processes were highly capable?

There is a risk to be considered when working to increase Process Capability Indices — suboptimization.

Let us recall the "Supplier-Process-Customer Chain" in the module, *Defining the Process*. Understanding a process in terms of its relation to the whole system, (i.e., the overall manufacturing/assembly/fabrication/service flow) is key to avoiding the risk of optimizing one process or output parameter to the detriment of others, especially those that are critical to product functionality, safety &/or reliability. Suboptimization can happen in terms of both effectiveness and efficiency.

Using Control Charts for Variables

Learning Objectives

By the end of this section, participants will be able to:

- ☑ Plot a run chart.
- ☑ Describe the different types of control charts used for variable data and their applications:
  - Average and Range — X-bar and R
  - Average and Standard Deviation — X-bar and s
  - Individual and Moving Range — IX and MR
- ☑ Describe the "Central Limit" effect as it relates to control limit calculation.
- ☑ Apply the concept of short-term vs. long-term standard deviation to control limit calculation.
- ☑ Plot control charts for variables data.
- ☑ Calculate control limits for variables charts.

Why Use Control Charts

We can use histograms to look at the history of the process, but we also need a way to look at the process in real time.

- Control charts help us track changes in the process as it is running.
- Control limits are used to show whether the process is in or out of control.
- Process owners can make good decisions on whether or not to take corrective action.

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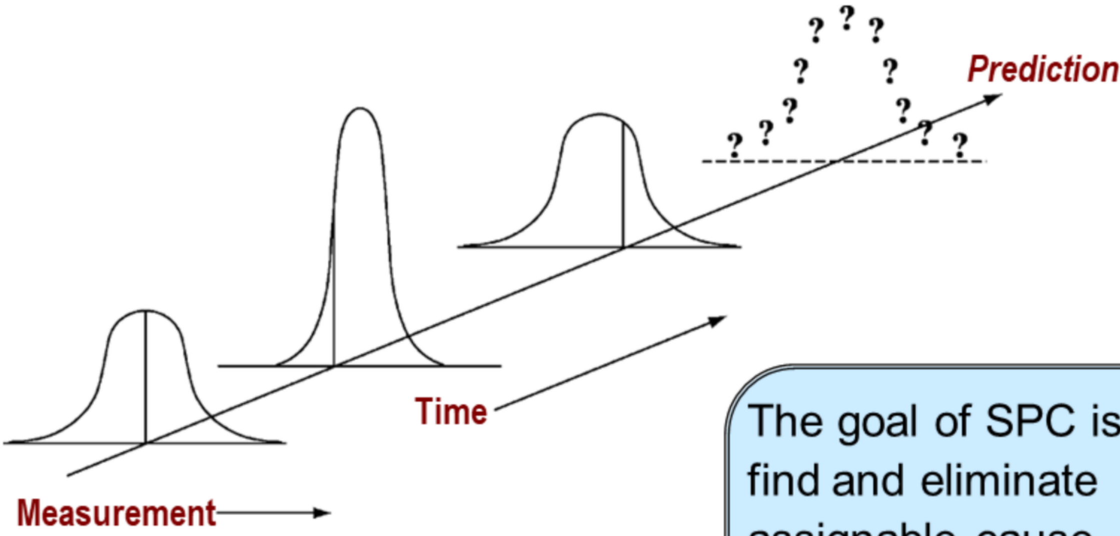
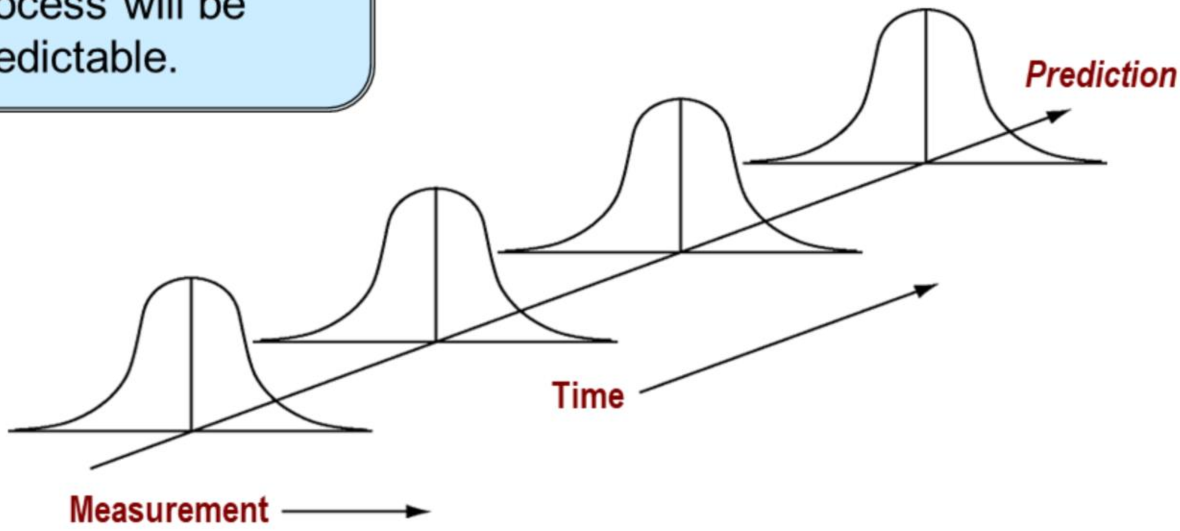
Assignable Cause Distributions



The goal of SPC is to find and eliminate assignable cause variation, so the process can operate in control.

Common Cause Distributions

With only common cause variation, the process will be predictable.



Variable Data

We learned earlier that there are two types of data—variable and attribute. Variable data are measured; attribute data are counted or pass/fail.

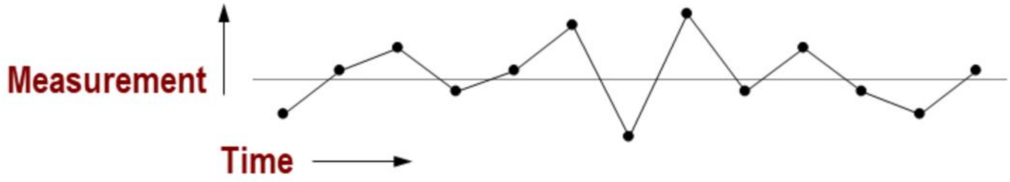
Different types of control charts are used for variable data than for attribute data.

Variables control charts will typically be used for processes that are Setup and/or Time Dominant.

There are several types of variable data control charts.

Using the Run Chart

The simplest kind of variable data chart is a *Run Chart*. Data points are plotted over time, and show the pattern of variation.



As with all the charts we will use in this module, measurement is shown on the vertical scale, and time is shown on the horizontal scale.

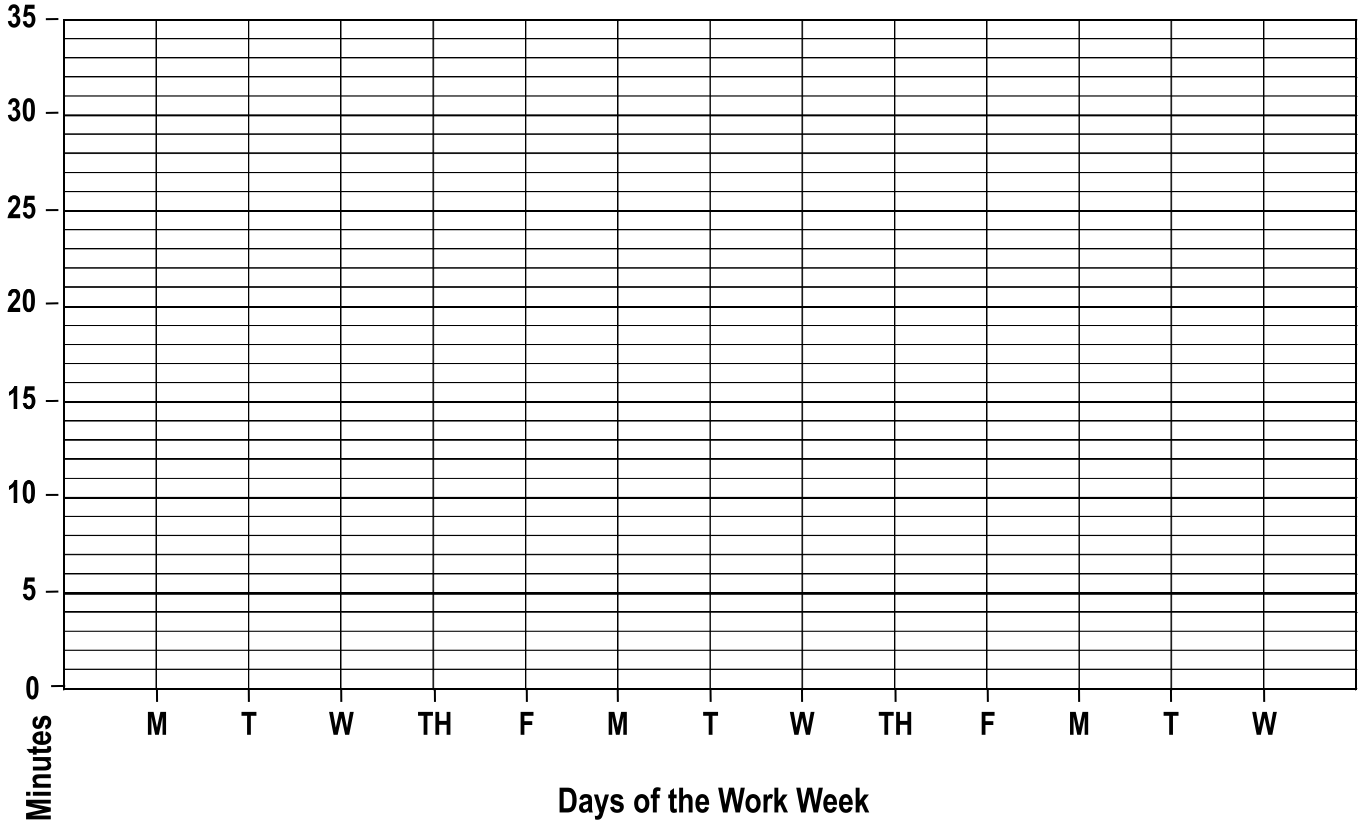
CREATING A RUN CHART
Worksheet

Instructions

Let's say the data below represents your commute time to work in minutes:

	M	T	W	TH	F
Week 1	15	25	27	18	22
Week 2	28	9	19	21	11
Week 3	30	14	21		

Plot the commute times on the run chart form below:



What might cause your commute times to change from day to day?

Looking at your run chart, can you tell whether the points happened due to assignable or common causes?

Run Chart

A run chart can only show the data points over time. It does not give any information on what kind of variation is present.

- For this reason, run charts are used when we want to see general trends, but don't need detailed information on variation type.
- Typical uses are for tracking non–manufacturing business processes like: Monthly Sales, Number of Customer Orders, Engineering Change Orders per Week, Overtime Hours per Week, etc.

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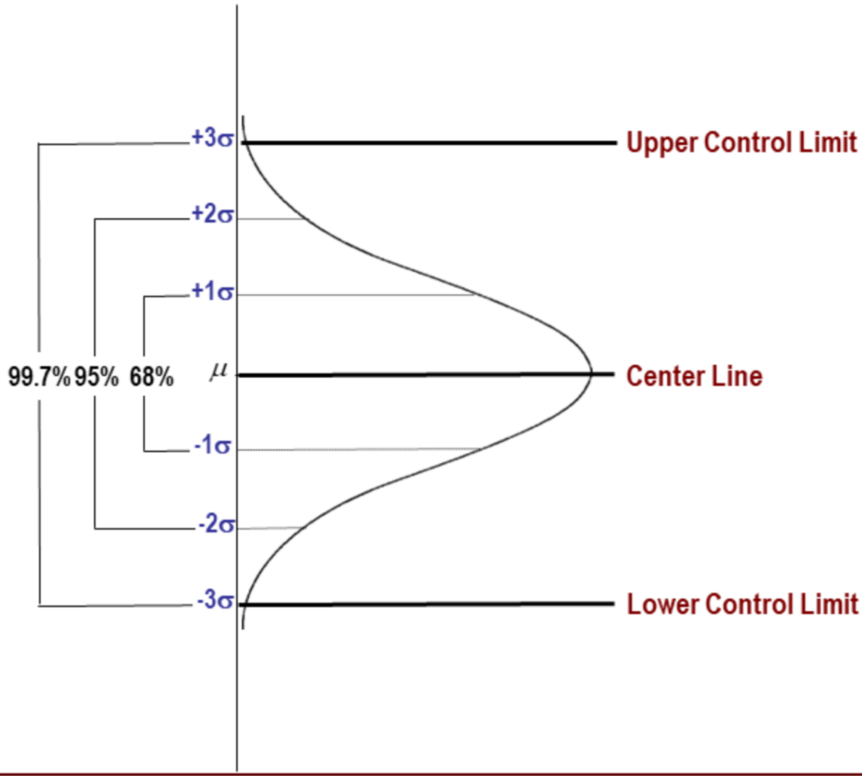
What do run charts get used for in your area, and/or the organization?

How might knowing what kind of variation is present be helpful in the types of business process applications above?

Describing Control Charts



To get information on what type of variation is occurring in a process, we need to use the Normal Distribution.

If we tip the Normal Distribution on its side, we can see how to draw a control chart.

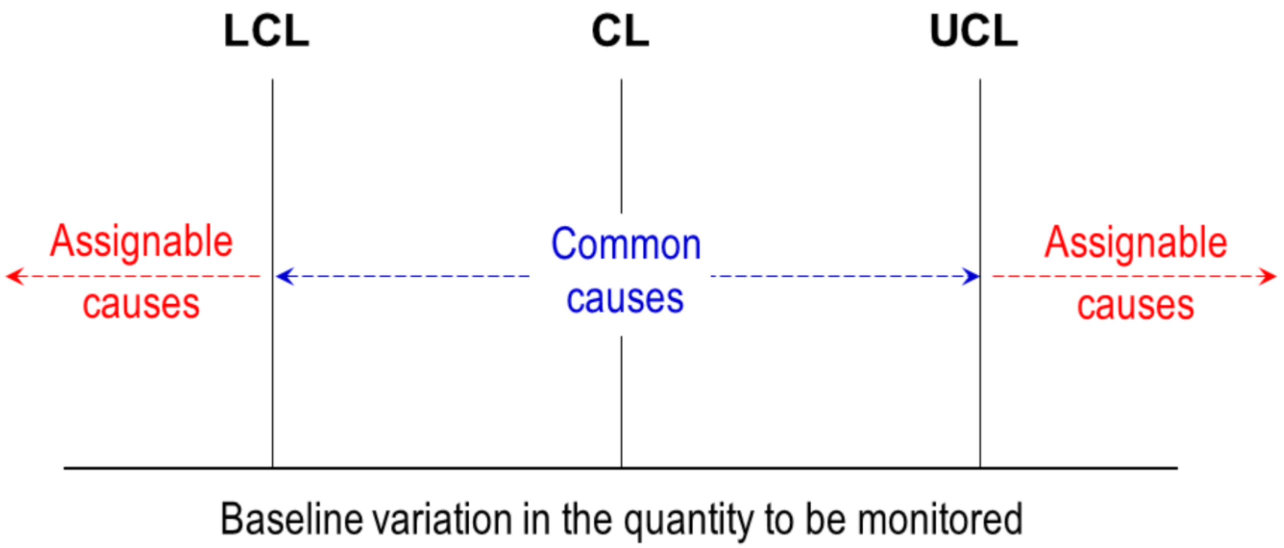
Describing Control Charts

The control limits are drawn at the center of the distribution (the average), and at ± 3 standard deviations.

- Based on what we know about the Normal distribution, if the process is operating *normally*, 99.7% of the data will fall inside ±3 standard deviations.
- Any data that falls outside these limits will be due to assignable cause variation.
- Control limits are *not* the same as specification limits.

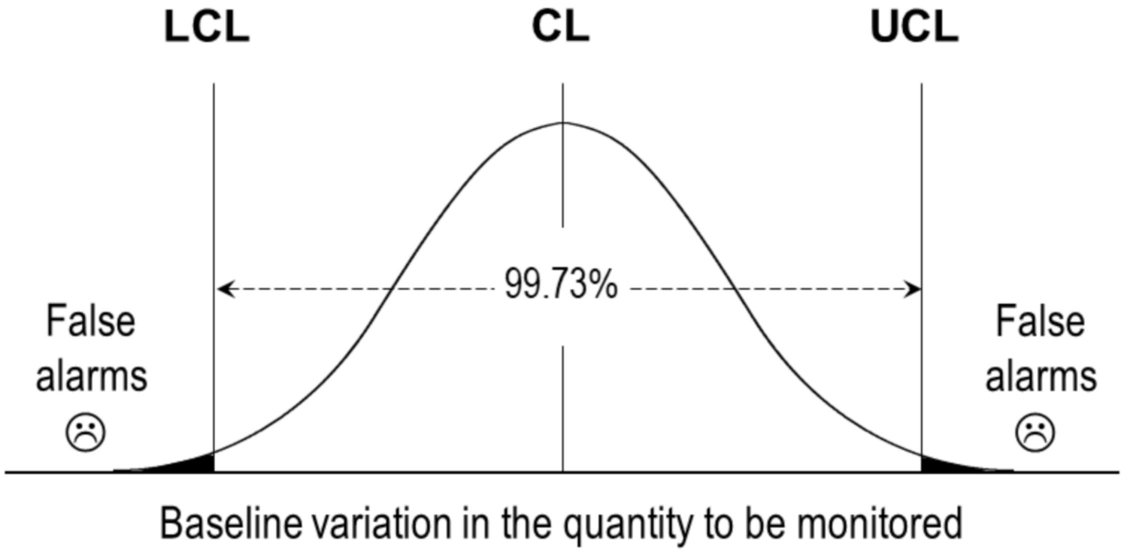
Describing Control Charts

Control limits provide an *operational definition* of common cause variation

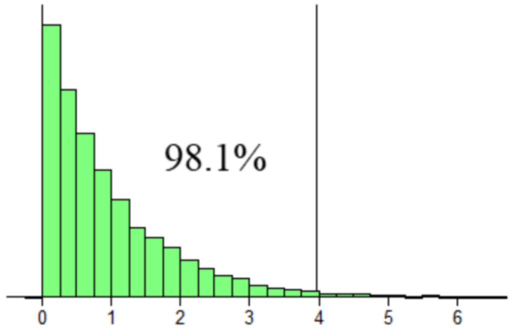


Describing Control Charts

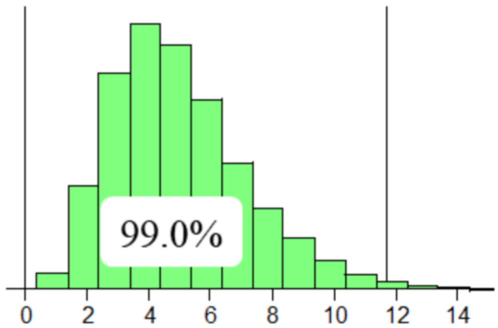
If the quantity to be monitored follows a Normal distribution, the chance of a *false alarm* is 0.27%

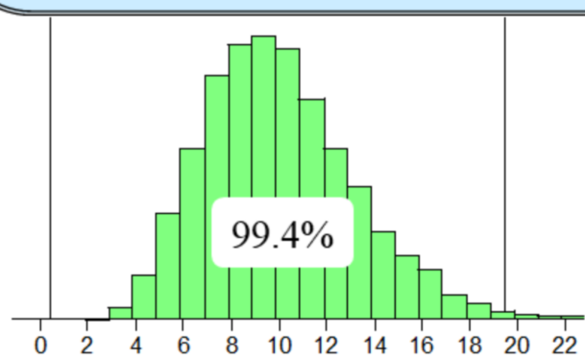


Common Cause Variation



- Control limits at $\pm$ 3 standard deviations are shown for these non-Normal distributions
- We do not need to assume a Normal distribution
- These control limits are an economic compromise between *false alarms* and *missed signals*





Using Control Charts

With variables control charts, we pull samples from the process and use them to estimate how the process as a whole is performing. We can then answer two questions:

1. Is the process staying centered?
2. Is the process staying consistent?

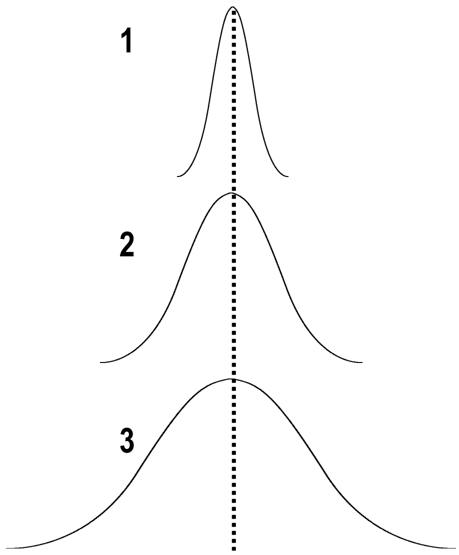
An important assumption for control charts is that the samples are statistically independent.

What statistic have we used to describe the center of the data set?

For the consistency?

Variables Control Charts

SCENARIO A



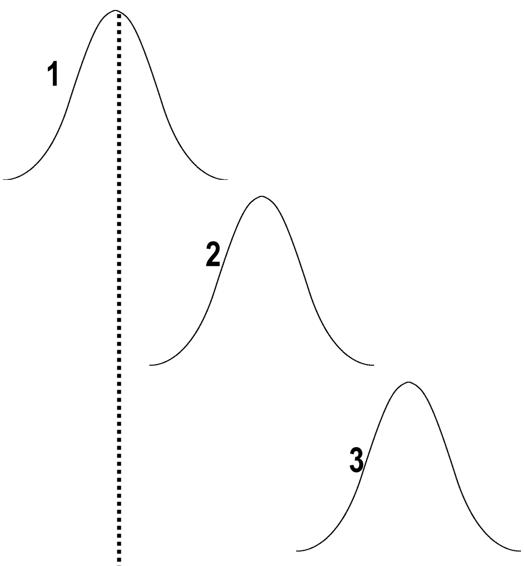
The centering is ____________________

____

The consistency is __________________

____

SCENARIO B



The centering is ____________________

____

The consistency is __________________

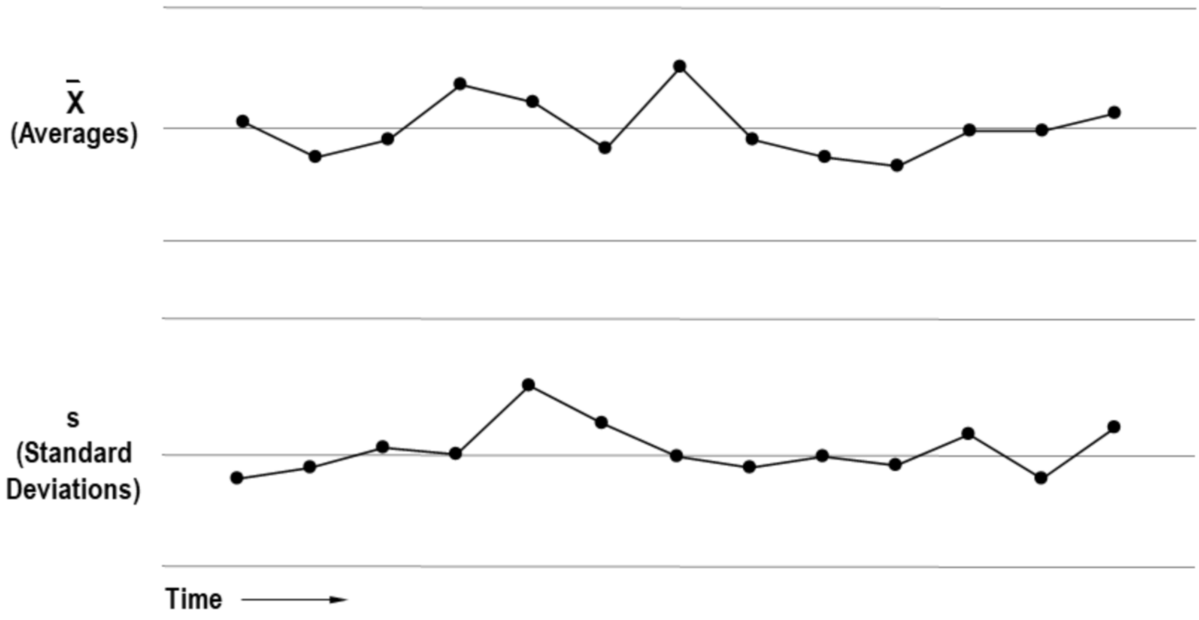
____

Variables Control Charts

Because we need two *statistics* (average and range/standard deviation) to answer our questions, variables control charts have two graphs:

- The first is a plot of averages (or individuals), showing whether the process is staying centered from sample to sample (long–term variation).
- The second is a plot of range or standard deviation for each sample, showing the amount of spread (consistency) within the sample (short–term variation).
- Each graph will have its own set of control limits, based on what's "normal" for that statistic.

Example: X-bar and s Chart



Establishing a Baseline

Data will need to be collected in order to determine the typical variation seen in a process. Some guidelines:

- Gather at least 25 samples from the process.
- Use sound data collection and sampling principles.
- Determine whether historical data is available and can be used.
- Sample over a long enough period of time to see typical variation, but not too long.

Remember to apply the measurement and sampling concepts discussed in the module 'Measuring the Process.'

Variables Control Charts

Control Charts	Statistics Plotted	Sample Size	Description
X-bar & R	Average & Range	2–5	The X-bar and R chart was the first and most common variables control chart used in SPC, only because in the days before calculators and statistical software, Range was easier to calculate than Standard Deviation. The X-bar and R chart can be useful for monitoring product, process or environmental characteristics when the sample size is fairly small (say 5 or less). But given the prevalence of software tools available, it should really be replaced by the X-bar and s chart unless there is a particular need for spotting "outlier" range values.
X-bar & s	Average & Standard Deviation	5–15	The X-bar and s chart is useful for monitoring product, process or environmental characteristics, especially when the sample size is larger (say, more than 5). Again, the standard deviation chart will be more robust than range because all data are used, not just the highest and lowest numbers.
IX & MR	Individual & Moving Range	1	The IX and MR chart is used when the sample size is one. A single sample may need to be taken because: • It is expensive to take samples. • The measurement method is destructive. • It is the only sample size that makes sense for that process. Because an average cannot be calculated for a sample size of one, the individual data points are used. When there is only one number, standard deviation and range cannot be calculated. Instead, we use what is called the *Moving Range*.

The only difference in the several types of variables control charts is in which statistics are used.

We'll discuss another application of the IX chart for attributes charts in the next section.

Plotting the Points

As each process sample is taken, the "centering" statistic (X–bar or IX) is calculated and plotted on the top chart.

The "consistency" statistic (s, R, MR) is also calculated for each sample and plotted on the bottom chart.

There may be times when only the "centering" chart is used, e.g., for business process/project monitoring. (Remember the earlier question about using control charts for business applications where typically run charts are used?) In a classic manufacturing sense, it's best to look at both charts since they give important information about the type of adjustment needed for the process. For example, whether a piece of equipment is staying both centered and consistent.

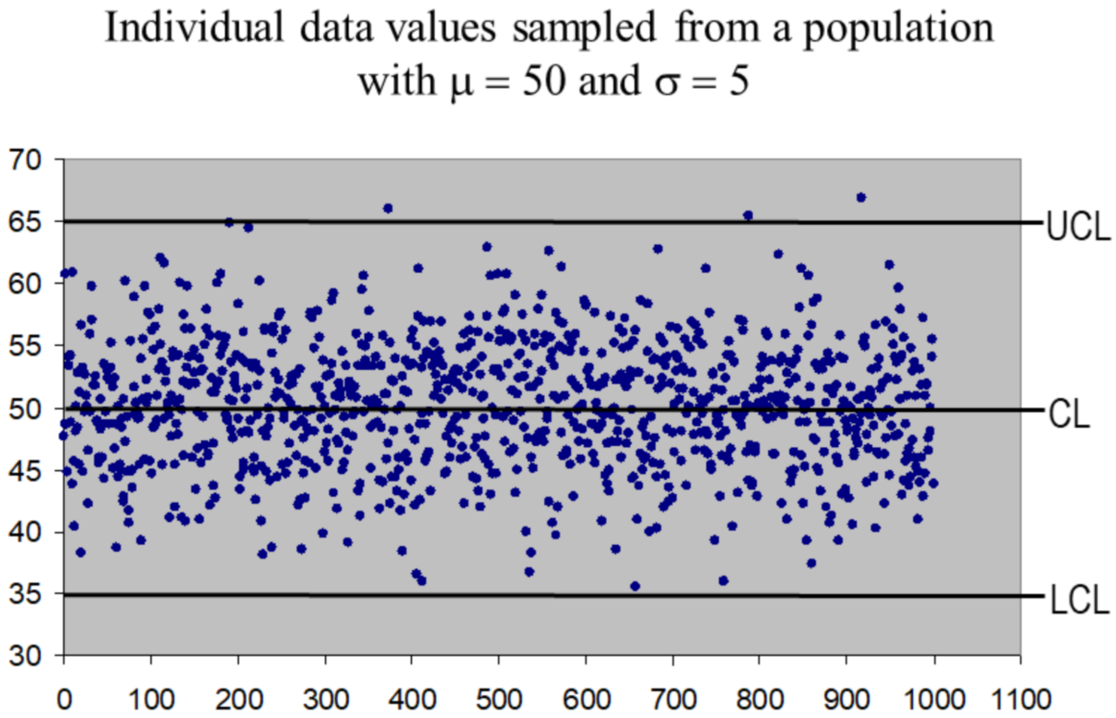
Calculating the Control Limits

Once enough historical/baseline data has been gathered, (usually at least 25 samples), we can calculate the control limits.

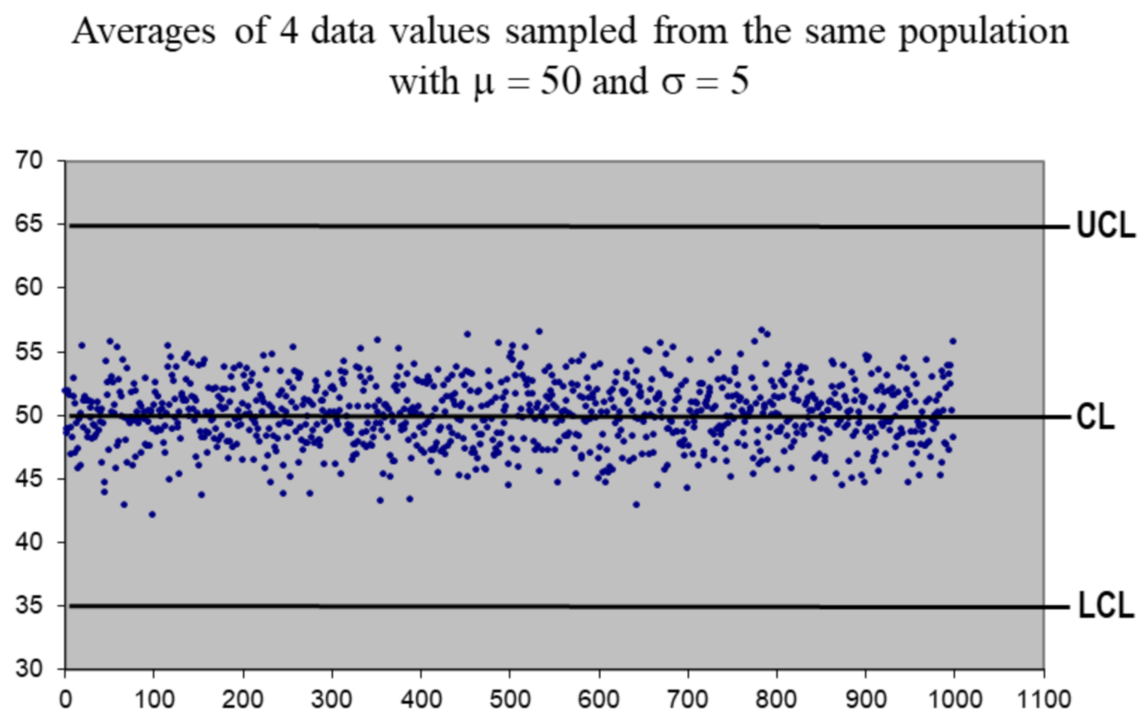
As we've seen, each graph has three control limits based on the statistic being plotted:

- The line drawn in the middle shows where the statistic is centered, and is called the Center Line (CL).
- The Upper Control Limit (UCL) is drawn at +3 standard deviations from the Center Line.
- The Lower Control Limit (LCL) is drawn at -3 standard deviations from the Center Line.

Behavior of Averages: The "Central Limit" Effect



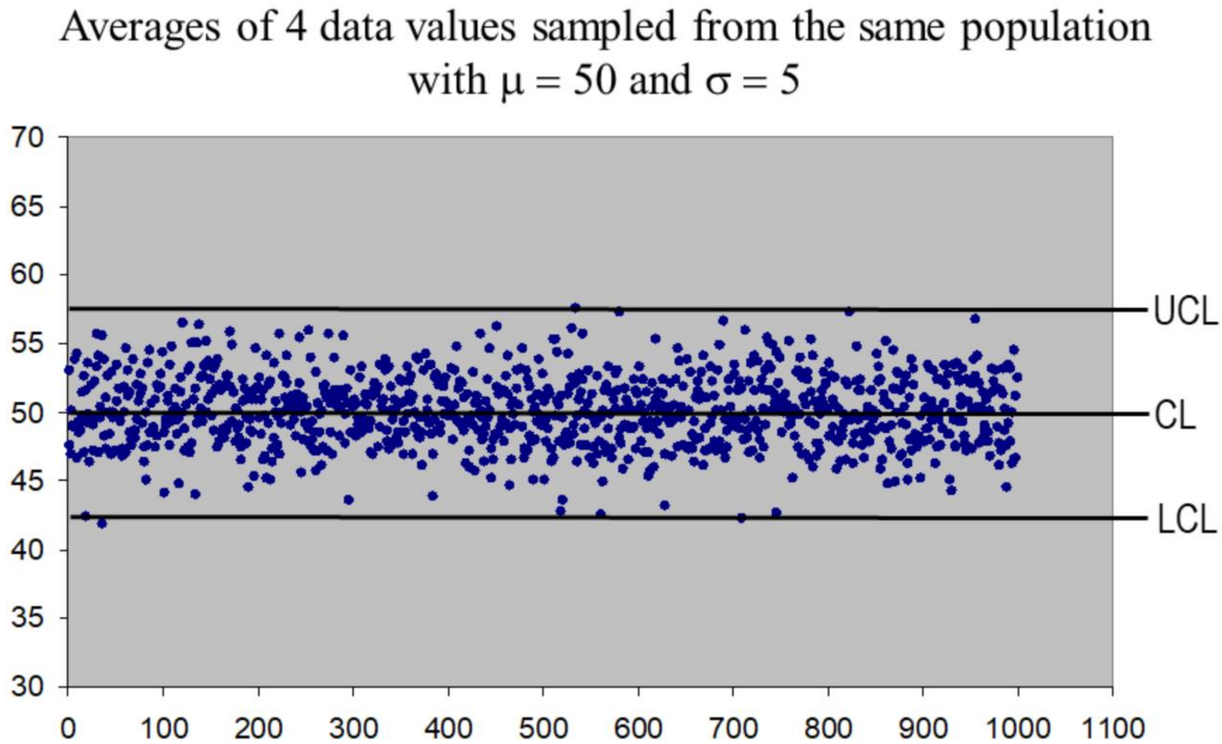
The "Central Limit" Effect



Why would the limits shown above (from the Individual data values) be ineffective for statistical monitoring of the averages?

Control limits for a distribution of averages must be calculated a different way.

The "Central Limit" Effect



These are the true control limits for the averages.

In addition to the obvious narrowing of the distribution, the Central Limit Theorem (stated simply), concludes that subgroup averages converge to a Normal distribution, even if the underlying distribution is non-Normal.

The Standard Deviation of Averages

If you repeatedly sample sets of N individual data values from a population with mean μ and standard deviation σ, and calculate the average in each case, the *standard deviation of the averages* is:

$$\frac{\sigma}{\sqrt{N}}$$

We're using official "Statistics Speak" here: *mean* is calculated the same way as mathematical average.

Control Limits for Averages

If you repeatedly sample sets of N individual data values from a population with mean μ and standard deviation σ, and calculate the average in each case, the *three-sigma limits for the averages* are:

$$\text{UCL} = \mu + 3\frac{\sigma}{\sqrt{\text{N}}}$$

$$\text{LCL} = \mu - 3\frac{\sigma}{\sqrt{\text{N}}}$$

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Control Limits for X–bar and s Charts

Metric to monitor	*Statistic(s) needed*	*Control limits*
Average	Average (μ) Standard deviation (σ)	$UCL = \mu + 3\frac{\sigma}{\sqrt{N}}$ $CL = \mu$ $LCL = \mu - 3\frac{\sigma}{\sqrt{N}}$
Standard deviation	Standard deviation (σ)	$UCL = \bar{\sigma} + 3\frac{\sigma}{\sqrt{2(N-1)}}$ $CL = \bar{\sigma}$ $LCL = \bar{\sigma} - 3\frac{\sigma}{\sqrt{2(N-1)}}$

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N = sample subgroup size during baseline monitoring period (if quantities differ slightly, their average can be used)

UCL = Upper Control Limit

CL = Center Line

LCL = Lower Control Limit

μ and σ are the estimates of the *population* average and standard deviation, which we calculate from the baseline data.

For monitoring averages and standard deviations, a negative value of LCL is meaningless; use LCL = 0 in this case.

Control Limits for X–bar and R Charts

Metric to monitor	*Statistic(s) needed*	*Control limits*
Average	Grand Average (μ, estimated by $\overline{\overline{X}}$) Average Range ($\overline{R}$)	$UCL = \overline{\overline{x}} + A_2\overline{R}$ $CL = \overline{\overline{x}}$ $LCL = \overline{\overline{x}} - A_2\overline{R}$
Range	Average Range ($\overline{R}$)	$UCL = \overline{R}D_4$ $CL = \overline{R}$ $LCL = \overline{R}D_3$

Since a range is being used to estimate the standard deviation of the population, mathematical constants are used to adjust for this fact and are dependent on the sample size of the subgroups used. See next page for a table of these constants.

UCL = Upper Control Limit

CL = Center Line

LCL = Lower Control Limit

The "Grand Average" is the average of all the subgroup averages, which is mathematically equivalent to averaging all the individual values. Without software, this latter calculation was too time consuming.

As with the X-bar and s chart, a negative value of LCL is meaningless; use LCL = 0 in this case.

Constants used with Control Limits

Constants for sample size n

n	A_2	D_3	D_4	d_2
2	1.880	0.000	3.267	1.128
3	1.023	0.000	2.574	1.693
4	0.729	0.000	2.282	2.059
5	0.577	0.000	2.114	2.326
6	0.483	0.000	2.004	2.534
7	0.419	0.076	1.924	2.704
8	0.373	0.136	1.864	2.847
9	0.377	0.184	1.816	2.97
10	0.308	0.223	1.777	3.078

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n = sample subgroup size during baseline monitoring period (if quantities differ slightly, an average can be used)

Using the $\bar{X}$ AND s CHART
Worksheet

Instructions

We want to use X-bar and s control charts to monitor a critical dimension, diameter, of the parts we are producing.

Use Excel formulas for the following:

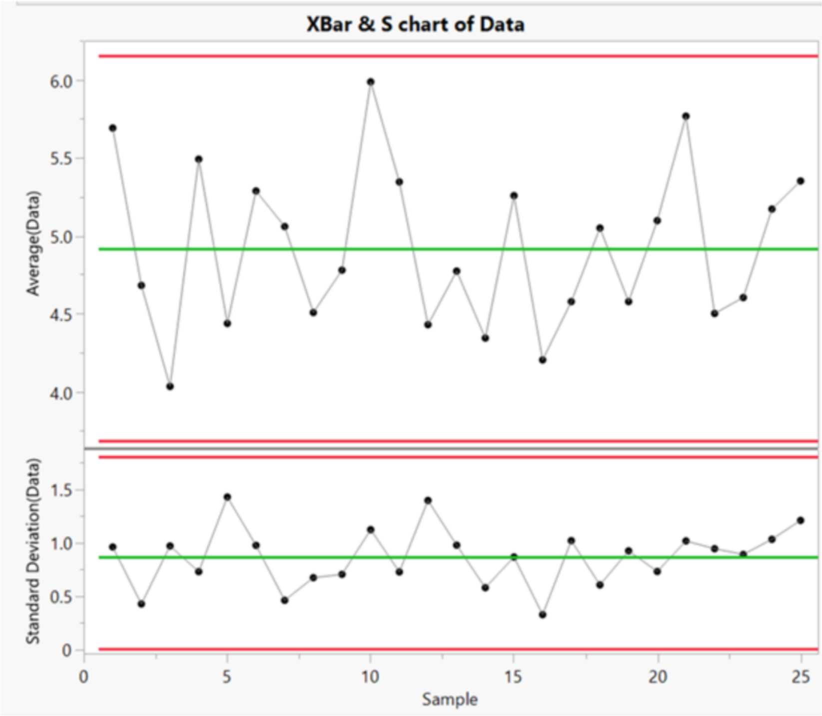
1. Open Data sets for exercises \ diameter. Does the baseline data appear to be adequate to represent process variation?
2. Calculate the average (X-bar) and standard deviation (s) for each subgroup of five parts.
3. Calculate the overall average, which will be the center line (CL) of the X-bar chart.

   There are two ways to do so: take the average of all the data points or take the average of the subgroup averages.

   The name given to the statistic from the second method is X-double bar (a second line is added over X-bar) or the Grand Average.
4. Calculate the average of the subgroup standard deviations, (s-bar), which will be the Center Line (CL) for the standard deviation chart.
5. The estimates of the standard deviation of the distribution of averages and the distribution of standard deviations have been calculated for you. They are used in the "3-sigma" quantities that are added to and subtracted from the Center Lines.
6. Use the numbers found above to calculate the upper and lower control limits for each chart.

$UCL_{\bar{x}} =$	$UCL_s =$
$CL_{\bar{x}} =$	$CL_s =$
$LCL_{\bar{x}} =$	$LCL_s =$

X–bar and s Chart for Diameter



This chart was created in JMP, a statistical software package. For learning purposes, we are looking at the various control limit formulas to aid in understanding the concepts of control charting.

In practice, statistical software will be doing the calculation work for you. However, understanding the statistical concepts behind these calculations is critical to creating accurate and appropriate digital control charts.

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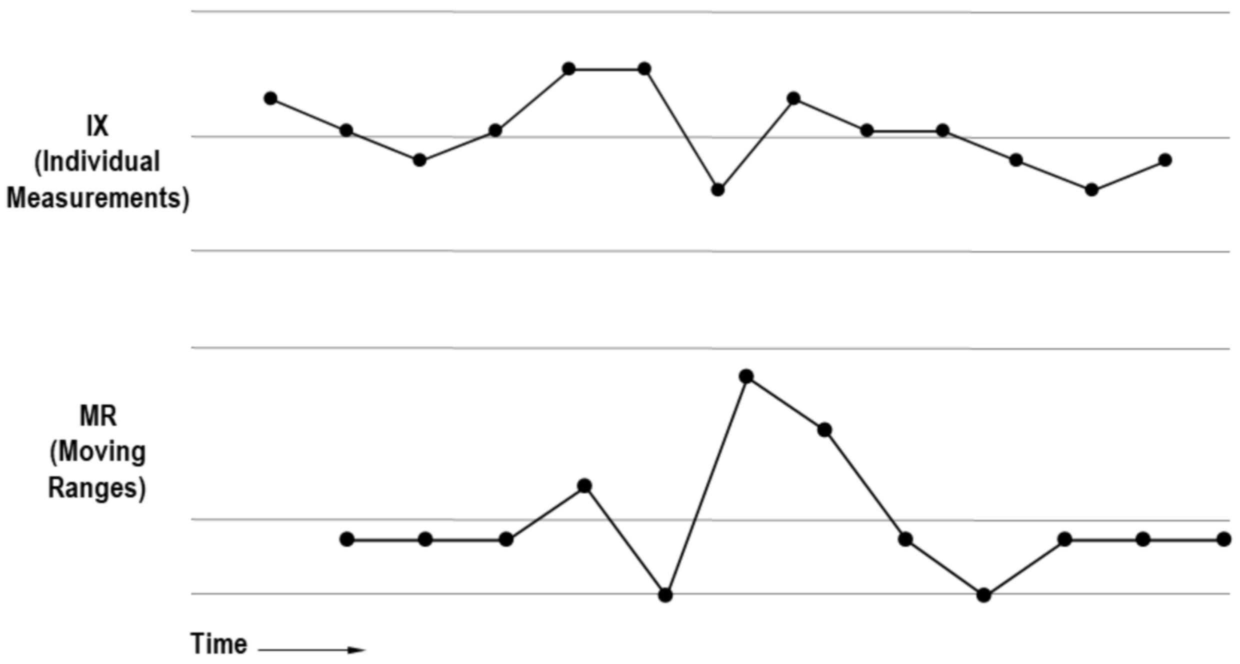
Using the IX and MR Chart



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Both charts are shown above. There is debate in the statistics field about the value of plotting the Moving Ranges. The argument "for" is that it provides a way to look at consistency between samples. The argument "against" is that it duplicates the signals on the IX chart and can give false alarms. ETI's advice is to use just the IX chart (and if at all possible, try to get a bigger sample size and use averages and standard deviations!).

Control Limits for the IX Chart

The control limits for the Individuals (IX) chart can be calculated with the same formula for the X-bar chart given previously (although the sample size of N = 1 simplifies it).

$$UCL = \mu + 3\sigma$$

$$CL = \mu$$

$$LCL = \mu - 3\sigma$$

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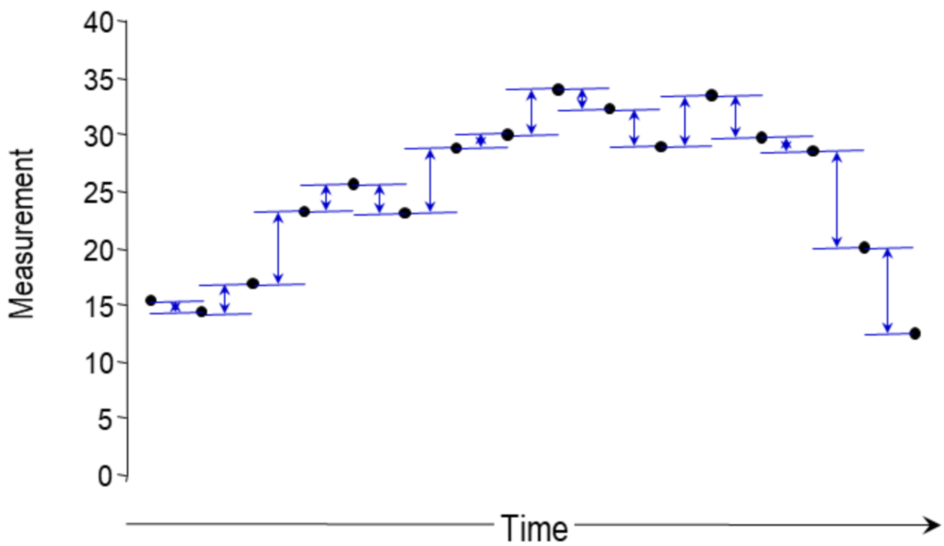
Here again, μ and σ are the estimates of the population parameters calculated from the baseline data.

MR Calculation

If desired, the Moving Range is calculated and plotted.

The word "moving" is used because the range "moves" along with the individual data points.



MR Calculation

- Calculation of moving range (MR) begins with the second sample. The second value is subtracted from the first sample's value.
  - Let's say we are measuring length: the first sample is 0.50 inches long, and the second is 0.52 inches. MR = 0.52 – 0.50 = 0.02
- We always take an "absolute value" so the result will be positive.
  - We are only interested in the amount of variation between the samples, i.e., number itself, not whether it's negative or positive.
- A typical Moving Range "length" is between consecutive samples, but it could be computed at different intervals.

More on absolute value:

In a subtraction, it means always reporting a positive number. If you were doing the subtraction manually, it would mean putting the higher number first so the result would be positive.

Control Limits using Moving Range

Metric to monitor	*Statistic(s) needed*	*Control limits*
Individual X	Average of Individuals (μ) Average Moving Range ($\overline{MR}$)	$UCL = \bar{x} + 3\frac{\overline{MR}}{d_2}$ $CL = \bar{x}$ $LCL = \bar{x} - 3\frac{\overline{MR}}{d_2}$
Moving Range	Average Moving Range ($\overline{MR}$)	$UCL = D_4\overline{MR}$ $CL = \overline{MR}$ $LCL = D_3\overline{MR}$

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These formulas use the average Moving Range to estimate the standard deviation, along with the constants discussed previously. The quantity ($\frac{\overline{MR}}{d_2}$) is the estimate of standard deviation, and is also referred to as "Short-term Sigma." For a sample size of two (moving range of two consecutive points), the constants are: $d_2 = 1.128$, $D_3 = 0$ and $D_4 = 3.267$.

When the distribution is stable (common cause variation only), the two different calculations shown herein for standard deviation of the Individuals will produce similar numbers.

UCL = Upper Control Limit

CL = Center Line

LCL = Lower Control Limit

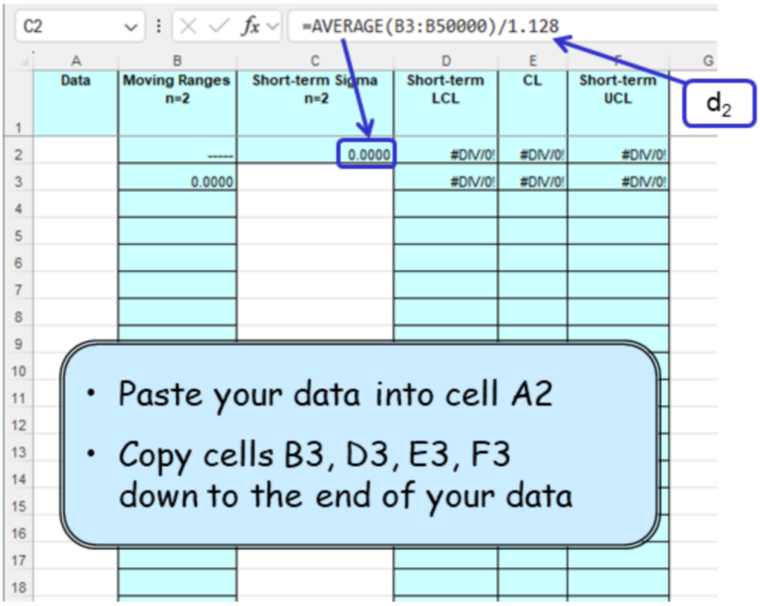
$MR = |x_i - x_{i-1}|$ (The "absolute value" formula.)

For monitoring individuals and moving ranges, a negative value of LCL is meaningless; use LCL = 0 in this case.

Using Excel: Individual Chart using Moving Range

To make it easier to calculate the moving range and control limits, open

Forms-tools-examples \ calculator - individual chart using moving range



Using the IX Chart with MR
Exercise

Instructions

1. Open *Forms-tools-examples \ calculator - individual chart using moving range*.
2. Open *Data sets for exercises \ solution properties*.
3. Use the calculator to create an Individuals (IX) chart, using all the *solution properties* data.

	A	B	C	D	E	F
1	Data	Moving Ranges n=2	Short-term Sigma n=2	Short-term LCL	CL	Short-term UCL
2		-----	0.00	#DIV/0!	#DIV/0!	#DIV/0!
3		0.00		#DIV/0!	#DIV/0!	#DIV/0!
4						
5						
6						
7						
8						
9						
10						
11						

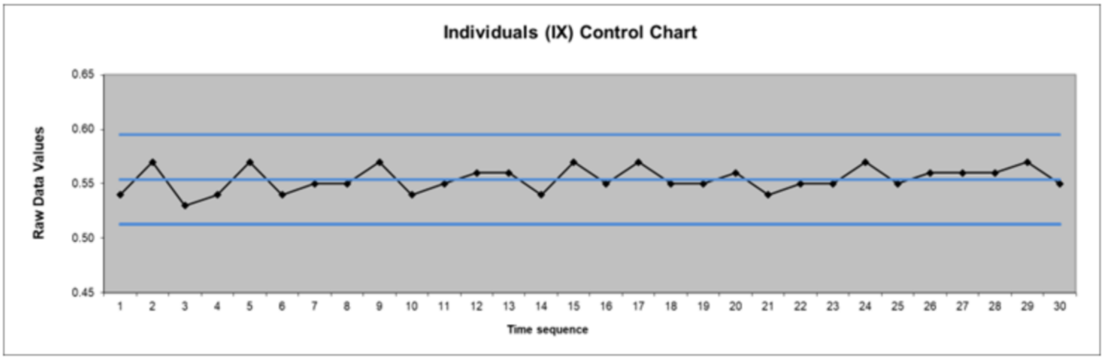
- Paste your data into cell A2
- Copy cells B3, D3, E3, F3 down to the end of your data

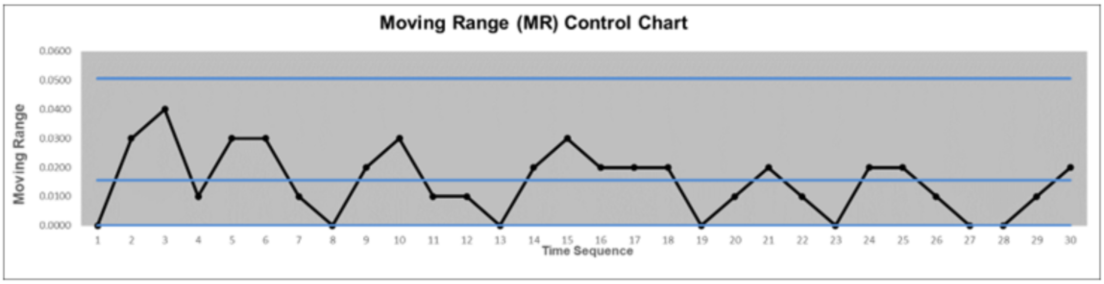
	A	B	C	D	E
1	Lot	Vial	Conductivity	pH	Spec grav
2	1116	1	294	5.766	0.9239
3	1116	2	290	5.773	0.9233
4	1116	3	290	5.768	0.9236
5	1116	4	288	5.768	0.9224
6	1116	5	282	5.763	0.9231
7	1116	6	287	5.766	0.9224
8	1116	7	290	5.768	0.9231
9	1116	8	292	5.768	0.9236
10	1116	9	289	5.774	0.9230
11	1116	10	288	5.766	0.9233
12	1116	11	290	5.767	0.9229
13	1116	12	285	5.774	0.9232
14	1116	13	287	5.771	0.9225
15	1116	14	283		
16	1116	15			
	1116	16			

Example: IX and MR chart calculator

This example goes one step further. Open the file:

Forms-tools-examples \ example_calculator - individual and moving range charts_raw data





Optional: create an MR chart for the previous exercise (hint: pull formulas and set-up from Forms-tools-examples \ example_calculator - individual and moving range charts_raw data).

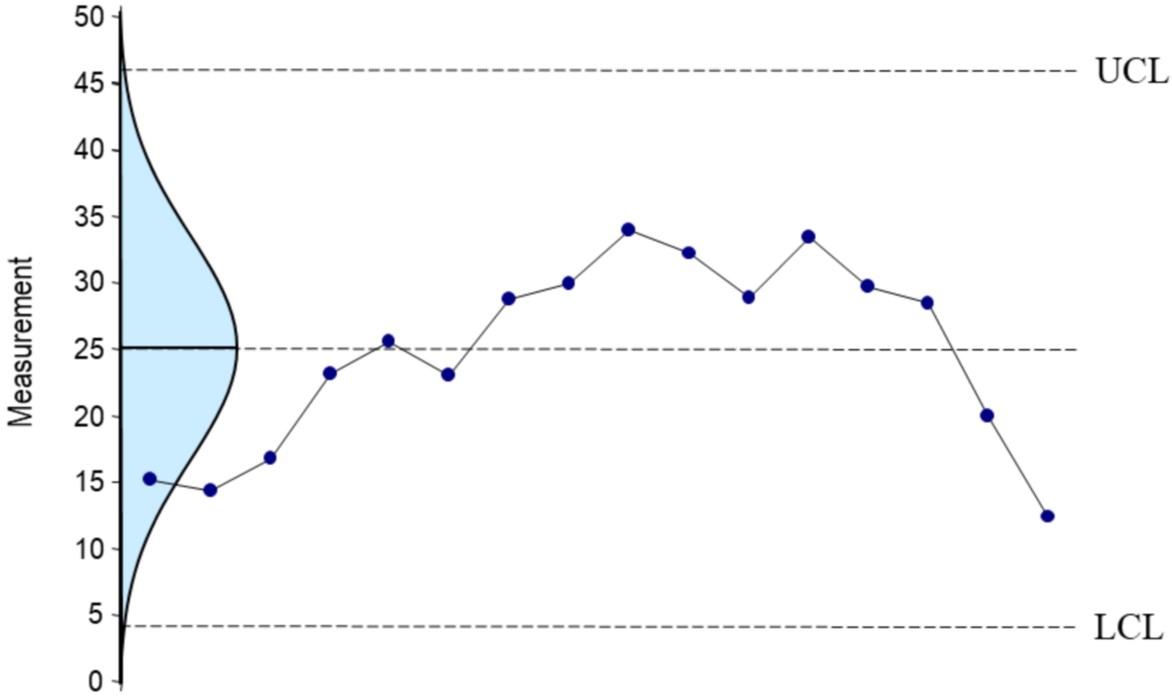
Special Cases for Variables Control Charts

Sometimes control charting is not always straightforward.

This section will introduce you to some situations you may encounter during SPC implementation.

Control Limits Based on Long-term Sigma

Example: $\mu = 24.7$, long-term $\sigma = 7.1$



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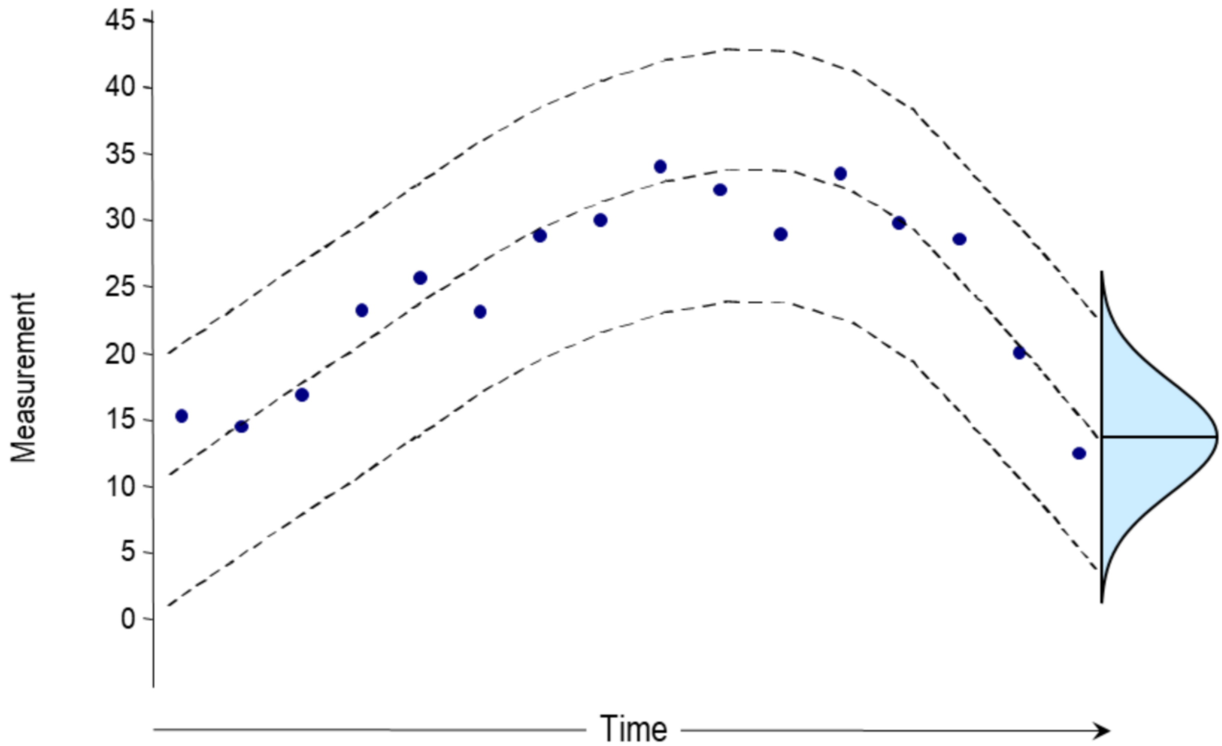
To set up control limits, we need to calculate a baseline average and standard deviation (aka sigma) for the parameter to be charted. The typical standard deviation formula used, (STDEV function in Excel), measures the variation of the individual data points from the average. This value is also referred to as "long-term" or "overall" sigma, because it captures all aspects of the variation in the data.

The example above shows a data set with control limits based on long-term sigma. These are the correct control limits to use going forward if we view the trending behavior in the data as an inherent characteristic of the process, or a known assignable cause that we are unable to remove.

This sort of underlying trend is referred to as "autocorrelation." It can occur when a process or product parameter correlates with another variable, often an environmental factor.

What could cause autocorrelation for processes in your area?

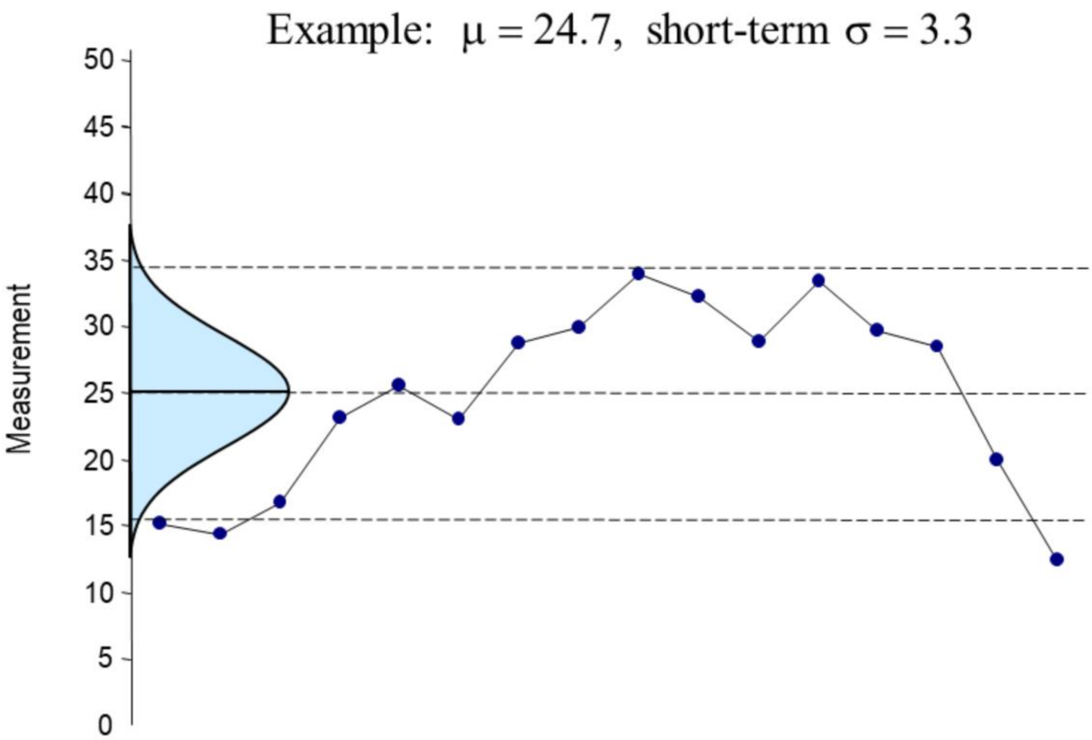
The Concept of Short-term Sigma



The concept of short-term sigma is illustrated above.

Short-term sigma, also referred to as "within sigma" measures the variation of individual data points from the trend, not from the sample mean. The mean of the Normal distribution curve based on short-term sigma is not constant, but instead follows the trend. Short-term sigma is usually smaller than long-term sigma.

Control Chart Based on Short-term Sigma



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As before, the centerline is the average of the baseline data. The control limits above are based on short-term sigma instead of long-term sigma. These are the correct control limits to use going forward if we view the trending behavior in the data as an assignable cause, and most importantly, a cause which we understand and can eliminate. Using short-term sigma allows us to "salvage" the autocorrelated baseline data to establish beginning control limits.

For some processes, an autocorrelation *cannot* be removed. For example, suppose a liquid solution is continuously piped from a tank to points of use. At the same time, new solution is continuously added and blended into the remaining old solution. The blended solution in the tank has "memory." Common-cause variations in the properties of the incoming solution do not show up immediately in the properties of the blended solution. Instead, the effects of incoming variation are averaged over time, thereby producing a known trend. For this type of process, control limits based on short–term sigma will produce a constant stream of false alarms. Control limits based on long-term sigma should be used instead (as shown previously).

Sigma Short-term Example 1

Open the file: *Forms-tools-examples \ sigma short-term example 1*

	A	B	C	D	E	F
1	Data	Moving Ranges n=2	Short-term Sigma n=2	Short-term LCL	CL	Short-term UCL
2	15.10	-----	3.30	14.78	24.69	34.61
3	14.30	0.80		14.78	24.69	34.61
4	16.70	2.40		14.78	24.69	34.61
5	23.10	6.40		14.78	24.69	34.61
6	25.50	2.40		14.78	24.69	34.61
7	23.00	2.50		14.78	24.69	34.61
8	28.70	5.70		14.78	24.69	34.61
9	29.90	1.20		14.78	24.69	34.61
10	33.90	4.00		14.78	24.69	34.61
11	32.10	1.80		14.78	24.69	34.61
12	28.90	3.20		14.78	24.69	34.61
13	33.40	4.50		14.78	24.69	34.61
14	29.70	3.70		14.78	24.69	34.61
15	28.50	1.20		14.78	24.69	34.61
16	19.90	8.60		14.78	24.69	34.61
17	12.40	7.50		14.78	24.69	34.61

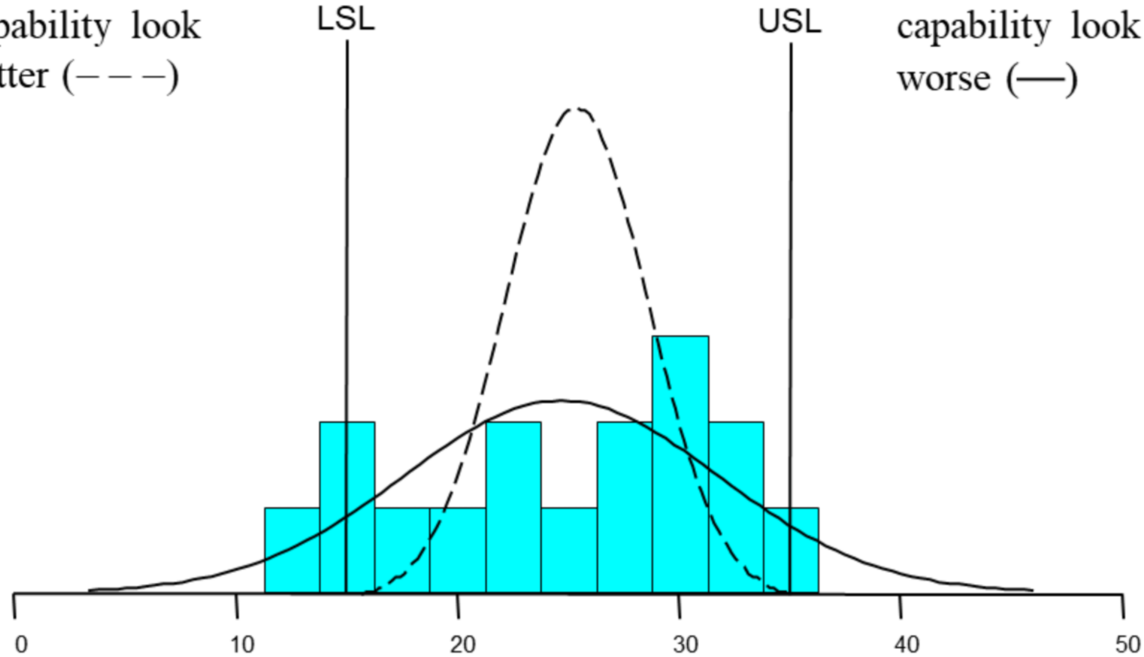
The data in *sigma short-term example 1* is the source for the charts shown in the preceding slides (see the accompanying control chart in this Excel file).

The moving range method is the most widely used way of calculating short-term sigma. It is based on the ranges between pairs of consecutive data points instead of the distances between data points and the sample mean. It can be applied to any set of quantities in time sequence.

The details of calculating short-term sigma by the moving range method are given in *Forms-tools-examples \ calculator - individual chart using moving range*. Refer to the section on the Individual and Moving Range control chart.
See also *Forms-tools-examples \ sigma short-term example 2* for an example with a negative LCL; in this case the LCL is ignored or considered to be zero.

Capability Complications with Short-term Sigma

- Short-term sigma makes process capability look better (– – –)
- Long-term sigma makes process capability look worse (—)



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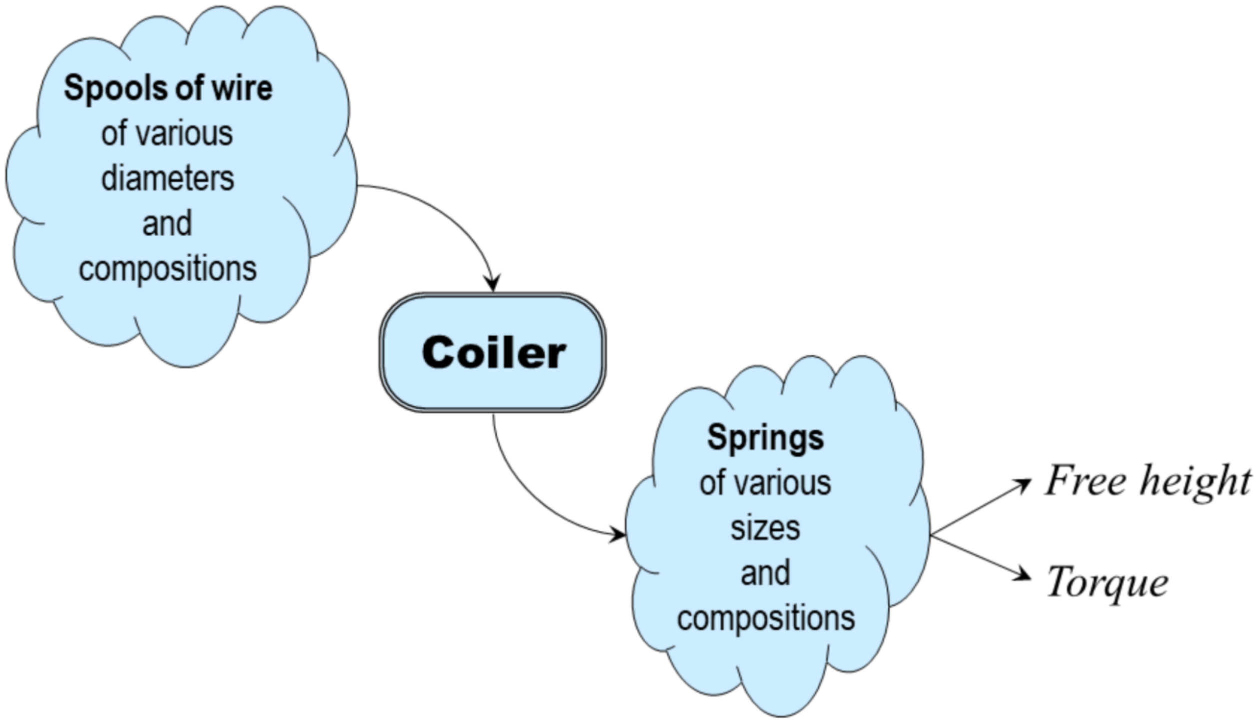
The reported value for process capability needs to properly reflect the "sigma situation" for the associated control chart. If the use of short-term sigma for control limit calculation is appropriate, then it's correct to use short-term sigma for the Process Capability index (once the assignable cause is addressed and its trending affect on product parameters is removed). If not, then long-term sigma should be used.

Just as it's helpful to contrast C_p and C_{pk} (to see if the process is off-center), it can also be helpful to look at both short and long-term calculations for these indices for further indications of trending (e.g., assignable causes, autocorrelation). If a process is stable with only common cause variation present and data observations are independent of each other, then short and long-term capability should be nearly identical.

Software Note: Commercially available statistical software packages will typically provide options for process capability calculations using both short-term (within) and long-term (overall) standard deviation and may apply different terms for the resulting indices. Sometimes different terms are used for C_p and C_{pk} as well. It is critically important to understand both the terms and formulas used by a particular S/W program.

Short-run SPC

Example: spring coiling process



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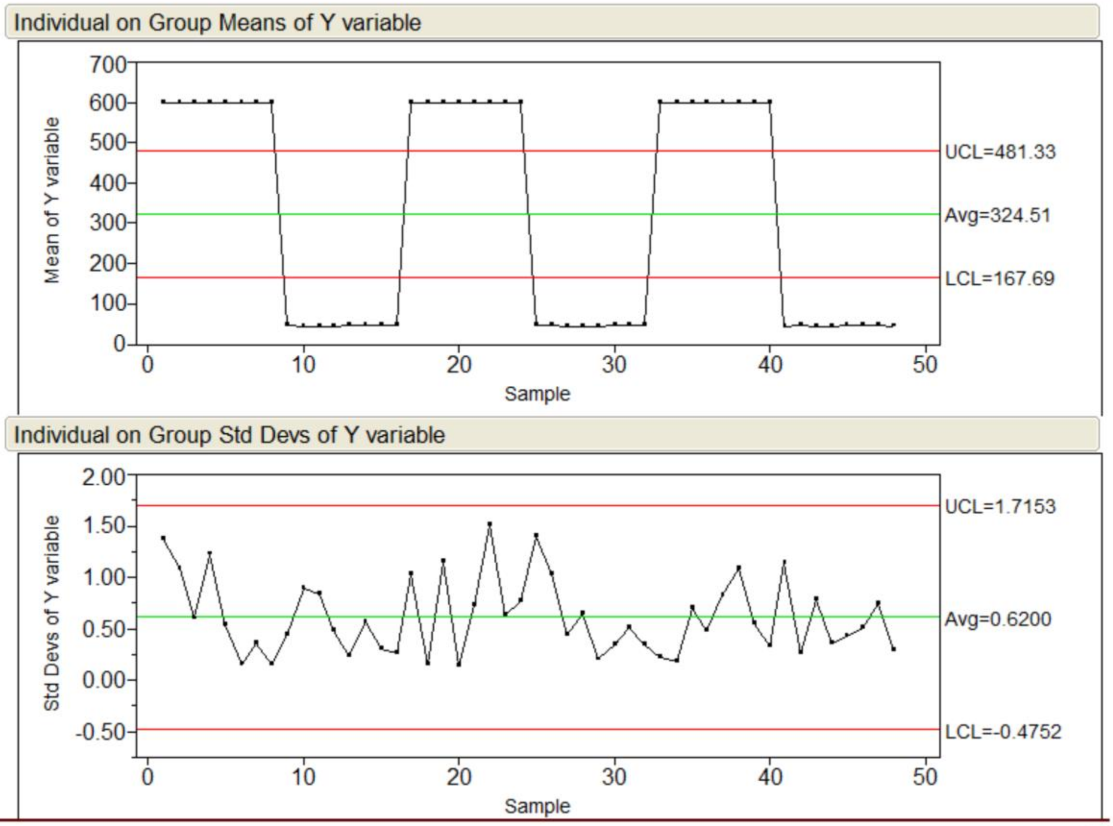
"Short-run SPC" refers to the common situation where a single machine or process produces a mix of different products. Work orders for each product are small relative to the total production volume. The spring coiling process is an example.

As in the spring coiling example, the products in question are often of a similar type, and they often have certain Y variables in common. The difficulty is that the common Y variables have different nominal values for different part numbers, and possibly different tolerances.

Other manufacturing applications of short-run SPC include solder thickness for circuit boards and dimensions of parts formed by extrusion, injection molding, casting, forging and machining. Business process applications include cycle times for purchase orders of different sizes or types, product or service delivery times relative to differing customer requests and days sales outstanding relative to differing supplier requests.

Short–run SPC

Can't combine data for all part numbers



The solution to doing SPC in a short–run context is to focus on the single process rather the many products. But how do we do this? For example, even though we have a common Y variable, we can't just plot Y for all part numbers on the same chart. Different nominal values imply different ranges of Y for different part numbers. Charts for individual values or subgroup means will show us nothing but the differences between the part numbers.

Deviation–from–nominal

5/0 Cols / 192/0	W/O	Part	Y variable	Nominal	Dev Nom
17	102	B	599.68	600	-0.32
18	102	B	600.65	600	0.65
19	102	B	599.53	600	-0.47
20	102	B	600.36	600	0.36
21	102	B	600.95	600	0.95
22	102	B	600.60	600	0.60
23	102	B	600.87	600	0.87
24	102	B	600.70	600	0.70
25	102	B	599.90	600	-0.10
26	102	B	600.53	600	0.53
27	102	B	600.47	600	0.47
28	102	B	600.75	600	0.75
29	102	B	600.09	600	0.09
30	102	B	600.18	600	0.18
31	102	B	600.19	600	0.19
32	102	B	600.44	600	0.44
33	103	C	50.26	50	0.26
34	103	C	49.91	50	-0.09
35	103	C	49.55	50	-0.45
36	103	C	49.20	50	-0.80
37	103	C	49.42	50	-0.58
38	103	C	49.31	50	-0.69
39	103	C	47.70	50	-2.30

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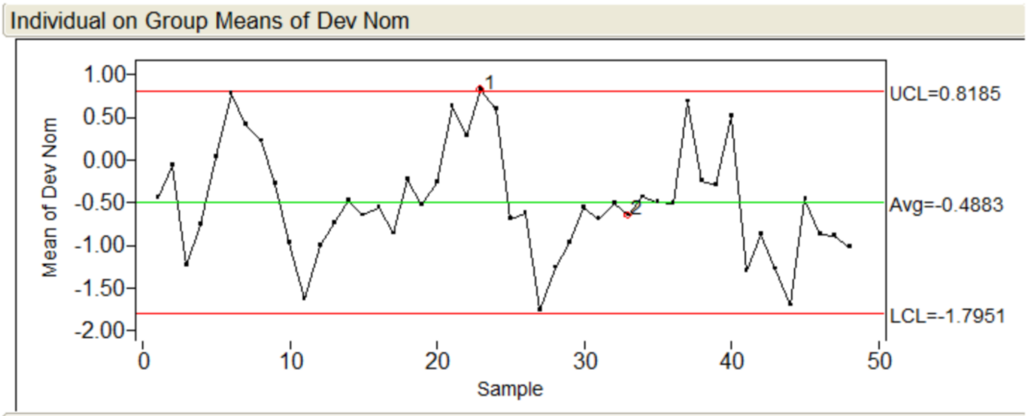
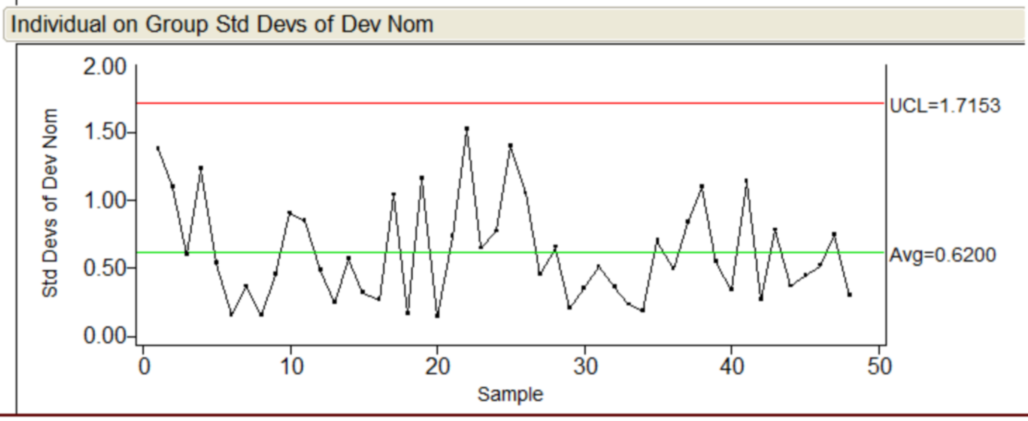
The most common, and easiest, method of short–run SPC is to chart deviations from nominal values. In this hypothetical example, there are four "part numbers" A, B, C and D. The nominal value for products A and B is 600, the nominal value for C and D is 50.

The data table above shows a calculated column of deviation–from–nominal values. This baseline Dev Nom data would be used to establish control limits. The process would then be monitored over time by plotting future Dev Nom data on a single control chart, regardless of which part number is being run.

The choice of charting technique is not affected by the transformation of Y values to deviations from nominal. We can chart individual values, or means and standard deviations presummarized by subgroups of our choosing.

Deviation–from–nominal

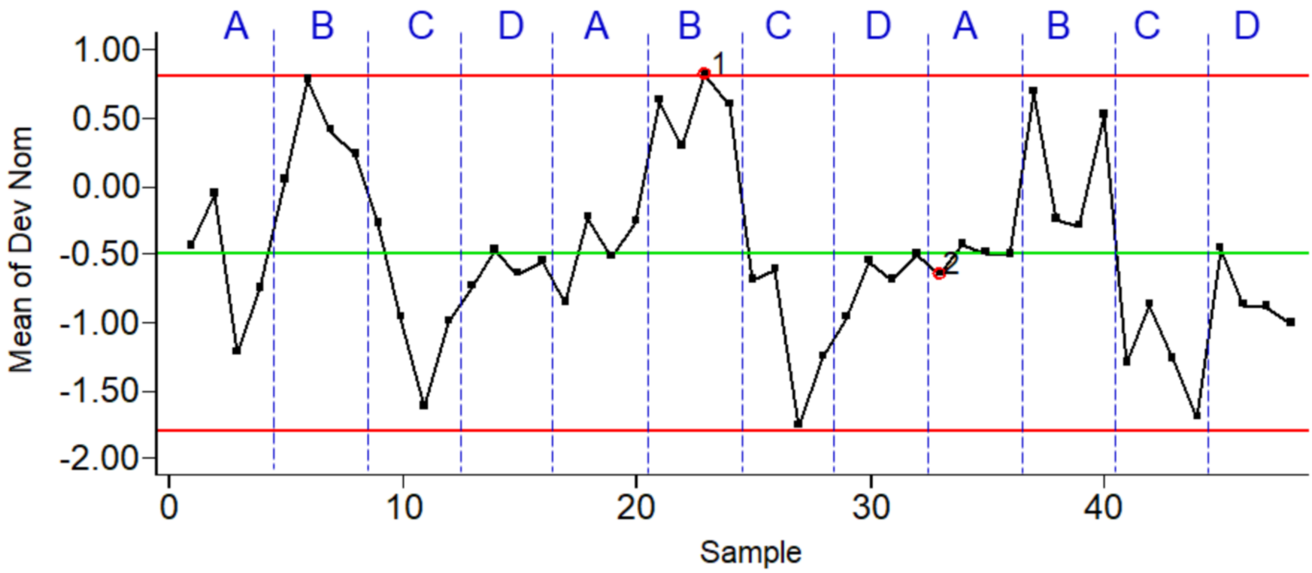




Here are the resulting control charts of means and standard deviations of Dev Nom plotted by consecutive subgroups of size 4. The standard deviations chart is the same, but the means chart is vastly improved.

We do see some assignable causes flagged on the means chart. The deviation–from–nominal method is based on the assumption that subtracting the nominal values from Y eliminates assignable causes due to differences between part numbers. As shown as on the next page, we can check this assumption informally by identifying part numbers on the chart.

Deviation–from–nominal



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Here is an enlargement of the means chart. An informal way of testing whether "part number" is an assignable cause for Dev Nom is to label each point by the part number it represents, then look for patterns. In this hypothetical example, each work order consisted of 16 parts. We used subgroups of size 4, so each work order is represented by four subgroup means.

Notice that the means for Part B are always above the centerline and the means for Part C are always below the centerline. We have to conclude that "part number" is an assignable cause for Dev Nom.

The deviation–from–nominal method is easy to implement and often works quite well. It is the method you should try first. However, this hypothetical example reminds us that it doesn't always work. In these situations, another method is needed.

Deviation–from–mean

- "Deviation-from-nominal" is easy and often works well
- When it doesn't work, use "deviation-from-mean"
- "Deviation-from-mean" always works better
- Requires historical average Y for each part number

Deviation–from–mean

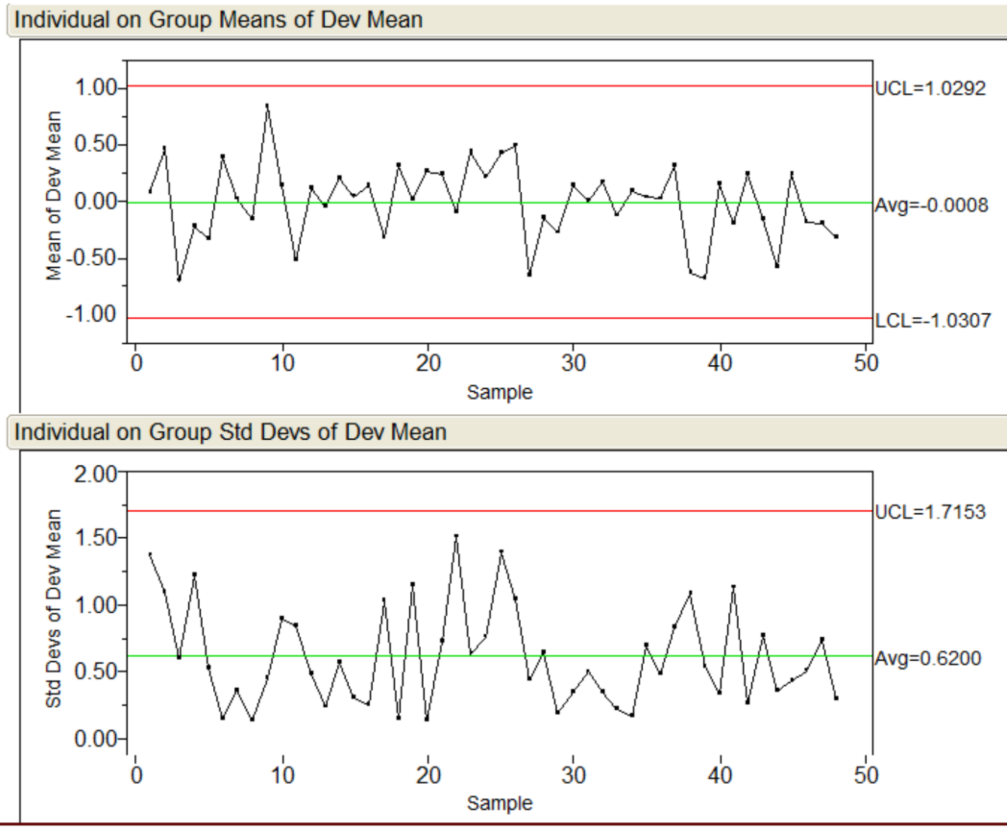
6/0 Cols / 192/0	W/O	Part	Y variable	Nominal	Dev Nom	Dev Mean
16	101	A	598.14	600	-1.86	-1.33
17	102	B	599.68	600	-0.32	-0.70
18	102	B	600.65	600	0.65	0.27
19	102	B	599.53	600	-0.47	-0.85
20	102	B	600.36	600	0.36	-0.02
21	102	B	600.95	600	0.95	0.57
22	102	B	600.60	600	0.60	0.22
23	102	B	600.87	600	0.87	0.49
24	102	B	600.70	600	0.70	0.32
25	102	B	599.90	600	-0.10	-0.48
26	102	B	600.53	600	0.53	0.15
27	102	B	600.47	600	0.47	0.09
28	102	B	600.75	600	0.75	0.37
29	102	B	600.09	600	0.09	-0.29
30	102	B	600.18	600	0.18	-0.20
31	102	B	600.19	600	0.19	-0.19
32	102	B	600.44	600	0.44	0.06
33	103	C	50.26	50	0.26	1.37
34	103	C	49.91	50	-0.09	1.02
35	103	C	49.55	50	-0.45	0.66
36	103	C	49.20	50	-0.80	0.31
37	103	C	49.42	50	-0.58	0.53
38	103	C	49.31	50	-0.69	0.42

"A" ⇒ *Y variable* - 599.47
"B" ⇒ *Y variable* - 600.38
"C" ⇒ *Y variable* - 48.89
"D" ⇒ *Y variable* - 49.31

The data table above shows a calculated column of deviation–from–mean values. This baseline Dev Mean data would be used to establish control limits. The process would then be monitored over time by plotting future Dev Mean data on a single control chart, regardless of which part number is being run.

As with Dev Nom, the choice of charting technique is not affected by the transformation of Y to Dev Mean. We can chart individual values or means and standard deviations, summarized by subgroups of our choosing.

Deviation–from–mean

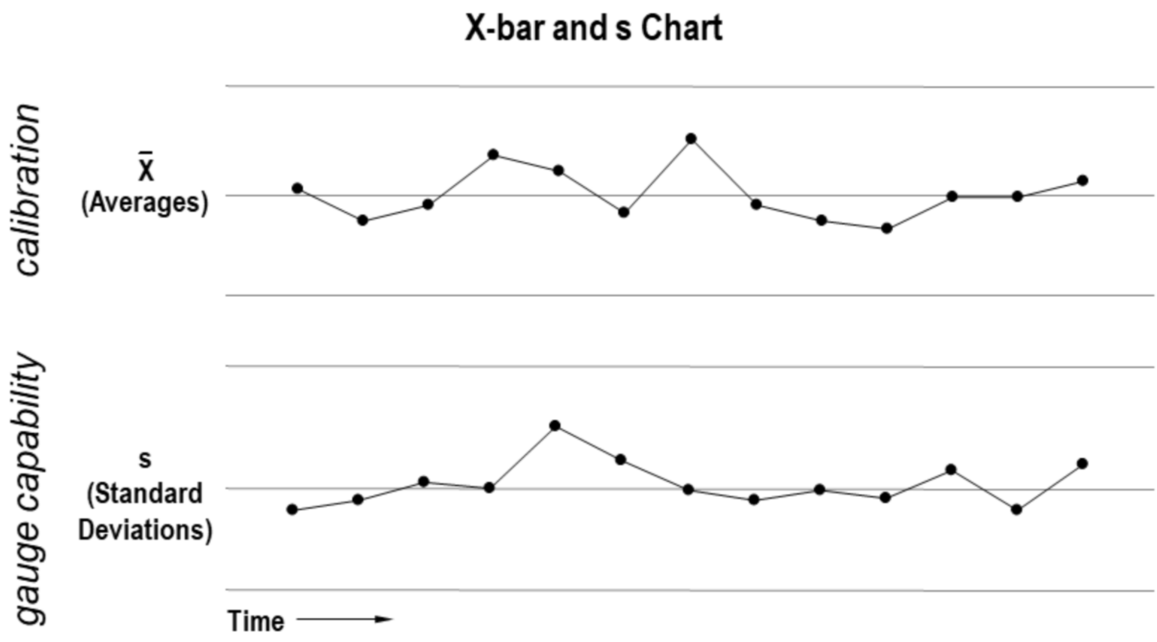


Here are the resulting control charts of means and standard deviations of Dev Mean. The standard deviations chart is the same as for Dev Nom, but the means chart is further improved. In particular, there are no assignable causes.

When a new part number is introduced, there is no historical average from which to calculate Dev Mean. The solution is to plot Dev Nom for the new part number until the average is established. This may result in the new part number being an assignable cause, but it should simply be noted as such and ignored until the average is established.

The average for a new part number should be based on data from several work orders. There is no point in trying to establish averages for one–time or extremely infrequent orders. Dev Nom should be plotted in such cases, with the understanding that they may be assignable causes.

Variables Control Charts for Measurement Systems



Control charts can be used for quantitative measurement systems (aka gauges) to monitor calibration and precision in real time by measuring a Check Standard. This method can signal when unscheduled calibration or gauge troubleshooting is needed, as well as showing when unnecessary calibrations and adjustments can be avoided.

The purpose of calibration is to check accuracy of a gauge. In a control chart, accuracy (centering) is shown by the plot of the averages.

Gauge studies look at consistency of the gauge, i.e., precision, as shown by the standard deviation chart. If a sample size of one is the only practical option, an Individuals and Moving Range chart can be used.

Control limit calculations for measurement system charts have an important difference from regular control charts: the average used is the “true value” of the Check Standard and for standard deviation, sigma precision (σ_{prec}) is used. Sigma precision is the value obtained from a gauge study (the combination of repeatability and reproducibility).

Measurement system control charts are most cost effective and useful for gauges whose stability can vary and/or where measurements must be very precise.

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Using Control Charts for Attributes

Learning Objectives

By the end of this section, participants will be able to:

- ☑ Describe the different types of control charts used for attribute data, and their applications:
  - p and np charts
  - u and c charts
- ☑ Plot control charts for attributes data.
- ☑ Calculate control limits for attributes charts.
- ☑ Apply the Individual X and Moving Range control chart method for attribute data.

Attribute Data

We learned earlier that there are two types of data—attribute and variable. Attribute data are counted or pass/fail; variable data are measured.

Different types of control charts are used for attribute data than for variable data.

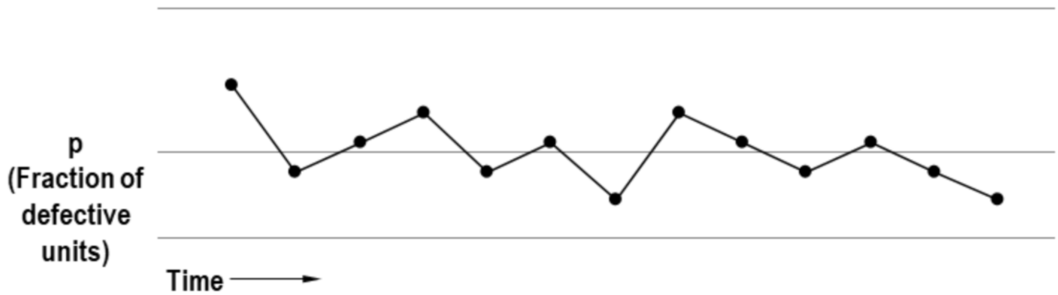
Attributes control charts will typically be used for processes that are Operator or Component Dominant.

All the same concepts discussed for variables control charts apply to those for attributes.

Attributes Control Charts

Attributes control charts have:

- Control limits drawn at the average, and ±3 standard deviations of the process.
- One graph that shows the defect rate per sample (short term variation), and the variation from sample to sample (long term process variation).



Attributes Control Charts

Control Charts	Statistics Plotted	Sample Size	Examples
p	Fraction of defective units (Pass/Fail, Yes/No)	≥30	Fraction of parts that fail final test.
np	Number of defective units (Pass/Fail, Yes/No)	≥30	Number of parts that fail final test (when sample size is always the same).
u	Defects per unit	≥30	Number of cosmetic defects per parts.
c	Number of defects	≥30	Number of cosmetic defects (when sample size is always the same).

p = d/n

p = fraction defective, d = number of defective units in the sample, n= sample size

In this case, defective means that the *whole unit* (part, subassembly, component, etc.) is bad — it has failed an inspection or test.

The np chart is just a special case of the p chart. An example would be a process where it is always possible to pull a sample of 50 parts. This chart shows the actual number of defective units in each sample, instead of a fraction or percentage.

u = c/n

u = defects per unit, c = total number of defects in sample, n = sample size

In this case, a unit (part, subassembly, component, etc.) can have more than one defect.

Multiple defects can often happen on a complex unit. For a u (and c) chart, the defect types must be independent of each other.

The c chart is just a special case of the u chart, when it is always possible to use the same sample number. The c chart shows the actual number of defects in each sample, instead of a fraction or percentage.

Attributes control charts are used when variable data is not available for a process or product.

Variables control charts will give more information than attributes but using attributes can be helpful when a product is complex and has more than one key characteristic to monitor.

Sample Size Guidelines

- Sample sizes often vary with attributes charts.
- If the individual sample sizes are within ±25% of the average sample size (N), the same control limits can be used.
- If an individual sample size is outside ±25% of N, the control limits need to be recalculated for this sample using its actual sample size (n).
- Most SPC software programs will automatically recalculate control limits for these cases.

Control Limits for Attributes Charts

Metric to monitor	*Statistic(s) Needed*	*Control limits*
Fraction of Defective Units (Yes/No, Pass/Fail, Go/No Go, etc.) p chart	$\bar{p}$ = total # of defective units across all samples/n n = total # of units inspected	$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$ $CL = \bar{p}$ $LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$
Defects per Unit u chart	$\bar{u}$ = total # of defects across all samples/n n = total # of units inspected	$UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$ $CL = \bar{u}$ $LCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$

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The average p and u are the estimates of the *population* parameters.

UCL = Upper Control Limit

CL = Center Line

LCL = Lower Control Limit

The sample size (n) can be an average of the sample sizes used during the baseline monitoring period.

For attributes charts a negative value of LCL is meaningless (convention is to use zero instead).

For attributes charts a value of UCL exceeding 1 (or 100%) is meaningless (convention is to use 1 (or 100%) instead).

Control Limits for Special Sampling Cases

For the special cases where sample size is always constant (which is rare) the control limit calculations need to change a little.

Special case p Chart

np Chart:

$$UCL = \overline{np} + 3\sqrt{\overline{np} \times (1 - \frac{\overline{np}}{n})}$$

$$CL = \overline{np}$$

$$LCL = \overline{np} - 3\sqrt{\overline{np} \times (1 - \frac{\overline{np}}{n})}$$

Special case u Chart:

c Chart:

$$UCL = \bar{c} + 3\sqrt{\bar{c}}$$

$$CL = \bar{c}$$

$$LCL = \bar{c} - 3\sqrt{\bar{c}}$$

$$\bar{c} = \frac{\text{total number of defects}}{\text{total number of samples}}$$

Moving Range Revisited

In more recent times it has become customary to plot p and u charts as Individuals (IX) charts, with sigma calculated using the Moving Range method.

With this method, we are treating the plotted fractions defective as quantitative measurements.

- A possible problem: the control limit calculation ignores the subgroup sample sizes.
- A possible strength: it filters out assignable causes in the baseline data.

Our recommendation: calculate control limits both ways and see which ones seem to match best to what you know about the process.

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The control limits calculated using these two methods may be very different, hence the comment above. What is important to remember is the *purpose* of the control chart — to establish reasonable baseline limits and monitor against those going forward to determine if the process is changing. (In other words, pick something that makes sense and stick with it.)

The same caveat given in the module for variables control charts applies regarding the “filtering” of assignable causes in baseline data — the assignable cause needs to be eliminated in order to use the control limits going forward.

Attributes Charts Exercise

All files are in the *Data sets for exercises* folder. For each example, calculate the average and short–term sigma using *Forms–tools–examples \ calculator - individual chart using moving range*, and create the corresponding control chart. Then calculate control limits using the "classic" formulas (long–term sigma) and compare.

			Short term			Long-term		
		CL (Ave.)	Sigma	LCL	UCL	Sigma	LCL	UCL
(a)	*File: parts inspected & defective.xls* (calculate fraction defective first)							
(b)	*File: number & size of defects.xls* (use number of defects)							

Identifying Patterns and Trends

Learning Objectives

By the end of this section, participants will be able to:

- ☑ Identify patterns and trends in control charts.
- ☑ Determine whether a process is in or out of statistical control.
- ☑ Describe when to take action on a process.
- ☑ Define responsibilities for identifying and correcting out of control situations.

What Are Patterns and Trends?

Over time, data on control charts will form a picture of the process variation. We need to be able to look at this picture and understand what it's telling us about the process.

- Is the process in control?
- Is it out of control?
- Are there warning signs that the process may go out of control soon?

What Are Patterns and Trends?

The rules we'll discuss for deciding whether a process is in or out of control work only for control limits—*not* for specification limits.

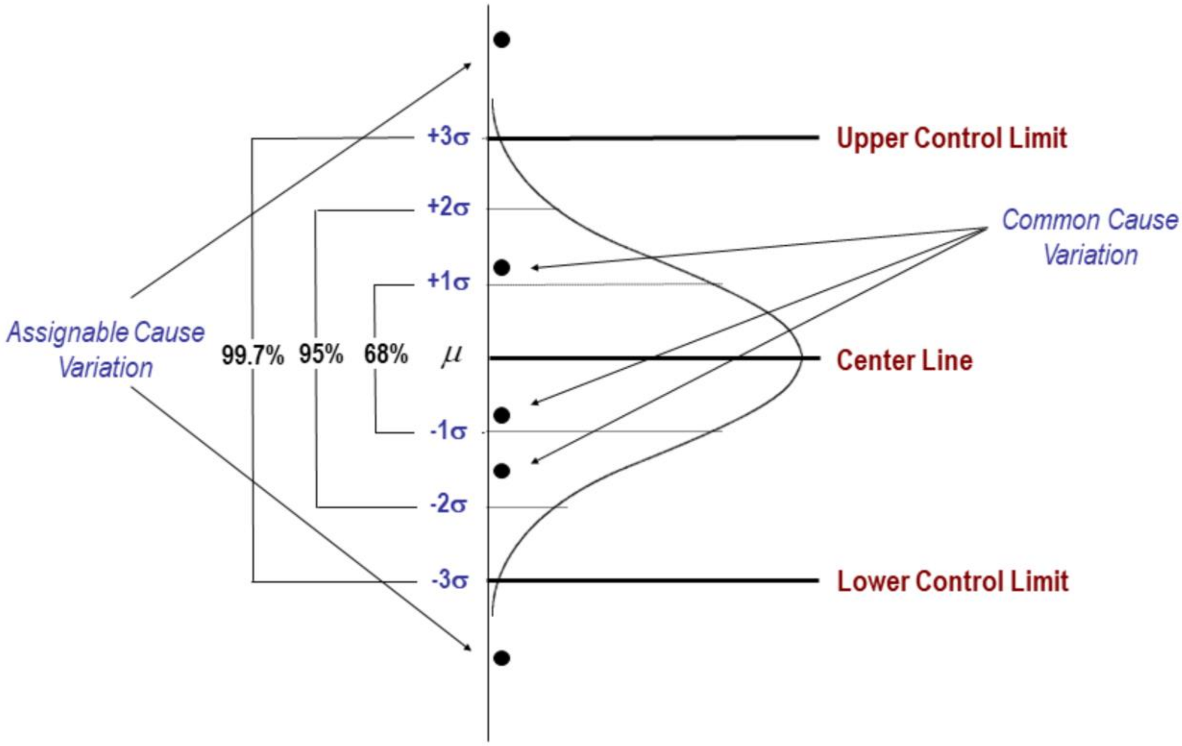
Our concern with specification limits is whether we are in or out of specification.

The question we're asking with control limits is whether the process is running normally, or whether something in the process (the "6 M's") has changed.

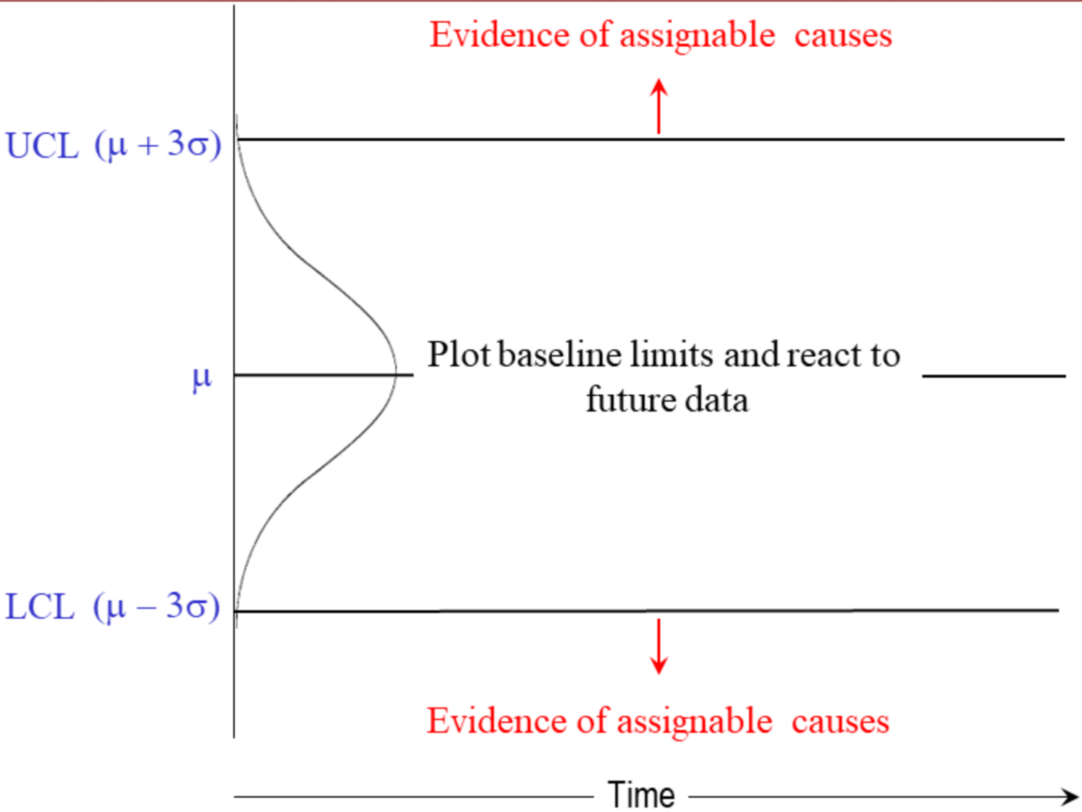
The question we're asking with specifications is whether an individual part is in or out of conformance, i.e., a pass or fail.

These are two very different questions! Putting specification limits on a control chart is generally not a good idea and can lead to incorrect decisions.

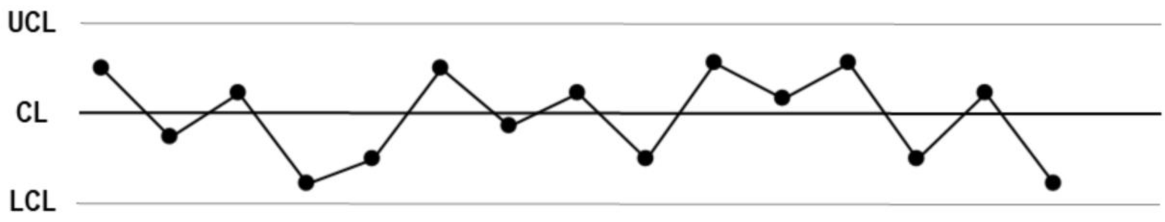
How to Spot Patterns and Trends



Using Control Limits



In Control

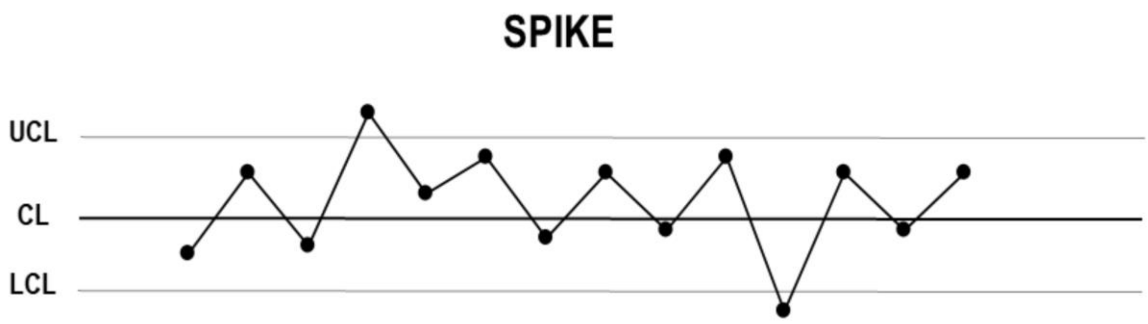


If a process is operating in statistical control, the points will fall inside the control limits in a random pattern.

- Because the Normal distribution is symmetrical, the points have an equal chance of falling above or below the center line.
- All variation will be from common causes.

What might be some sources of common cause variation in your process?

Out of Control

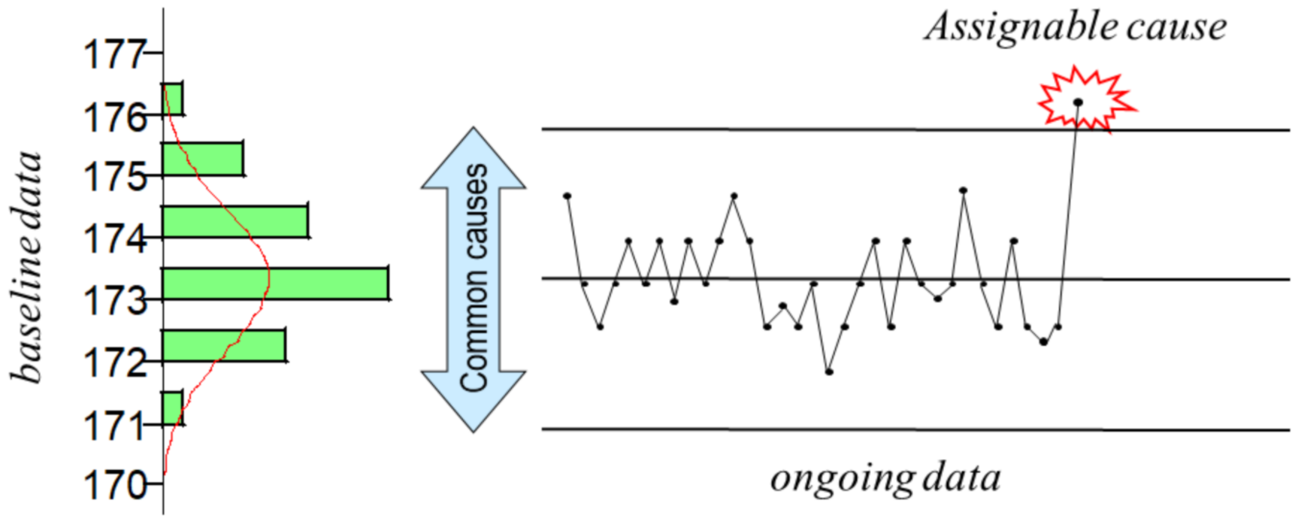


A process with points falling outside the upper and lower control limits is out of statistical control. The chart is giving a signal that something assignable or *non–normal* has happened in the process.

Points on or near the upper and/or lower control limits can also be a warning that the process is about to go out of control.

What could cause your process to "spike" out of control?

Control Limits and Probability



1. This event has probability 0.00135 (0.0027 ÷ 2)
2. Investigate to determine the cause
3. Take corrective action to eliminate the cause

Out of Control

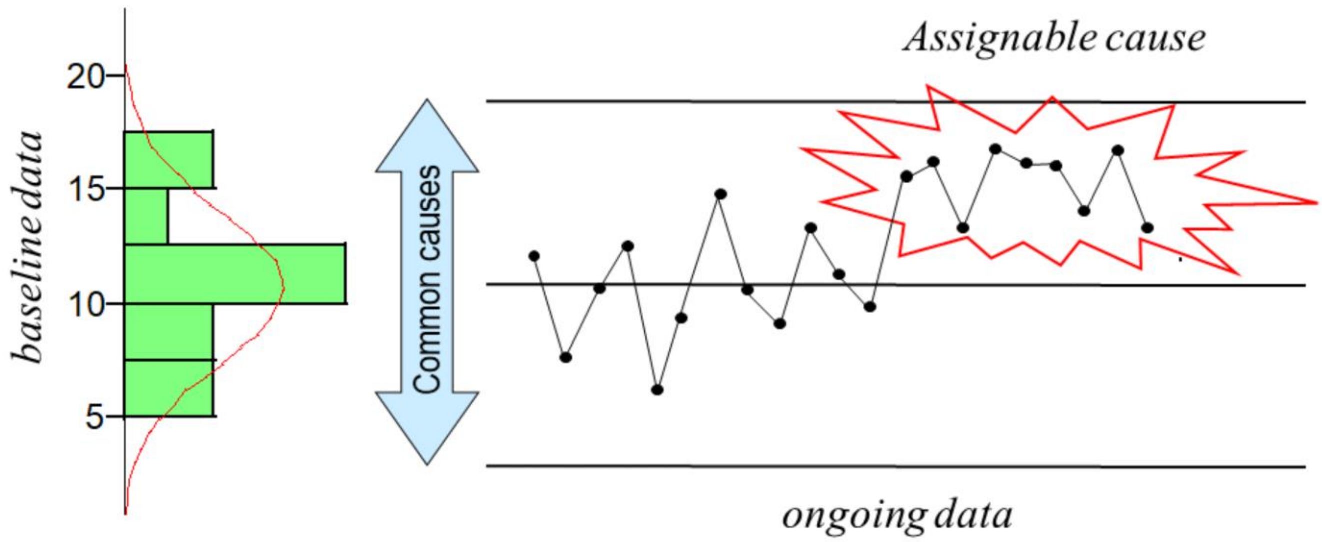
A process with points inside the control limits can also be out of control if there is a *non-random* pattern.

- As we said before, a process in control will have points in a random pattern.
- The chance of getting a specific pattern or "picture" in a chart is very low.
- The appearance of a non–random pattern is a warning that something assignable is happening in the process.

When your process is out of control, will that always be a bad thing?

The following pages show some typical non–random patterns seen in control charts.

Control Limits and Probability



1. This event has probability 0.00195 [$(0.5)^9$]
2. Investigate to determine the cause
3. Take corrective action to eliminate the cause

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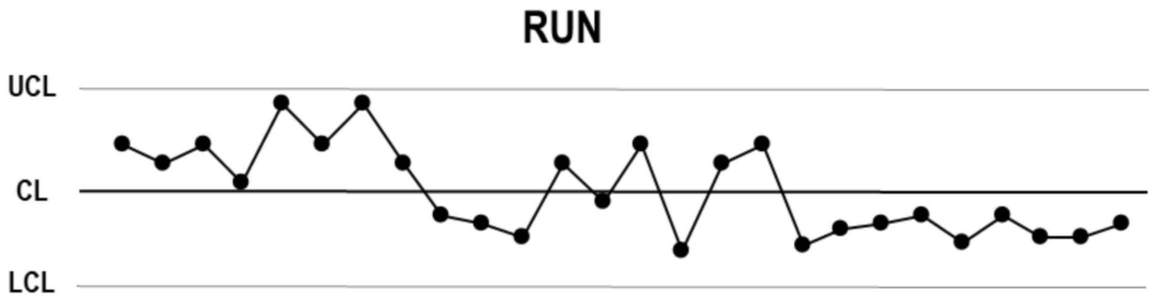
Out of Control

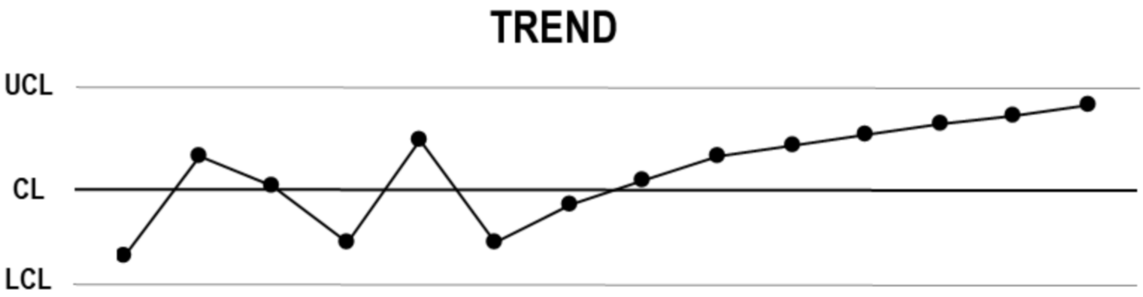


Nine or more points in a row, all above or all below the center line.

What could cause a "run" of points in your process?

The number of points used may change, e.g., using 8 instead of 9.

Out of Control

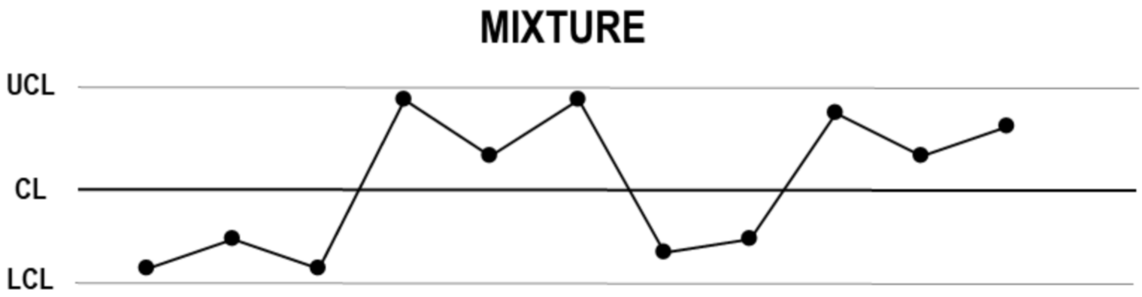


Six or more points constantly moving either up or down.

What could cause your process to “trend” upward?

What could cause your process to “trend” downward?

Out of Control

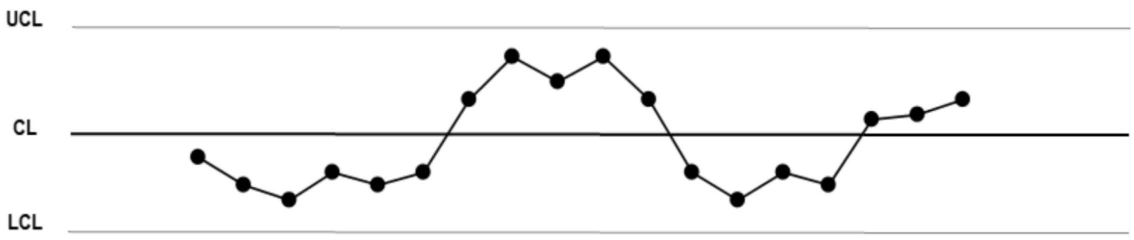


Points are too close to the control limits; chart shows two different levels of performance.

What could cause a “mixture” in your process?

Out of Control

CYCLE



Points cycle from high to low in a repeating pattern.

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What could cause your process to "cycle"?

Out of Control

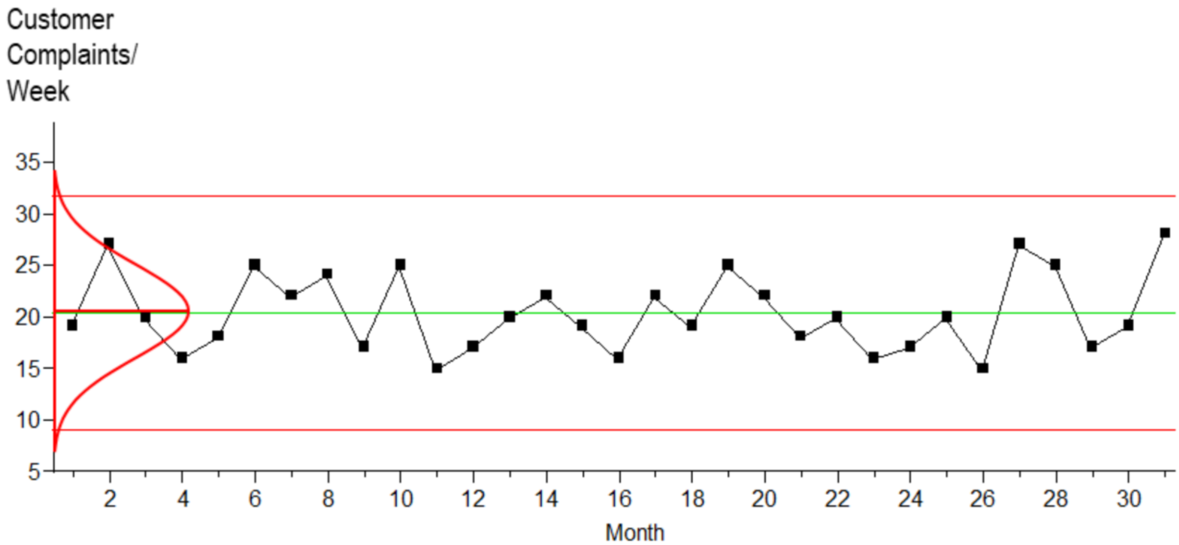
Points are all close to the center line, with very little variation.

What could be happening in your process if points were too close to the control limits?

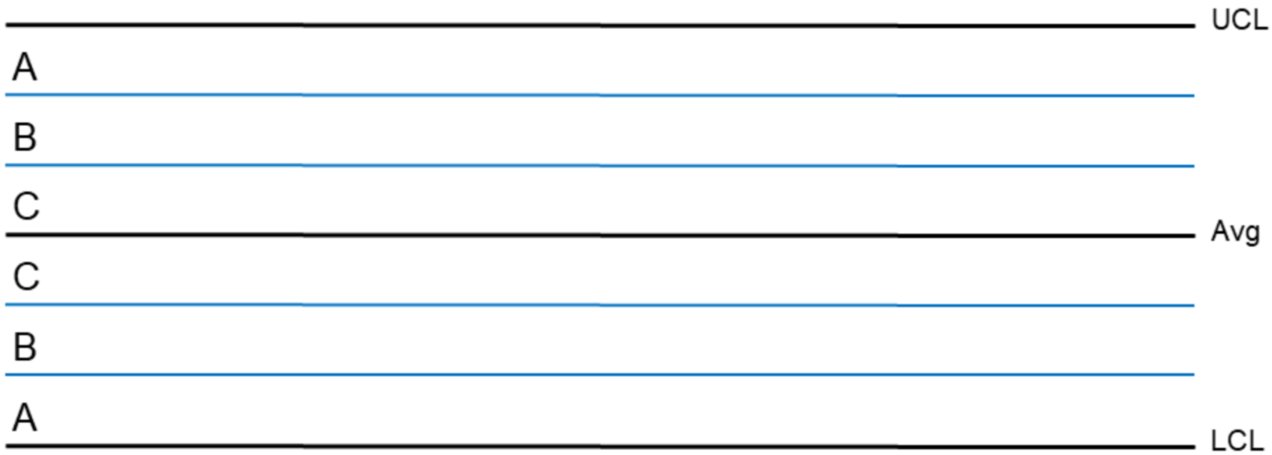
Over-reacting to Data

Over-reacting (cont'd)

No assignable causes!



Control Chart Zones



"Point outside control limits" is the most widely used operational definition of assignable (aka special) cause. Other rules can be used to sensitize a control chart to particular types of assignable cause.

The zone system shown above is based on three-sigma limits. Zone C is the region within one standard deviation of the mean. Zone B is the region more than one but less than two standard deviations from the mean. Zone A is the region more than two but less than three standard deviations from the mean.

Tests Using Zones

Test 1	One point beyond Zone A.	Shift in the mean, increase in the standard deviation or a single aberration.
Test 2	9 points in a row in Zone C or beyond, on the same side of the centerline.	Shift in the mean.
Test 3	6 points in a row steadily increasing or decreasing.	Trend or drift in the mean.
Test 4	14 points in a row alternating up and down.	Systematic effects, for example different machines, vendors or operators.
Test 5	Any 2 out of 3 points in a row in Zone A or beyond.	Shift in the mean or increase in the standard deviation.
Test 6	Any 4 out of 5 points in Zone B or beyond.	Shift in the mean.
Test 7	15 points in a row in Zone C, above and below the center line.	Stratification within subgroups.
Test 8	8 points in a row on each side of the center line with none in Zone C.	Stratification between subgroups.

Test #1 and #2 are the most commonly used (and most useful).

These tests are also referred to as the "Western Electric Rules."

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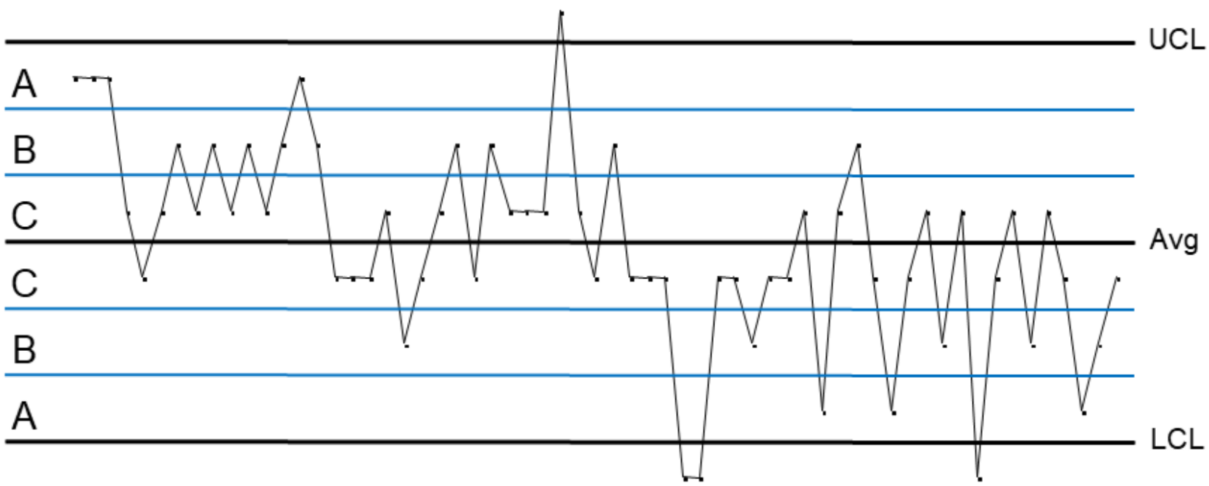
OOC Exercise

Circle occurrences of Tests 1 and 2 on the control chart shown below.



Control charts can be used as data analysis tools. As such, they are often used in conjunction with process capability analysis. We have more faith in the predictive validity of a process capability analysis when the associated control chart shows no evidence of assignable causes.

The most important use of control charts is for process monitoring. Identifying and removing assignable causes of variation as they occur is a tried and true method of improving process capability over time.

"Point outside control limits" is the most widely used operational definition of assignable cause. Other rules can be used to sensitize a control chart to particular types of assignable cause. They are based on the zone system shown above.

Taking Action

The value of SPC charts is in having real–time information about the process. When a process goes out of control (OOC), the operator needs to take immediate action.

Some general guidelines are to:

- Confirm the OOC condition.
  - Make sure data are correct.
  - Check that the gauge is functioning properly.
  - Check for software problems.
- Decide whether the out of control situation is good or bad.
- Diagnose the process or ask for help with troubleshooting.
- Document the cause of the OOC situation, and the corrective action taken (process changes, containment, analysis, etc.).

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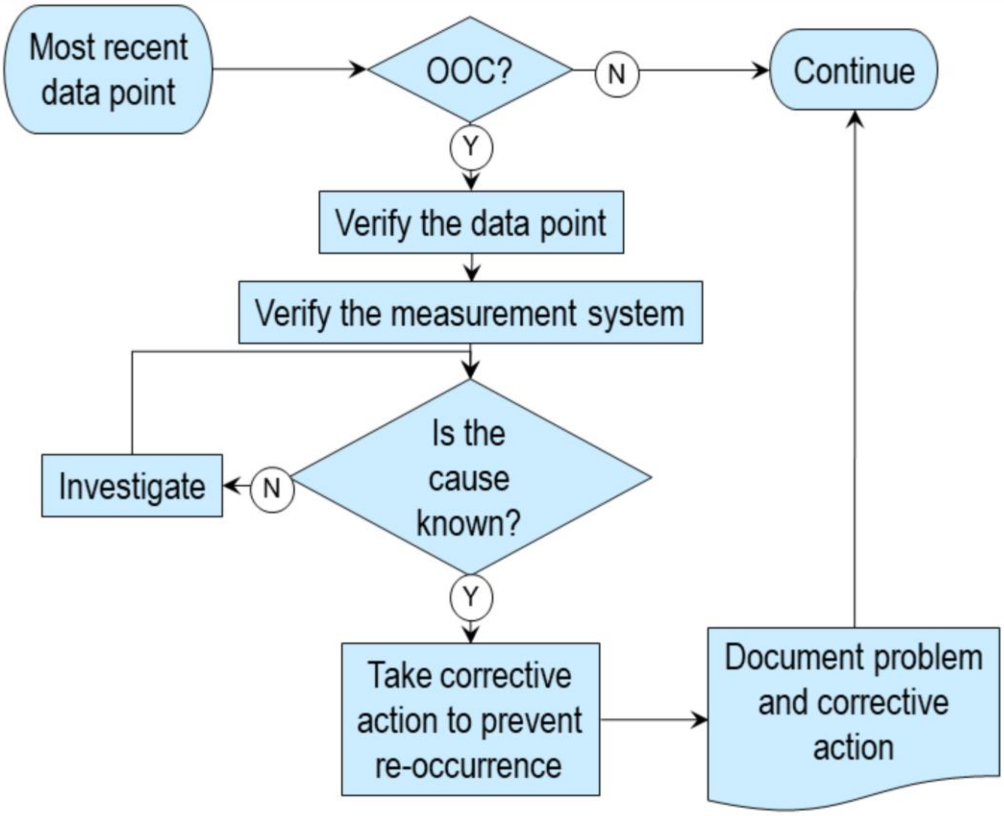
The response plans in this section focus on control charts. Overall, operators will have to pay attention to whether the process is in control *and* whether parts are staying within specifications. A Response Plan in flowchart form can be a helpful way to give guidance to operators and could include responses for both out of control (OOC) and out of specification (OOS) situations. It is important to note that OOC and OOS must be interpreted differently: one is providing a statistical signal while the other is simply an inspection.

What would a response plan for your process look like?

Response Plan "Skeleton"



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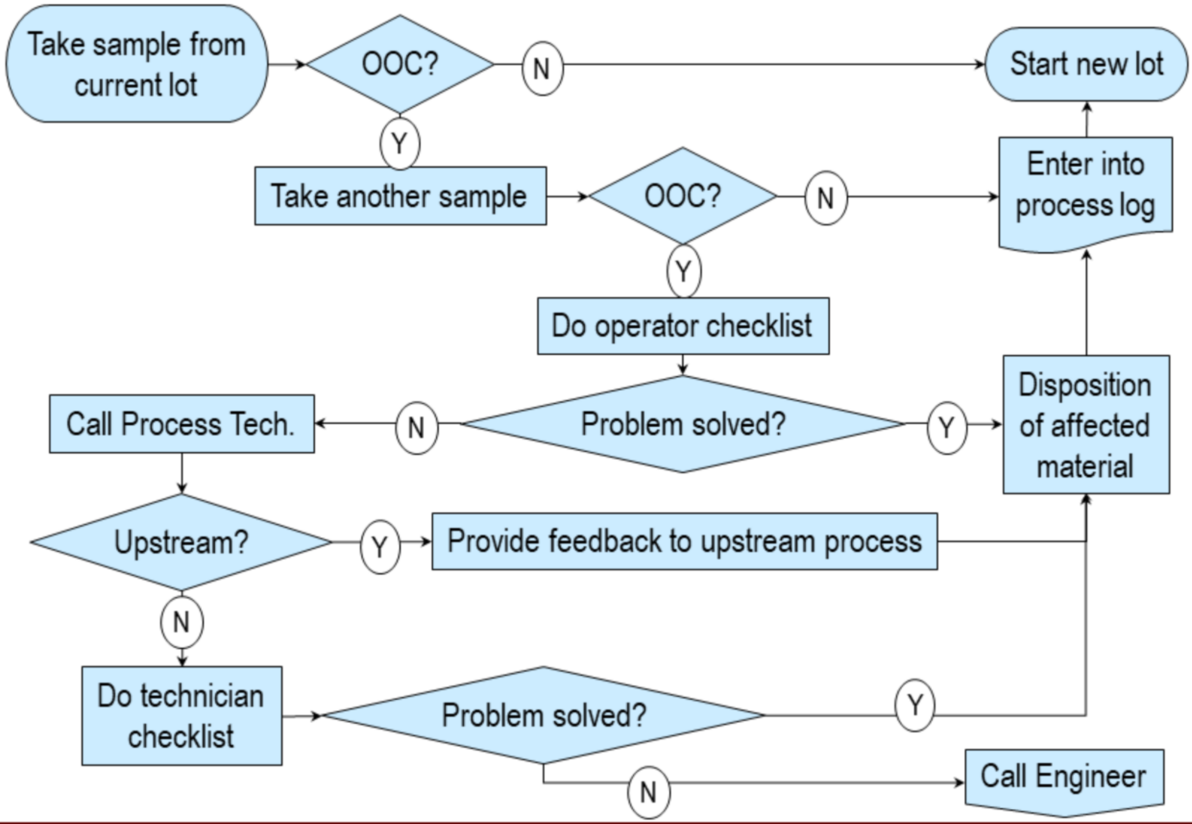
The success of statistical monitoring depends on having a documented plan for responding to OOC signals. The most successful form of documentation for a response plan is a process map like the one shown above, accessible and clearly visible to process participants.

Response Plan Example



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This is a real example ("sanitized" a little) from a high-volume automated assembly process. It was developed by a team including operators, technicians, engineers and the manufacturing area manager.

Based on experience, they wanted to verify an OOC on the first sample with a second sample from the same lot before going into investigation mode. Note the escalation from Operator to Technician to Engineer. Note that their decision to pull a second sample was based on experience, as this is not something that should be done automatically.

Once investigation mode was entered, production was halted until the "Start new lot" point in the response plan was reached. This may seem like harsh discipline, but it worked. Within a few months of implementation, previously chronic equipment and process issues were quickly sorted out. As a result, unplanned downtime and use of Engineering support plummeted. Manufacturing productivity increased dramatically, and engineers were able to spend more of their time on development projects.

Taking Action

Sometimes a short-term action may need to be taken to keep the process operating while a long-term solution is being investigated.

It is important to communicate both short and long-term solutions to everyone involved with the process.

Information on OOC situations should be collected and summarized routinely for use in continual improvement efforts.

Taking Action

About 85% of the variation typically seen in a process comes from common causes.

- Reducing this type of variation must happen at the process and product design level, and is the responsibility of Engineering and Management.

The rest of the variation (around 15%) will come from assignable causes.

- People closest to the process are in the best position to give suggestions on what the possible assignable cause(s) of variation are, and how they might be eliminated (or made permanent).

Once the variation (assignable and/or common cause) has been reduced, control limits should be recalculated to reflect the improved process distribution.

Control Plans are another way to capture and communicate plans for process control.

Control Plans

Part Number/Family:	
Engr. Owner:	
Revision date:	

Critical Paramenter	Lower Spec. Limit	Nominal/Target	Upper Spec. Limit	Units	Metric to monitor	Gauge Used	Gauge R & R	Control limits			Response plan owner	Response plan reference	Cpk/PPM
								LCL	CL	UCL			

blank control plan-1

The control plan is a table that summarizes the plan for process control.

When *audit* is the control method, many of the columns in the table are not relevant. When *control chart* is the control method, all columns are relevant. In particular, we must specify control limits. The calculation of control limits depends on the baseline data.

Control Plans

Process name:	
Process owner:	
Revision date:	

Process step	Control method	Responsibility	Frequency	Data variable	Type of variable			Measurement system	Metric to monitor	Control limits		Response plan owner	Response plan reference
					External X	Internal X	Y			Lower	Upper		

blank control plan -2

Example 1

Part Number/Family:	P/N 2468-1357 Rev. H
Engr. Owner:	CK, Process Engr.
Revision date:	1-12-XX

Critical Paramenter	Lower Spec. Limit	Nominal/Target	Upper Spec. Limit	Units	Metric to monitor	Gauge Used	Gauge R & R	Control Chart Type	Response plan owner	Response plan reference	Cpk/PPM
Widget Length	0.9	1	1.1	inch	Average	Digital Micrometer	15% (0.01 inch resolution)	X-bar and s	CK	WI-003	1.46

Example 2

Process name:	Tool Testing Process
Process owner:	Testing Area Manager
Revision date:	

Process step	Control method	Responsibility	Frequency	Data variable	Type of variable			Measurement system	Metric to monitor
					External X	Internal X	Y		
Determine run conditions	Audit compliance with new procedure requiring special approval to change weight or line speed	Quality Engineer	Monthly, then Quarterly	Run conditions		✓			
Determine run conditions	Disable weight and line speed controls on test line	Testing Engineer							
Release to manufacturing	Control chart	Testing Area Manager	Weekly	Number of days in testing			✓	Database	Average
Release to manufacturing	Control chart	Testing Area Manager	Weekly	Number of rework cycles			✓	Database	Average
Dimensional inspection	Install DVT gage and trainer testers to use it	Testing Engineer							
Dimensional inspection	Periodic gage R&R	Testing Engineer		Spec dimensions			✓	DVT	% of Tolerance

tool development control plan

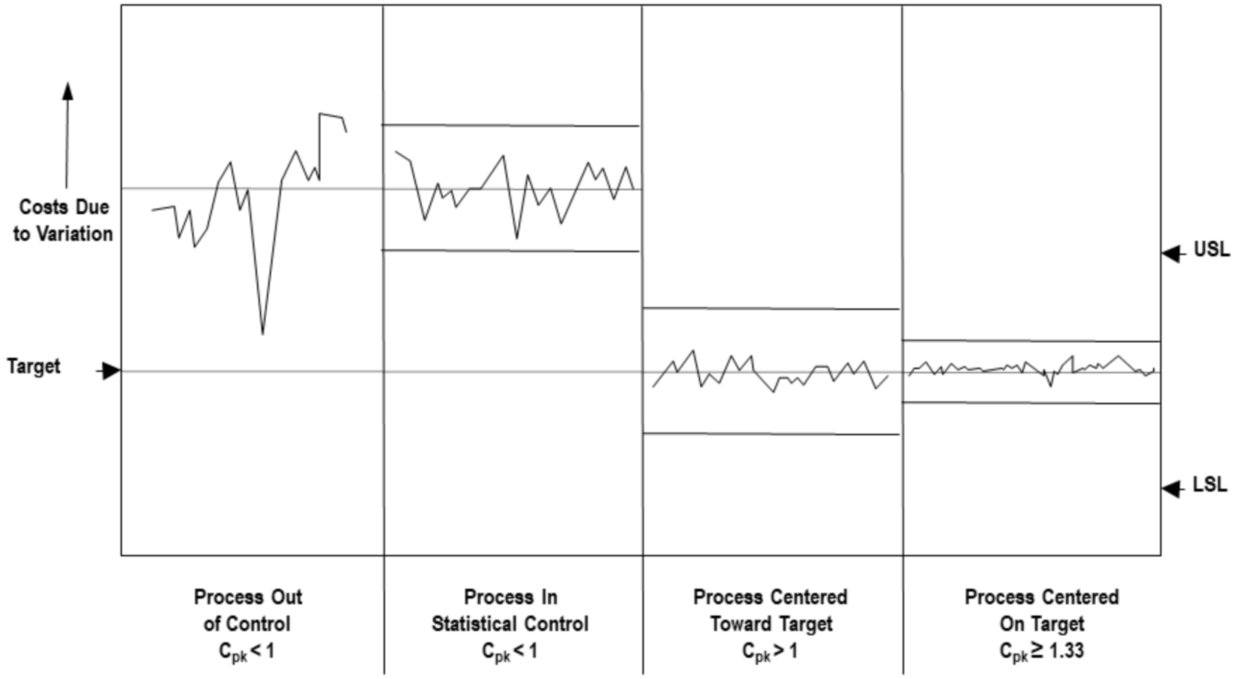
Example 3

Process name:	Quotation Process
Process owner:	Technical Sales Coordinator (TSC)
Revision date:	

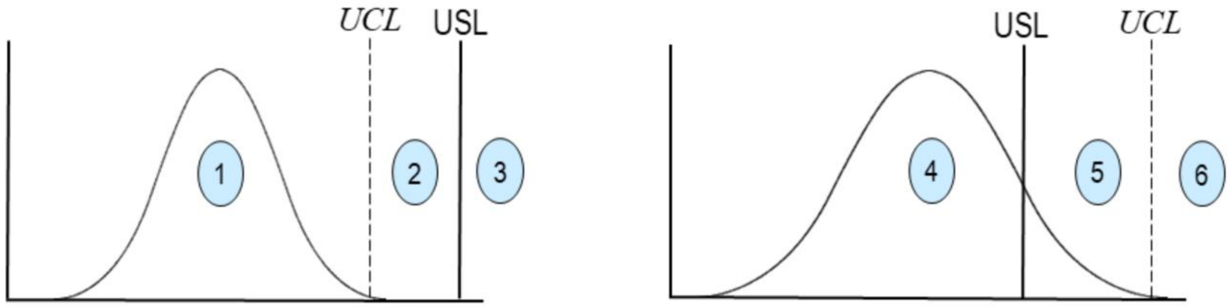
Process step	Control method	Responsibility	Frequency	Data variable	Type of variable			Measurement system	Metric to monitor
					External X	Internal X	Y		
Pre-submit preparation	Train account managers in new process	TSC							
Pre-submit preparation	Audit compliance to new process	TSC	Monthly, then Quarterly						
Develop an offer	Train business units to use configuration workbook	TSC							
Develop an offer	Audit compliance to use of configuration workbook	TSC	Monthly, then Quarterly						
Send quote or request for revision	Control chart	TSC	Weekly	Turnaround time			✓	Quote log	Average

quotation process control plan

Continual Improvement with SPC



Taking Action Exercise



Imagine a control chart point in each of the 6 zones above. Check the appropriate action(s) for each scenario.

Zone	*Use OOC response plan*	*Scrap, rework, do over, etc.*	*Do nothing*
1			
2			
3			
4			
5			
6			

Diagnosing the Process

Learning Objectives

By the end of this section, participants will be able to:

- ☑ Explain the Pareto principle (80/20 rule).
- ☑ Construct and interpret a Pareto chart.
- ☑ Build a Cause and Effect diagram.

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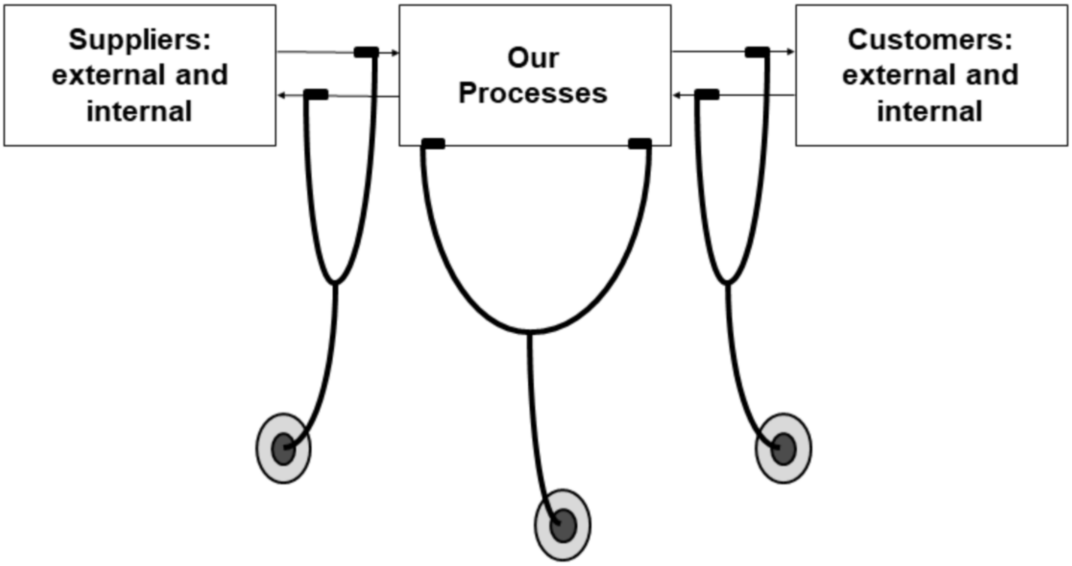
Why Diagnose the Process?



Why Diagnose the Process?

SPC charts and process capability studies are used to show whether or not a process is in control and capable.

- Depending on what is found, we may need to eliminate assignable causes of variation and/or reduce common cause variation.
- Pareto charts and Cause and Effect diagrams are helpful tools for making a process diagnosis. They can help identify defect sources and possible causes for out of control or incapable processes.

Using Pareto Charts

The Pareto principle is named after an Italian economist of the late 19th century, named Vilfredo Pareto (1848-1923), who developed a theory of unequal distribution and proposed the "80/20 Rule." An example of this rule is that 80% of the wealth is held by 20% of the people.

Using Pareto Charts

Joseph Juran applied this principle in the late 1940s to quality problems. He had noticed that the majority (80%) of problems (defects, scrap and rework costs, etc.) were the direct result of only a few (20%) causes.

- For example, if an organization kept track of scrap categories and had a monthly total scrap cost of $1000, $800 of the scrap would be caused by only a couple (20%) of the categories.
- Juran developed a charting technique for separating these "vital few from the many useful " causes and called it Pareto analysis.

Using Pareto Charts

We use Pareto analysis when we need to identify defect sources and decide which problems to tackle first.

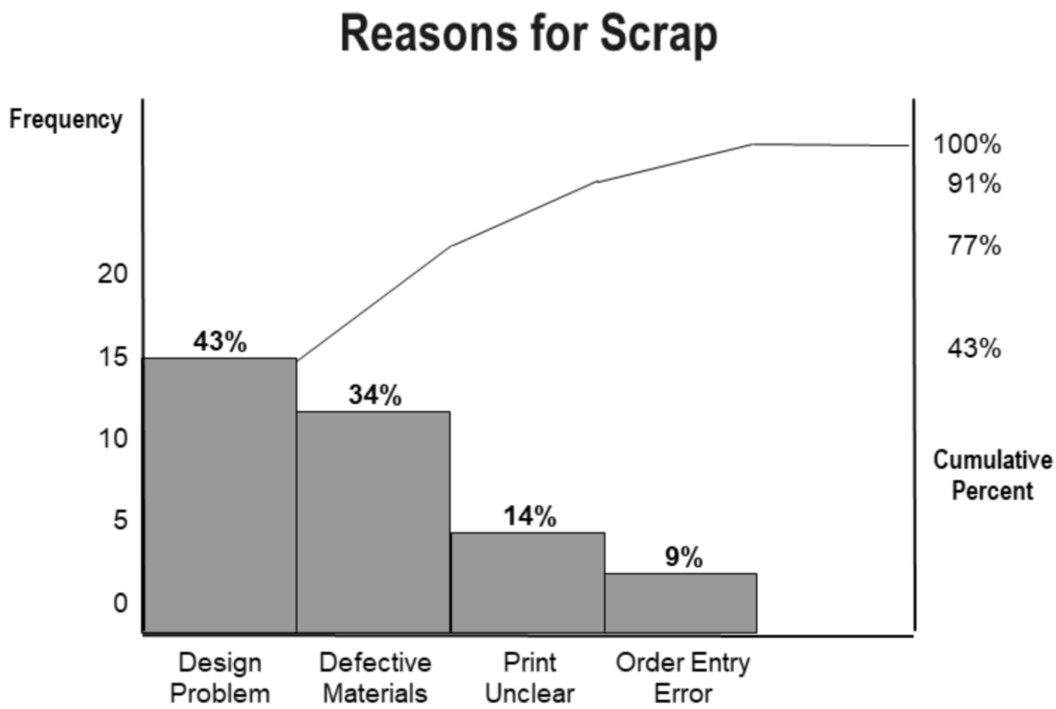
- If we're trying to improve a process, we want to concentrate on the areas where we can have the most impact.
- Our efforts will be most effective if we can eliminate 80% of the problems by removing just one or two causes.

Using Pareto Charts

The Pareto chart is basically a bar chart, with the categories ordered from highest to lowest frequency (or cost).

A cumulative percent line can also be used to show how the defects add up (accumulate) to 100%.

Pareto Chart Example



BUILDING A PARETO CHART

Worksheet

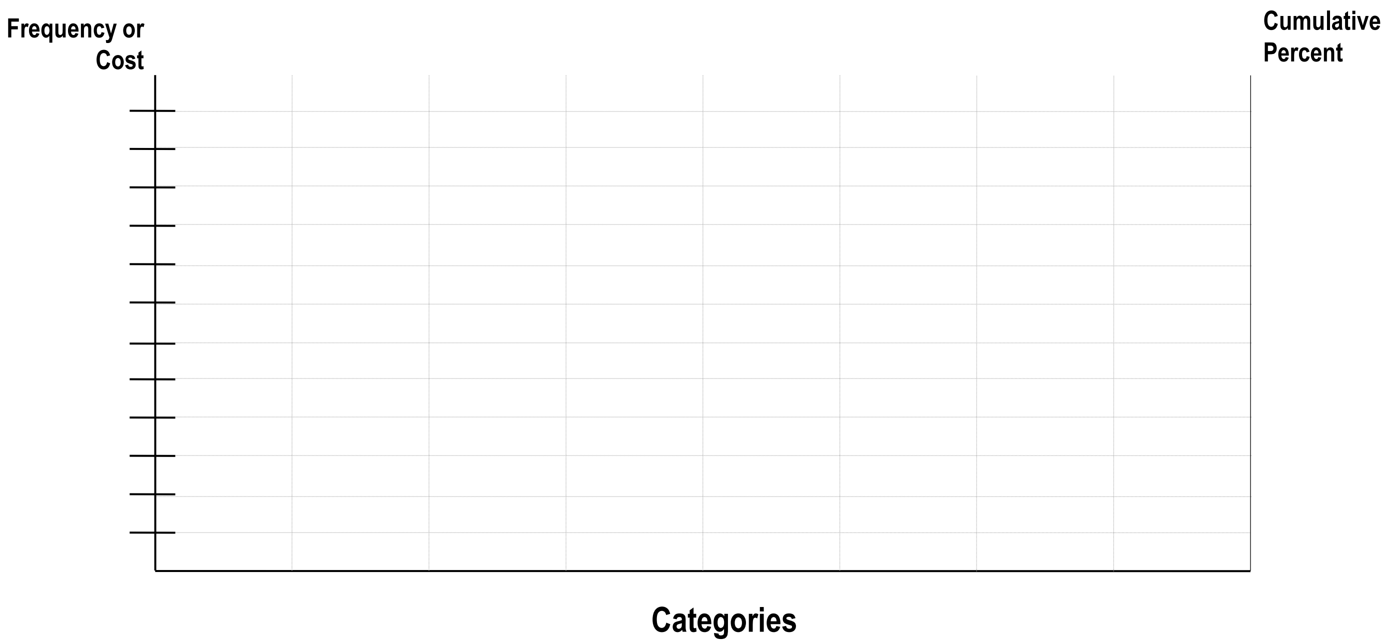
Instructions

1. Collect data by category over a specified time period.
2. Rank by category, highest to lowest.
3. Fill in chart title, frequency/cost scale, and category titles.
4. Draw bars in ranked order.
5. Determine cumulative percentages.
6. Add percentages to chart.

Data

The following is manufacturing data for internal rejections due to part marking. The data represents the cumulative defects for one month of production.

Category	One Month Total
Smudged Ink	5
Ink Adhesion Failures	80
Wrong Location	20
Missing Letter(s)	30
Incorrect Number(s)	64
Missing Information	25



Interpreting Pareto Charts

Once the Pareto chart is plotted, we can see the biggest problems, most frequent defects, etc.

- We may want to look at how often a defect or problem occurs and at how much the defects cost.
- A small number of very expensive defects may have a higher priority than a larger number of inexpensive defects.

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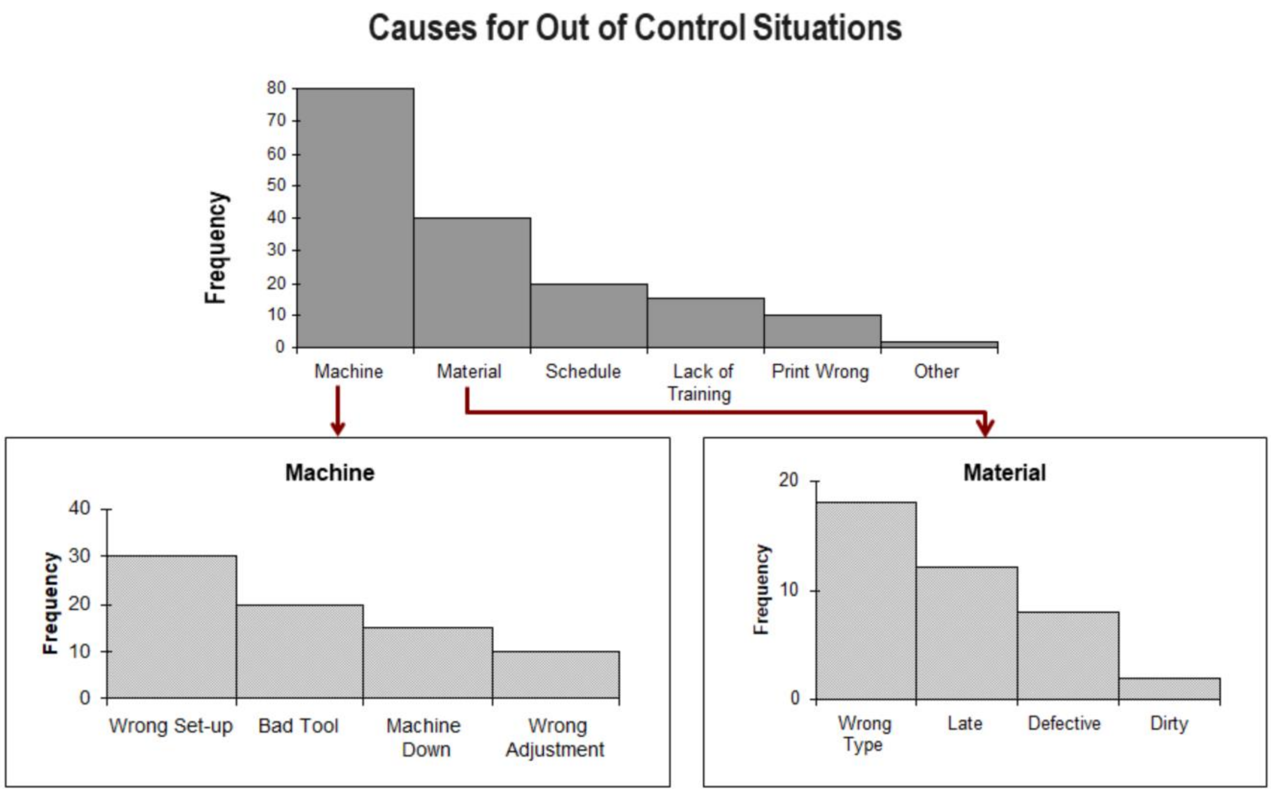
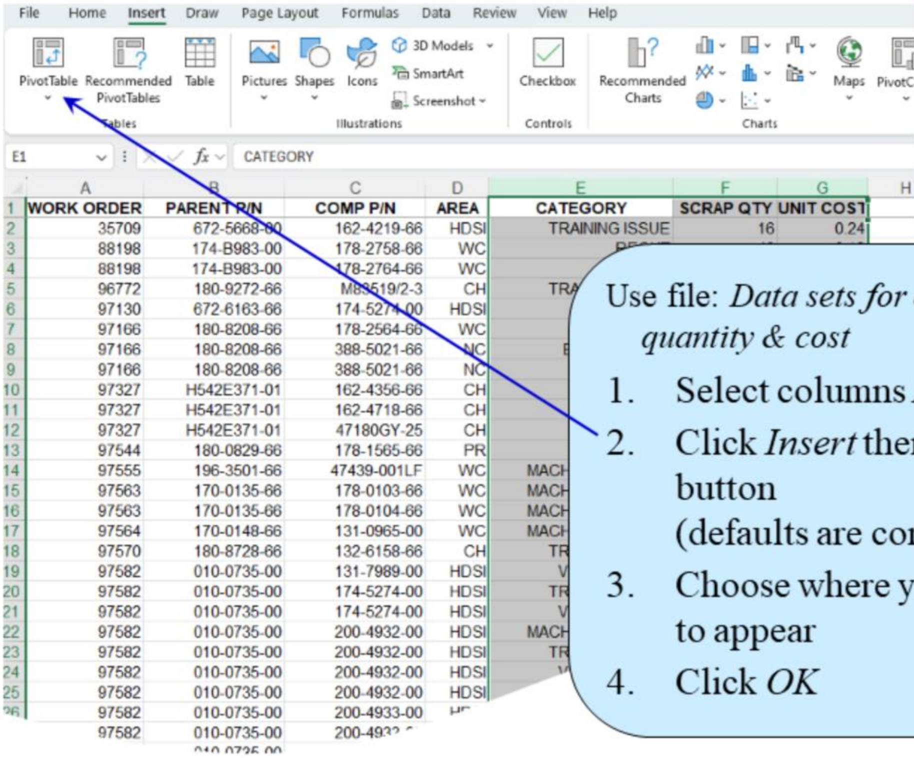
What would be some useful data to examine with Pareto charts for your process and/or the organization?

Pareto Chart Examples



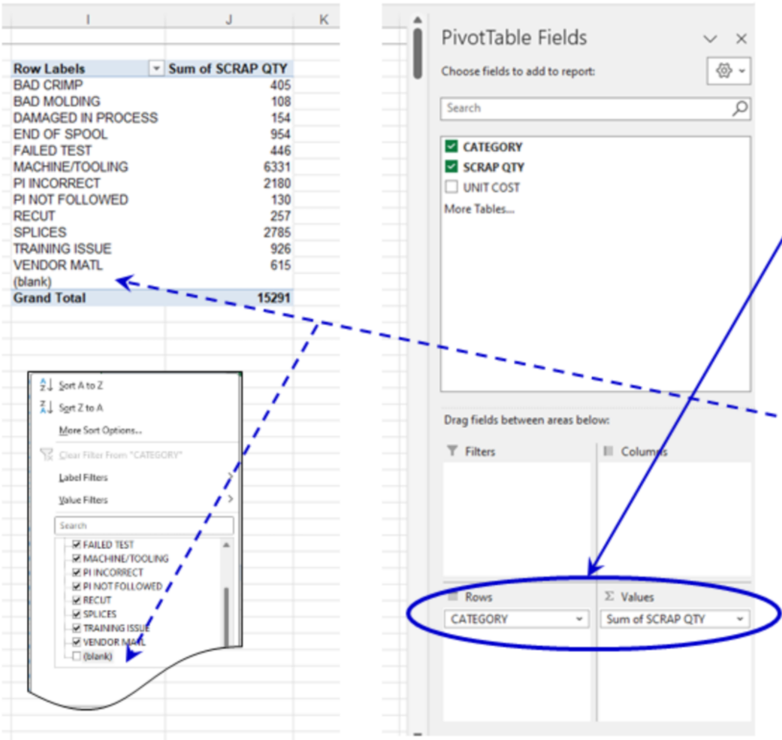
Using Excel: Pivot Table for Pareto



Use file: *Data sets for exercises \ scrap quantity & cost*

1. Select columns *E-G*
2. Click *Insert* then click *PivotTable* button (defaults are correct)
3. Choose where you want the table to appear
4. Click *OK*

Using Excel: Pivot Table for Pareto



5. Drag/drop *Category* to *Row Labels*
6. Drag/drop *Scrap Qty* to *Values* (Excel defaulted to "*Sum*" of scrap qty which is what we want)
7. Uncheck *(blank)* on the *Row Labels* menu
8. Go to the next slide

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Using Excel: Pivot Table Sorting

3	Sum of SCRAP QTY	
4	CATEGORY	Total
5	BAD CRIMP	405
6	BAD MOLDING	108
7	DAMAGED IN PROCESS	154
8	END OF SPOOL	954
9	FAILED TEST	446
10	MACHINE/TOOLING	6331
11	PI INCORRECT	2180
12	PI NOT FOLLOWED	130
13	RECUT	257
14	SPLICES	2785
15	TRAINING ISSUE	926
16	VENDOR MATL	615
17	Grand Total	15291

9. Click on any of the values in the *Sum of Scrap Qty* column.
10. Click *Sort Descending* button or use *Data → Sort → Descending*

3	Sum of SCRAP QTY	
4	CATEGORY	Total
5	MACHINE/TOOLING	6331
6	SPLICES	2785
7	PI INCORRECT	2180
8	END OF SPOOL	954
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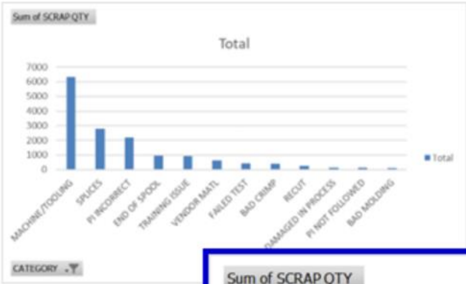
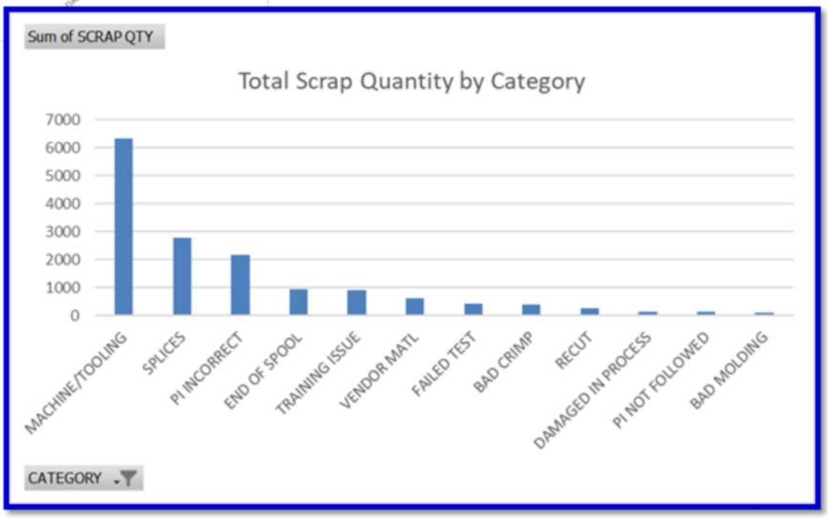
12	BAD CRIMP	405
13	RECUT	257
14	DAMAGED IN PROCESS	154
15	PI NOT FOLLOWED	130
16	BAD MOLDING	108
17	Grand Total	15291

Since Pareto charts are graphed high to low, we need to sort the data in descending order.

Using Excel: Pareto Chart

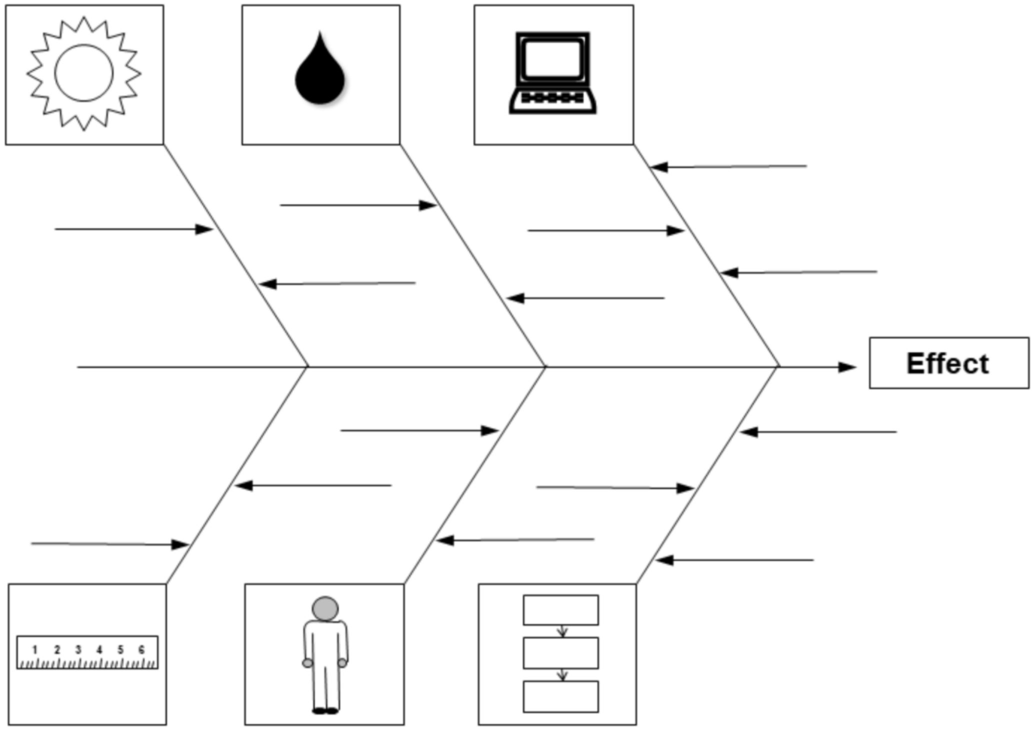


11. Click anywhere in the *Pivot Table*
12. Insert a column chart
13. Format the chart as desired



Next, create a Pareto Chart for the Sum of Scrap Cost. What did you find out?

Using Cause and Effect Diagrams



Using Cause and Effect Diagrams

The Cause and Effect diagram was developed in 1943 by Kaoru Ishikawa. This tool can be used to brainstorm possible causes for out of control situations and/or incapable processes.

The diagram starts with the naming of the *effect*, which is a process issue or problem symptom. An effect might be “parts out of tolerance” or “inconsistent processing temperature.”

Using Cause and Effect Diagrams

The next step is to identify the *major sources* of variation. The "6 M's" are most commonly used, but the sources can be modified to fit the process.

The process begins when the team brainstorms possible root causes under each of the major source headings.

Using Cause and Effect Diagrams

It is important to note that Cause and Effect diagramming is a team process. Getting ideas from a variety of people involved in the process will be more effective than if one person tried to think of all the possibilities.

Brainstorming

Some tips for brainstorming are:

- Do not evaluate or criticize your own or other's ideas.
- List all ideas (repetition is okay).
- Do not discuss ideas or solutions (this throws the brainstorming off track).
- Questions for clarification are okay.

Brainstorming

Only after brainstorming is completed, are the ideas evaluated. The goal is to identify a few top causes for further investigation.

Additional data collection (and Pareto charts) may be needed to determine the top causes—be careful not to jump to causes and solutions too quickly.

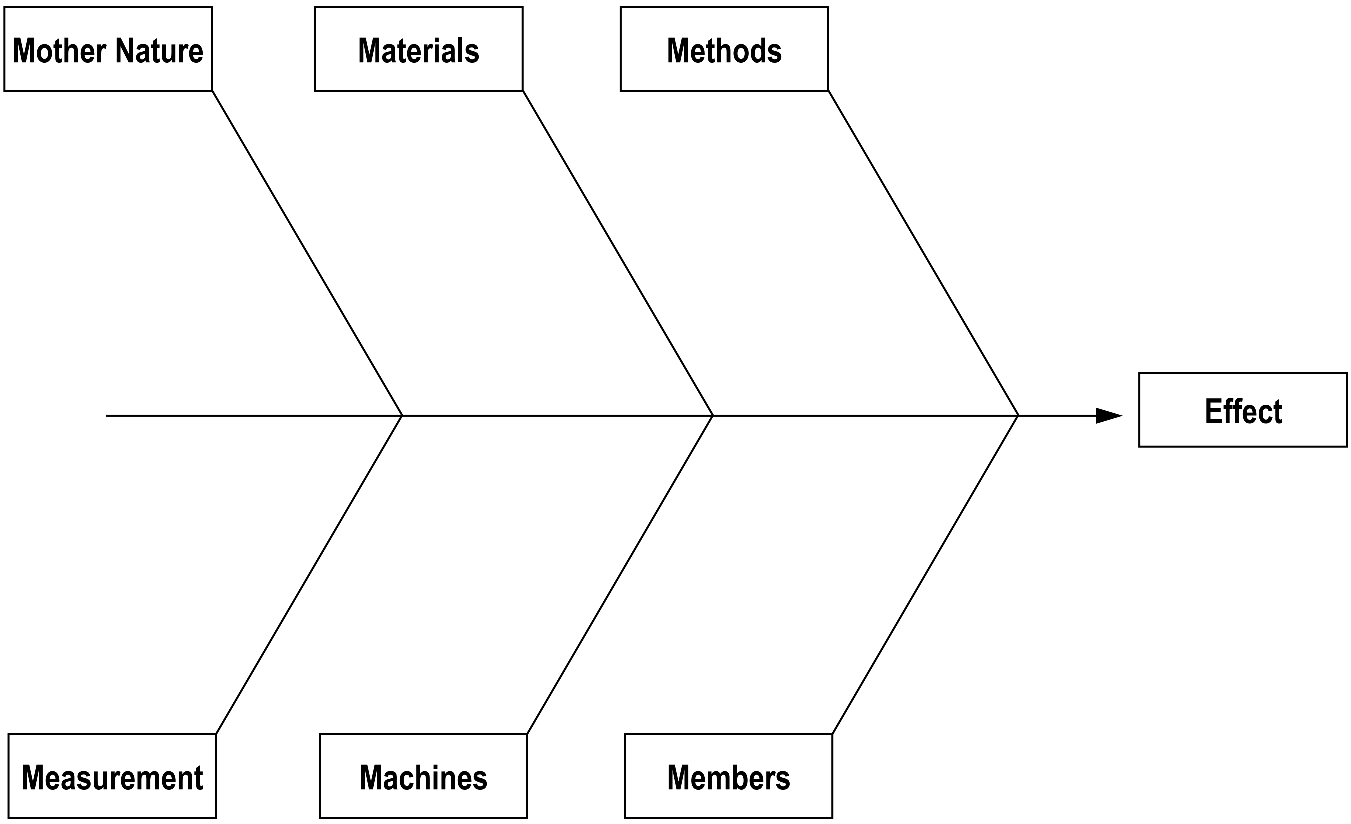
The purpose of Statistical Process Control is to manage by facts, not opinions.

BUILDING A CAUSE & EFFECT DIAGRAM

Worksheet

Instructions

Choose an issue or problem symptom from your process and build a Cause and Effect diagram.



Summary

Summary of Modules

Why Use SPC explained the reasons for and benefits of implementing Statistical Process Control. It explained how the use of SPC. would further the organization's mission, and how SPC would be integrated with daily work life.

Defining the Process created a model for the process by looking at its inputs, the characteristics of the process vs. product, and outputs of the process. It explained how to establish key characteristics for process monitoring. Internal and external suppliers and customers were discussed, and flow charting methods were utilized to further define the process.

Measuring the Process built on the principles of process definition discussed previously by choosing the most appropriate measurement method for the identified key characteristics.

It also discussed the different dimensions of process measurement, why to measure and the types of data that get measured. The principles of process measurement were described, including how to collect meaningful data, use good measurement methods, sample the process, and plan for data collection.

Using Statistics then introduced basic statistical tools used to give data meaning. The module discussed frequency distributions and histograms, with an emphasis on the Normal Distribution. Calculations for average, range, and standard deviation were explained, and the Normal distribution was related to common and assignable cause variation.

Determining Process Capability explained how to compare the natural variation of a process to the defined specification limits. Calculations were used to show whether or not the process is capable of meeting required tolerances, and if not, to estimate the percent defective output of the process.

Control Charts for Variables explained how to create control charts for tracking the variation of processes with variable data. Techniques utilized were run charts, control charts for average and range (X–bar and R) and average and standard deviation (X–bar and s), and individual data points with moving range (IX and MR).

Control Charts for Attributes explained how to create control charts for tracking the variation of processes with attribute data. Techniques utilized were control charts for fraction of defective units (p, np) and number of defects (u, c).

Identifying Patterns and Trends explained how to use patterns and trends in control charts to determine whether a process is in or out of statistical control. Also discussed was when to take action on a process, and who is responsible for identifying and correcting out of control situations.

Diagnosing the Process explained how to use the Pareto chart and Cause and Effect diagram to diagnose process problems.

Key Learnings

Please take a few minutes to think about and note some key learnings from this session.

What seemed most important to you?

How much do you now feel you know about Statistical Process Control and why it is used?

Nothing A little A lot