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DEPARTMENT OF
INDUSTRIAL ENGINEERING 

Machine Learning Lesson #9

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Warm-up

- Please, connect to Kahoot!



Today's lesson

- Process and product quality monitoring
 - statistical process control SPC
- Specifications and capability
- Intro on quality engineering



Statistical process monitoring and control

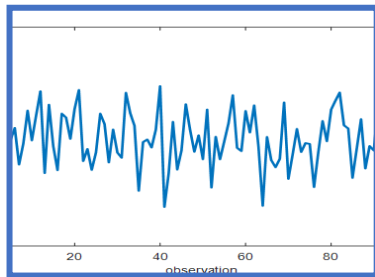
Uni- and multi-variate monitoring charts

Statistical process control (SPC)

- SPC is a field of technology whose philosophy is to **supervise the process performances**:
 - emphasizing the **anomalous events** leading to the degradation of the process and of the product quality
- SPC **goal**: *quick and reliable **detection of the existence, the amplitude and the time of occurrence of the changes** that cause a process or a quality feature to deviate from a prescribed standard in the manufacturing of a product*
 - facilitates to observe a process behavior that does not conform to the expected one
 - provides information on the state of a plant and the product
 - assists the operators and the process engineers to remedy process abnormalities
 - helps investigating what does not work in a process
 - assists in undertaking the corrective actions before non-conforming products are manufactured
- The main **results** obtained by applying SPC are:
 - safer operations
 - downtime minimization
 - yield maximization
 - product quality and process improvement
 - reduced manufacturing costs

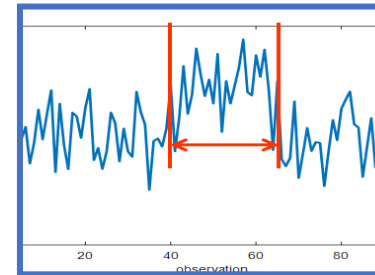
Common-cause/assignable-cause variability

- In the industrial practice every process exhibits some **variability** regardless how well it is designed, operated, instrumented, and controlled
- Two different types of variability are usually present



**common cause
variability
(natural and random)**

- cumulative outcome of unavoidable phenomena
- “background noise” with only “chance causes of variation”
- processes/products **in a state of statistical control**



**abnormal non-
random variability
(assignable causes)**

- process changes, faulty conditions, errors, etc. caused by:
 - improperly maintained (or controlled) machinery
 - operator errors
 - defective raw materials
 - unavoidable events, etc.
- leads to unacceptable levels of process performances or product defectiveness
- determines an **out-of-control state**

- Process monitoring is not only **understanding the status of the process**, but also the **possibility of controlling the process and the product quality**
 - direct inspection of the quality is usually impractical and delays the discovery of the abnormal process conditions
 - the appearance of the defects in final product takes time
 - information about the quality is encoded in the process variables, which:
 - are measured online, frequently and in an automatic fashion
 - enable the inference of the product quality
 - if the process operates with **little variability around an assigned target** (i.e., the nominal conditions), both the process performance and the product quality ensure process:
 - **repeatability**
 - **stability**
 - **capability**

Control charts

- Traditional monitoring methods raise alarms when the state of the system goes beyond a **predetermined thresholds**:
 - some limits should be imposed to the process
- To detect the departures from a prescribed state of statistical control, **control charts** are used:
 - improve productivity
 - effectively avoid defects
 - prevent unnecessary process adjustments
 - provide diagnostic and process capability information



- In statistical terms, the control charts are **hypothesis testing techniques** that verify if a process/product is **in a state of statistical control**:
 - the in-statistical-control condition is the null hypothesis to be proved
 - the null hypothesis is to be verified with a certain **degree of confidence/significance**
 - it is verified if the status of the observed phenomenon stays in proximity of the nominal conditions identified by the process average conditions determined by standard operations

Control charts: hypothesis testing for monitoring

- The **statistical hypothesis** statement for control charts is formulated as:

$H_0 = \text{the system is in a state of control}$

$H_1 = \text{the system is out of control}$

- H_0 is called the **null hypothesis**
- H_1 is called the **alternative hypothesis**



Procedure for building control charts

■ Procedure for control-charts hypothesis testing:

1. taking a **random sample**
2. computing an appropriate **test statistic**
3. **rejecting or failing to reject the null hypothesis** H_0 based on the computed value of the test statistic
4. identifying the **critical region** (i.e., **rejection region**) for the tests
 - specifying the set of values for the test statistic that leads to rejection of H_0

■ Two kinds of errors may occur in monitoring:

- **type I error**: false alarm
 - the null hypothesis is rejected when it is true
- **type II error**: alarms not warned
 - the null hypothesis is *not* rejected when it is false
- the **significance level** of the test, namely the probability of type I error, is chosen a priori
 - design the test so that the probability of type II error has a small value

Procedure for statistical process control SPC

- The procedure for statistical process control goes through:
 1. selection of the most representative historical data to build the model, the so called **normal operating conditions, NOC**
 2. **pre-treating** of the input data to facilitate the statistical analysis
 3. **data-based monitoring model building**: adopt a probabilistic methodology for decision-making through statistical hypothesis testing
 - type I error (or α -error, or **false positive**) is rejecting a correct null hypothesis
 - an out-of-control state is warned by the monitoring charts when there is no assignable cause
 - type II error (or β -error, or **false negative**) is failing to reject a null hypothesis when it is false
 - the risk that a point may still fall within the confidence limits of the monitoring charts when the status is really out of control and an assignable cause occurs
 4. **testing the efficiency of the monitoring model** through a **validatory procedure**
 - testing how the model works on new and unknown data (not included for model calibration)
 5. checking the performance of the monitoring model in the **diagnosis of the special causes** that affect a process/product and determine a detriment of the quality or a loss of process performance

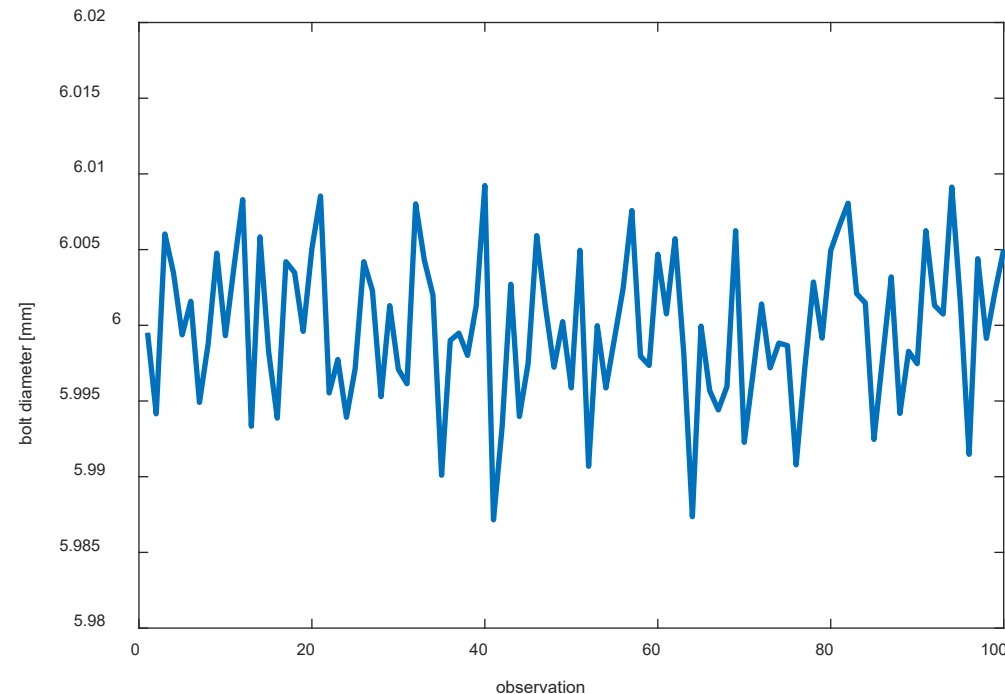
Hypothesis testing for SPC

- The attributes of a process are expected to stay *close to a predetermined target value* without changing perceptibly
- SPC assumes that the process adheres to a state of **statistical control** (conformance) if it is within certain limits
 - it is possible to find out **statistical confidence limits** that work as efficient detectors of **in-control** or **out-of-control** states for a single variable
 - this is also possible to analyze jointly a lot of variables through PCA (and, we will see, PLS)
- Confidence limits:
 - are constructed on a **given reference dataset**
 - are interval estimators of population parameters
 - describe the interval where it is likely to include the product/process parameters which can be considered acceptable
- **Mathematical formulation:**
 - if θ is an unknown parameter from a population and Ω the set of all the possible θ , a confidence region $CR(\mathbf{X})$ of likely θ values can be determined by a set of data measurements \mathbf{X}
 - $CR(\mathbf{X})$ is said to be a $100(1 - \alpha)\%$ confidence region when:
$$P[\theta \in CR(\mathbf{X}) \rightarrow \theta \in \Omega] = (1 - \alpha)$$
 - namely, the probability P that the parameter belongs to the population is $(1 - \alpha)$ if it is found to belong to the confidence region

SPC in practice

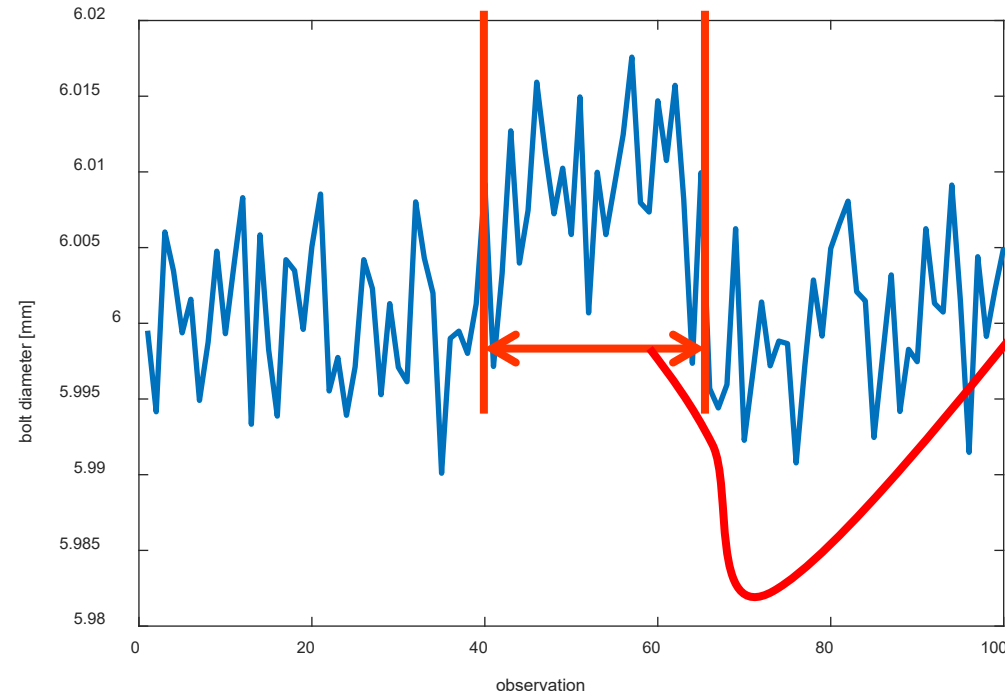
Natural variability

- **Natural (common-cause) variability** is always present in processes and products:
 - independent from process design
 - independent from process maintenance status
 - determines the so-called “noise”
- A process which is subject to common-cause variability is **“in control”**



Assignable causes

- Other types of variability may occasionally occur in the process/product
- **Assignable (special) causes** determine an **“out-of-control” state**
 - improper process control
 - different raw materials
 - operators' errors
 - defective materials/equipment

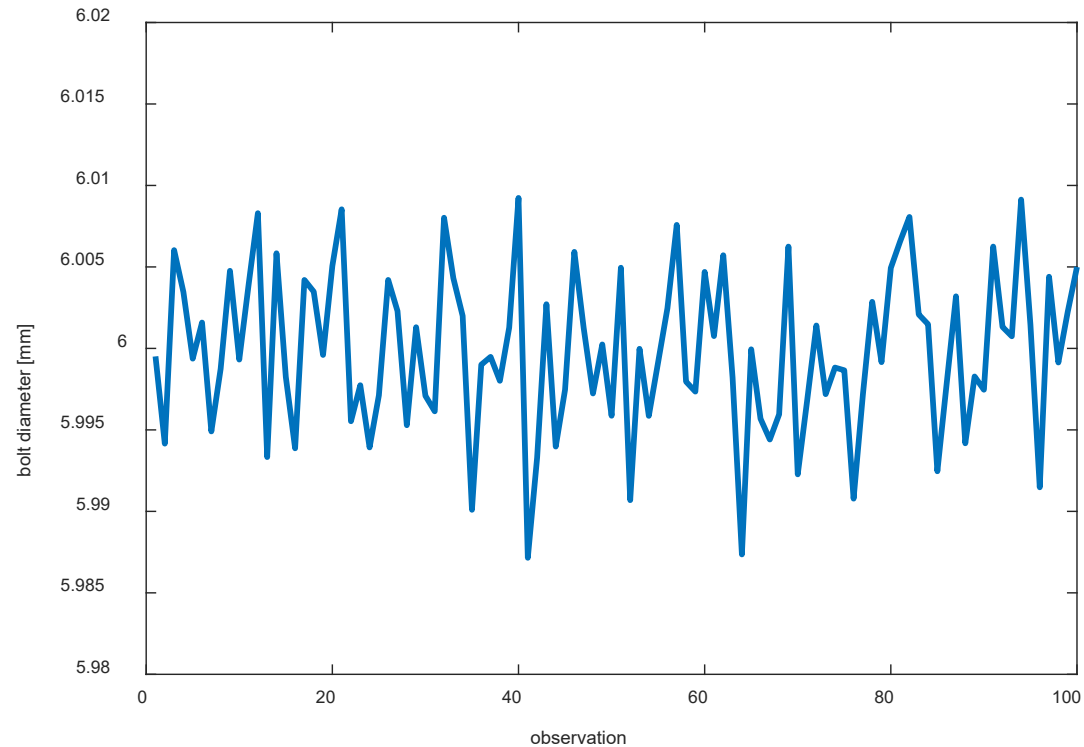


**ASSIGNABLE
CAUSE
VARIABILITY**



Identifying natural variability

- Any ideas on how to identify the natural variability in the case of the bolt diameters?

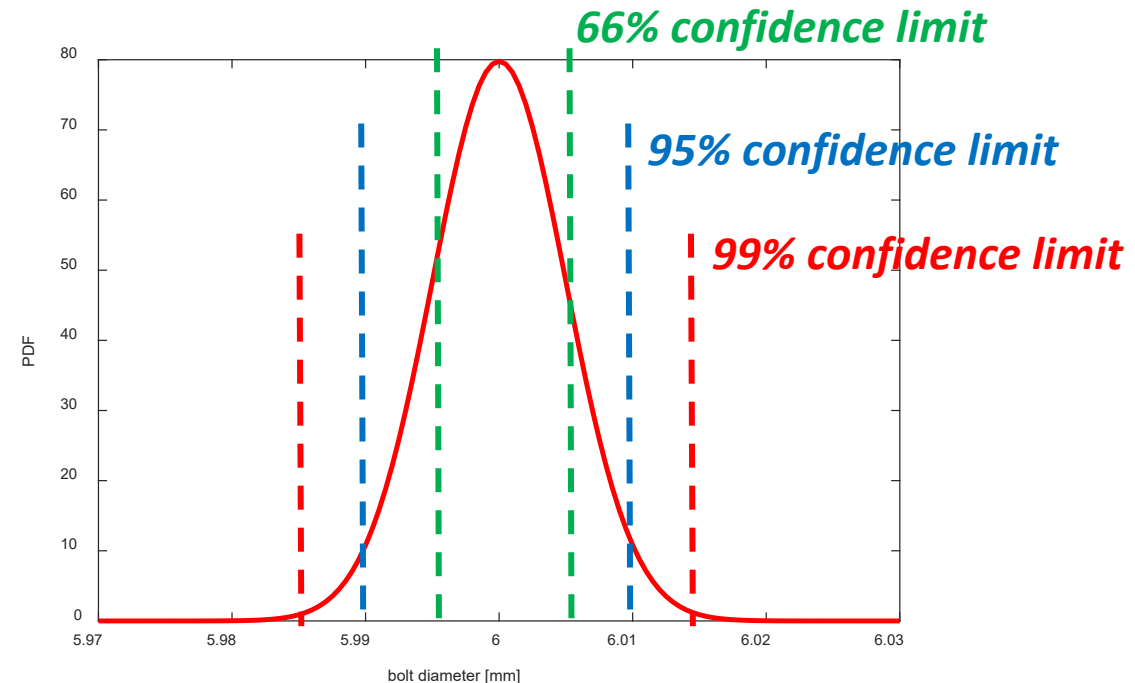


Basic concepts for univariate SPC

- From observations it is possible to infer the statistical indices of sample mean and variance



- It is possible to build the PDF of a measurement of a phenomenon that is in a state of statistical control
 - in particular, for the characteristics of the Gaussian distribution:
 - 1σ is approximately the limit of confidence of 68.27% ~66.6%
 - 1.96σ ($\sim 2\sigma$) is approximately the limit of confidence of 95%
 - 3σ is approximately the limit of confidence of 99.73%



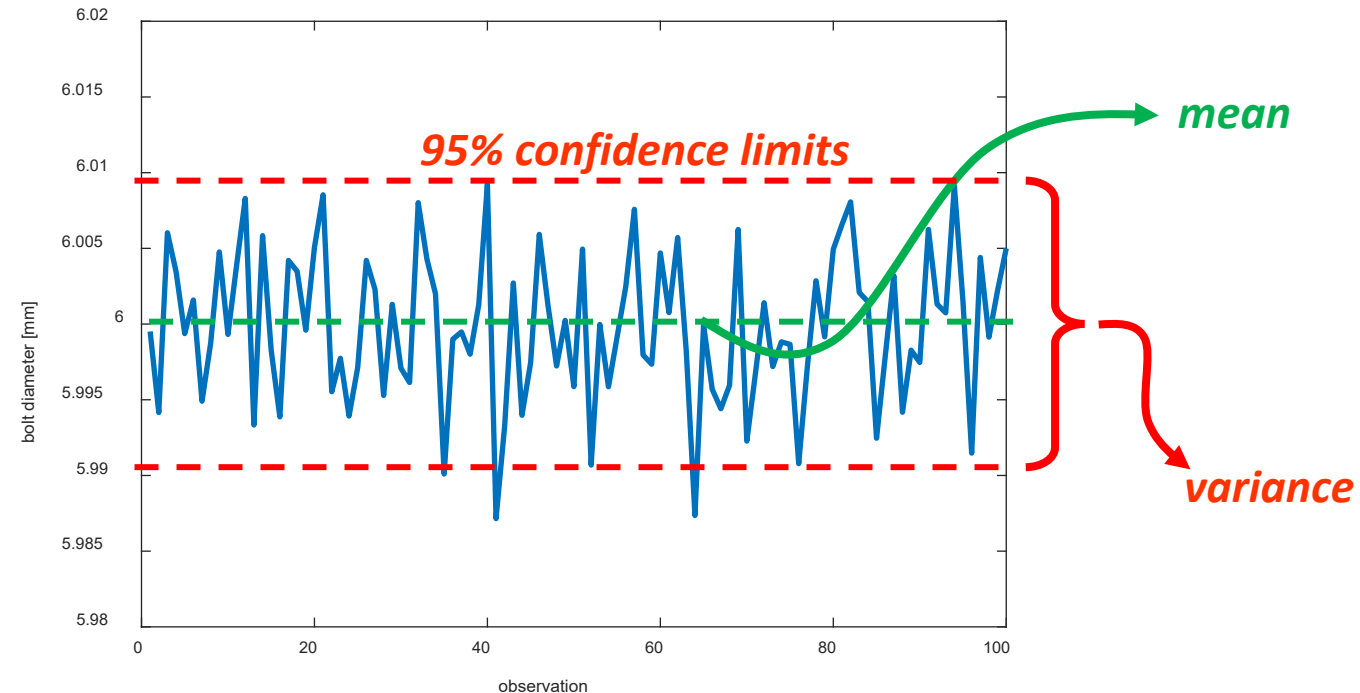
Analysis of the product quality

- When a process is *in a state of statistical control mean and variance do not change significantly*
- Special causes can change mean and variance



- A **Shewhart chart** can be built:
 - mean is the target point
 - standard deviation fixes the “normal variability”

Shewhart chart



Building control charts

■ Phase 1: **calibration**

- select the monitored variable(s) and collect the **historical dataset**
- identify both the target and the variability for standard observations
- build the monitoring model and calculate the **confidence limits**
- remove anomalous observations (if they really are anomalies, namely, if it is found that assignable causes are present)
- recalibrate the model

■ Phase 2: **validation**

- project into the model **new observations**
- judge the state of the new observations
- eventually *update* the model with the new “normal” observations, otherwise *diagnose* the causes of the anomalies

■ Phase 2: **testing**

- **real-life application**

Control charts efficiency

■ Facts:

- when using control charts one has to accept:
 - **false positives**
 - an alarm is warned when it is a regular observation
 - **false negatives**
 - an alarm is not warned when an assignable cause occurs
- 95% confidence limits are built intrinsically to leave out 5% of the observations
 - 99% confidence limits leave 1% of the observations out
 - etc...

■ **Western Electric rules** are a typical procedure to manage the alarms

- the most **efficient control charts** show:
 - an appropriate number of false alarm (e.g.: 5% when the confidence limits are set at 95%)
 - promptly detect true positives!

Western Electric rules

these are 3σ control limits

Some Sensitizing Rules for Shewhart Control Charts

Standard Action Signal:

1. One or more points outside of the control limits.
2. Two of three consecutive points outside the two-sigma warning limits but still inside the control limits.
3. Four of five consecutive points beyond the one-sigma limits.
4. A run of eight consecutive points on one side of the center line.
5. Six points in a row steadily increasing or decreasing.
6. Fifteen points in a row in zone C (both above and below the center line).
7. Fourteen points in a row alternating up and down.
8. Eight points in a row on both sides of the center line with none in zone C.
9. An unusual or nonrandom pattern in the data.
10. One or more points near a warning or control limit.

Western
Electric
Rules

Specifications and capability

Strategies for quality improvement

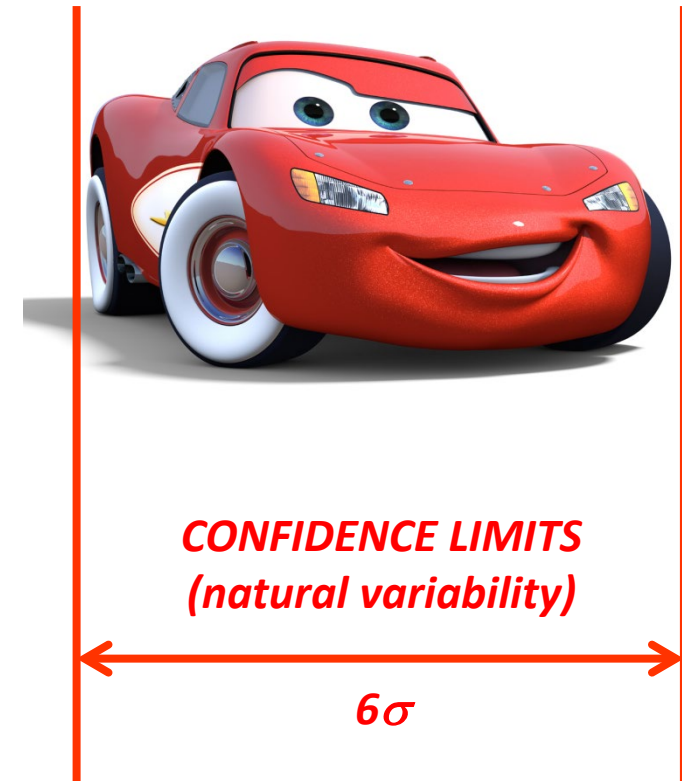
Warning!!!

Do not confuse
confidence limits with
specification limits!!!

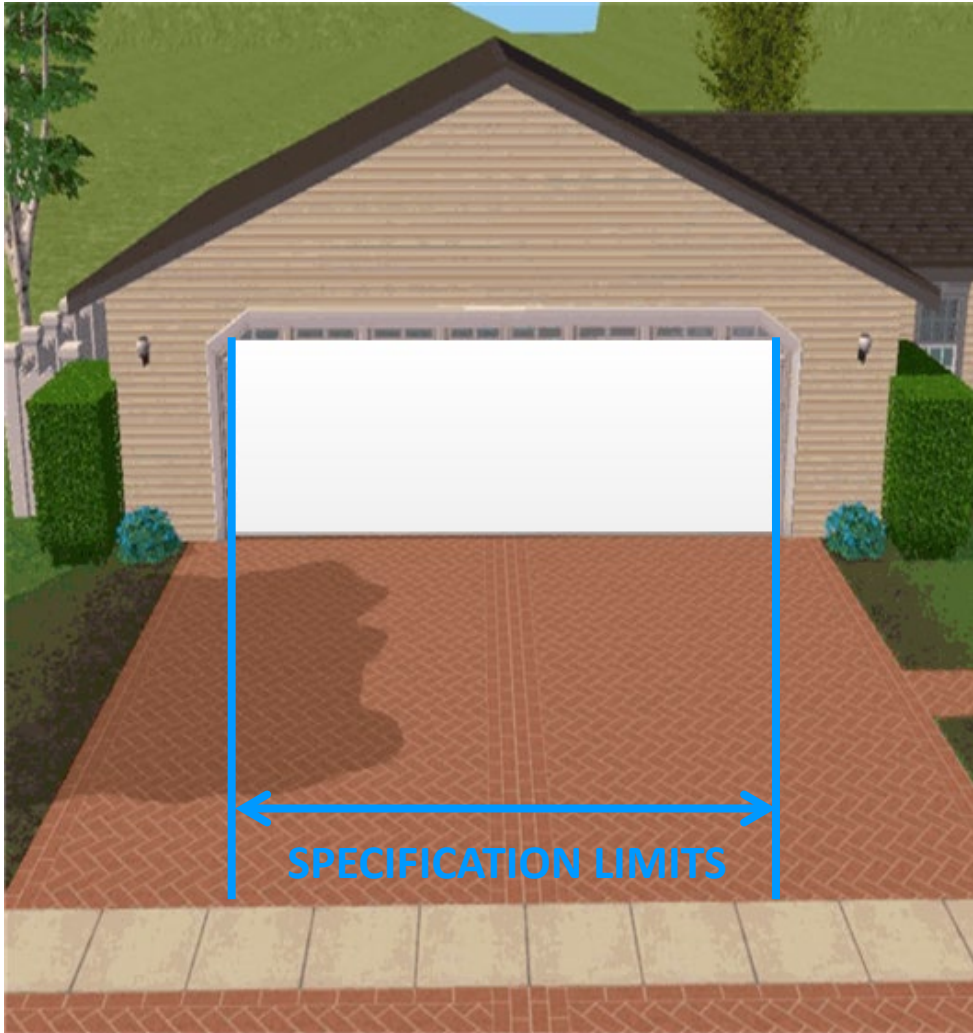


Confidence limits

The **confidence limits** are determined by the natural variability of both the process and the product and depend on the *common cause variability*

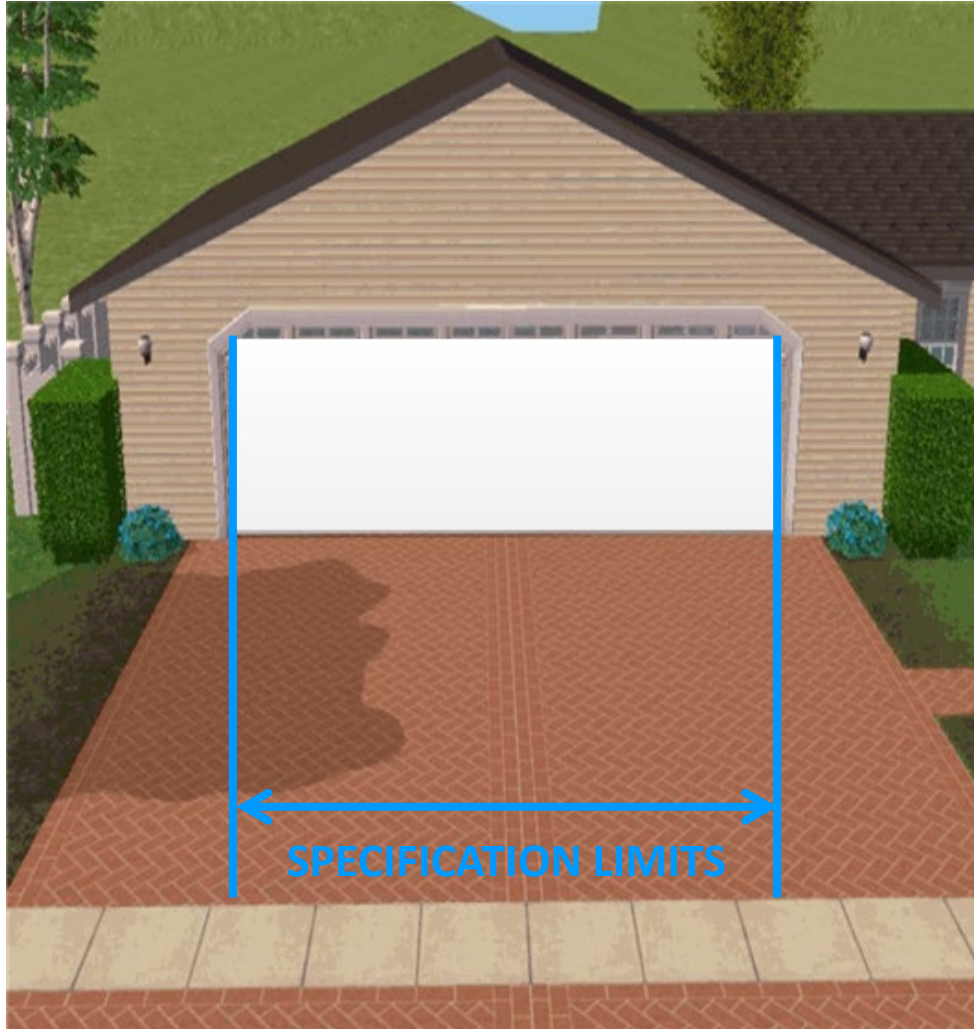


Specification limits

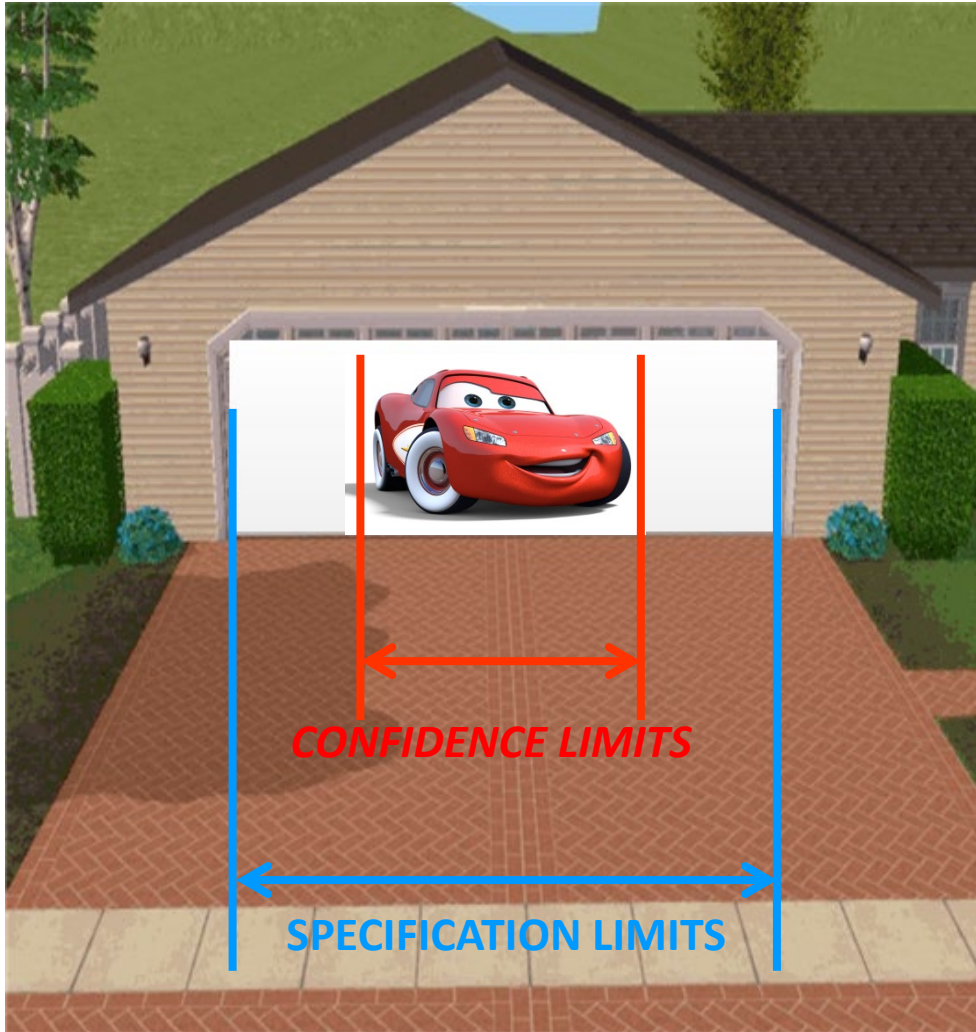


- The **specification limits** are defined by the **manufacturer** considering:
- the requirements of the *clients* (based on the use of the product)
 - design constraints
 - **completely independent from process natural variability**

Confidence limits vs. specification limits



«Capable» process

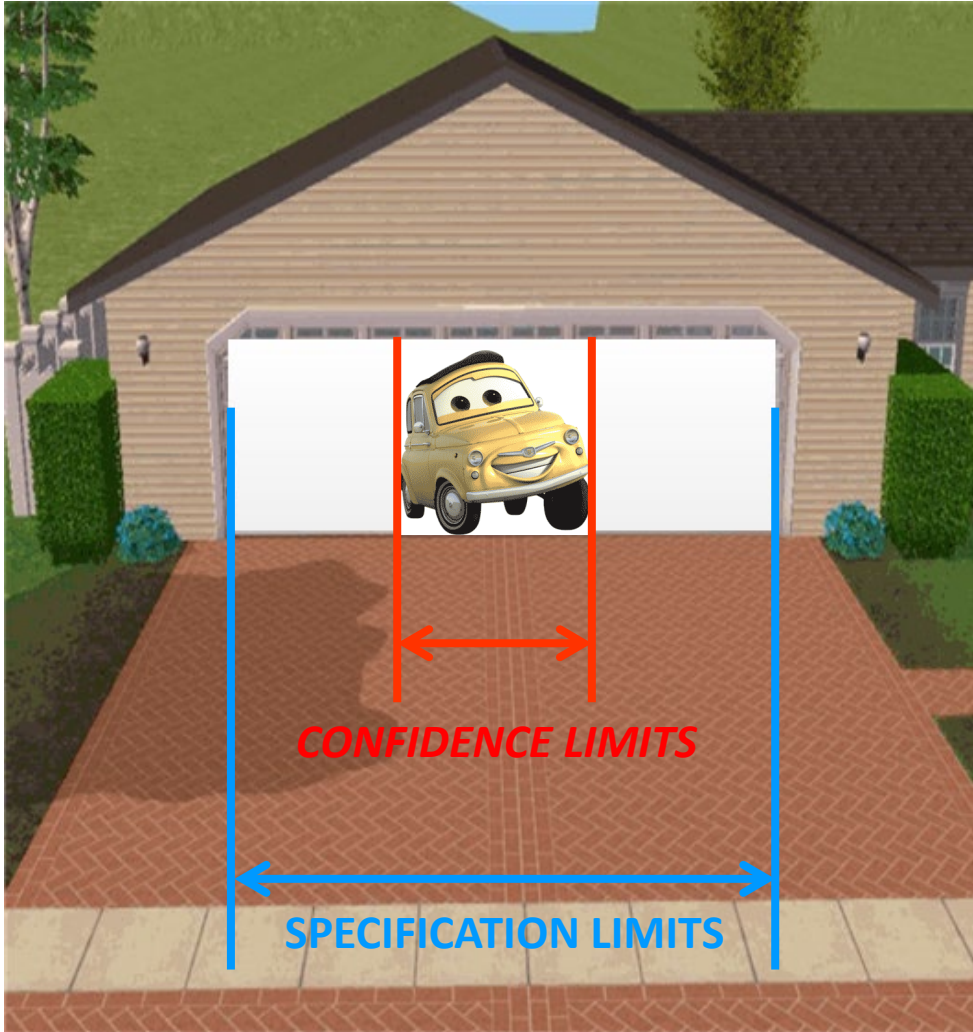


specification limits $>$ confidence limits



CAPABLE PROCESS!!!

Very capable process



specification limits \gg confidence limits



VERY CAPABLE PROCESS!!!



Process capability

- The **process capability** c_P is the ratio between the difference of the specification limits and the natural variability of the process:

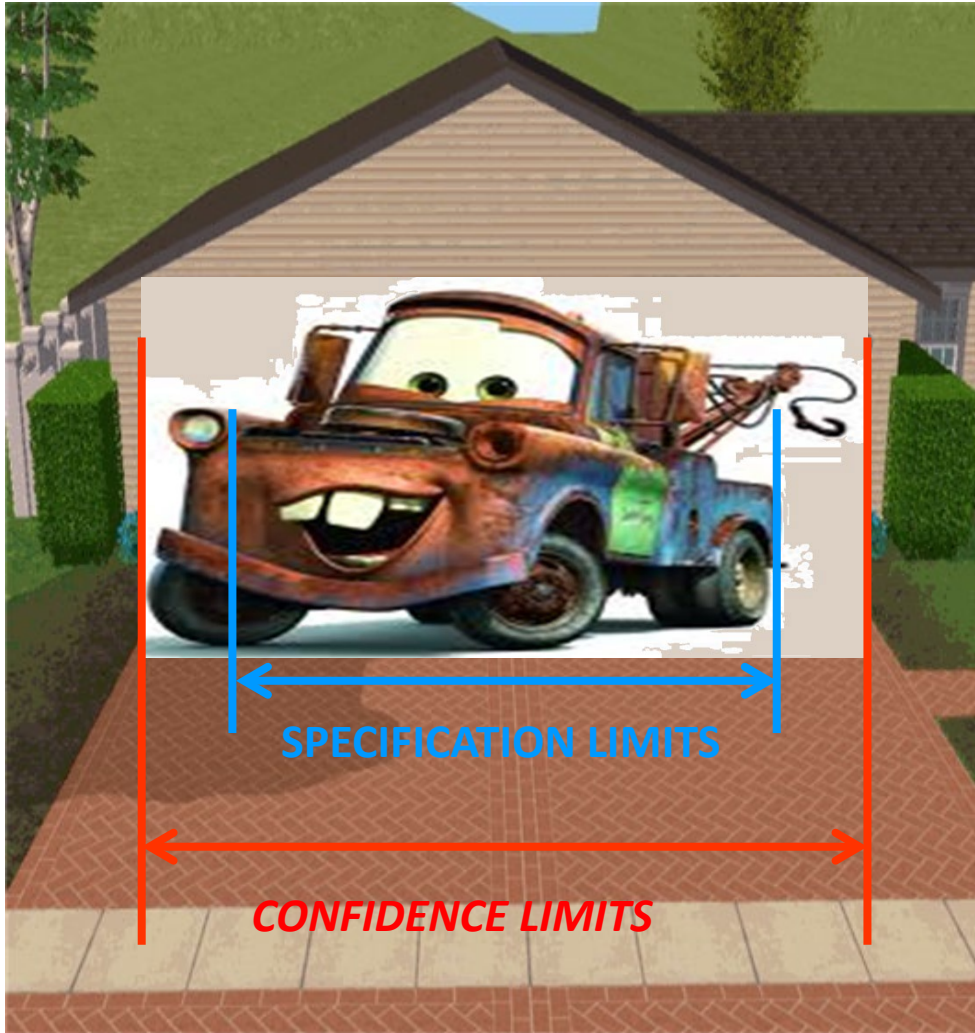
$$c_P = \frac{USL - LSL}{6\sigma}$$

where:

- USL = upper specification limit
 - LSL = lower specification limit
- The higher the process capability is, the more *uniform* the product is!

... but unfortunately...

Non-capable process



specification limits < confidence limits



NON-CAPABLE PROCESS!!! $C_P < 1$



need to improve the process (reduce process variability):

1. detect the major sources of variability
2. reduce the variability of these sources

Take-home message

- **SPC** is the basis for:
 - process monitoring
 - product quality monitoring
- Control (namely, monitoring) charts are the basic (statistical) tools for process and quality monitoring:
 - Shewhart charts are the univariate basis of control charts
- The **monitoring charts** are defined identifying the **common-cause variability** of the **normal operating conditions**, namely, the standards defined by the standard variability of the data on processes and products quality
- The aim is improving the **process capability**, once that the **specifications** are fixed, by decreasing the variability of the process/product quality



- This is strictly related to **quality engineering**...

Quality engineering

Product quality in the global market

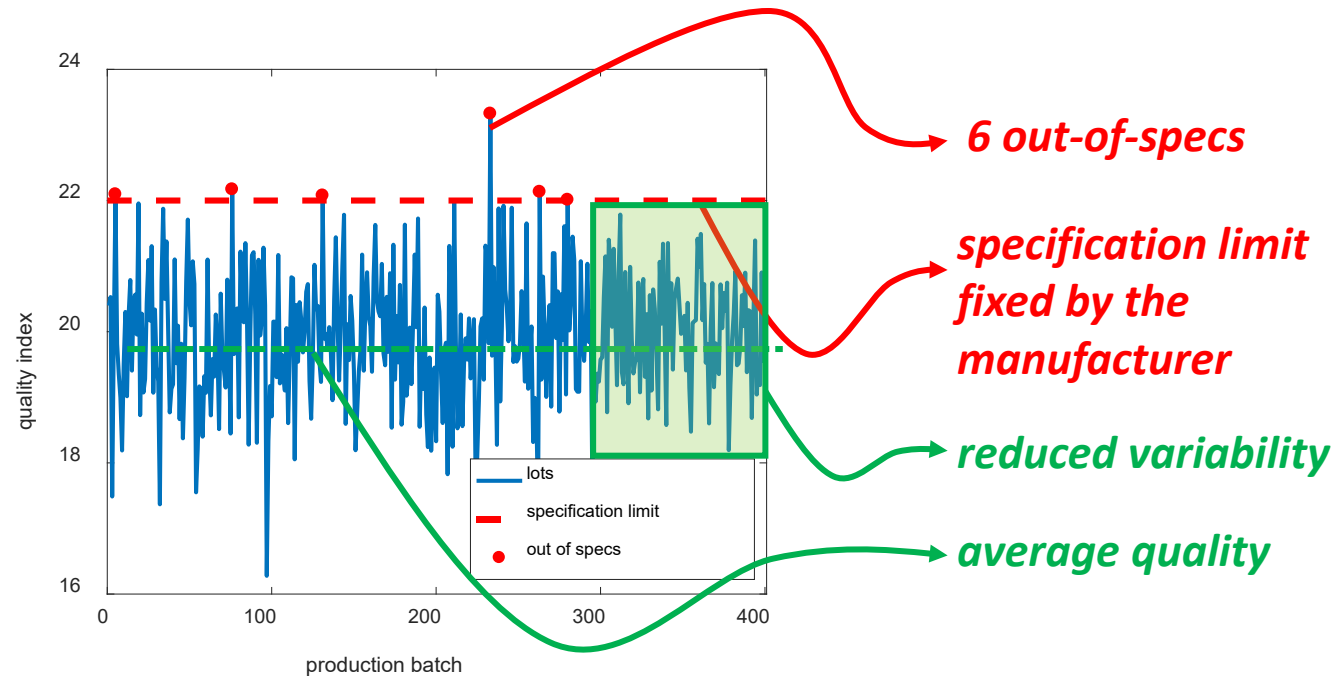
- How can be obtained the **economic success** in today global market?



Ensuring absolute excellence to the product quality!

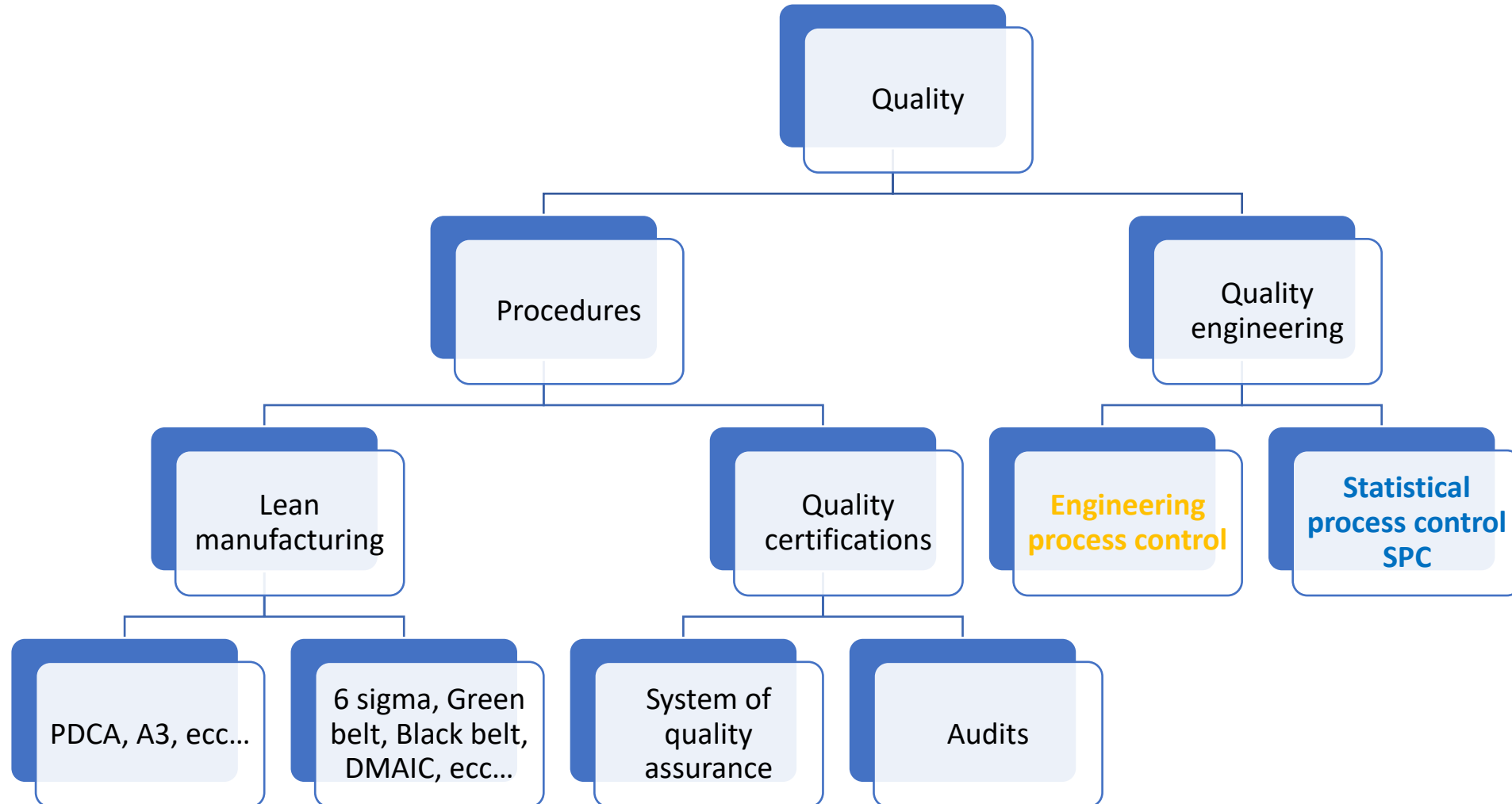
Product quality

quality index of 400 production lots of a drug are analyzed



Improving quality means reducing the variability of processes and products important features

Strategies for quality improvement



Areas of quality control and improvement

- Major areas of quality control and improvement are:
 - **design of experiments DoE**
 - in the development stage: to systematically varying the controllable input factors in the process and determining the effect these factors have on the output product parameters
 - **descriptive statistics**
 - process understanding and troubleshooting
 - **statistical process control SPC**
 - during manufacturing: to understand if a process is running in normal conditions or a product conforming to the standards or anomalies/malfunctions are taking place, and possibly diagnose the causes of anomalies
 - **acceptance sampling**
 - inspection and testing of product: inspection and classification of a sample of units selected at random from a larger batch or lot and the ultimate decision about disposition of the lot
 - usually occurs at two points: incoming raw materials/components, or final production
- These methodologies are useful in analyzing quality problems and improving the performance of **processes** (together with a number of other statistical and analytical tools)

Management aspects of the quality improvement

Management of quality improvement

- Among others, Statistical Process Control and Design of Experiments are the **technical basis for quality control and improvement**
- These techniques must be implemented within the **management system**, which must:
 - organize and direct the overall quality improvement philosophy
 - ensure its deployment in all aspects of the business
- The effective management of quality involves successful execution of three activities:
 1. **quality planning**
 2. **quality assurance**
 3. **quality control and improvement**

1. Quality planning

- **Quality planning** is a **strategic activity**, and it is vital to an organization's long-term business success
- Without a **strategic quality plan**, an enormous amount of time, money, and effort will be wasted by the organization dealing with:
 - faulty designs
 - manufacturing defects
 - field failures
 - customer complaints
- Quality planning on a systematic basis is a vital part of this process which involves:
 - identifying customers and costumers' needs (**voice of the customer VOC**)
 - developing products/services that meet or exceed customer expectations
 - determining how products/services will be realized

2. Quality assurance

- **Quality assurance** is the set of activities that ensures:
 - quality levels of products/services are properly maintained
 - supplier and customer quality issues are properly resolved
- **Documentation** of the quality system is an important component and involves 4 components:
 1. **policy:**
 - what is to be done and why
 2. **procedures:**
 - focuses on the methods and personnel that will implement policy
 3. **work instructions and specifications** oriented to:
 - products
 - departments
 - tools
 - machines
 4. **records:**
 - documenting the policies, procedures, and work instructions that have been followed
 - tracking specific units or batches of product
 - developing, maintaining, and controlling documentation dealing with:
 - customer complaints
 - corrective actions
 - product recalls



3. Quality improvement and control

- **Quality control and improvement** involve the set of activities used to ensure that:
 - products and services meet requirements
 - quality improvement on a continuous basis
- The **statistical techniques** such as SPC and DoE are major tools of quality control and improvement (since large variability is a source of poor quality)
- Quality improvement is:
 - often done on a **project-by-project basis**
 - projects should be selected so that they have significant **business impact**
 - projects should be linked with the overall **business goals**
 - involves **teams** led by personnel with specialized knowledge of statistical methods and experience



Quality and productivity improvement

- The philosophy of **Deming's 14 points**:

1. create a constancy of purpose focused on the improvement of products and services
2. adopt a new philosophy that recognizes we are in a different economic era
3. do not rely on mass inspection to “control” quality
4. do not award business to suppliers on the basis of price alone, but also consider quality
5. focus on continuous improvement
6. practice modern training methods and invest in on-the-job training for all employees
7. improve leadership, and practice modern supervision methods
8. drive out fear
9. break down the barriers between functional areas of the business
10. eliminate targets, slogans, and numerical goals for the workforce
11. eliminate numerical quotas and work standards
12. remove the barriers that discourage employees from doing their jobs
13. institute an ongoing program of education for all employees
14. create a structure in top management that will vigorously advocate the first 13 points

Deming's 7 deadly management diseases

1. Lack of constancy of purpose
 - continuous improvement assure in the enterprise that dividends will continue to grow to all stakeholders
2. Emphasis on short-term profits
 - too much emphasis on short-term profits might make the “numbers” look good, but reducing research and development investment, eliminating employees’ training, and not deploying quality improvement activities
3. Evaluation of performance, merit rating, and annual reviews of performance
 - performance evaluation encourage short-term performance, rivalries and fear, and discourage effective teamwork
4. Mobility of top management
 - job hopping determine that a manger spends very little time in the business function and this results in key decisions being made by someone who really does not understand the business
5. Running a company on visible figures alone
 - management by visible figures alone (e.g., number of defects, customer complaints, and quarterly profits) suggests that the really important factors are unknown and unknowable
6. Excessive medical costs
7. Excessive legal damage awards

Obstacles to success

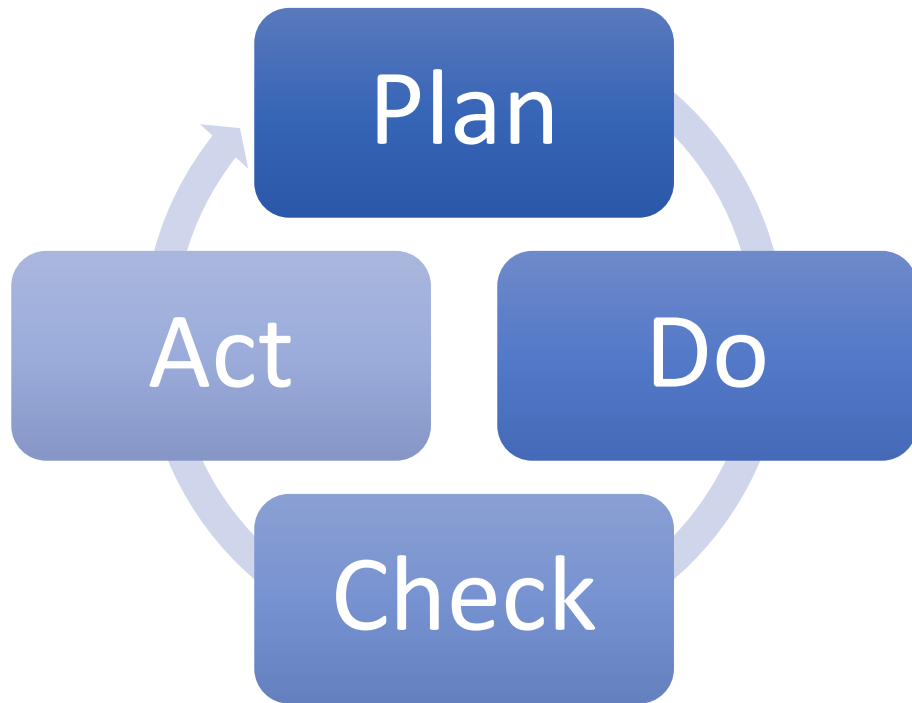
1. The belief that automation, computers, and new machinery will solve all the problems
2. Trying to copy existing solutions
3. The “our problems are different” excuse
 - the principles that will solve them are universal
4. Obsolete (business) schools, where graduates have not been taught how to successfully run businesses
5. Poor teaching of statistical methods in industry
6. Reliance on inspection to produce quality
7. Reliance on the “quality control department” to take care of all quality problems
8. Blaming the workforce for problems
9. False starts
 - example: broad teaching of statistical methods without a plan as to how to use them, quality circles, employee suggestion systems
10. The fallacy of zero defects (companies fail even though they produce products and services without defects)
11. Inadequate testing of prototypes
 - a prototype may be a one-off article, with artificially good dimensions, but without knowledge of **variability**, testing a prototype tells very little
12. “Anyone that comes to help us must understand all about our business”
 - competent people who know everything about the business may not have any idea on how to improve it
 - new knowledge and ideas must be fused with existing business expertise to bring about change

Models for quality improvement

- Shewhart cycle
- Juran trilogy
- Total quality control
- Total quality management
- Quality systems and standards
- Malcolm Baldrige National Quality Award
- Six-sigma program
 - DMAIC approach
 - lean manufacturing
- Just-In-Time approach
- Poka-Yoke approach

- quality is an essential **competitive weapon**
- **management** must play a central role in quality improvement
- **statistical methods and techniques** are powerful tools for quality improvement

Shewhart cycle



■ Plan-Do-Check-Act (PDCA) cycle

- a.k.a. PDSA, where S = “study”
- iterative, may require several iterations to solve complex problems
- **Plan**: propose a change aimed at improvement
- **Do**: implement the change, possibly in a pilot scale
- **Check**: analyze the outcomes of the change
- **Act**: adopt the change, if effective; abandon it, if unsuccessful

Juran trilogy

■ Planning:

- identify external customers and determine their needs
- products or services that meet the customer requirements are designed
- the processes for producing these products or services are developed
- performed on a regular basis

■ Control:

- employed by the operating forces to ensure that the product/service meets the requirements
- SPC is one of the primary tools of control

■ Improvement:

- aims to achieve higher and higher performance and quality levels
- must be on a project-by-project basis
- improvement can either be continuous (i.e., incremental) or by breakthrough:
 - breakthrough improvement is the result of:
 - studying the process
 - identifying a set of changes that result in a large and rapid improvement in performance
 - designed experiments are an important tool that can be used to achieve breakthrough

Total quality control

- Company-wide total quality control is concerned with **organizational structure** and a **systems approach** to improving quality
- Three-step approach to improve quality:
 - **quality leadership**
 - **quality technology**
 - statistical methods and other technical and engineering methods
 - **organizational commitment**
- Key points of this methodology:
 - much of the technical capability is concentrated in a specialized department
 - in contrast to the modern view that knowledge and use of statistical tools need to be widespread
 - organizational aspects are important
 - a lot of management commitment to make it work

Total quality management

- **Total quality management (TQM):** organization-wide strategy for implementing and managing quality improvement
 - typically, organizations adopting a TQM approach have:
 - **quality councils or high-level teams** that deal with strategic quality initiatives
 - workforce-level teams that focus on routine production or business activities
 - cross-functional teams that address specific quality improvement issues
 - focal points:
 - participative organizations
 - work culture
 - customer focus
 - supplier quality improvement
 - integration of the quality system with business goals
- TQM has only had **moderate success**:
 - insufficient effort devoted to widespread utilization of the technical tools of variability reduction
 - lack of top-down high-level **management commitment and involvement**
 - inadequate use of statistical methods
 - general as opposed to specific business-results-oriented objectives
 - too much emphasis on widespread **training** as opposed to focused technical **education**
 - regarded it as just another “program” to improve quality:
 - **zero defects**
 - **value engineering**
 - **quality is free**
 - management worked on identifying the cost of non-quality, as the quality is free
 - identification of quality costs is very useful, but if associated to the idea about what to do to actually improve many types of complex industrial processes

Quality systems and standards

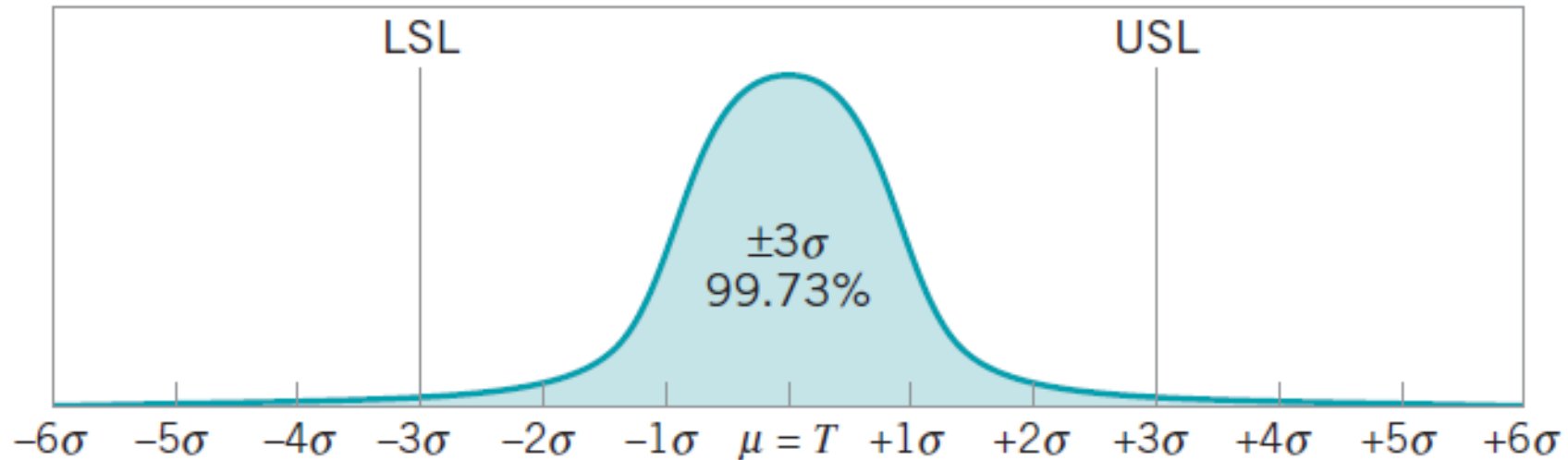
- The **International Standards Organization** (ISO founded in 1946 in Geneva, Switzerland) has developed a series of standards for quality systems:
 - the current version of the standard is known as the ISO 9000 series
 - generic standard, broadly applicable to any type of organization, and it is often used to demonstrate a supplier's ability to control its processes
- The three standards of **ISO 9000** are:
 - ISO 9000:2000 Quality Management System—Fundamentals and Vocabulary
 - ISO 9001:2000 Quality Management System—Requirements
 - ISO 9004:2000 Quality Management System—Guidelines for Performance Improvement
- ISO 9000 is also an American National Standards Institute and an ASQ standard

Limits of ISO 9000

- Focus of ISO 9000 is on **formal documentation** of the quality system
 - **quality assurance** activities
 - organizations usually must make extensive efforts to bring their documentation into line with the requirements of the standards
- Limits:
 - too much effort devoted to documentation, paperwork, and book-keeping
 - not enough effort to reducing variability and improving processes and products
 - many of the third-party registrars, auditors, and consultants that work in this area are not sufficiently educated or experienced enough in the **technical** tools required for **quality improvement**
 - often unaware of what constitutes modern engineering and statistical practice
 - they concentrate largely on the documentation, record keeping, and paperwork aspects of certification
 - ISO certification does little to prevent poor quality products from being:
 - designed
 - manufactured
 - delivered to the customer
 - it is a \$40 billion annual business worldwide:
 - this money flows to the registrars, auditors, and consultants
 - this amount does not include all of the internal costs incurred by organizations to achieve registration
 - there is no assurance that certification has any real impact on quality
 - many quality engineering authorities believe that ISO certification is largely a waste of effort

Premise to the Six-sigma program

- The aim of quality control is **reducing variability** in key product quality features
- Example:
 - consider a **normal probability distribution as a model for a quality characteristic**
 - set the **specification limits** at three standard deviations on either side of the mean
 - the probability of producing a product within these specifications is 0.9973
 - 2700 parts per million defective
 - this is referred to as **three-sigma quality performance**



Example of junk food

- A meal served at the fast food with a 99%-good quality independent components:

- hamburger
 - bun
 - meat
 - cheese
 - lettuce
 - onion
 - tomato
 - pickle
 - souce
- fries
- soda

$$P(\text{single meal is good}) = 0.99^{10} = 0.9044$$

acceptable

- A family of 4 persons @ the fast food

$$P(\text{family meal is good}) = 0.9044^4 = 0.6690$$

not good

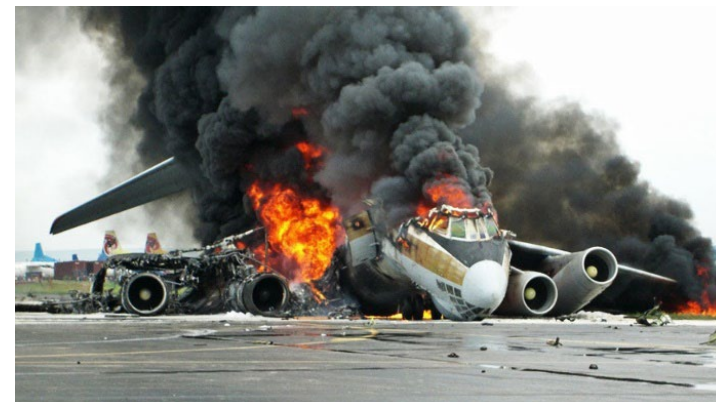
- A family of 4 persons @ the fast food once a month (if their heart can stand...)

$$P(\text{single meal is good}) = 0.6690^{12} = 0.0080$$

unacceptable



- Suppose to have a product that consists of an assembly of **100 independent components**
 - if all 100 of these components must be non-defective for the product to function satisfactorily with a probability of 0.9973, this means that:
$$0.9973 \cdot 0.9973 \cdot \dots \cdot 0.9973 = (0.9973)^{100} = 0.7631$$
 - **23.69% of the products produced under three-sigma quality will be defective!**
- Is this acceptable?
 - a fast-food service activity for a family of 4 persons involves the assembly of several dozen components
 - a typical automobile has about 100 000 components
 - an airplane has up to 2 000 000 components!



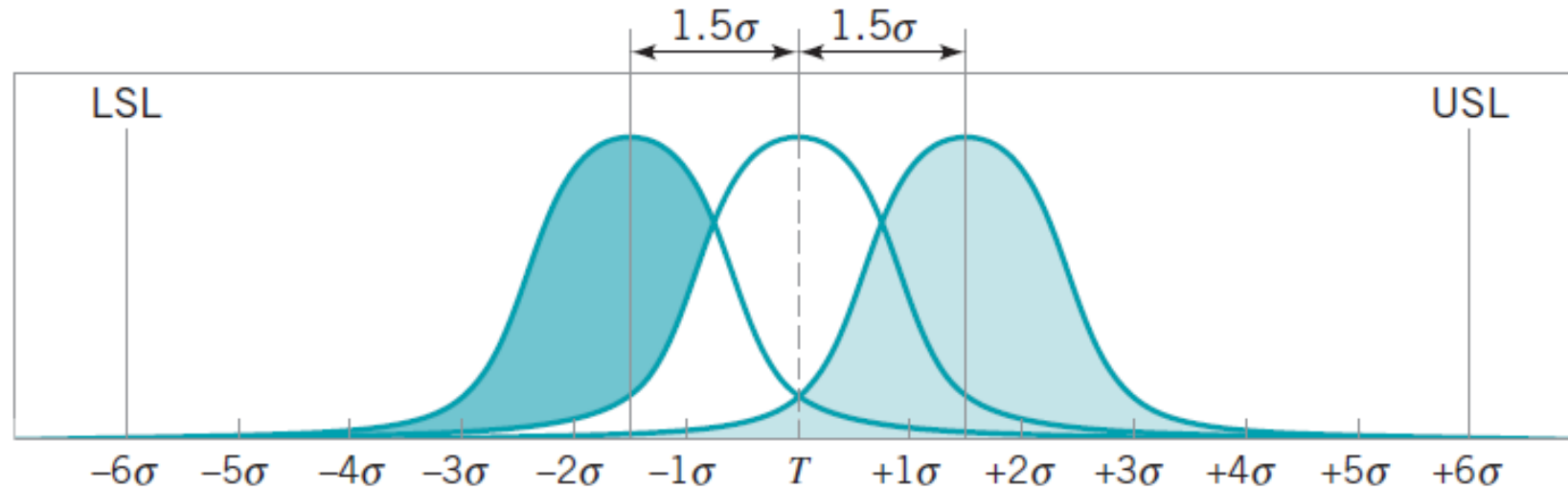
Six-sigma program

- Products with many components typically have many opportunities for failure or defects to occur
 - Motorola developed the **Six-Sigma program** in the late 1980s Focus: reducing variability in key product quality features to **extremely low levels of failure and defects**
 - the specification limits are set at least six standard deviations from the mean
 - only about **2 parts/1 000 000 000 result to be defective**
 - under **six-sigma quality**
 - the probability that any specific unit of the hypothetical product above is non-defective is 0.9999998: much better!!!



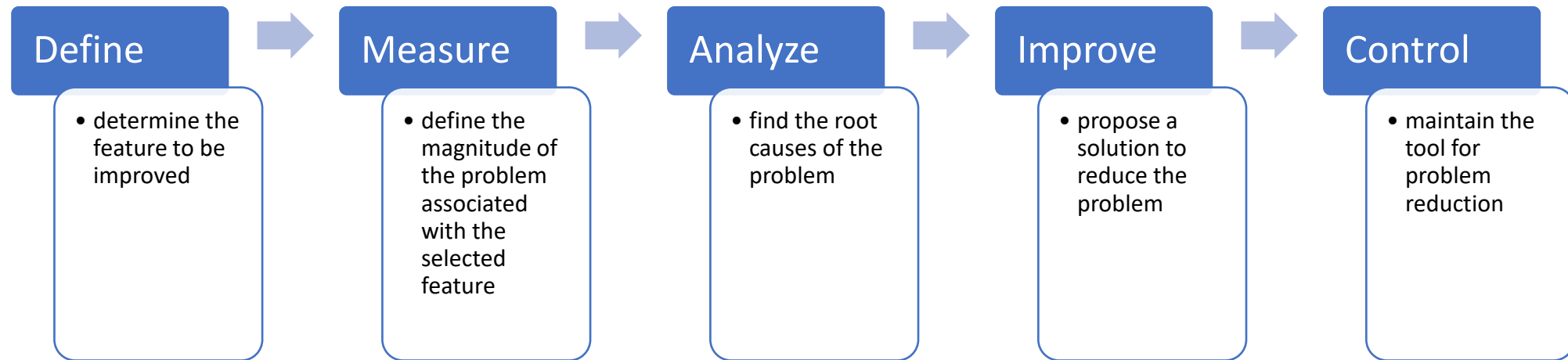
Outcome of the Six-sigma program

- The six-sigma concept was developed under the assumption that the **process mean was still subject to disturbances that could cause it to shift by as much as 1.5 standard deviations off target**
 - a six-sigma process would produce about **3.4 ppm defective** under this scenario



Six-sigma problem solving approach

- **DMAIC** is a 5-step problem solving approach applied in the Six-sigma program



- The DMAIC framework utilizes as basic tools:
 - control charts
 - design of experiments
 - process capability analysis
 - etc...

Limit of the Six-sigma program

- The concept of a six-sigma process is one way to **model quality**
 - it has proven to be a useful way to think about process performance
 - Motorola reduced defectivity by 1300% in 6 years!!!
 - it is not exactly right
- Process **performance** is not predictable unless the process **behavior** is **stable**
 - when the mean and standard deviation are **constant**
- Unfortunately, processes are usually not truly stable
 - disturbances occur
 - process mean shifts off-target
 - increase in the process standard deviation
 - both
- If the mean is drifting and deviates as much as 1.5 standard deviations off target, a prediction of 3.4 ppm defective may not be very reliable!

... per sempre a fianco a me!

