Desk Reference Guide
For
Quality Improvement Tools and Techniques
Or
Concepts: Control Charts and Improvement Tools

E-Learning class at www.QualityWBT.org

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Important Note: The Desk Reference Guide is a facsimile of the on-line class. It includes some images but does not include: direct links to glossary, interactive exercises, quizzes, graded tests with feedback, animations, hyperlinks to handouts, lesson reviews, and EG Bag examples.

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Lesson 01: Fundamental process analysis and control tools

[This lesson is medium length and discusses the use of charts, diagrams, and forms, which are designed to be tools.]

[Description of topic: Identify, interpret, and apply Pareto charts, cause and effect diagrams, flowcharts, and check sheets. Control charts, scatter diagrams, and histograms will be discussed in Lessons 4 and 5.]

This class is designed for **quality practitioners, managers, professionals, auditors and improvement team members,** and others that need an introduction or refresher of analysis and control tools. You will become aware of the tools and concepts, how they should be applied, and why.

The time allocated for this class is not sufficient to provide a comprehensive study of statistical and other tools. **Additional study is recommended for weak areas**. A supplemental reading list is provided at the end of class. If you want to be a quality engineer or Six Sigma Black Belt, you will need in depth knowledge of statistical techniques.

1. Check sheets, checklists, guidelines, and log sheets

Quality practitioners utilize check sheets, checklists, guidelines, and logs to **improve the effectiveness of activities and processes.** Example processes are audits, inspections, and repetitive tasks. Check sheets are used as records and reminders of tasks to be completed. Checklists are prepared by auditors, assessors and examiners to ensure that all the specified controls and criteria are examined. **Guidelines provide special instructions** and are normally prepared and controlled by a management organization (i.e. company, certification body, government agency). The words **guidebook** and **guide** are also used to describe a set of instructions.

Log books or log sheets are used to **record observations, information or data**. An auditor may need to keep a record of samples taken or the order of interviews, or as a place to record supplemental information when the checklist comment space is full. Quality practitioners, professionals, operators, and team members may need to keep a record for communication purposes. Organizations that operate over multiple shifts keep shift logs; researchers keep log of their experiments; and truck drivers keep logs of their driving histories. Logs may be on paper or electronic. **Logs are always created after an activity is completed where as checklists are created before an activity begins.**

Checklist Rules

1. Prepare before performing the task
2. Link questions, statements to a source document

3. Leave space for comments and observations

A checklist is like a grocery list. You write down the things you are going to check for and you prepare the list before you go to the store. It also provides a place to put your notes, keep track of your progress, and record observations. The checklist should be designed to help the user perform the task, service or process. Checklist **questions or statements** should be **linked to a requirement**.

Checklist

The **purpose of a checklist is to gather information**. It helps guide the user and provides a place to record information. A checklist can be **questions, a series of statements, or even key words** organized in an outline, spreadsheet, flowchart, or tree diagram.

A checklist should be **properly identified** (page, version, title). Include your referenced question or statement, and allow space for collection plans and recorded observations.

Canned or standardized checklists may be issued by organizations for many purposes. **Canned checklists are good for repetitive tasks or for comparison purposes** such as comparing different suppliers or departments. A down side to standardized checklists is that users may rely too heavily on them and develop a **checklist mentality (observations are limited to checklist items).**

Check sheets

A check sheet is a wonderful tool to record events/actions.

Check sheets serve to **record facts versus opinion.** Besides being a simple and effective process control tool, a check sheet is used to **track the frequency of causes of problems or events.** When the product is improperly marked, it is due to: no ink, no pad, no template, smearing, and so on. Each occurrence can be checked off and totaled on the check sheet.

Steps to create a check sheet

1. **Identify the processes and events, steps, and activities to be recorded.** Ask questions such as "What data needs recorded? Why is it needed? How will the data be used?"
2. **Create a form** for collecting data. Typically this is some type of list or matrix (event versus time or group) with space to check off steps or tally observations.
3. Determine **who will collect the data** for the items being recorded.
4. Tally or **summarize the data** by totaling the number of occurrences for each category or verifying all activities checked off.

Note that a **check sheet may actually be a drawing or picture**. Instead of listing items to check such as cylinder surface defects, the cylinder is pictured and the defects are recorded as checks on the cylinder.

2. Flowcharts, process mapping and process flow diagrams (PDFs)

The purpose of a **flowchart is to describe a process or system** (e.g. how work is performed). Flowcharting is like drawing a picture. Quality practitioners, auditors and improvement team members are encouraged to flowchart processes to better understand them. Flowcharting is a useful **technique for understanding complicated procedures and identifying redundancies**.

There are many different flowchart styles and techniques. Flowcharts can be constructed using pictures and/or symbols, and put in horizontal and vertical arrangements. Flowchart symbols can be found at ANSI/Y15.3.

To construct a flowchart:

1. Define the process steps by brainstorming (new process) or from a reference document (existing process).
2. Sort the steps as they occur in the process.
3. Place a box or the appropriate flowchart symbol around each process step.
4. Evaluate the steps for completeness, efficiency, and possible problems.

The benefits of flowcharting include:

- It provides common understanding of the process steps/sequence.
- It helps with identification of problems/improvements.
- **It is a valuable tool for training programs.**
- Checkpoints are easy to identify.
- Responsibilities are easy to identify.

Process tools

The increase in popularity of process-based management systems, six sigma and process auditing techniques has dramatically increased the use of flowcharts. Other similar charts that depict process flow or process steps are process maps and process flow diagrams (PFD).

Process maps are very good tools that **show process activities of each area or department along a timeline** until the process output is achieved. **Process maps show area or department interfaces** well. The complexity of process maps can vary depending on the process and what the map will be used for.

The sequential process steps may not be as straight forward using a process map compared to a flowchart, but area **responsibilities are much easier to see and understand.**

Process flow diagrams (PFDs) have been used in the process industry for many years. **A PFD focuses on the sequential steps or activities of a process. It is easy to view the order of the steps, responsibilities, and testing or decision points.** Department interactions are not as clear, and techniques, such as using different colors, may be needed. A process diagram may look like the following image taken from *Process Auditing Techniques Guide.*

3. Line, bar, pie charts, and matrices

There are several basic charts and graphs used to display data. Displaying data in certain ways helps us **visualize patterns and trends** we would not otherwise notice. Also, large amounts of data can be shown in one simple chart or graph.

Other data display tools are matrices and data systems. Matrices may be used as guides by listing elements or controls to be checked on the left column and functions or departments to be checked in the top row. For example, it is very clear which departments must be checked to verify management review controls. **Matrices are visual aids for linking information.**

Element/ Control	Engineering	QA	Management	Purchasing	Sales
Management Review		X	X		
Design	X				
Corrective Action	X	X	X	X	X
Internal Auditing		X		X	

Data can also be displayed in spreadsheet formats. Organizations use spreadsheet formats to report progress or status. More **detailed data can be reported in spreadsheet format**.

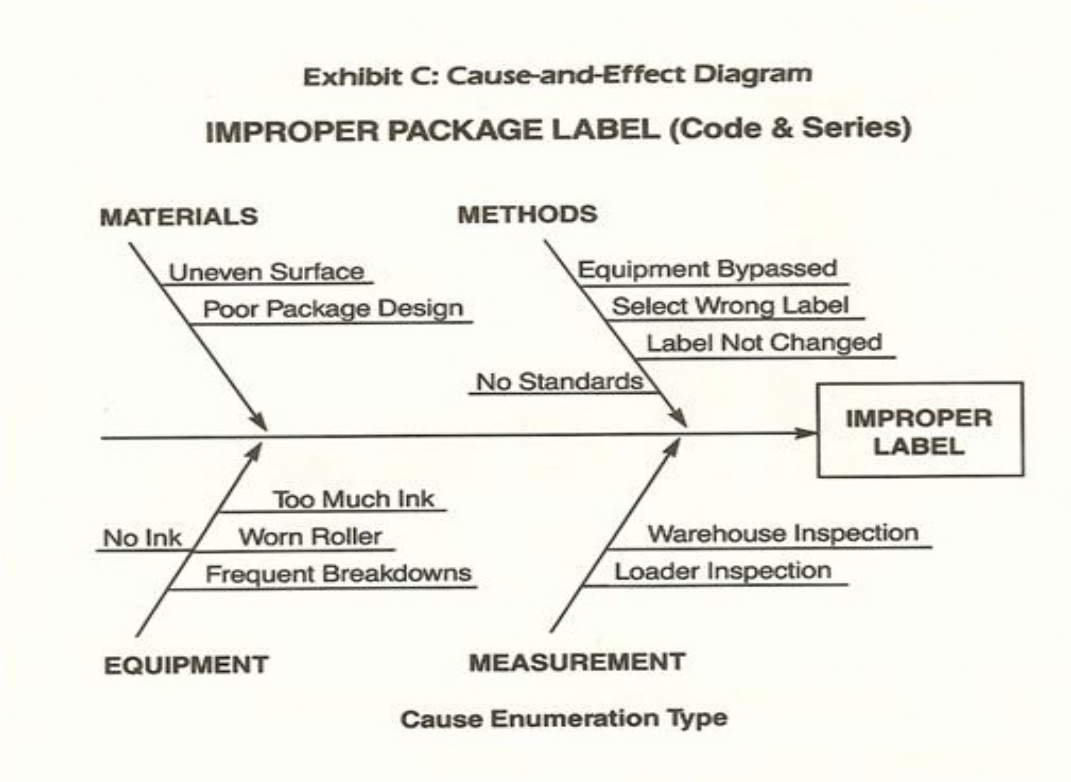
4. Cause and effect diagrams

The purpose of the cause and effect diagram (CE, fishbone, or Ishikawa diagram) is to **identify and sort causes of a problem**, issue, concern, or undesirable situation. The causes of the effect are sorted by causal groupings.

The steps for constructing a CE diagram are:

1. Draw the diagram as shown above.
2. Define the quality defect, characteristic, or problem and place in the box to the right. For example: Incomplete audit reports.
3. Define the main causes of the problem and group according to the 6 causal groupings. For example: cause #1 could be: *not trained*, cause #2 could be: *no format provided on disk*, cause #3 could be: *no report standards*.
4. Identify the most likely causes and collect data to validate.

Managers and facilitators may use brainstorming techniques to identify causes in number 3. The diagram **clearly shows the relationship among causes and effects**.



5. Pareto charts

The purpose of a **Pareto diagram is to rank problem/cause categories to identify the most important**. Pareto diagrams are based on the **Pareto Principle**, which suggests that most of the effects come from the *vital few* causes (also called the **80/20 Rule** or the **vital few versus the trivial many.**

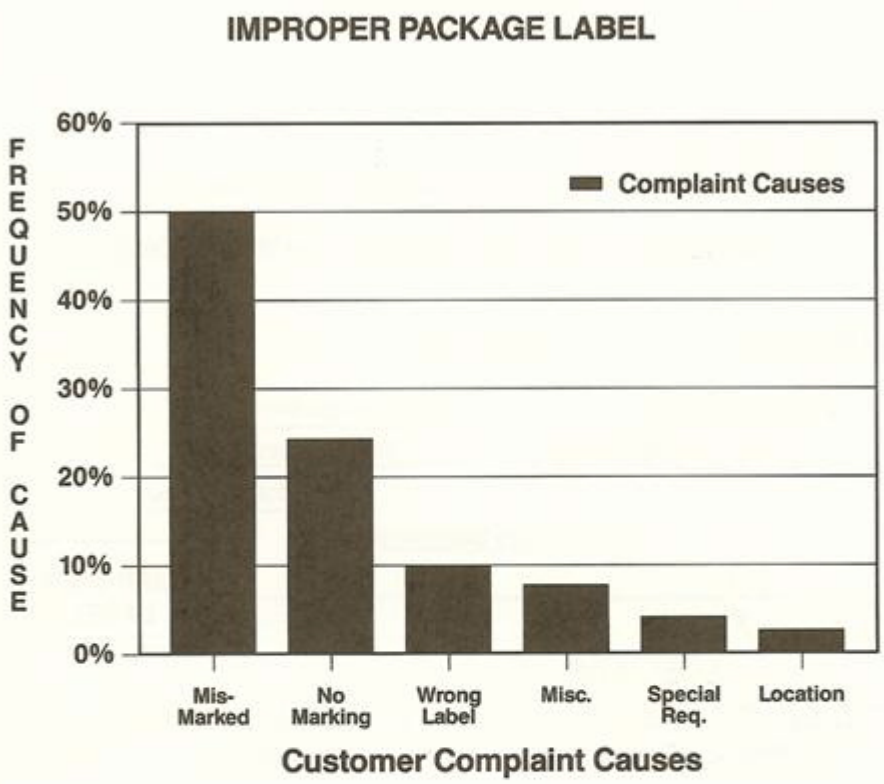
Pareto charts are powerful **decision tools**. A modification of the original Pareto chart can be used to show the **dollar effects of causes**; the thinking being that ultimately it is

the economic effect, not the frequency of a cause, that is the most important to an organization.

The steps for constructing a Pareto diagram are:

1. Collect the problems/causes/categories and corresponding frequency of occurrence information.
2. Sort data by the highest frequency first and place on the chart, as above
3. The data will graphically show which problems are the most important and need to be to worked on first.

Exhibit D: Pareto Chart



Complaint Causes & Frequency Summary

50% Code and series not complete or illegible
25% No code or series markings
10% Wrong code and/or series
8% Miscellaneous
4% Special customer requirement missing
3% Label in wrong location

In the next lesson you will learn about improvement programs that have been effective. Organizations have adopted certain strategies to achieve continual improvement.

Lesson 02: Improvement tools and techniques

(This lesson is medium length. It discusses popular programs and techniques for improvement such as six sigma, lean, corrective and preventive action, and root cause analysis. There is a case study at the end that you must read and be tested on before you can continue.)

(Description of topic: Identify, interpret and apply problem-solving tools, such as root cause analysis, the six sigma model (DMAIC), lean tools, Plan-Do-Check-Act (PDCA) and corrective and preventive action (CAPA) methods.)

Quality practitioners, managers, professionals, auditors and improvement team members should be familiar with **problem solving tools so that they are better able to communicate with others, contribute to an organization's success and direct resources.** This is important for improving the effectiveness of all organization processes by eliminating causes of problems and making changes for improvement.

1. Six sigma model (DMAIC):

Six sigma is a program for using an **organized project approach for applying techniques and tools, which focus on providing defect-free products and services**. Statistically, six sigma is the achievement of a certain confidence level of defect-free outputs. Numerically, attainment of **six sigma is 3.4 defects per million possible defects**.

Six sigma programs **require strong management commitment**. Many organizations are implementing six sigma programs due to the promised claims of bottom line benefits. The people who are trained to implement six sigma programs are **given titles such as *Master Black Belt, Black Belt,* and *Green Bel*t**. For example, persons who have passed the six sigma training may identify themselves as CSSBB, which stands for *Certified Six Sigma Black Belt*. The requirements for certification vary from training organization to training organization.

The six sigma improvement approach is based on Edward Deming's Plan-Do-Check-Act cycle. The six sigma model is referred to as **DMAIC** (see next screen) **and can be used for new designs and ongoing improvement of processes**.

The DMAIC steps are:

D – Define: Identify the problem or opportunity, define requirements and set goals.

M – Measure: Gather data to establish a baseline and to validate the problem or opportunity. This may include mapping or flowcharting the process and identification of critical steps and key measures.

A – Analyze: Analyze data and identify potential root causes and select the ones to be included in the improvement project.

I – Improve: Develop approaches for eliminating root causes and implement them.

C – Control: Monitor changes and verify benefits. Modify the process improvements as needed.
Six sigma programs **require a significant investment in training and management commitment,** similar to the TQM programs of 10 to 20 years ago. Six sigma has revitalized interest in continual improvement and is credited with making significant improvements; however, **six sigma (statistically) is rarely achieved.**

> Note: Six sigma programs can be abused just as any other program. Six sigma claims should be verified. I was conducting an audit of a six sigma company and found defective product that had to be returned. I was wondering how they could be a six sigma company and ship defective product. It was explained to me that it is all in how you determine the possible defects. For example, the packing slip that goes with the product could be a defect, each word on the packaging slip could be a defect, and so on.
>
> Before doing business or entering into a contract with a six sigma company, you should always verify claimed improvement program achievements to expose superficial attempts. The same applies to corrective action, preventive action and lean programs.

Examiners, assessors and auditors can verify six sigma program benefits, ensure that the program is sustained and provide input for additional improvements using continual improvement assessment[1] techniques.

2. Lean tools (5Ss):

Lean improvement programs are focused in process efficiency and optimization. Lean programs are associated with the **5Ss for maintaining a clean and efficient workplace**.

The five Ss (taken from Japanese) are:
1. Seiri: Separate needed tools, parts and instructions from the unneeded. This would be the first step to de-clutter an area or work process.
2. Seiton: Arrange and identify tools, parts and instructions for ease of use.
3. Seiso: Clean up.
4. Seiketsu: Make cleaning up a habit and part of the job-process.
5. Shitsuke: Be disciplined, apply yourself by following procedures.

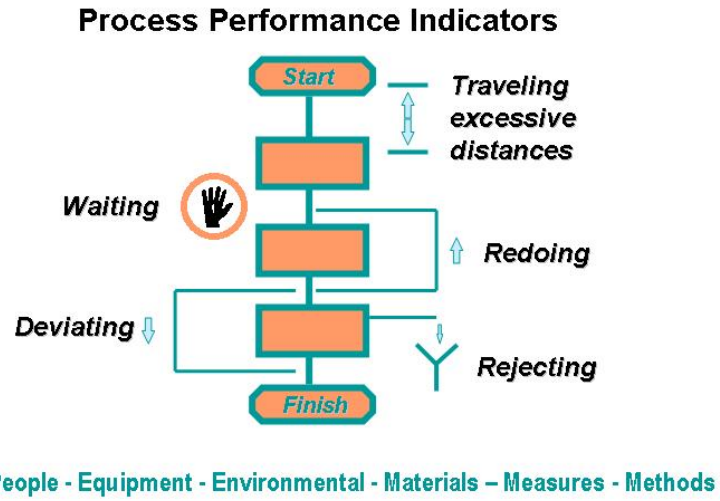
The 5Ss help reduce wasted or inefficient operator steps (movements).

Lean thinking is also about reducing waste and cycle times. Lean thinking includes:

- Balancing production
- No waiting
- Minimizing work-in-progress
- Reducing process time
- Making controls simpler
- Building quality in the process
- Self inspecting
- Preventing

Mistake or Error proofing (also called Poka-yoke) is a popular technique used in lean programs. **Error proofing helps prevent defects from occurring, cuts costs, improves cycle times, and achieves product/service quality goals.** Quality practitioners, managers, professionals, auditors and improvement team members may observe **process performance indicators** and report opportunities for improving efficiency. Process Performance Indicators[1] are:

- **Waiting:** Material on-hold waiting for the next step of the process
- **Redoing:** Rework of any kind is an indication of waste
- **Deviating:** Skipping or adding process steps
- **Rejecting:** Scrapping material
- **Traveling excessive distances:** Wasted energy



Lean program benefits should be monitored by management. Techniques for monitoring and sustaining improvement programs can be accomplished by using continual improvement assessment techniques

3. Corrective and preventive action methods (CAPA):

Eliminating the causes of a nonconformity, problem, or undesirable situation has been a mainstay of improvement through the adopting of standards such as ISO 9001. Standards require corrective and preventive action and **organizations must provide evidence they are meeting the requirements**. Organizations are largely left to their own devices for taking corrective and preventive action but ISO 9001 does have specific steps that must be followed.

ISO 9001:2000, Clause 8.5 -Improve Requirements and Steps	
Corrective Action	**Preventive Action**
1. Identify problem	1. Identify potential problem
2. Identify causes	2. Identify causes
3. Determine and implement action	3. Determine and implement action
4. Record results of action	4. Record results of action
5. Review	5. Review

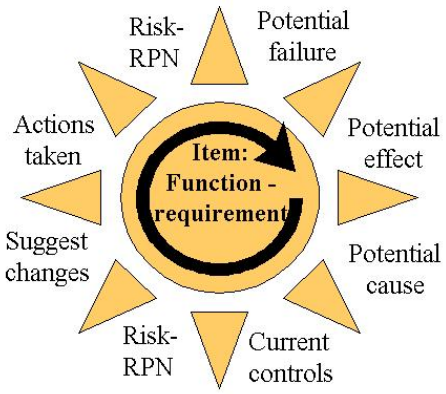
Auditors can verify that corrective/ preventive action programs have been implemented and maintained, and that improvements have added value and provide input for additional improvements by using continual improvement assessment[1] techniques.

4. Failure Mode and Effects Analysis (FMEA):

Failure Mode and Effects Analysis (FMEA) is a structured and disciplined approach to **identify potential failures and their effects, and to identify actions to minimize or eliminate potential failures**. Regardless of whether your business is manufacturing or service-oriented, FMEAs are critical tools for effective management. **FMEAs can be used to facilitate preventive action and continual improvement**. They provide an **essential means of discovering and correcting potential process/ product weaknesses before they become a problem.**

FMEA is a method used to assess risk of undesirable outcomes in order to initiate action on higher risk events. **The key is determining the RPN (Risk Priority Number) based on severity, occurrence and detection ratings.** FMEAs are started by identification of **potential failures.**

FMEA Preventive Action Cycle



Typically, FMEA teams follow along by completing a form in a step-by-step manner.

5. Root cause analysis

The root cause is use with other problem solving tools, such as PDCA, the "5-WHY's" approach (Who, What, When, Where, Why), the Ford "8D approach to preventing the recurrence of defects," etc.

Root cause analysis is the **process for determining the root cause** (or basic reason) for a problem, defect, or undesirable situation. There is a reason for everything; unfortunately, most of the time organizations stop short of identifying the underlying cause of a problem and problems reoccur.

The **PDCA cycle is the basis for problem solving** and finding root causes of problems. Organizations have developed various modifications of the PDCA cycle to address problems. For example, the motor companies have the Chrysler 7 Step, the Ford 8-D, and the General Motors PR&R. Also, answering the questions *who, what, when, where, and why* each step of the problem solving process is a good technique. Here is a summary of the basic steps for problem solving:

Root cause analysis is an integral part of the corrective action process discussed earlier. Many of the tools described in Lesson 1 and this lesson are used as part of the root cause investigation. Each situation may be different and require a different set of tools to analyze and fix the problem.

In the next lesson we will discuss the world of sampling and why it is so important. Improvement efforts must be based on creditable information.

Lesson 03: Sampling methods

This lesson is medium length. It discusses sampling products and processes for the purposes of decision making, and has a test at the end that you must pass to continue.]

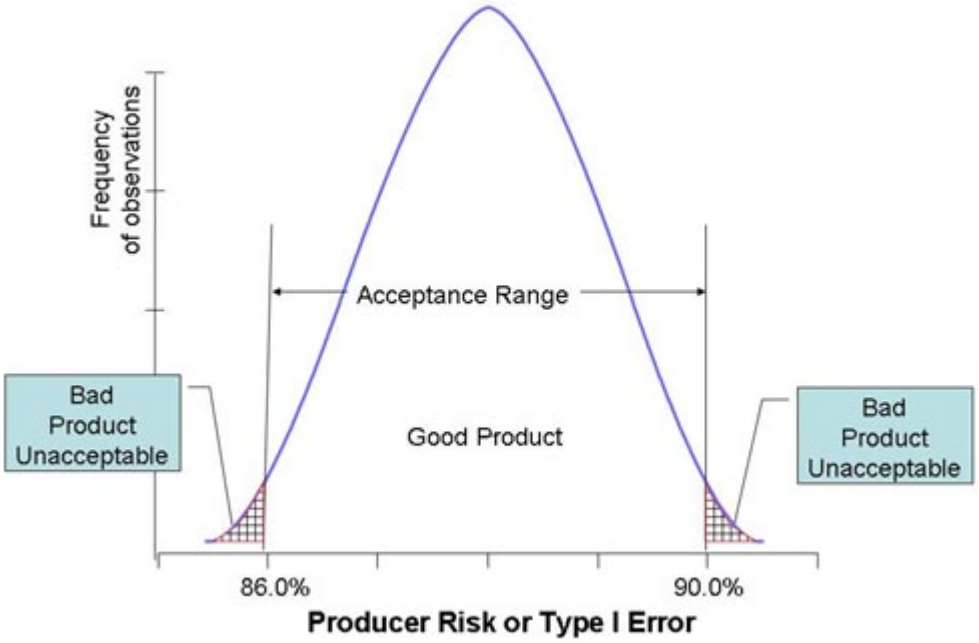
[Description of topic: Identify, interpret, and use various sampling methods (such as acceptance and random), and define related concepts (e.g., consumer and producer risk, and confidence level).]

This lesson is divided into three parts. The first part is about important sampling concepts. The second part is about **nonstatistical sampling used routinely by quality practitioners, managers, professionals, auditors and improvement team members to gather information.** It is important to know the advantages and shortcomings of sampling techniques. The third part is about **statistical sampling used to reduce appraisal costs** (100% inspection) for certain confidence levels

1. Sampling Concepts

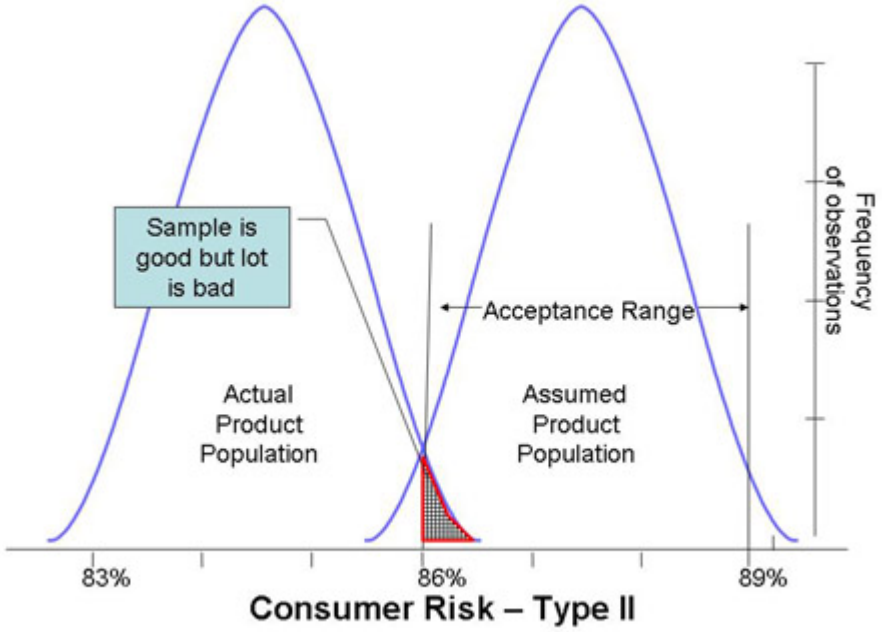
Hypothesis Testing is creating two hypotheses to arrive at a decision based on sampling. **Sampling is used to make business decisions regarding the marketability of a product or quality control decisions regarding the acceptance of a batch, lot, or process.** A hypothesis may be: *if the lot achieves a certain acceptable quality level (AQL), it will be approved*. Or a decision rule may be: *if X number of parts are found to be defective, the lot will be rejected*. Consumer and producer risk are the chances of making decision errors based on the sample taken.

Producer Risk, or Type I Error, is the probability that **good quality product is rejected** or the probability that a product survey would indicate that a product is not marketable, when it actually is. The producer suffers when this occurs because good product (or marketable product or service) is rejected. The math symbol used to represent producer risk is alpha (α risk).



Consumer Risk, or Type II Error, is the probability that **bad quality product is accepted** or the probability that a product survey would indicate that a product is marketable, when it actually is not. The consumer suffers when this occurs because bad product is accepted (released). The math symbol used to represent consumer risk is beta (β risk). For example: A product recall may be the result of a Type II error.

Sufficient samples of the population must be taken to achieve a certain confidence that Type I and Type II errors will be avoided. Statistically, we can define a sampling plan as one that will give us confidence in the results. Typical **confidence levels** are 95% or 99%. There is a **trade off between the confidence level you want to achieve versus the cost** of sampling.



2. Non-statistical sampling techniques

This section describes some easy-to-use techniques that will **improve the quality and reliability of the information gathered** from taking non-statistical samples.

Samples are taken to save time and resources. 100% inspection is rarely economical and in many cases not appropriate. Non-statistical sampling is the most popular type of sampling and can be done at a lower cost compared to statistical sampling. **Non-statistical sampling is used to collect information or data. The information is taken at face value.** Information from non-statistical sampling may be used to make decisions about a project, audit finding, problem, business issue or system/ process effectiveness.

For example: The engineer sampled the last 10 design packages and found 7 of them to be incomplete. Or, the investigation revealed all damaged product is from the new purple line

Samples

For the purposes of many investigations, such as audits, sample selection is **random and taken from a homogeneous population**. "Random" means that every item in the population (universe or strata) being sampled has an **equal chance of being picked**. "Homogeneous" means the population must be **uniform throughout** (no bias or segregation). For example: many states use floating balls for random (any ball can be

selected) and homogeneous sampling (all balls are identical) to select winning lottery numbers.

Simple random sample techniques used during an audit or other types of investigations may include:

- **Selecting an arbitrary number from a log or list** or pointing (looking away and pointing to a number or entry)
- **Physical selection from a batch or group,** such as a file from a file drawer or item from a basket
- Selecting lots, batches, customers, orders, or complaints by using a **random number table** (found in a statistical textbook). Other sources of a random number selection are: 1) opening a thick book to a page and using the page number as a random number, 2) picking a number from a hat, 3) spinning a dial, and 4) asking a disinterested party to pick a number.
- To get a good cross section, samples may be selected at **periodic intervals** and a random unit within that interval (interval sampling). For example, if you wanted to examine 10% of the 120 devices under calibration or security control, you may select an interval of 10 and examine the 3rd device of each interval (3, 13, 23, 33, etc).

The selection technique will depend on what is being sampled (bucket of material versus insurance policies issued for November).

Most auditors, investigators and examiners, use non-statistical techniques. **Cluster sampling (block) is used to limit the population** to what is relevant (i.e. only orders over $1,000, lot numbers of product produced this month). **Directed or judgmental sampling is used to root out problem areas** or evaluate high risk processes (i.e. sample the line with the most defects or product line with the most complaints).

Sampling strategy is an important part of any investigative process. For external compliance or conformity assessments, auditors may want to take random samples that represent current operations. For internal investigations, you may want to focus on the known weak or problem areas.

Auditors and other investigators may **determine the sample size based on his/her experience**. A common technique is to take a 10% sample.

If one problem is uncovered or a minor defect is identified, **another 10% sample may be taken** to determine if the observation was an isolated incident or there is a systemic issue. Investigators should **record the results** of the sampling.

A good practice for investigators (auditors) is to report the significance or relative importance of the sampling data. Sampling data should not be used to misrepresent the situation or mislead anyone. For example, if your organization receives 100 orders per

day, you may want to investigate order errors. You start sampling and find that 2 of the first 3 orders had errors. Since you found errors right away, you stop sampling orders and report that 66% of the orders evaluated had errors.

3. Statistical sampling

Statistical sampling (as opposed to non-statistical) is used when **higher levels of confidence are needed** in the sampling results. This may include **decisions about product release, process control, safety, environmental,** and other high-risk areas. Statistical sampling requires taking a random sample from a population. A population may be a lot, batch, or a process stream.

The results of sampling testing are used to make decisions about the status of a process, designated lot, or batch of product. The sampling frequency and size will affect the confidence level of the sampling results. As the **frequency and sample size increase, the confidence level in the results increases**. Typically, organizations want to work at 95% to 99% confidence. However, **as frequency and sample size increase, so does the cost of the sampling program**.

Compared to 100% inspection, **sampling saves labor hours**. Sampling is a **practical approach** when there are **large numbers of items** to check and when testing makes an **item unusable for its intended purpose**. A history of high quality levels could **justify reduced sampling,** which would lower cost. As processes improve, sampling can be reduced or eliminated. Sampling also allows **low-risk items to be sampled less** and **high-risk items to receive more scrutiny**.

a. Attribute and variables sampling

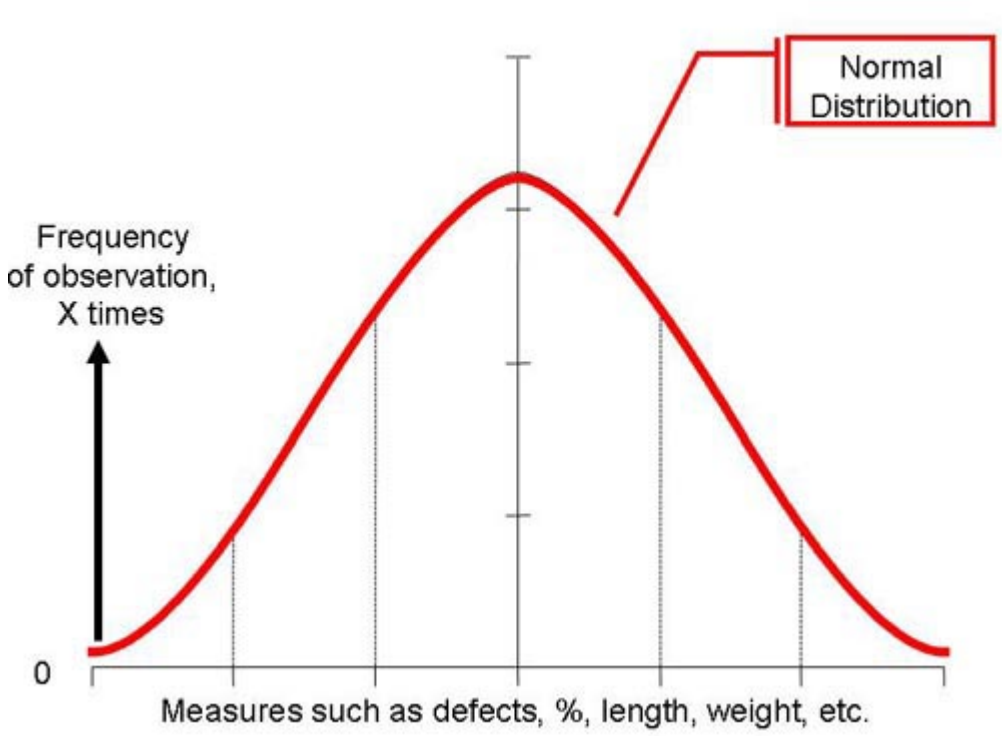
Statistical sampling to determine the percent of nonconforming product can be either attribute sampling or variables sampling.

1) Attribute sampling is when an item is checked to determine if it is **conforming or nonconforming** (good or bad, pass or fail). In some cases degree of conformance may also be reported such as bad, very bad, good, and very good. Lots may be accepted or rejected based on attribute sampling results. Go/No-go gauges are good examples for checking dimensions. Go/No-go gauges can determine if a diameter or item length is too small or too large.

2) Variables sampling is when an item in a lot is checked for **percent of nonconforming product**. Lots are accepted or rejected based on actual measurements. Variables sampling yields **a number that varies from sampled item to sampled item or test to test (numbers such as 243 or 1.3356, and so on)**. Acceptability may be based on a defined **plan specifies a minimum or maximum, range (interval) of a value or a function of variable**. A function of the measurement (variable) may be the mean, or standard deviation (discussed in the next lesson under descriptive statistics).

Variables sampling normally requires fewer samples (compared to attribute sampling) for a given level of assurance (95% or 99% confidence), but may be more costly to implement and is limited to one variable or measured characteristic of a product.

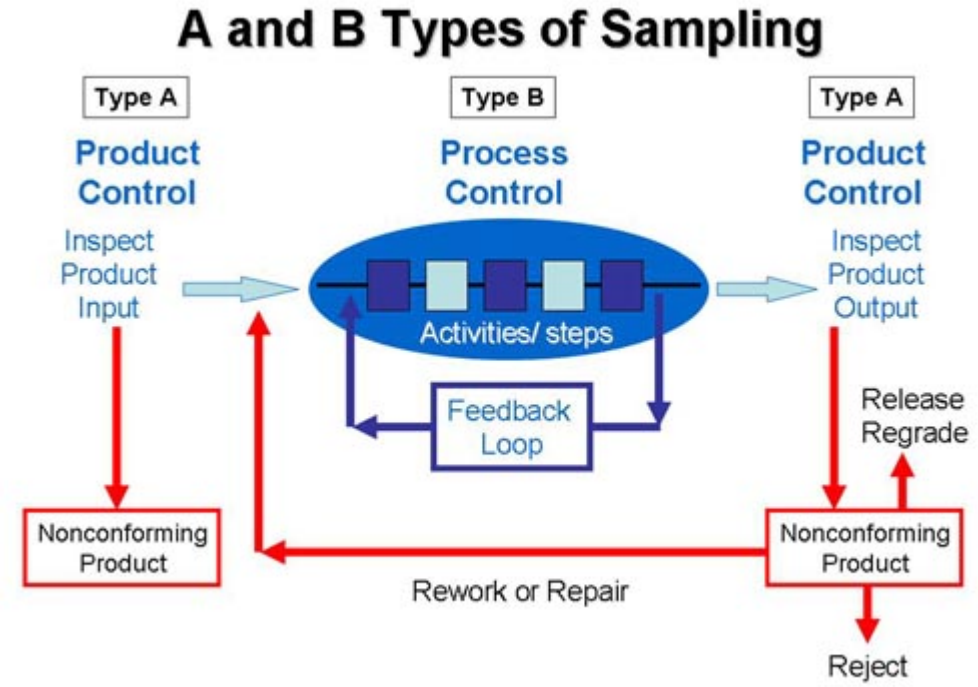
It should be noted that many of the variables sampling techniques for estimating percent of nonconforming product assume a normal distribution (data equally distributed around an average value and with the most frequent values being near or around the average, see diagram below).



b. A and B Types

Acceptance sampling plans are tailored for product or process sampling. This division is referred to as Type A and Type B sampling.

- **Type A** sampling is for **rejecting or accepting** a lot (batch) of **product**
- **Type B** sampling is for **determining if the process** producing the product is operating **within acceptable limits**



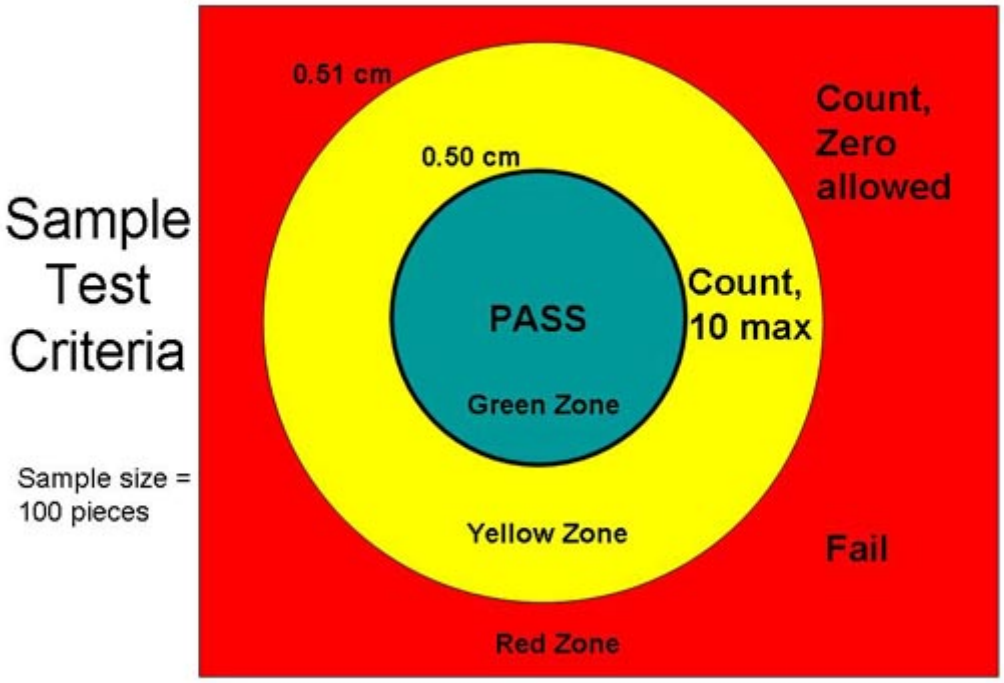
Acceptance sampling and **statistical control charts** (such as statistical process control charts, SPC) are frequently used to make decisions regarding product and process control.

c. Lot by lot acceptance sampling

Samples are randomly taken from a specific lot or batch. A decision to accept or reject a lot or batch is based on the test results of the samples taken.

Depending on the situation and level of confidence needed, there are several sampling plans to choose from. Example acceptance sampling plans are:

- **Single sampling** : One sample is taken from the lot. A sample may be several parts, units, or pieces. The quality of the sample determines acceptance or rejection. For example, the pass criteria may be 10 max disks with a diameter over 0.50 and 0 disks with diameters over 0.51. If one of the sampled disks had a diameter greater than 0.51 then the entire lot would be rejected.



- **Double sampling** : One sample is taken, and if it is clear that the lot meets or fails the criteria, a decision is made to accept or reject (2 disks with diameter greater than 0.50 and zero disks with diameter over 0.51). **If it is not clear that the lot should be accepted or rejected based on the first sample, then a second (or double) sample is taken.** The results of the second sample are used to accept or reject. For example, if the sample had 9 to 11 disk diameters between 0.50 and 0.51, a good lot could be rejected or bad lot accepted. **Borderline product** often poses a dilemma for professionals and organization management. If the first sample failed and the second sample passed, should the lot be accepted because it passed the most recent test?
- **Multiple sampling**: Multiple sampling is considered an extension of double sampling. Multiple samples are taken to reach a decision. It involves inspection of 1 to *n* consecutive samples as needed to reach a final decision. **Normally the sample size is smaller than those in single or double sampling plans.** Some texts suggest that *n* equal to 7 is sufficient. Tables are referenced (see reference standards at the end of the lesson) to determine the sample size for a given probability.
- **Sequential sampling**: Sequential sampling is random sampling without specifying a sample size. The **sample size is determined by the information gathered.** Sequential sampling is considered an extension of multiple sampling. Items are selected one at a time and then inspected. Then a decision is made to either accept or reject the lot or to take another sample. The process is continued until a decision is made to accept or reject the lot. For example if the diameter of

the first disk inspected was over 0.51, the lot could be rejected without sampling additional units. The advantage of sequential sampling is the small sample size. If a lot is truly homogeneous such as a batch of paint, this type of plan may be the most effective.

- **Skip lot sampling**: Skip lot sampling is when only **a portion of lots submitted are tested or inspected.** The plan may be to test 10 consecutive samples. If there are no defects or nonconformities, every other lot may be tested. Plans are developed on a case-by-case basis.

Sampling plans depend on the Acceptable Quality Level (AQL) and Lot Tolerance Percent Defective. (LTPD). Both of these are simply targets of how much poor quality is acceptable. The concept of allowing a certain number of defects is strongly criticized, but it is a practical reality in many situations.

Sampling plans normally **establish the sample size to lot size**. A single sampling plan for attributes specifies a sample size and acceptance/ rejection numbers, which defines the acceptance criteria for lot acceptance. The **sample size normally does not increase in proportion to the lot size**.

Product acceptance **sampling is used to approve product for release and for product audits involving high-risk product**. Though sampling and inspection are very common today the basic tenants of quality are to eliminate inspection, where possible, due to the high cost of identifying bad product after is it produced.

For more information about acceptance sampling go to: *NIST/SEMATECH e-Handbook of Statistical Methods,* http://www.itl.nist.gov/div898/handbook/ Section 6.2.

d. Continuous sampling:

Continuous sampling is appropriate for processes that yield a **continuous stream** of product or where **no lot can be clearly identified**. The plan may **start with 100% inspection** until 100% conformance (or other target value)is achieved at which time a sampling plan goes into effect. If a defect or nonconformity is reported, 100% inspection is restarted and the cycle is repeated. The plan may be initiated upon start-up or restarting after an upset condition or loss of control has occurred. The aim is the average outgoing quality limit (AOQL).

Continuous sampling plans include the one discussed above and others such as Narrow-Limit Gauging and Lot Plot.

In lesson 5, we will discuss how the sampling information is used to control a process.

If you need to set up an acceptance sampling plan, you should consult a quality engineer or statistician.

e. Other statistical methods

The statistical techniques in this section are used to monitor product and processes. Other techniques that may be used in reliability analysis, such as in design review may include risk analysis, regression analysis, design of experiments, tests of significance, and analysis of variance. For additional study of these techniques see a textbook on statistics.

Lesson 04: Statistical tools

[This lesson is medium length. It discusses histogram distributions and descriptive statistical tools.]

[Identify, interpret, and use histograms and various measures of central tendency (mean, median, and mode), and dispersion, such as standard deviation and frequency distribution, qualitative/ quantitative analysis and attribute/ variables data.]

For the scope of this class, we will only provide an overview and point out key statistical concepts. If you identify weak areas, you will need to do a more detailed study.

A fundamental principle used in statistics is that there is always variation. **Variation is inevitable** in every process. For example, if you throw 100 darts at a target and measure the distance from the center to each dart, you will get variation. The variation in distances from the center **will have a pattern** (or distribution).

All things being equal (no one hit your arm, the target was not moved, dart size and weight stays the same, etc.), there will be a normal distribution of distances from the center of the target. Some dart throwers will have a very narrow distribution, while others will have a very wide distribution of values.

By using statistics, organizations will know the distribution of process outputs and operate them within acceptable levels of variation (according to needs). Some processes must be very precise and **operate within a very narrow range of variation**, while less critical processes can operate within a wide range.

1. Histograms

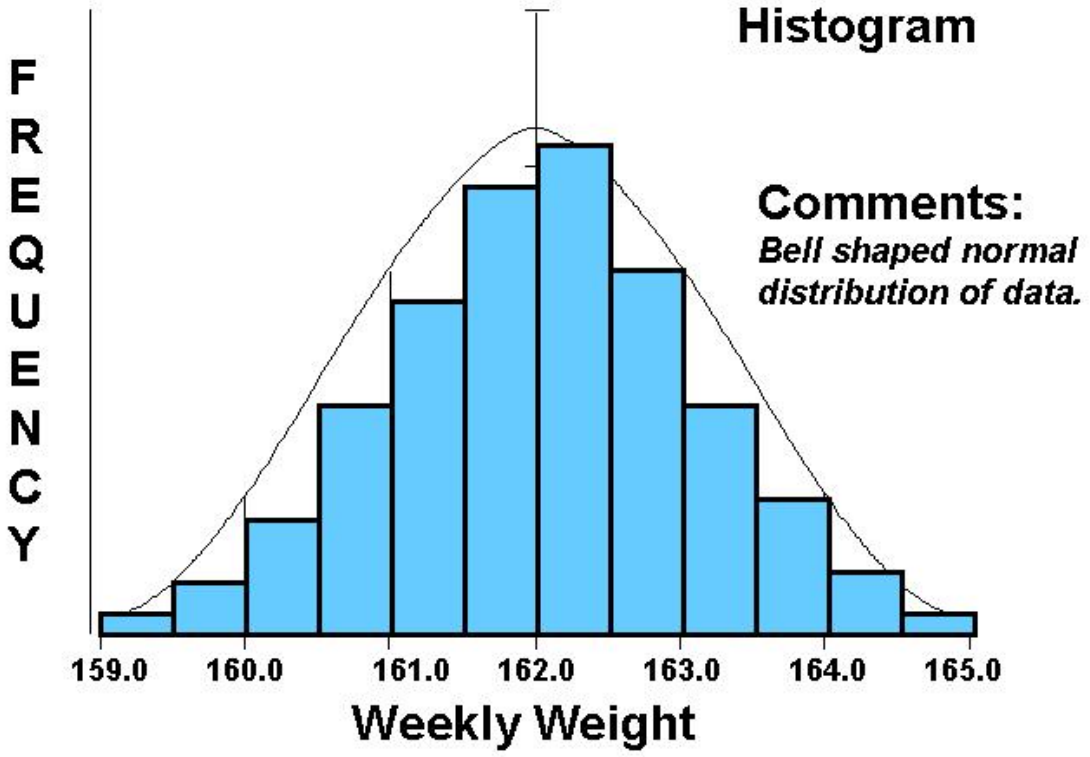
Histograms tell a story. They have a center, width, and shape. Histograms can graphically **show the distribution of large amounts of data**. You can analyze histogram graphs to learn about the **stability of the process being measured** and the effects of specification limits on the data. Variations in data patterns are called distributions. A histogram is a series of bars plotted against a vertical and horizontal axis that **shows distribution frequency**. In the image on the left, a normal distribution

(bell-shaped curve) is superimposed to better assess the distribution of the data. A bell-shaped curve indicates a normal distribution.

To construct a Histogram:

1. Collect data (e.g. weekly weight since the start of weight maintenance program [see image on the previous page] or distance, or height, or activity and so on).
2. **Group measures into intervals**. The intervals become the bars of the chart. For example, from the previous image, 0.5 units.
3. **Plot the bars versus frequency** of observation or measure. For example, all the data points between 162.0 and 162.5 would be a bar. Histograms can be plotted with vertical or horizontal bars (stand up or turn sideways).

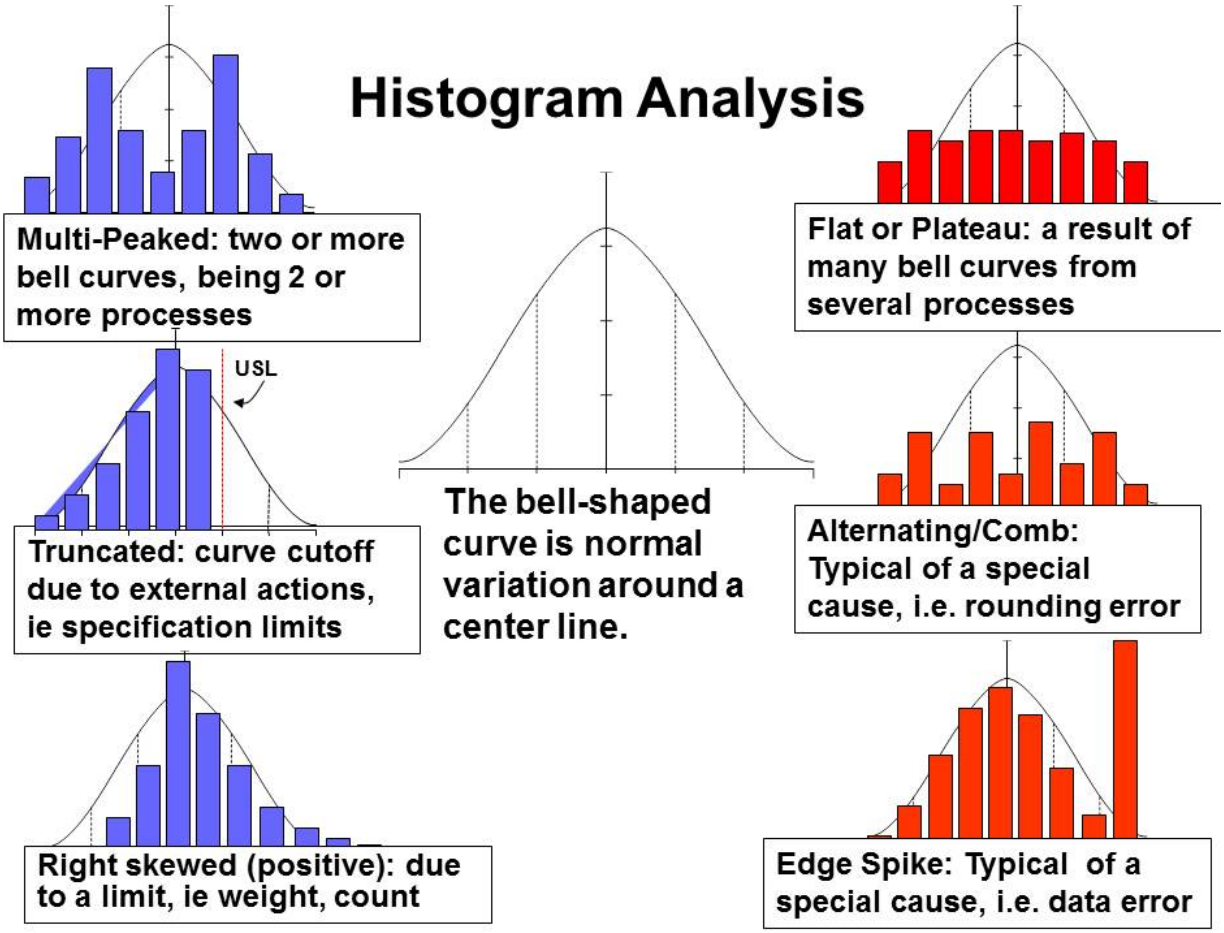
How did you do? Based on the data you were given, your histogram should have a normal distribution with a peak on the right. The cause of the peak on the right could be an error in the data or another type of special cause.



After the histogram is created, you should **analyze it and draw conclusions** based on the distribution of data. Continue on by scanning the different histogram distributions on the next page to learn more about the distribution of the data.

If a process is **stable, data will form a normal distribution** (bell-shaped curve) and is symmetrical around a centerline. If the distribution is **not stable (normal), you must investigate** and determine the reason. You can learn a lot about a process by picturing it in a histogram but **some cautions are advisable.**

1. Verify any conclusions drawn.
2. Ensure that the data is representative of current processes.
3. Take a large enough sample that you feel confident in the conclusion. Note: Some texts suggest a minimum of 40 data points.



2. Descriptive statistics

Statistics is a scientific method for collecting, organizing, summarizing, presenting, and analyzing data, as well as drawing valid conclusions and making decisions based on the analysis. Descriptive (deductive) statistics is the analysis of a **given group of data and does not attempt to draw conclusions on the entire population**.

Statistical tools

Organizations use statistical tools to manage and control their processes. In today's environment, many quality practitioners, managers, professionals, auditors and improvement team members must be knowledgeable enough to know if the tools are being properly interpreted and applied. Descriptive statistics use the concepts of ***central tendency*** (where is the center?) and ***dispersion*** (how is the data distributed around the center?).

Measures of central tendency are:

Mean = mathematical average = sum of all the data points divided by the number of points.

Formula:

$$\bar{X} = \sum X / n$$

$\bar{X}$ = **mean**

$\sum X$ = **sum of all the data points**

n = **number of data points or sample size**

Median = data midpoint = half the data point values above the median and half below.

Mode = most repeated measure = the discrete data point that occurs most frequently in the data set.

Use the data table below to answer the following three questions:

Mean / Median / Mode	
Row 1	**Row 2**
Raw Data Reading from scale: • 162.0 • 162.4 • 162.9 • 161.8 • 163.1 • 167.5 • 162.4 • 162.4 • 160.4 • 161.6 • 162.6 • 162.9	Same data in numerical order: • 160.4 • 161.6 • 161.8 • 162.0 • 162.4 • 162.4 • 162.4 • 162.6 • 162.9 • 162.9 • 163.1 • 167.5

Let us assume that you have decided to start a physical fitness maintenance program and that as part of your program you monitor your weight on a weekly basis. What would descriptive statistics tell you about the data collected?

The statistics show that the weight maintenance program is fairly stable but that the mean is skewed to the right (heavier side). Perhaps a holiday weekend eating binge

skewed the data. Look at the image below to see where the mean, median and mode are.

The **mode is the value for which the frequency is a maximum:** i.e. the value that occurs most frequently or the most common value. Mode is derived from the French meaning a prevailing fashion or style of dress or behavior. For those of us in statistics, **it is the most common or frequent (fashionable) value or measure.**

The **median is the 50% mark or middle value.** It splits the data in to two halves.

The **mean is the average value** or arithmetic mean. In many cases the mean value never exists. i.e. the average married couple has 2.3 children.

Dispersion

Next we want to utilize measures of dispersion (distribution). **Data are normally always scattered around a central tendency (affinity)**. The two most common measures of scatter or data dispersion are *range* and *standard deviation*.

Range: the difference between the highest and lowest value. Now determine the range of our weight program data. What is it?

Use the Formula:

$R = X_{high} - X_{low}$

R = Range

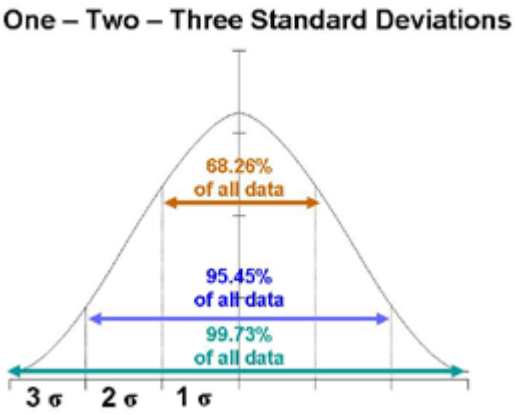
X = data

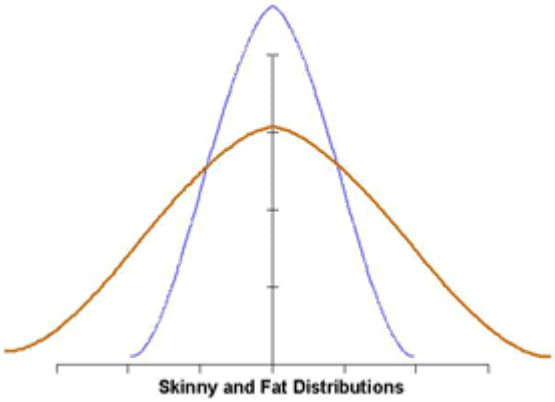
Range

Range is **more useful when used with a small number of data points** (i.e. ten or less). For example: If I kept a log of my arrival time at work for a week, my arrival time range may be ten minutes (earliest being 7:41 a.m. and latest being 7:51 a.m.). Now, if I record my arrival time to work for the last six months, the range may be four hours because it included a temporary road closure due to an accident. With **larger data sets, there are greater probabilities of extreme values.** My boss would not be impressed if I told her that she can count on me to arrive at work within a four-hour time period. Knowing the range may be important, because if the statistics department reported that my average arrival time at work for the last six months was 8:12 AM (on-time being 8 a.m.) with a range of four hours, I would realize that something was amiss because of

the four-hour range and I could investigate before my boss got concerned about my chronic tardiness.

Standard deviation: The standard deviation is simply a **reference number that has statistical implications regarding the spread or dispersion of the data.** Given a normal distribution (bell-shaped curve), 68.26% of all data points will fall within +/- one standard deviation from the center of the data. **The more standard deviations from the center of the data, the more data are included.** For example: +/- 3 standard deviations contain 99.73% of all data points.





If we have a good weight maintenance program, there will be a small standard deviation. The same is true for a quality product or service. If we have a **small standard deviation, there is less dispersion (narrow distribution)and the product will be more consistent**.

To determine the standard deviation, you must use the following formula:

$$\sigma = \sqrt{\frac{\sum (X-\bar{X})^2}{n-1}}$$

X = data points

n = number of data points or sample size

$\sum X$ = sum of all the data points

$\bar{X} = \sum X / n$ = mean

σ = standard deviation

Note: When the sum of all data points is the same as the sum of the entire population (not just a sample), *n* should be used as the denominator in the standard deviation

equation. If the sum of all data points is a sample of the population (which is the case most of the time) *n-1* should be used as the denominator in the standard deviation equation. **Samples of the population are taken to estimate the standard deviation** (an estimate of the actual).

Using the above formula, calculate the standard deviation for our weight maintenance program.

A weight maintenance program with a standard deviation of +/- 1.688 lbs is not too bad even with the occasional holiday feast. However, we will need to watch the central tendency to see if the average continues to move toward higher numbers.

3. Qualitative/ quantitative analysis and attributes/ variables data

Data come in various shapes and sizes for analyzing and viewing. The terms *qualitative/ quantitative* and *variable/ attribute* are used to identify methods and types of data you may encounter.

Qualitative and quantitative analysis:

Quantitative analysis identifies **important information related to quantity** (amount, frequency, repetition). There were 7 complaints for one lot compared to the company average of 20 complaints per 100 lots. Other examples are: 50% of the records were not completed correctly; ice buckets were not emptied in 15 of 40 rooms; the last 3 units had to be reworked and so on. Qualitative analysis, on the other hand, identifies **important information related to the kind of data** (high risk, danger, safety). One bottle of tablets was contaminated. Other examples are: a radiation leak was detected; the wrong prescription was issued; there was one overpayment of $10K and so on.

Variable and attribute data:

Variable data are characterized as measures of something. Data can vary within and outside acceptable ranges. One bottle weighed 204.21 grams and the next bottle weighed 204.18 grams. There can be measures of time, volume, weight, pressure, width, length, temperature, diameter, etc. **Variable data are expensive to collect, are precise, and require the use of reliable measuring equipment.**

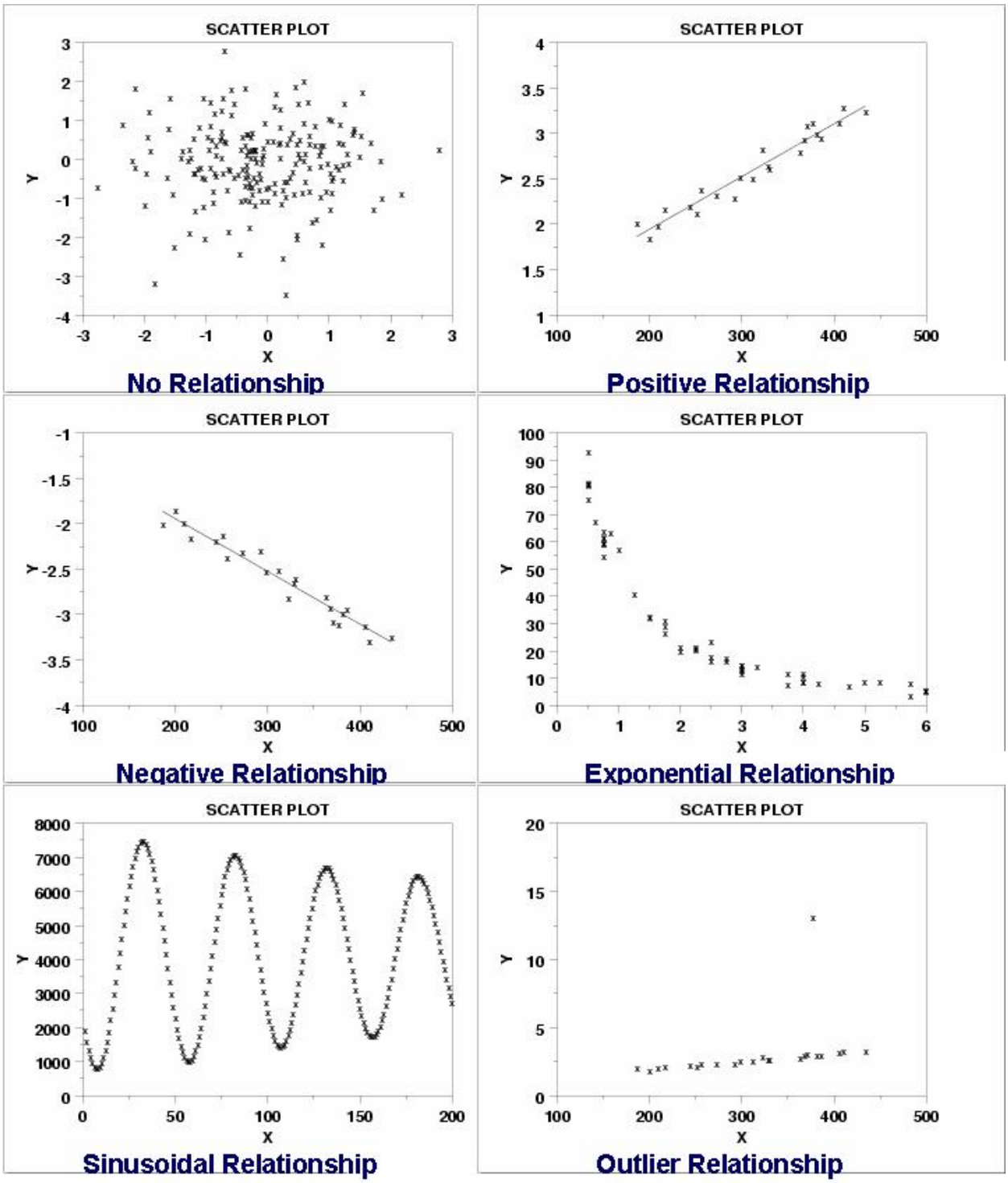
Attribute data are characterized as countable (number of defects) or pass/fail. There were 12 defective bottles in lot 123. Other examples are: all the bottles had acceptable weights over 200 grams; the material had the right *hand*; the paint had the acceptable luster. In some cases only attribute data are available (hand, luster) and in other cases an organization may decide (for cost or other reasons) to use attribute criteria for pass/fail, go/no-go decisions.

4. Scatter diagrams

Scatter diagrams are considered one of the seven quality tools. The main reason for using a scatter diagram is to **determine if a relationship or association exists between two variables**. If some type of relationship exists, more sophisticated statistical tools such as regression analysis may be used to determine the degree of the functionality or correlation.

To construct a scatter diagram, you need to collect paired data such as months of the year and the corresponding electric bills. You could plot the data on an xy axis chart to see if there is a correlation. You could collect data about product defect rates, product returns, and so on.

The scatter of data **points plotted provides a picture. Now you must interpret** the picture (similar to histograms).



All examples came from: NIST/SEMATECH e-Handbook of Statistical Methods, http://www.itl.nist.gov/div898/handbook/, date.
http://www.itl.nist.gov/div898/handbook/eda/section3/scatterp.htm#examples

There are positive and negative relationships, as well as no apparent relationship. Exponential relationships, sinusoidal relationships(such as electric bill vs month), or outliers may be identified.

Lesson 05: Control charts and process capability

[This lesson is medium length. It discusses process control charts and determination of process capability. It has a test at the end that you must pass to continue.]

[Description of topic: Identify and distinguish between natural process limits and specification limits, upper and lower control limits, common and special causes, etc., and use basic rules for determining statistical control. Identify and use process capability indices Cp and Cpk and assess their significance.]

Statistical methods can be applied to any product or service. Statistical quality control (SQC) is a powerful and proven measurement tool for **reduction of variability in products and processes**. Reduced variability means a more consistent and reliable product or service upon which the customer can depend. The application of SQC leads to controlled **processes with little or no waste**. A detailed explanation of SQC methods (also called SPC, statistical process control) can best be covered by technically-focused texts.

1. Introduction

We discussed data and distributions in the last lesson. This lesson is about how to use some of that knowledge to control processes. **Diligent operators make adjustments to keep machines or processes within prescribed limits.** The tighter the tolerances, the more frequent the adjustments. Studies show that many of the operator adjustments are not needed. The unnecessary adjustments actually create more scrap and waste. Some call **this phenomenon "over control."**

Perhaps you have experienced someone trying to keep the room temperature just right by constantly adjusting the room temperature controls. However, the constant adjustments result in the room being either too hot or too cold.

If you are in a dart game and your last dart hit below the target, do you aim for the ceiling (over-control) next time in hopes of hitting the center, or do you determine that the low shot was part of your normal distribution and continue to aim for the center?

2. Adjustments

When operators observe a data point toward the end of the range, they must decide if they need to make an adjustment or wait for the next data point. Statistical process control (SPC) uses statistics to tell the operator **when to adjust the process and when to leave it alone**[1]. SPC (control charting) recognizes that the same random variation (normal distribution) always exists. **Control charting helps to control the distribution** rather than the individual piece dimension or property or characteristic.

In 1926, Walter Shewhart of Bell Labs found a way that we could use our statistical knowledge to **graph process outputs and determine control limits** based on normal distributions. If a data point was within the control limits, the operator did nothing. If a data point was outside the control limits, something **caused the distribution to change**. A data point outside the control limits was identified as an out-of-control point. The reason for an out-of-control point has an **assignable or special cause**.

3. Variation

The **cause of variation within the control limits is determined by chance** or common causes that are not assignable (in other words, normal and expected variation of the process). We all have our upper and lower control limits in almost everything that we do. For example: is the food too bland, too salty, or just right? For most of us, the acceptable seasoning of food has a wide range; but if someone adds two tablespoons of salt instead of two teaspoons, it will be too salty. Whether the teaspoons of salt are level or heaping could be considered chance or common causes of variation. Adding two tablespoons instead of teaspoons would be due to one (or more) special or assignable causes such as the chef needing glasses.

4. Control charts

A **control chart is a tool** used by operators to control processes. They have a certain look and tell us how really good or bad the process is (in-control or not).

We can **control processes by selecting a key variable to monitor**. Control charting uses key variable data to give us additional information. A key monitoring variable of our fitness program was "weight." For other processes, it may be percent activity, tolerance level in microns, time of delivery, etc. For this section, let us assume we want to ensure our process for getting to work on-time is "in-control" and "capable" (the boss doesn't like it when you are late). The data we will monitor is arrival time. We plot the data (arrival time) on a line chart as shown on Chart 1 (red).

This is interesting but it does not tell us much about the process except it appears that you arrive between 7:30 and 8:10 in the morning.

To plot a control chart, we need to take the weekly **arrival time** data collected and calculate upper and lower control limits (UCL and LCL), plot a center line (CL), and then plot them as shown in Chart 2 (green).

Please note that the system determines the upper and lower control limits (UCL, LCL) and the competition determines the upper and lower specification limits (USL and LSL).

Control charts

The normal (or Gaussian) distribution of data from this process will fall within the upper and lower control limits. If the key variable **data are consistently within the upper and lower control limits, the process is considered to be "in control."** Any point that falls outside the control limit lines is considered to be **"out-of-control" (not stable) and requires action**. Now you can see graphically that your process (route and mode of transportation to work) is "in control." You can report to your boss that statistically (Chart 2), you arrive at work within the upper and lower control limits 99.73 percent of the time (out-of-control every one-and-one-half years). However, you need to take another step to determine if you actually arrive on time. Have you ever noticed someone who always arrives late for work? Their process may be "in-control" to always arrive ten minutes late.

The last concept of process capability is determined by adding the product or service upper and lower specification limits (USL, LSU) to the control chart (Chart 3, blue). If the upper and lower control limits are within the specification limits, the process is considered "capable." A capable process (depending on a normal distribution and confidence levels) will result in a product or service that will be within specifications at least 99.73% of the time (+/- 3 standard deviations or 3 sigma). Chart 3 (blue) shows a **process that is "in-control" and "capable."** You can relax knowing you have a good process for getting to work on time. You share your information with a friend and agree to control chart his process too. However, his chart (see Chart 4, black) looks different from yours.

Note that the key variable points (Chart 4, black) frequently fall outside the control limits (not in-control) and that the upper specification limit is inside the upper control limit (not capable). Your colleague should evaluate **each "out-of-control" point (circled) and take corrective action to stabilize the process** and bring it in-control. Perhaps your colleague should set the alarm for an earlier time or change his route to work to avoid frequent delays due to road repairs.

Other rules for identification of out-of-control points are observing **seven successive data points** below or above the center line, or if there are **six successive points**

increasing or decreasing. For normal distributions, you would expect the data to randomly fall above and below the center; if not, something must be causing the shift.

Organizations with capable processes operate with tighter tolerances, reduced waste, and reduced rework. When processes change, new upper and lower control limits must be determined for control charts to remain meaningful. The use of statistical tools improves an organization's competitive position in the marketplace.

5. Types of control charts

There are several different variations of control charts to choose from depending on the type of data being monitored. The two main types are charts with variable data and attribute data.

Charts for **variable data** have a scale, a measure, and a number (such as length, activity, weight, pH, time, friction, hardness, and so on). Simply put, there is a measurement. This is also referred to as a "continuous variable."

Charts for **attribute data** may only have a count or percentage of good or bad, or conforming and non-conforming. Attribute data are collected either when a measurement is not possible (color, scratches, errors) or measurement is too costly or time-consuming (go/no-go gauges for diameter, length, etc.). This is also referred to as a "discrete variable" (assumes only whole number values). The rules for attribute charts are slightly different because of the nature of the data being collected.

Note: Some texts equate attribute data with qualitative data and variable data with quantitative data.

Attribute control charts (p, u & c charts)

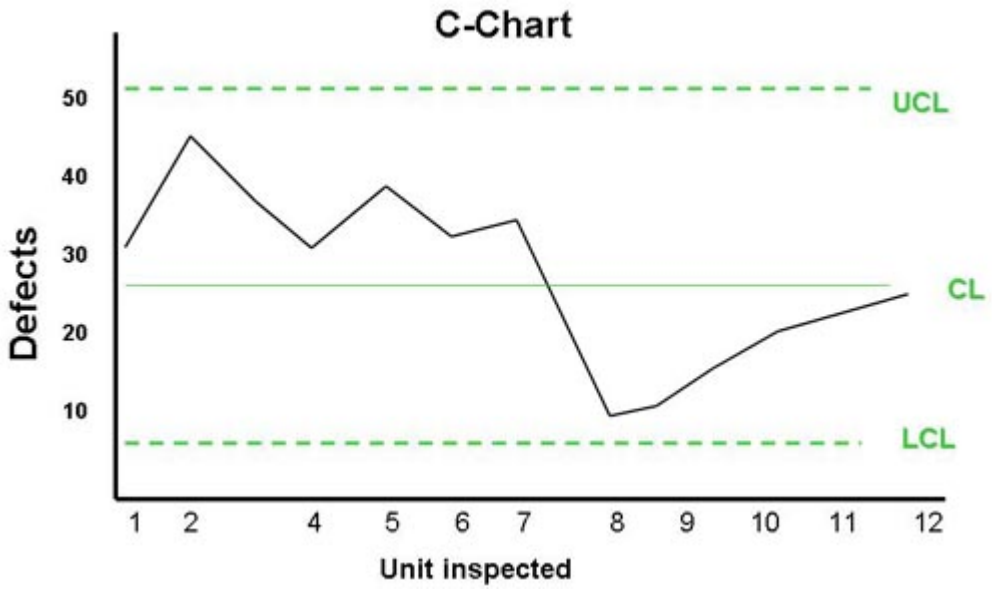
Typically, statistical process control (SPC) charts use variables (numerical) data. In our example, we measured weight. We could also measure data such as height, thickness, position, and concentration. When we cannot measure by a number, we may sort by conforming or nonconforming, which we described on attribute data.

There are three main **types of attribute charts (p, u and c)**:

P stands for proportion; p control charts monitor **proportion** or fraction defective
U stands for unit; u control charts monitor defects per **unit**
C stands for count; c control charts monitor number of defects or nonconformities

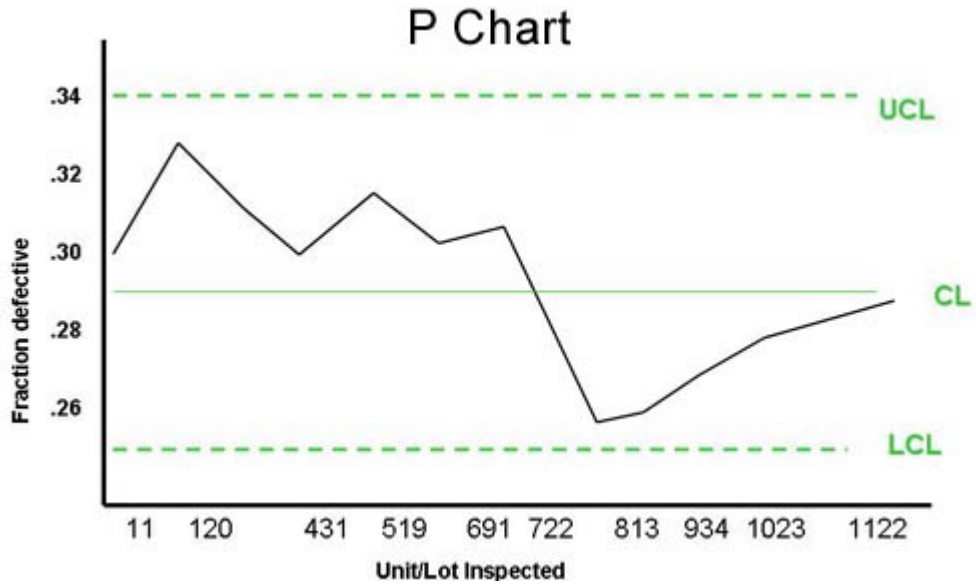
C charts

A c chart could be created for total number of defects or average number of defects found per test or inspection. For example: the number of black granules in a liter or the number of scratches on a pressure tank.



P charts

A p chart is the proportion or fraction defective in an entire population. For example, we may monitor a 1000 unit run of ¾ inch bolts and identify 10 defective bolts. The proportion defective would be 1%. A p chart will look similar to a c chart except the ordinate (y axis) would be proportion defective and the abscissa (x axis) would be unit inspected.



The center line and upper and lower control limits are determined by separate formulas for each type of chart.

For more information on p,u and c charts go to:
http://www.itl.nist.gov/div898/handbook/pmc/section3/pmc3.htm

6. Process capability interpretations

The purpose of statistical quality control tools is to **establish process stability** (in-control). The process stability is a result of detection and removal of **special cause sources of variation** (the out-of-control points). The remaining variation is a result of **common causes that are inherent in the process**. Indices (Cp and Cpk) are used to numerically describe what can be viewed on the control chart.

When viewing control charts, one must remember that the upper and lower control limits are a function of the nature of the process; and that the upper and lower specification limits are a function of the marketplace or customer need. Control charts do not determine if a process is meeting specifications.

Process capability interpretation

The **Cp index** (capability index) has been developed to **show the relationship between the process and specification**. It is used to describe how well an in-control process conforms to specification limits. The formula for the capability index (assuming a normal distribution) is:

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

USL = Upper Specification Limit
LSL = Lower Specification limit
σ = standard deviation

A Cp value of 1.0 or greater would indicate that all the values (99.73%) would be within specification if the process were centered at the middle of the specification range. A **capability of less than 1.0 would mean that a reduction in common causes is necessary to be capable** and within specification. In the case where we measure work time arrival, your Cp would equal a number greater than 1 (i.e. Cp = 3), while your colleague would have a Cp of less than one (i.e. Cp = 0.61). Because 99.73% is still less than 100% and there is shifting of the distribution (real life), the acceptable Cp index for a process should be 1.33 minimum. Some organizations set even higher standards for Cp, such as 2.

We can use Cp as a measure as long as the data (the process) is centered around the specification.

When the mean of the process is **not centered around the specification limits** (which is very common) the Cpk index is used. For the Cpk use:

$$Cpk = \frac{(USL - \text{mean (CL line number)})}{3\ \sigma\ (3 \text{ std. deviations})}$$

or

$$Cpk = \frac{(LSL - \text{mean (CL line number)})}{3\ \sigma\ (3 \text{ std. deviations})}$$

The lower number (using USL or LSL) represents the Cpk for the process.

One can **only use the Cp and Cpk when the process is in-control** with a normal distribution.

If an organization is operating a process with a Cpk of O.6, a considerable amount of the output will not meet specifications.

The material out of specification will need to be sorted and re-worked, recycled, regarded (sold as off-grade or seconds), or scrapped. The same concepts of capability can be applied to services, as well.

When people experience processes that are not capable, they may describe them as:

- It only works half the time.
- You never know what you are going to get next.
- They do it differently every time.
- You never know what to expect.
- It seems like we always have to take it back before it is fixed right.

Lesson 06: Cost of quality: Improvement benefits

[This is a short lesson that discusses financial implications of a quality strategy to improve organization effectiveness and efficiency. It has the class post test at the end that you must pass to pass the class.]

[Description of topic: Identify the basic cost of quality (COQ) principles, and describe the four COQ categories: prevention, appraisal, internal failure, and external failure.]

Measuring and monitoring costs or increases in revenue are important improvement tools. **Tools which improve an organization's effectiveness and efficiency should benefit that organization.** Dr. Edwards Deming (quality guru) established the concepts of reducing waste, narrowing variation and elimination of inspection in the 1980s. These concepts linked quality improvement with increasing organization wealth instead of increasing costs.

A good starting point for our discussion is the traditional **quality cost or cost-of-poor-quality** systems that determine the **cost associated with providing good products and services.** Many quality cost systems focus on easily identifiable costs and expenses.

1. POC and PONC

Traditional quality costs are comprised of the following:

Prevention costs: New product/service review, design review, quality planning, supplier assessment, quality improvement team meetings, quality system audits, quality process audits, process capability studies, and education and training.

Appraisal costs: Incoming inspection, source inspection, product/service audits (to verify a product or service meets requirements), compliance audits (product and process), testing, test equipment, and calibration of test equipment.

Price of conformance(POC)is the combined cost of prevention and appraisal.

Failure (internal and external) costs: Scrap, rework, re-inspection, retesting, sorting, re-grading, processing customer complaints, claims, recalls, redo's, returns, etc.

Some failure costs are obvious and other costs are hidden (See the image below).

Some organizations use **activity-based costing (ABC)** to better identify some of the hidden costs of a process or product. The total internal and external **failure cost make up the price of nonconformance cost (PONC)**.

There are costs associated with every failure (nonconformance) or potential failure (nonconformance). Many organizations do not take into account all the costs associated with a failure. Consider the following:

The total cost and potential cost to an organization should include:

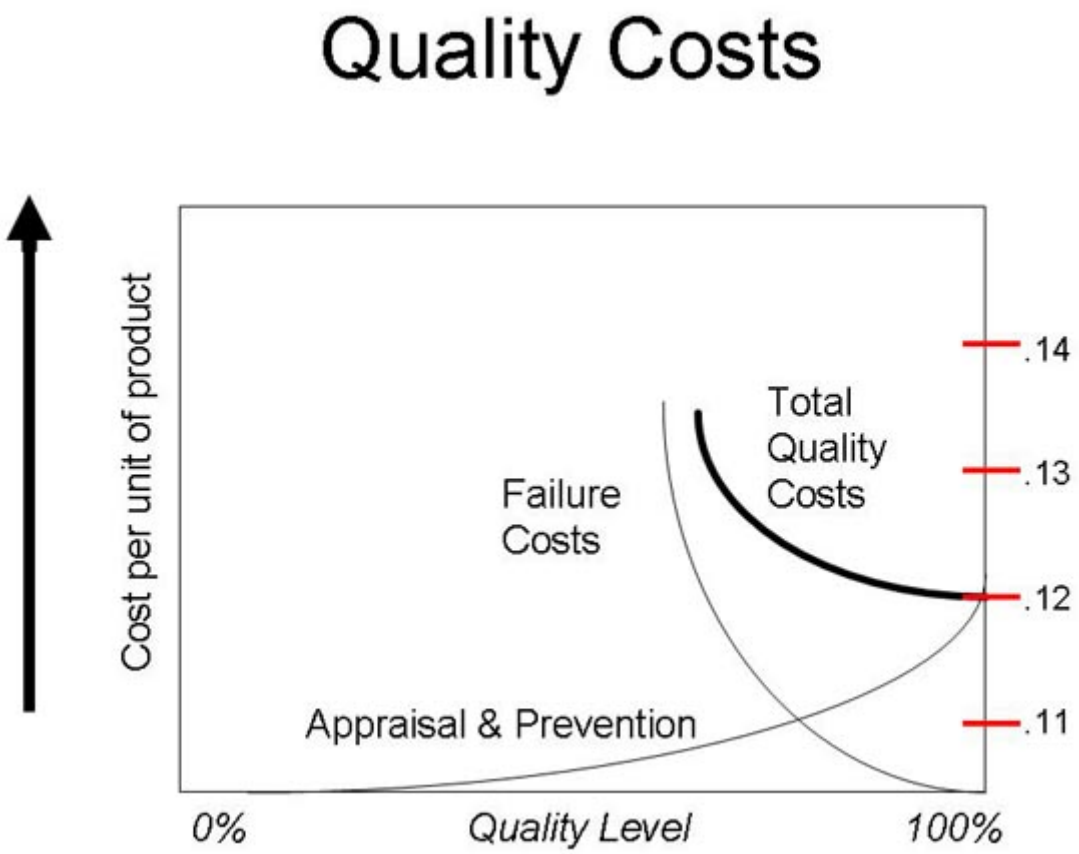
- potential loss of orders from existing customers (lost profit)
- loss of future customers (lost profit)
- savings from capital investment avoidance or delay in capital spending
- avoiding potential claims, potential citations and regulatory costs
- interest saved due to reductions in working capital cost (the money needed to operate the organization on a daily bases)
- productivity losses for rescheduling, re-planning, reorganizing

Often, estimated internal costs are too low. A good reality check is to ask an outside organization to do the rework or provide the service and compare their costs to your estimated costs.

2. Quality cost savings

Prior to the 80s conventional thinking was that as an organization increased the quality of its product or service, costs would keep increasing. Organizations believed they could only afford to achieve 95% quality levels. This type of thinking condoned high levels of scrap and rework. We now know that this is not the case and that we have the capability to achieve near perfection at a defined cost.

See the image below.



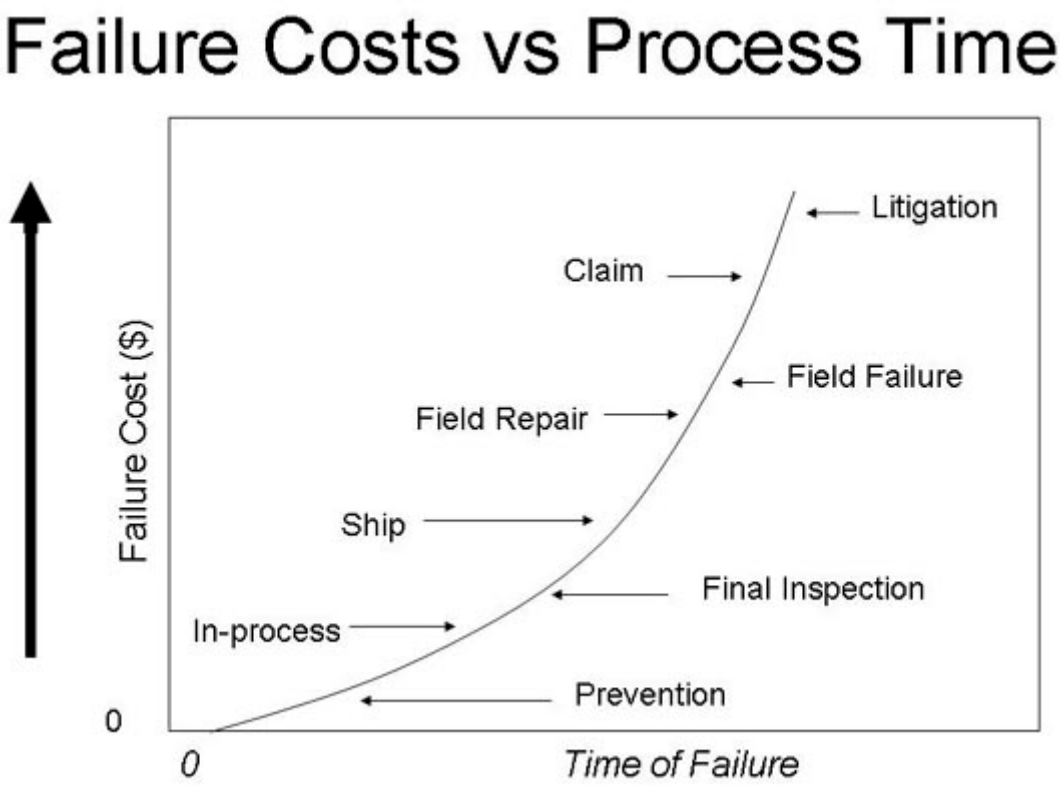
As appraisal and prevention costs increase, failure costs approach zero.

Improvement programs should focus on eliminating nonconformances and potential nonconformances that benefit the organization. First drive failure costs to zero; then focus on reducing appraisal and prevention costs.

Failure can only be prevented by eliminating the root cause of the failure (discussed in prior lessons).

3. Field failures

We also know that the earlier a failure or potential failure is detected in the life cycle of a product, the less the cost of correction. It is more economical to fix problems in the design phase of development than the production or use phase. FMEAs have become very productive and popular prevention tools.



The same is true of a construction project. Early on, it does not cost very much to change the scope of work, but to change the scope during installation or construction is very expensive.

As organizations gain confidence in their ability to provide defect-free product, they can reduce appraisal costs. For example, a product characteristic could be monitored for failures for a long period, such as year. After a year of no failures, the organization could eliminate testing as long as the process remains stable.

This approach is straight forward but it can not be sustained unless data are collected and savings are identified.

You have completed the last lesson of this class.

END

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[3] After the Quality Audit, 2000, Quality Press

