Contents

1. DEVELOPMENT AND IMPORTANCE OF QUALITY MANAGEMENT

The catchphrase trust is good, control is better is often used to justify and characterize quality management in businesses.

We would like to take a look at QM, not only in its control function, but also in the manner in which it fulfills diverse duties.

1.1 Origins of quality control and quality management

The Babylonians and Egyptitians used to seal their wine and oil jugs with wax for transport. With these seals, they guaranteed the quality of the contents. In medieval times quality control in the form of a so-called *Schaumeister* (They would regularly check workshops for compliance with guild regulations. If customers could also address this inspector in the cases of poor quality.

With the advent of mass production, more than 100 years ago in America and later in Europe, the problem of suitable quality management arose. The use of the assembly line led to a division of labour. This caused the production process to be divided into many individual sections. As a result, more and more semi-skilled workers could be deployed, for they only had to master a few acquired work steps. Because mass-produced wares were said to be of inferior make, businesses had to come up with a way of monitoring their production and providing their customers with certain degree of quality.

The more recently practiced **quality management (QM)** has historically evolved from earlier quality control.

This development can be explained thusly. Constant improvements in production led to higher production output and new technologies.

Quality control required an increasing effort; the necessary inspections became more complex and demanded more time. Furthermore with the introduction of legal regulations for product liability each producer was even more interested in comprehensive quality assessment of his products. How could this development be met in the face of

- increasing efficiency, i.e. lower costs from quality defects,
- and just-in-time-production?

Initially sector-specific systems of quality control were formed, e.g. for military applications, for space travel, for the automobile and microelectronics industries.

From the sector-specific systems it was attempted to sector-independely deduce a QS-system and to propose different levels of verification. The adaption of ISO 9000 through 9004 in the year 1987 replaced partially established national standards. These standards were adapted into the German standards the same year as DIN ISO 9000 through 9004. Currently DIN ISO 9000:2000 ff applies as of december 2000.

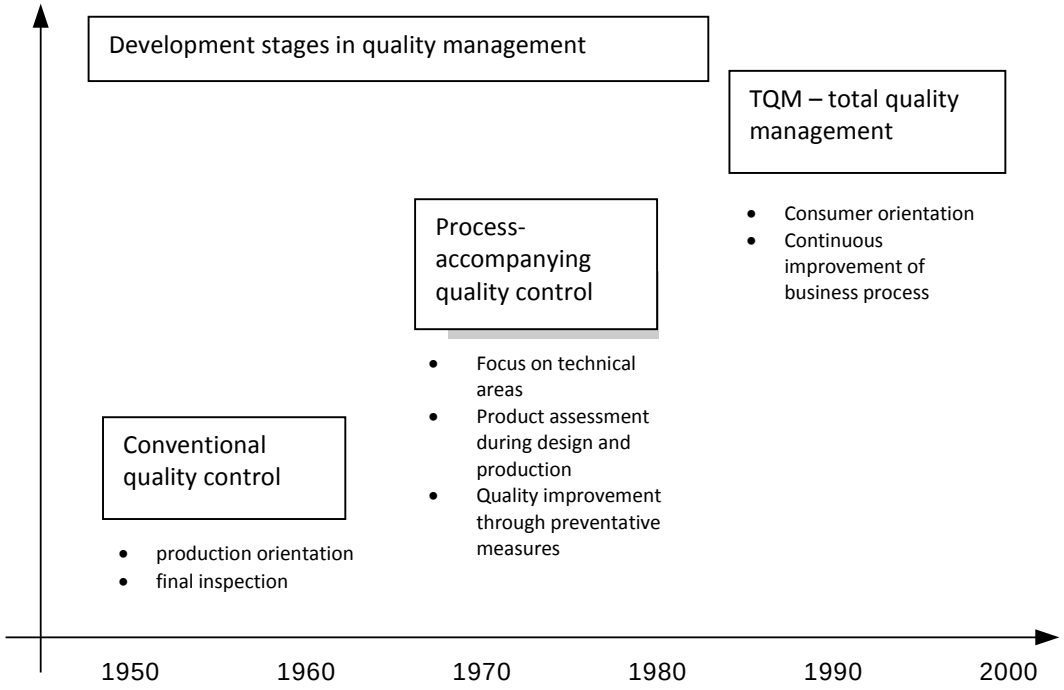


Figure 1.1: Development stages in quality management

1.2 Principles and goals of the quality management system according to DIN ISO 9000:2000 ff

Requirements and functions of a QS-/QM-system

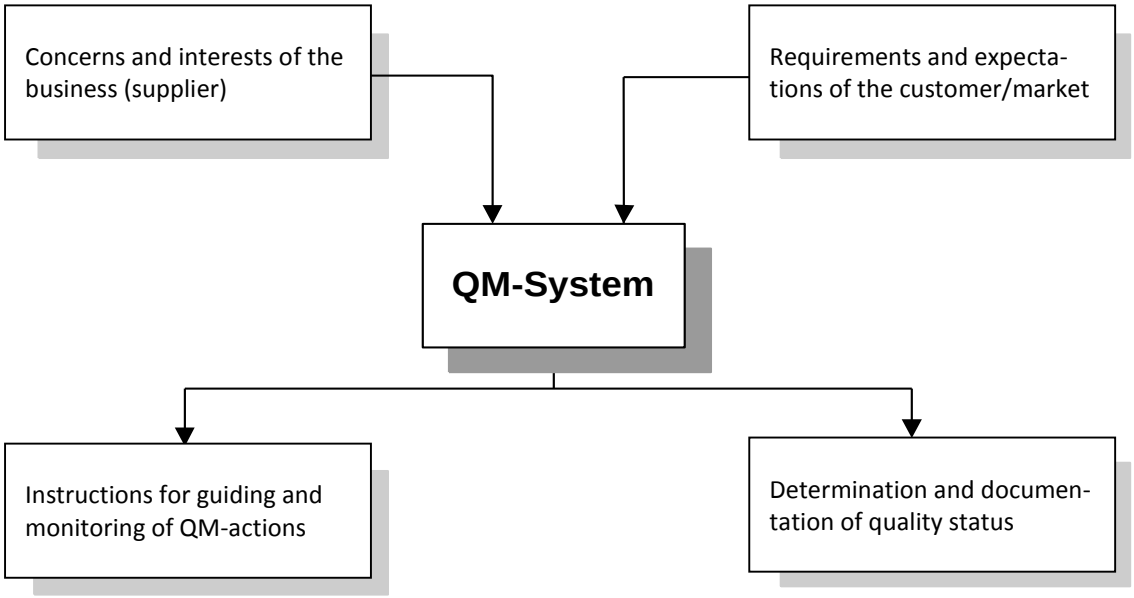


Figure 1.2

Note:	Definition ´quality management` (according to DIN ISO 8402) All activities of the total executive functions which determine quality policy, goals and responsibilities and actualize these through quality design, quality guidance, quality control and constant quality improvements in the framework of the quality management system.

For lasting business success, that is to say the market penetration of a business, quality is of foremost importance.

More and more customers demand DIN EN ISO 9000 ff quality control certification from their suppliers.

But not only customer requirements should be an incentive for the installation of a QS-system.
Cost reduction for customer complaints and other errors, overview of trust in quality capability, including warranty and liability and image improvement are sufficient grounds for installing and maintaining a QS-system, because:

Note:	Today inspection alone is insufficient. Quality rather has to be planned and developed, through quality capability in all process steps.

In addition the issues of product liability require a complete documentation of all responsibilities, processes and quality verifications.

The international interlacing of industry and economy made the establishment of a global standardized system for quality analysis obligatory.

Quality management according to ISO 9000:2000
The DIN EN ISO 9000 series of standards has proven itself and in short time achieved acceptance as all-purpose product-independent quality management system model; it even became the most widely used ISO-standard in the world!

DIN EN ISO 9000:1994, the previous series of standards (second revision since the original version from May 1987) was itself replaced by the advanced and amended ISO 9000:2000 series of standards.

What did the revision ISO 9000:2000 effect?
The previous 25 standards, guidelines an standard drafts are concentrated into only four core standards, everything else is either downgraded to technical reports or deleted. The four core standards are:

Concentration:
- ISO 9000:2000: terms/definitions
- ISO 9001:2000: verification requests (former ISO 9001/9002/9003)
- ISO 9004:2000: guide for performance improvement
- ISO 19011: auditing, guideline for auditing of QM- and UM-systems

Custom-made suit
ISO 9002 and ISO 9003 no longer exist. Instead the new standard explicitly provides the opportunity to customize the QM-system and with it the verification requests to individual business needs.

Practical orientation
A QM-system reflects the actual business processes. Thereby the previous 20 QM-elements are allocated to the individual processes, exactly where they naturally belong.

Customer orientation
Customer orientation is of outstanding importance. Businesses diligently ascertains customer wishes or rather demands of the market, check their own ability to fulfill these, provide the goods and/or services according to specifications and after conclusion determine customer satisfaction.

Product orientation
Product orientation was reinforced. Businesses check wether its products meet market demands and product specification requirements.

Constant improvement
Constant improvement is emphasized. Market and customer expectations change and with them successful businesses through constant improvement of their goods/services and processes.

Importance of leadership
The role of management is underscored more clearly. A management system is a control instrument of business administration. To maintain and develop this system is a leadership function. Top management has to spring into action and be able prove this.

Product-independent applicability
The new standard is equally well suited for application by manufacturers and by service providers, e.g. Software-developers, medical facilities, law-firms, engineering consultants, retail markets.

1.3 The DIN EN ISO 9000 ff series of standards

The DIN EN ISO 9000 ff series of standards, also called the ´ISO-9000-family`, delineates recommendations and guidelines for installation, maintenance, and continual improvement of QM-systems. In the process globally accepted minimum standards for structural and procedural organization and their documentation are defined.
The requirements for product and production safety and their documentation have to be realized sector- and product specifically in the applicable standards and regulations.

Many sectors and organizations, e.g. of the automobile and electric appliances sector, the NATO and other institutions insist not only on DIN ISO 9000 ff. certification but also on certification regarding product and process reliability.

The stated goal of the DIN EN ISO 9000 ff. series of standards is to achieve an universally accepted certification process through standardization of QS-systems and therefore has to apply to the QM-system and not only specific product requirements.

In the EU-market many economic sectors demand certification according to DIN ISO 9000 ff. by an accredited bodies. Wether this relatively expensive certification is worth it or necessary is sector- and marketdependent.

In some sectors liability insurers are very interested in their clients having certified QS-systems.

1.4 The eight quality principles

During the comprehensive revision of the standards family eight standard quality principles were formulated:

- customer orientation - customer satisfaction, i.e. to always and in future meet requirements and if possible to exceed them
- leadership - establishing goals and creating a capable environment
- human resources - inclusion of all individuals
- management - guidance of interactions and links
- constant improvement - of the organization's (company's) overall performance
- decision making - through data and analysis
- supply relationships - for mutual benefit with increased value creation for both parties

So a good QM-system not only serves to always reach agreed upon product quality and other customer requirements and verify them. It also helps to detect, avoid and mend weak points in production methods and operation processes and so to improve efficiency and added value of the organization.
The wide spread and implementation of the ISO 9000:2000 series of standards clearly shows, that quality management is not a passing fad, but an instrument of optimization of business performance, improvement of competitive positions and therefore a requirement for survival in the marketplace.

The customer is supposed to come back, not the product`, that is the goal of quality management.

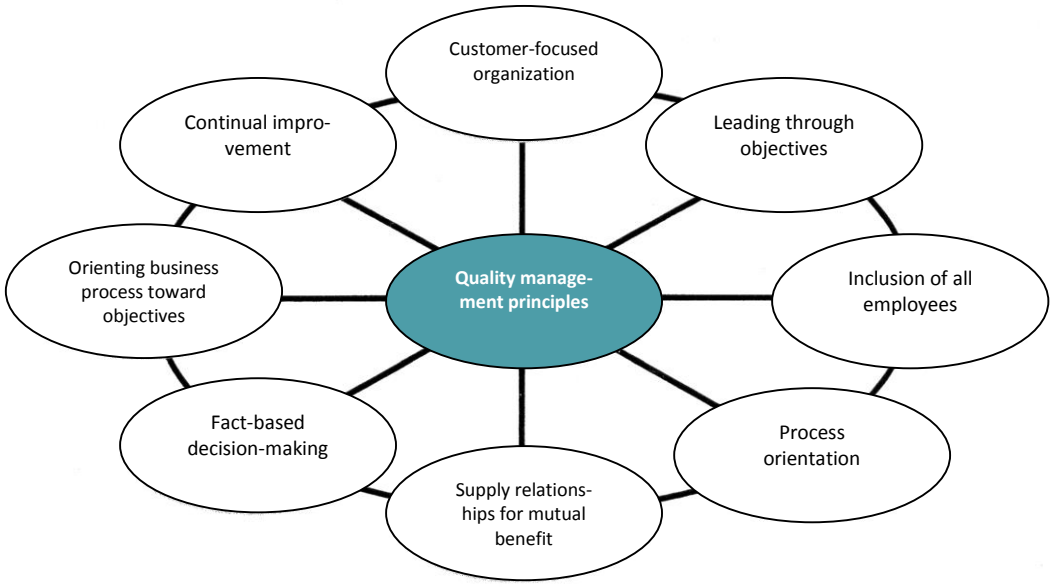


Figure 1.3

The new ISO 9000:2000 series of standards demonstrates more clearly than previously, that the installation of a QM-systems not just means fulfilling the standard's requirements on paper, but rather represents a strategic decision by company management.

This series of standards is based on 8 quality management principles as cornerstones, or guidelines for management action. Their systematic observance and application supports the improvement of the overall performance of a business.

If one were to equalise ´customer`with ´interested parties` and interpreted quality not as product related but as ´quality = meeting of requirements` these standards as managment-system-standards could also be applied to other organizations and planning safeguards, e.g. as basis of an environmental protection audit.

The basis for achievement of these goals remains:

- establishment of structural and procedural organization
- qualification of personnel, machines and resources
- regulation of responsibilities, accountabilities and authority
- obligation to document regulations and results
- duty to report up to the executive management
- control of risks and economic efficiency by assessing alternatives
- correctional and preventative measures to avoid problems with quality

1.5 Integrated management systems

On the basis of these new standards, the up to this day largely formally structured quality management system with its structural and procedural organization will evolve into a business-specific, integrated management system for controlling the whole company. In the process, quality management is combined expediently with environmental management and security, or risk management of the company to form an integrated system. Business objectives can then, in future, be secured and documented in the three areas quality, environmental protection and security in a comprehensive and uniform process.

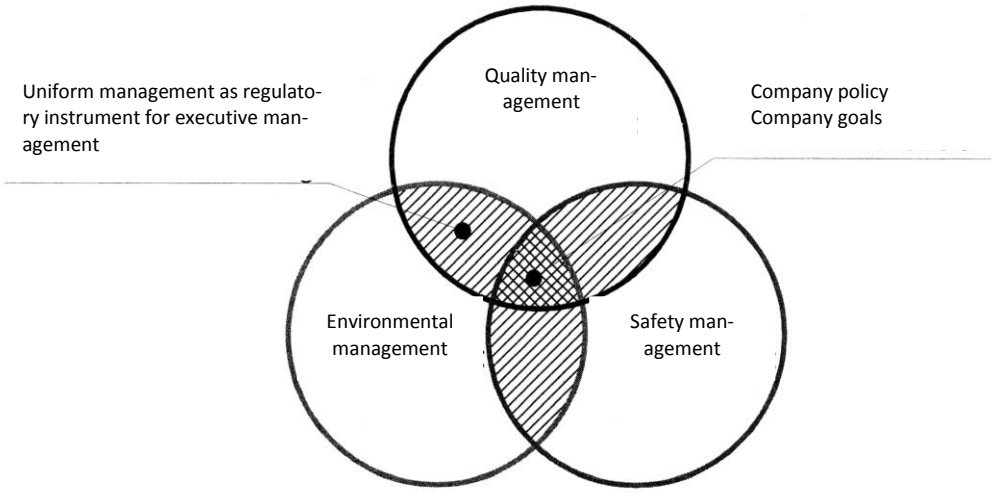


Figure 1.4

Aside from the further development of the QM-system, it will be of importance in future to link quality, environmental protection and security goals and achieve them in businesses through a common process. Despite the differing thematic directions, large analogies exist between these management systems.

1.6 Contents of DIN EN ISO 9000:2000 ff.

ISO 9000:
quality management systems - basics and definitions
Explains the previously mentioned eight principles of quality management and defines terminology (technical terms).

ISO 9001:
quality management systems – requirements
Determines the requirements for a QM-system for demonstrating the capability of meeting all requirements of customers and public authorities for the quality of products and therefore is the basis of the certification process.

ISO 9002:
Completely covered by IS0 9001, therefore deleted entirely.

ISO 9003:
Completely covered by IS0 9001, therefore deleted entirely.

ISO 9004:
quality management systems – guidelines for performance improvement
Provides recommendations for improving overall performance and efficiency of organizations/businesses.

1.7 The circle of quality

Guide for auditing of quality and environment management system (part of the QM-standards-family according to the new ISO 9000)
Product quality requirements are not subject of these standards. They are each part of product-specific regulations.

The regulations of this family of standards relate only to management and representation of quality-control-measures.
Scope and depth of the necessary representations are determined by the product requirements, delivery contracts, technical rules and laws. Particularly regarding design liability, safety laws and standards are the applicable regulations.

The previous versions of ISO 9000 ff. have therefore connected the familiar ´20 steps to quality` as elements of a QM-system to the phases of product life and development. In this the individual operations stood at the centre.

Note:	The circle of quality with the quality elements and phases of product life.

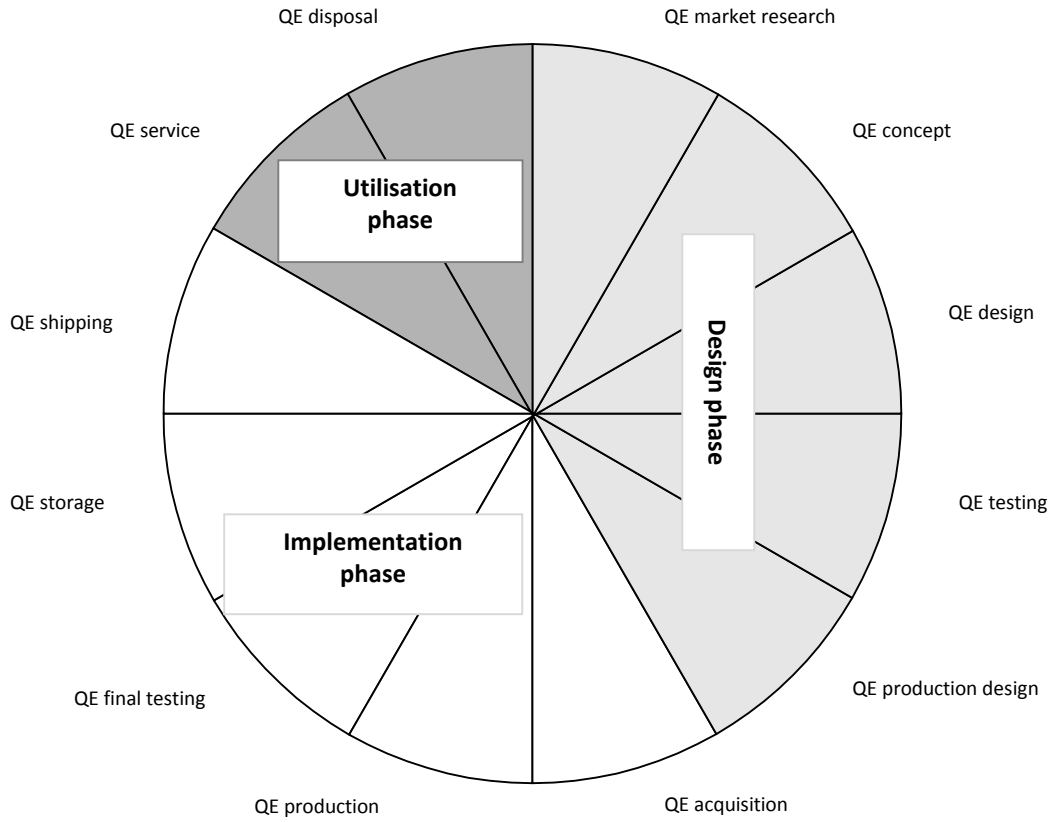


Figure 1.5: The circle of quality

1.8 process orientation models of ISO 9000:2000

A process-oriented QM-system accompanies all essential in-plant processes and analyses them: even with good organization this leads to opportunities for optimization. Management processes as well as functions of supporting areas are explicitly included.

For all functions

- the objectives to be attained, are to be clearly formulated.
- duties and responsibilities as well as their interfaces are to be defined.
- the for their acheivement necessary resources are to be provided.
- the execution of processes is to be monitored and evaluated regarding success.
- opportunities for improvements are to be systematically identified and implemented.

Note:	Core concern of ISO 9000 ff. is and was customer satisfaction and their trust in the ability of the supplier to achieve and maintain that trust.

Note:	The new ISO 9000:2000 ff. organizationally puts the transformation of input (requirements) into output (product) in the centre and attaches special importance to the conjunction of individual actions, i.e. they are no longer phase- but instead process-oriented.

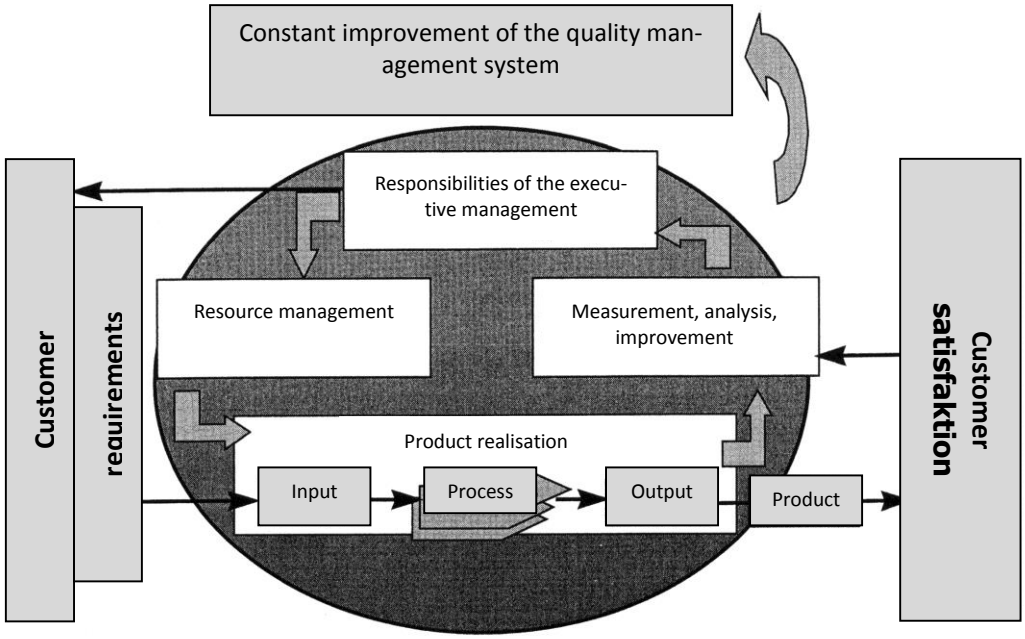


Figure 1.6: structure of a process-oriented QM-system

2. IMPORTANT INSTRUMENTS AND TOOLS OF QUALITY MANAGEMENT

2.1 Statistical methods in quality control

2.1.1 The concept of statistics

Up to now, we have used the term ´statistics` without knowing its precise meaning. Now, we would like to focus more clearly on what we understand today when we talk about statistics.

The origin of the word ´statistics` goes back to the Latin word ´status`, in English ´state or condition`. In Neo-Latin it acquired the meaning of ´of the state`.
Today, statistics is understood as the methodical approach for the recording, collection, organization, evaluation and presentation of all kinds of data.

Statistics, as a scientific branch of mathematics, has the goal of providing methods for

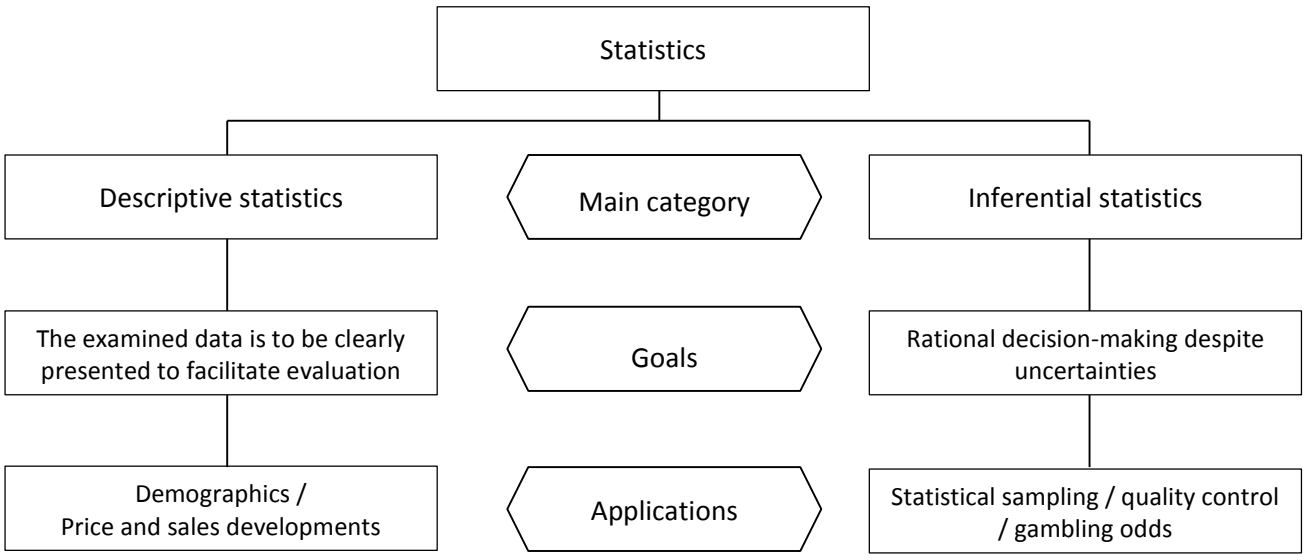
- the collection (of facts, numerical data)
- processing
- presentation
- interpretation
- analysis

of data for determining the structure of mass phenomena.

Statistics is divided into two main disciplines:

- descriptive statistics
- inferential statistics

Figure 2.1: descriptive statistics and inferential statistics



Descriptive statistics
This discipline of statistics collects, organizes, presents and analyzes numerical data.

Inferential statistics
This discipline uses available data to make estimates and predictions about larger quantities.

It can also be used to test hypotheses (e.g. political forecasting).

In production good quality is not achieved by sorting out the bad parts, but by not producing them in the first place. For this reason, one always has to be aware of the acceptable quality level and whether the entirety of parts meets this level by testing random samples in sufficiently large numbers.
Random samples from a production process, when averaged, show an image of the process. Individual samples, however, may show deviating results. Still, the expected range of the actual process value can be narrowed by statistical methods.

Random samples in a predefined range allow the assessment of production processes, the detection of non-random errors and the development of preventative measures for future avoidance.
In conclusion, it can be said that random sampling procedures and testing efforts should be arranged to meet the following requirements:

- Random testing must ensure the installation of production processes which only result in products of a predetermined quality level.
- The chance of detecting batches of insufficient quality, as such, must be estimable and, if possible, constant.

2.1.2 Basic concepts of statistics

Terms	Description
Characteristic	attribute that allows for differentiation of observed units
Observed units	individuals, objects, processes, products that are the subject of a statistical analysis
Base population **N**	entirety of all observed units for which a statistical statement is to be made
Sample size **n**	number of units in the random sample
Characteristic value	value adopted by a characteristic

Example:
During the production of bolts, the outer diameter of 80 out of 1000 bolts is measured.

Terms	Description
Characteristic	outer diameter
Observed units	specific measurements (actual measurements), e.g. 8.038mm
Base population **N**	**N** = 1000
Sample size **n**	a single bolt
Characteristic value	**n** = 80
Observed units	Work pieces

We will begin with discussing a simple random sampling.

2.1.3 Random sampling

Expectations regarding random samplings
In this correspondence course you have already read about complete and partial censuses and learned about their advantages and disadvantages.

At this point, we would like to take a closer look at random samplings.
First, we have to explain the terms base population and random sample.

Note:	The ´total` is the base population. The ´part` is the random sample.

The main task of a random sampling is to draw fairly reliable conclusions from the examination of a limited number (´part`) of units about all units of the corresponding base population (´total`), e.g. a sampling of parts in an incoming goods inspection.

The results of a random sampling are expected to reflect the actual situation and be reasonably trustworthy.

The sample (sample size) has to also be the right size relative to the base population to give an outline of the ´total`.

Since anything and everything can be examined through random sampling, different modes of sampling have been established.

2.1.4 Simple random sampling

Out of a base population elements are chosen at random and examined for the relevant characteristic.

Note:	Each element must have the same chance of ending up in the sample.

Examples:
- random drawing from a residential register
- drawing from a drum at a raffle
- random extraction of parts from an incoming delivery

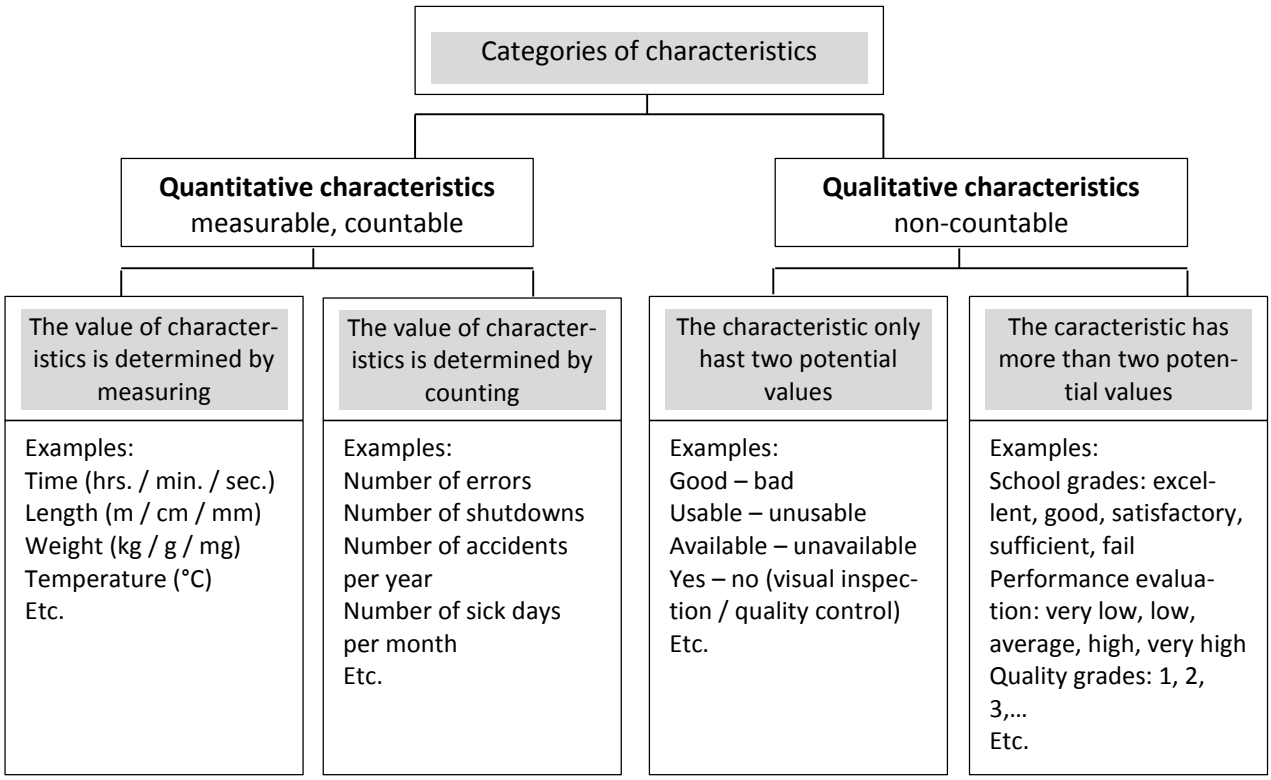
2.2 Data acquisition

Data and facts are the basis of every quality statistic (quality improvement).

Therefore, data acquisition requires thorough preparation and the correct application of the appropriate tools.

The following items are essential to data acquisition processes:
- keeping an eye on the goal of the data acquisition process
- keeping an eye on the samples representatively
- knowing the characteristic to be measured (see characteristic categories)
- mastering measuring methods and instruments
- accounting for accuracy (inaccuracy) of the measurement

Figure 2.2: Categories of characteristics



Quality assessment is usually done with two testing methods:

- Scaled testing
  Scaled testing uses measuring instruments with an appropriate scale to determine measure-ments (actual values), e.g. time (hrs. min., sec.), length (m, cm, mm), weight, temperature, etc.

- Attributive testing
  Attributive testing is also called ´pass-fail-testing`. This testing method uses gauges (pass – fail) for testing, for example. Visual inspection also belongs to this testing method, such as the deci-sions: yes – no; available – unavailable; usable – unusable; adequate – inadequate; etc.

Both testing methods are suitable for complete censuses and random samplings.

2.2.1 Original values lists

At this point we would like to explain something important.
An original value is what we called a single observed value (measured value), e.g. 2.4 mm.

Note:	An original values list accrues, when the observed values (measured values) are noted as they occur (are measured).Original values lists are unsorted series of observed values (measured values).

	Values in millimeter
Observed values list	2.4 2.5 2.6 2.7 2.6 2.7 2.4 2.8 2.5 2.3 2.5 2.6 2.4 2.6 2.5 2.3 2.5 2.5 2.5 2.4 2.8 2.6 2.2 2.4 2.4 2.5 2.6 2.6 2.5 2.6 2.4 2.3 2.1 2.3 2.2 2.7 2.7 2.5 2.9 2.4

2.2.2 Tally sheets

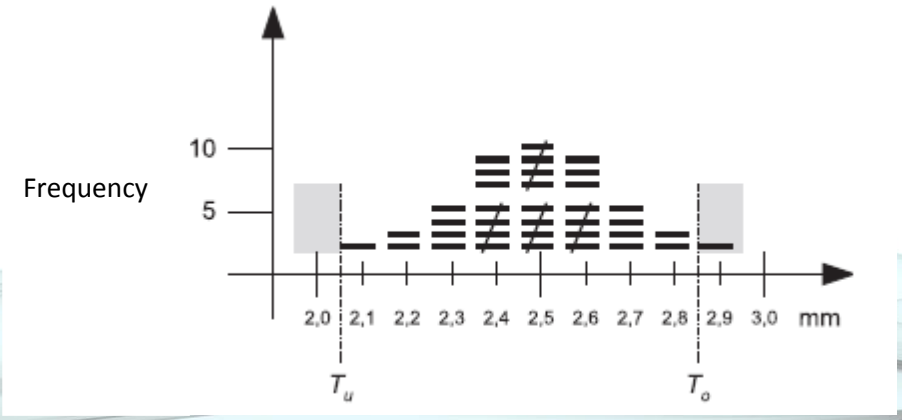
A tally sheet is an ordered series of observed values (measured values). A tally sheet shows how often each value occurred.

The advantages of a tally sheet relative to an observed values list are:
a) The data distribution is instantly discernible.
b) Mean value and maximum deviation can be promptly assessed.
c) Boundary values can be seen at once.
d) The share of rejects is directly visible after application of tolerance limits.

	Values in millimeter		Frequency	Cumulative frequency
Tally Sheet	2.0			
	2.1 I	T_u (2.05)	1	1
	2.2 II		2	3
	2.3 IIII		4	7
	2.4 ~~IIII~~ III		8	15
	2.5 ~~IIII IIII~~		10	25
	2.6 ~~IIII~~ III		8	33
	2.7 IIII		4	37
	2.8II		2	39
	2,9	T_o (2.85)	1	40
			40	

T_u – lower tolerance limit or B_{lo} - lower boundary value
T_o - upper tolerance limit or B_{up} – upper boundary value
This tally sheet could also be arranged a little differently, as it is sometimes done in statistics.
See figure 2.3

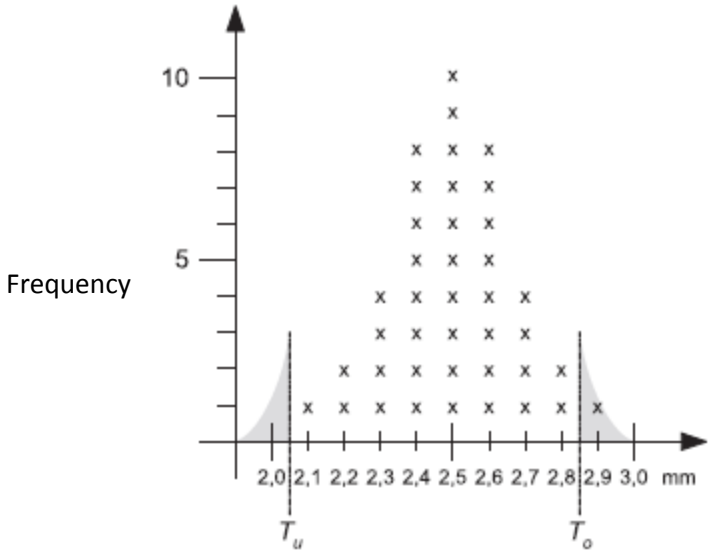
Figure 2.3: tally sheet



2.2.3 X-sheets

Another method of quickly and clearly presenting original values is the compiling of X-sheets.
X-sheets have the same advantages as the tally sheets above, the difference being that the data is entered in the form of Xs.
X-sheets for measured values
An example of measured value acquisition via X-sheet is shown in figure 2.4.

Figure 2.4: X-list for measured values



Here the common statistical parameters can quickly be read (see books of tables).

$\bar{x}$ = 2.5 mm
$\bar{x}$ = 2.5 mm
R = 0.8 mm
D = 2.5 mm

Note:	Since, and D are identical we have a normal distribution at hand.

These statistical parameters were already covered in the general section on basic qualifications (Please check the calculations!)

By inserting T_u and T_o (tolerance limits) we can see that one item is above T_o and is therefore defective. Thus, we can calculate the error percentage (p):

$p = \frac{x}{n} \cdot 100\ \%$

p = error percentage of the sample (%)
x = number of errors/defective items in the sample
n = sample size (number of measured values)

For our example figure 2.4 we now arrive at:

$p = \frac{x}{n} \bullet 100\ \%$

$p = \frac{1}{40} \bullet 100\ \%$

$p = 2.5\ \%$

The error percentage of this sample is 2.5%.

If the X-sheet does not yield a ´suitable distribution`, as demonstrated in figure 2.5, the data has to be categorized. We will now demonstrate a useful categorization method, e.g.:

Number of categories: k = 5
Width of categories: w = 0.05 mm

	Values in millimeter
Observed values list	3.87 3.81 3.78 3.80 3.77 3.81 3.75 3.74 3.71 3.76 3.76 3.76 3.85 3.83 3.77 3.82 3.69 3.72 3.79 3.72 3.70 3.90 3.86 3.84 3.73

Figure 2.5: Non-categorised distribution

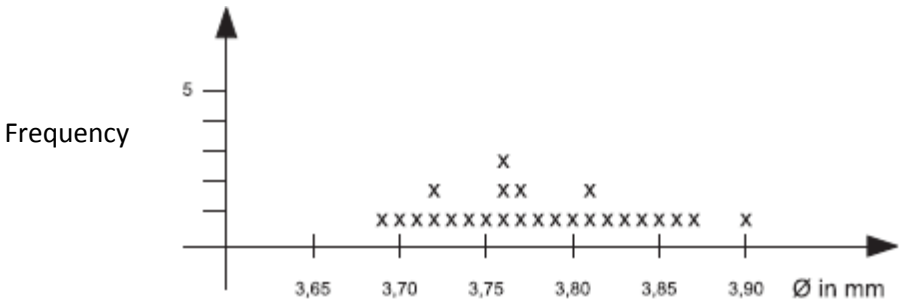
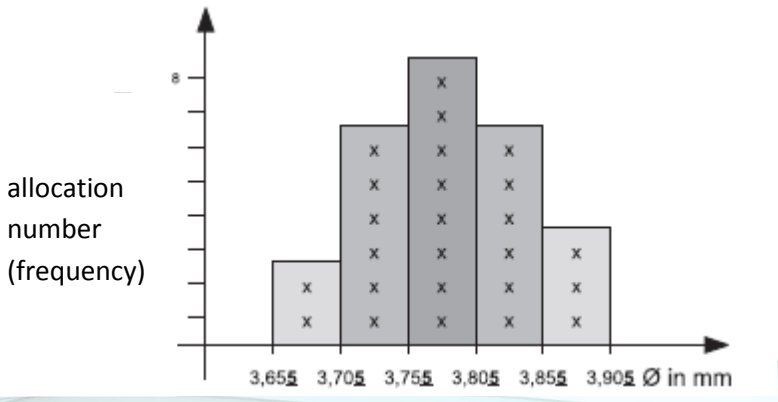


Figure 2.6: Categorised distribution



By slightly shifting the category limits by 0.005 mm, the measured values always fall into the lower category. Thus the value 3.70 falls in the left category since the category limit is 3.705mm (also see the chapter ´histograms`)

2.2.4 X-sheets for error counts

In quality management X-sheets for error counts are called number-of-errors-distributions. Number-of-error-distributions are of great importance in practical application, insofar as shipments or in-house manufacturing can be evaluated via the sampling results (number of errors/defects).

However, conclusions can only be drawn for longer observation periods or multiple shipments that have been documented in the form of number-of-errors-distributions.

The error count (x) of a test can be documented in various forms, either in the form of tables or as X-sheet for error counts.

Nowadays the X-sheet number-of-errors-distribution) is preferred in quality management.

Figure 2.7: X-sheet (ideal case)

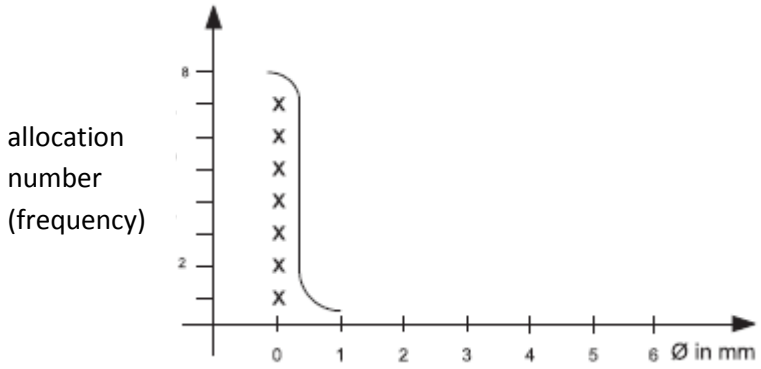
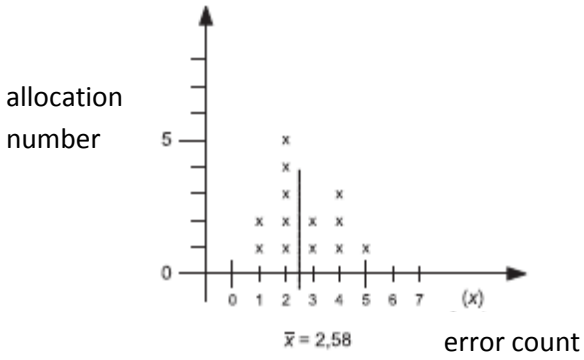


Table 2.1: Table of error counts

Sample No.	Error count (x)	
1	4	
2	2	
3	1	
4	2	
5	2	
6	3	
7	4	
8	2	
9	2	
10	3	
11	5	
12	1	
m =12	31	Σ x

Figure 2.8: X-sheet (number-of-errors-distribution)



Sequence for the generation of number-of-errors-distributions:

1. Draw a horizontal and a vertical axis.
2. Label the horizontal axis with x (error count) and the vertical axis with the allocation number (frequency of occurrence)
3. Plot the detected error counts in sequence as Xs (use x from table 2.1)

Advantages of the number-of-errors-distribution (X-sheet) are:
a) the distribution of errors can be immediately seen
b) the average $\bar{x}$ can be quickly estimated
c) minimum and maximum number of errors is immediately obvious

One disadvantage is that the order of occurrence of errors can no longer be determined.

Of course, it is important to know the average number of errors that occurred. This average $\bar{x}$ can be calculated using the following formula.

$$\bar{x} = \frac{\Sigma x}{m}$$

$\bar{x}$ = average number of errors
x = number of errors in the sample
Σ = summation operator (Σ x reads as: sum over all x)
m = number of samples

Our examples from the table of error counts (table 2.1) and X-sheet (figure 2.8) yield:

$$\bar{x} = \frac{\Sigma x}{m}$$

$$\bar{x} = \frac{31}{12}$$ (add all error counts)

x = 2.58

Plot the result to scale in the X-sheet (figure 2.1).

Other display formats are:

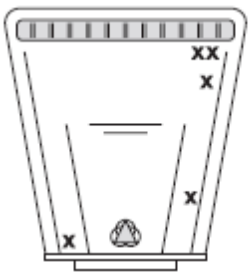
Table 2.2: check sheet for one type of error

Cracks	number
0	~~IIII~~ III
1	~~IIII~~
2	I
3	I
4	II
5	III
6	I
more	

Table 2.3: check sheet for multiple types of errors

Type of defect	Number
too much slackness	I
damaged	II
too corrugated	~~IIII~~ I
gap too large	II
overlap	III
measurement 86.6	I
4-45°	I
other	

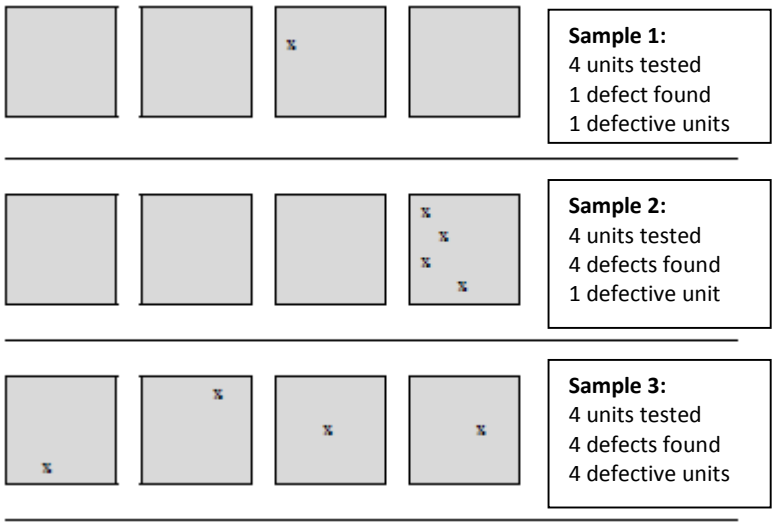
Table 2.4: defect-location-diagram

paint flaws front hood: X


Comment on defects and defective units:

When collecting attributive data one should distinguish between defects and defective units. Table 2.5 demonstrates this difference

Table 2.5: ´defects` and ´defective units`



2.2.5 Inspection charts

For a better overview of not only the error counts, but of all errors, in particular in respect to

- the type of error
- the frequency of errors
- the percentage of errors (%)

inspection charts are used in the practice.

This is how an inspection chart is handled:

15 samples were taken (m = 15) with sample sizes of n = 20 for each.
The parts were then tested according to specification (inspection instruction) and the error counts (x) assigned to the different types of errors and then noted. In the course of this procedure, one dimension error (diameter) and two fitting errors (drill hole) were found and noted for the first sample.

This was done 15 times.

Subsequently, the error counts of each type of error were added up.

The first error type had 17 errors.
The second error type had 11 errors.
etc.

Then the following formula was used to calculate the error percentage for each error type:

$$p_{FA} = \frac{\Sigma x}{n \cdot m} \cdot 100\ \%$$

p_{FA} = error percentage for each error type
n = sample size
m = number of samples
Σx = sum of all errors for each error type

We will now calculate the percentage of measurement errors (length) for an example:

$$p_{FA} = \frac{\Sigma x}{\text{n} \bullet \text{m}} \bullet 100\ \%$$

$$p_{FA} = \frac{17}{20 \bullet 15} \bullet 100\ \%$$

$$p_{FA} = 5.66\ \%$$

If you calculate the other error percentages yourself, you will certainly get the same results as in table 2.6. Finally, the results are presented graphically in the form of a bar chart. This way one can immediately see which error type occurred most often.

Table 2.6: Inspection chart

Inspection chart	**(work piece data) drawing number etc.**																	
Error type	**sampling**																	**Error percentage**
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**Σ x**	**%**	**Per error type**
Dimension errors (length)		1		2	1		3	1	1	2	1	2	2		1	17	5.66	
Dimension errors Ø	1		1	1	2	1	1			1		1	1	1		11	3.66	
Winding errors			1			1					1	1			1	5	1.66	
Fitting error	2	1		1	2	3	1	2	2		1		1	3	2	21	7.00	
																		$p_{FA} = \frac{\Sigma x}{\text{n} \bullet \text{m}} \bullet 100\ \%$
n = 20 / examiner	Jas.	Jas.	Jas.	Jas.										Jas.	Jas.			

n = 20 (sample size)
m = 15 (number of samples)
Σ x = sum of all errors (x) for each error type

2.3 Presentation of statistical data

Recapitulation: See part BQ and in subjects NTG and MIK for corresponding basics.

2.3.1 Spreadsheets

Statistical data is most useful when it is presented clearly and vividly.
The presentation process is part of the fourth stage of statistical work. One method of presenting data is the creation of spreadsheets (s. correspondence course ´statistics` in this course series).

Spreadsheets should appear and be labeled as follows: (See the following representation.)

The heading must contain:
a) a short statement of the factual contents (sales in €/age distribution/income development etc.)
b) date or period of data acquisition (from – till or date)
c) geographical scope (company, city, country, nation)
The structure of a spreadsheet

Table :_____(heading/title)

		Company ABC	**Table header**						
rows	→	**Pre-column**							
	→					**cell**			
	→								
			↑	↑	↑	↑			

Figures section

Table header and pre-column further categorize the contents of the presentation.
The rows are arranged horizontally and the columns vertically. They form the cells.
The figures section contains the data in the individual cells.

Should not all cells be filled, the following symbols are to be applied:

-	value does not exist (value is zero)
X	value cannot be determined
o	value is greater than zero (cannot be represented in the units of the table)
---	value is to be determined

2.3.2 Graphic representations

Another method of presenting data is graphical representation.
One advantage of this method is that the statistical data can be understood at a glance and interrelations are made easy to understand.

Graphical representations can give one an idea of measurements, test results and other data.
In this way a wide range of information can be contained in a minimum of space and clearly and succinctly explains complex situations.
The graphic should be large enough, as simple as possible and not present too much information at once.

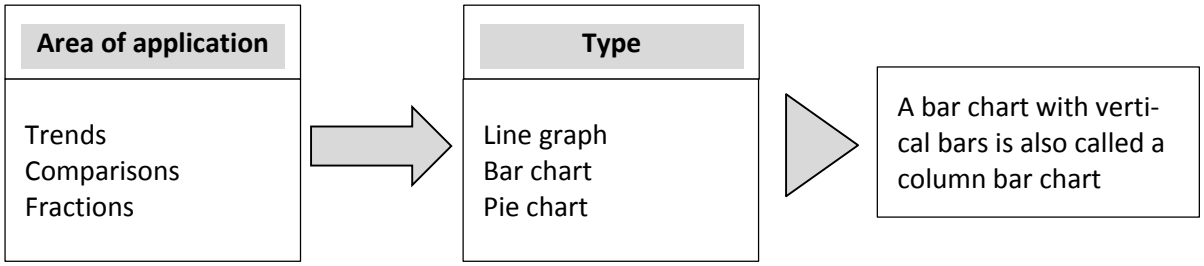
When creating graphical representations the following issues should be considered:

- graphical honesty (no deception through scale distortion etc.)
- consistency and uniform scaling
- use of standardised symbols
- simplicity, easy readability

There are numerous types of graphical representations. The following images show the most important and common ones.

Depending on the area of application quality management uses different types of diagrams.

Figure 2.9: Applications and types of diagrams



The line graph

1. Draw the vertical axis; determine range and scale, label (including units of measurement)
2. 2.Draw the horizontal axis, determine range and scale, label (including units of measurement)
3. Draw grid (if required)
4. Plot each measured value as data points (intersection)
5. Connect these points by a line
6. Add labels, add title/header

Figure 2.10: Line graph

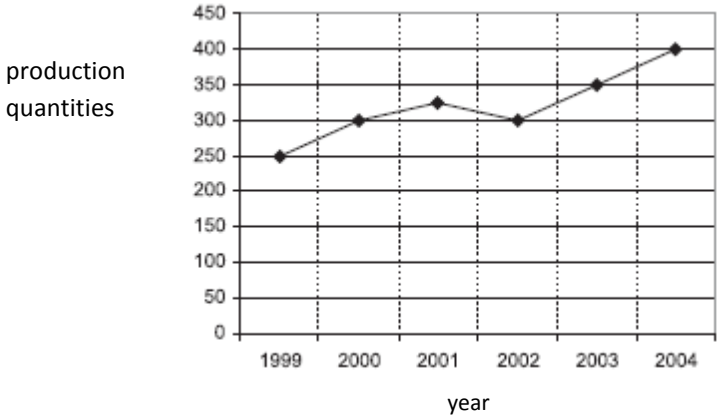


Figure 2.11: area chart (layered line chart)

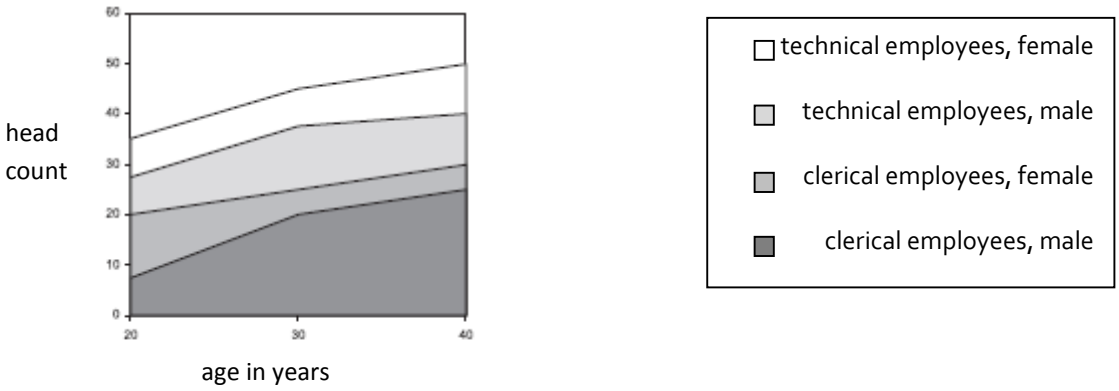


Figure 2.12: Frequency polygon

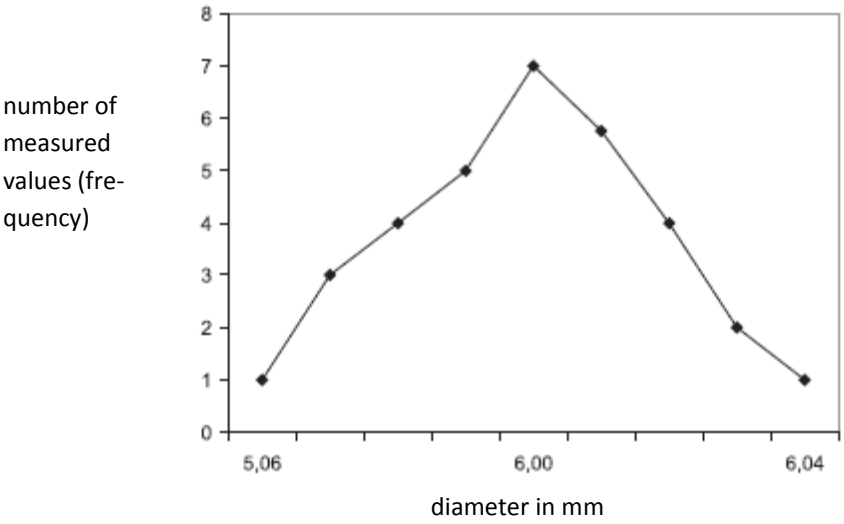
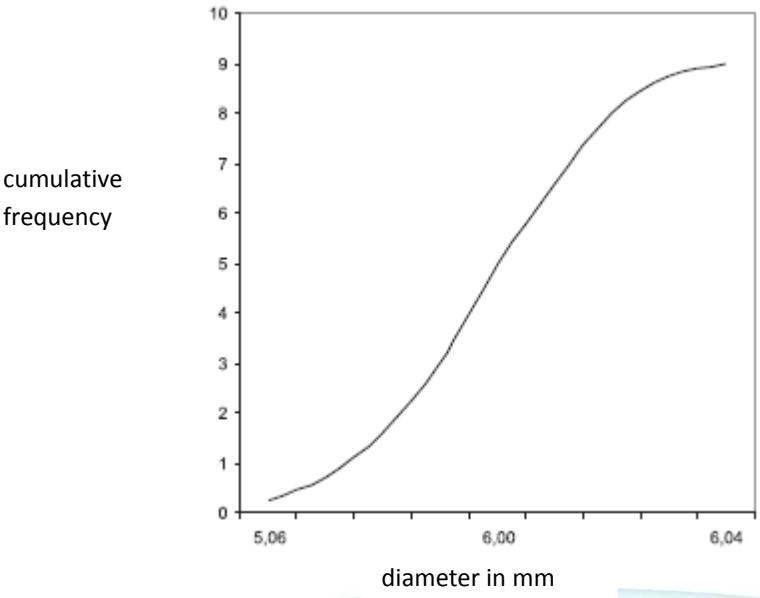


Figure 2.13: Cumulative frequency polygon (cumulative curve)



The bar chart

1. Draw the vertical axis; determine range and scale, label (incl. units of measurement)
2. Choose whether to use simple, stacked or grouped columns.
3. Determine the number of columns, draw and label the horizontal axis
4. Determine the column layout
5. Draw the columns
6. Add labels and chart title/header

Figure 2.14: Simple bar chart

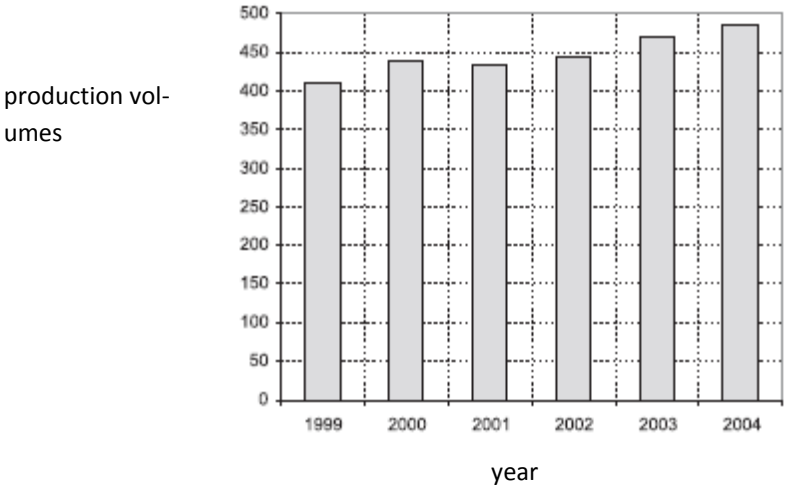


Figure 2.15: Stacked bar chart

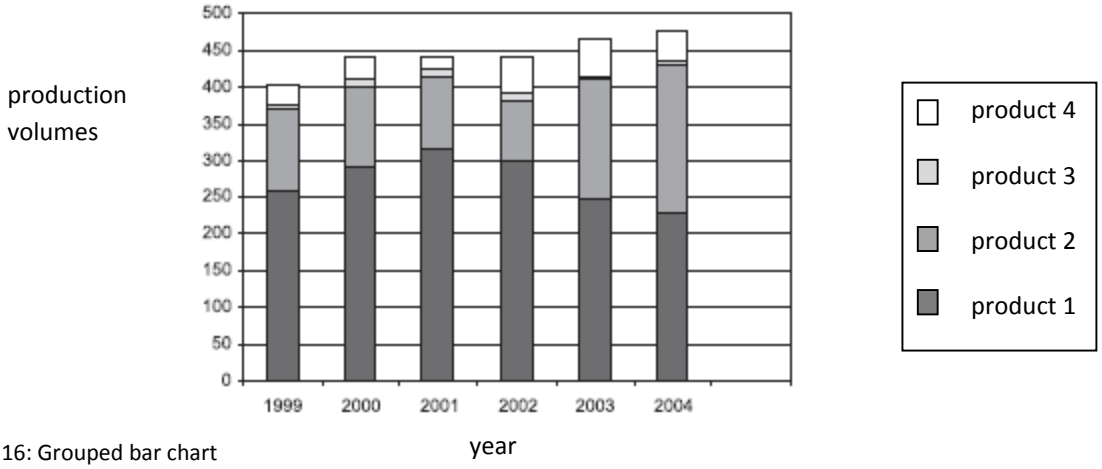
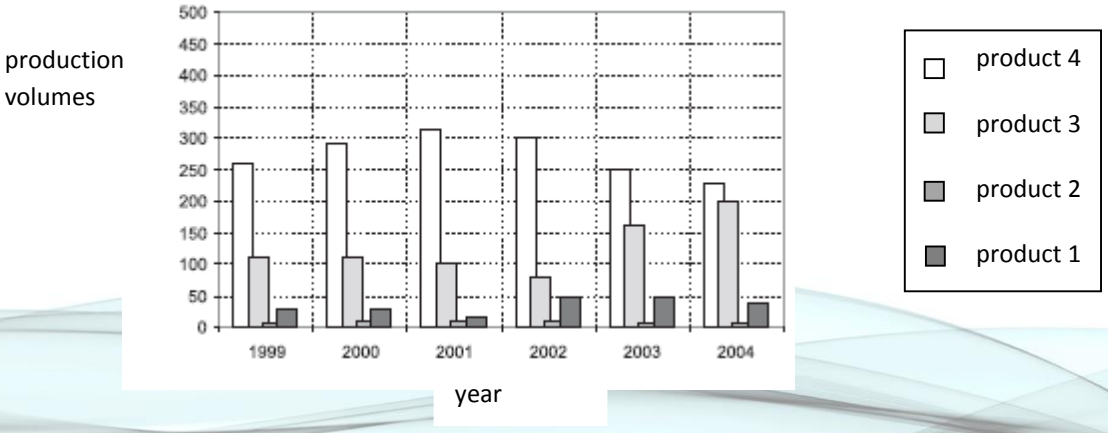


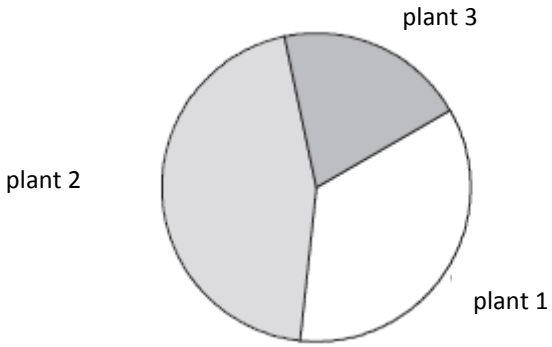
Figure 2.16: Grouped bar chart



The pie chart (circular chart)

1. Determine percentages for each category (class, group)
2. Convert percentages to angular degrees
3. Draw a circle and mark the circle segments of the pie chart (compass, protractor)
4. Label the segments and add chart title/header

Figure 2.17: Production in 2000 (distribution of numbers)

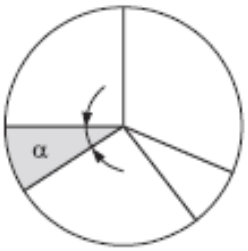


For pie charts the angle at centre for each percentage is calculated according to this formula for α.

$$\frac{100}{x} = \frac{360°}{\alpha}$$

$$\alpha = \frac{x \cdot 360°}{100} = x \cdot 3.6°$$

x = percentage



2.3.3 The histogram

The histogram is a chart of the frequency distribution.
When analyzing a series of measurements location, dispersion and form of the distribution can be identified at a glance.
A minimum of 50 measured values should be available.

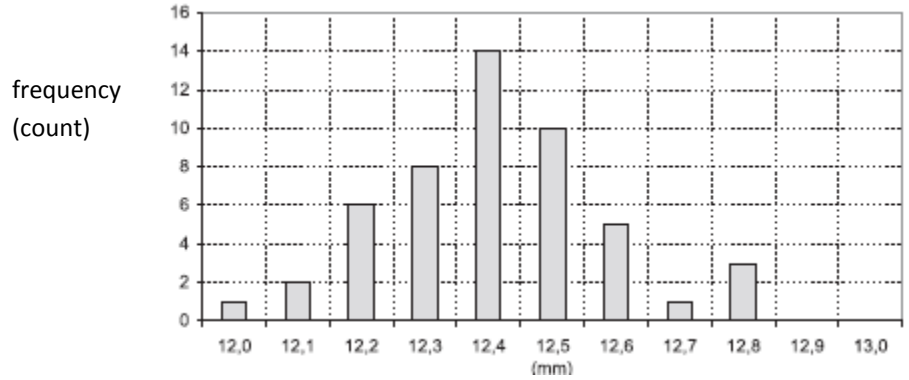
Histograms are closely tied to tally sheets for data acquisition (s. Chapter ´data acquisition`)
Two methods of approach (analysis) are available. The central positioning and the dispersion of the characteristic values (s. bell ´curve`.)

Central positioning is the tendency of data points to accumulate around a central point and to become increasingly rare at the edges of the distribution.
Dispersion describes the scattering of the data points over an area. In numerical terms, this can be expressed through the range ´R` or the standard deviation ´s`.

Value table:

characteristic value (mm)	frequency(count)
12.0	1
12.1	2
12.2	6
12.3	8
12.4	14
12.5	10
12.6	5
12.7	1
12.8	3
12.9	0

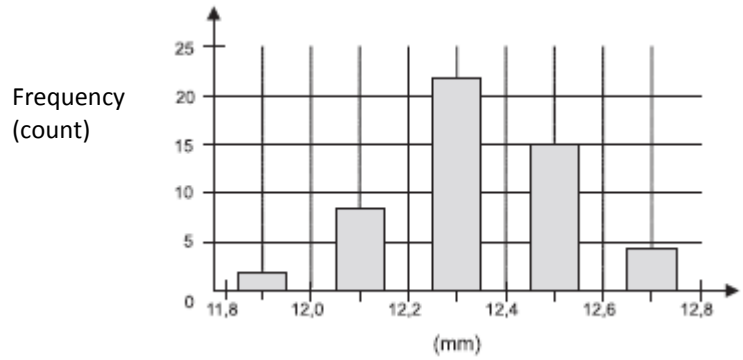
Figure 2.18: Histogram



Value table:

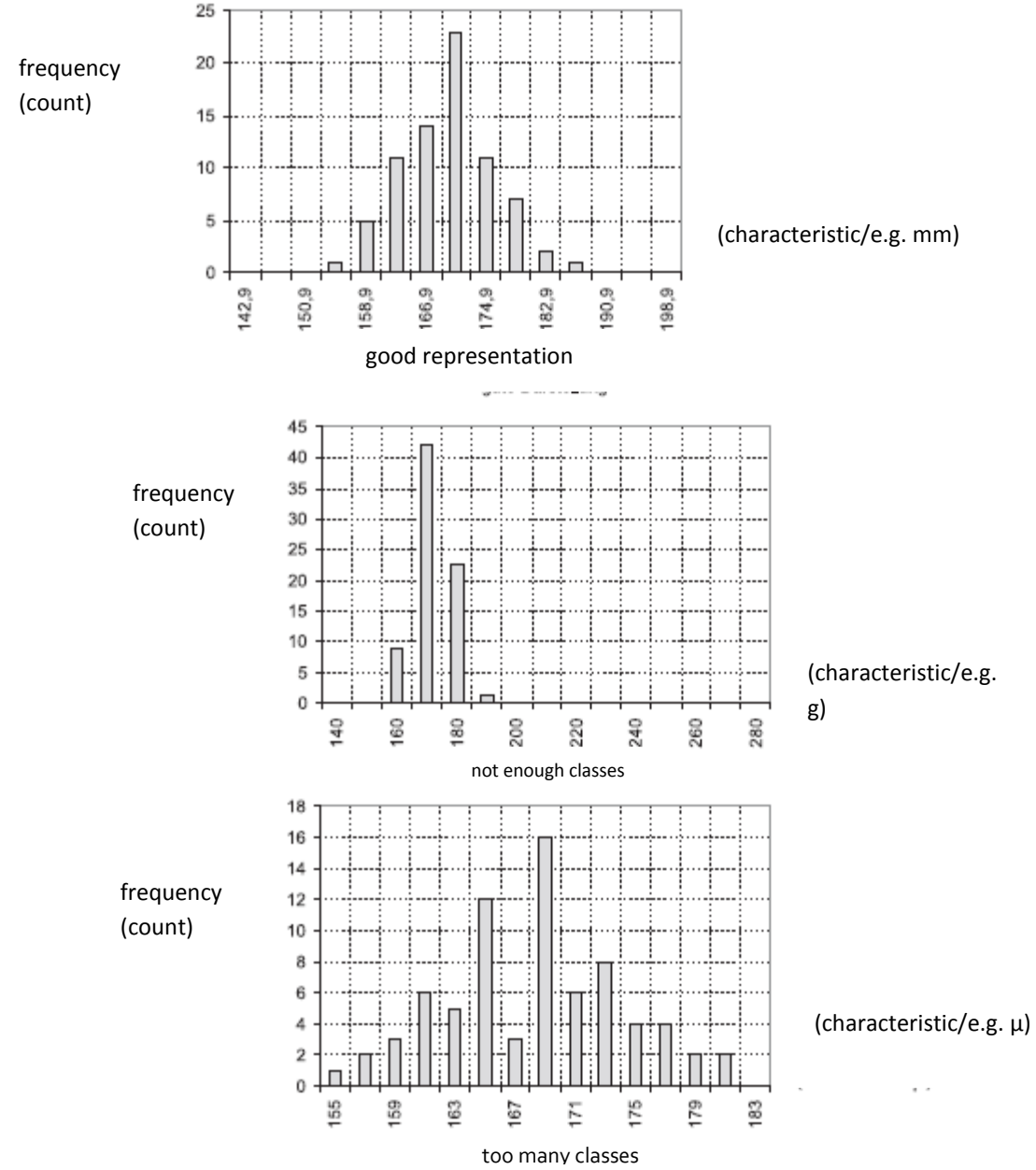
Class (mm)		frequency(count)
	11.8 - 12.0	1
larger	12.0 – 12.2	8
larger	12.2 – 12.4	22
larger	12.4 – 12.6	15
larger	12.6 – 12.8	4
larger	12.8 - 13.0	0

Figure 2.19: Example of a classed ´frequency distribution`



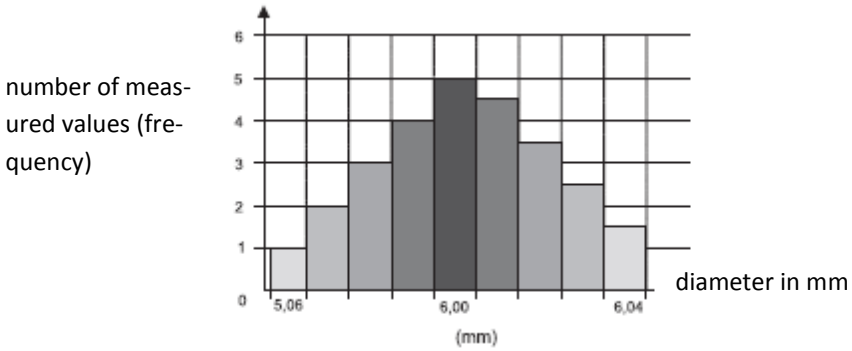
´Good` and ´bad` representations of classed data:

Figure 2.20 Examples of one correct and two distorted histograms



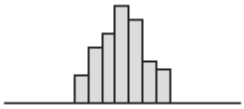
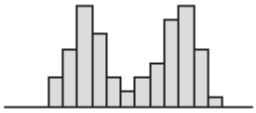
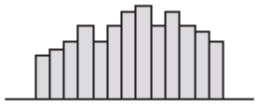
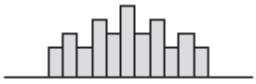
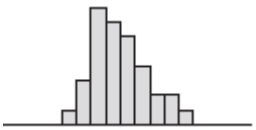
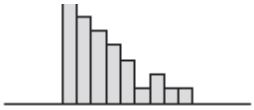
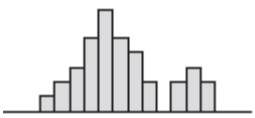
Sometimes histograms are designed with touching columns (s. figure 2.21).

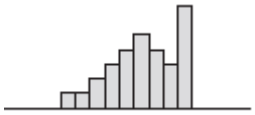
Figure 2.21: Histogram



In practice, different types of distributions (form, interpretation, cause, action) can be found.

Table 2.7: Possible distributions

 bell-shaped	bell-shaped distribution symmetrical, peak at the centre, ´normal` distribution = Gaussian distribution (deviations require investigation for external influences affecting the process)
 double-peaked	bimodal (double-peaked) distribution valley at the centre, peaks to both sides, combination of two normal distributions, most often mixture of two processes; form subgroups (stratification)
 rectangular	plateau distribution flat on top, no peaks, hardly any slopes at the ends, combination of multiple normal distributions, often: pronounced trend; create a flowchart of the process
 comb-shaped	comb-shaped distribution alternates between high and low frequencies, ´systematically` clefted distribution; often: measurement, rounding or classification errors; check data
 skewed	skewed distribution asymmetrical, ´short and long end`, distribution skewed to the left or right
 truncated*	truncated distribution* asymmetrical, abrupt termination on one side, truncated normal distribution; 100%-check, discarded parts; check necessity (audit/finance committee)
 isolated peak	isolated peak distribution 2 separate distributions of different size; normal distribution with an isolated ´island`, intermittently running 2. process (irregularity); check (measurement error, evaluation?)

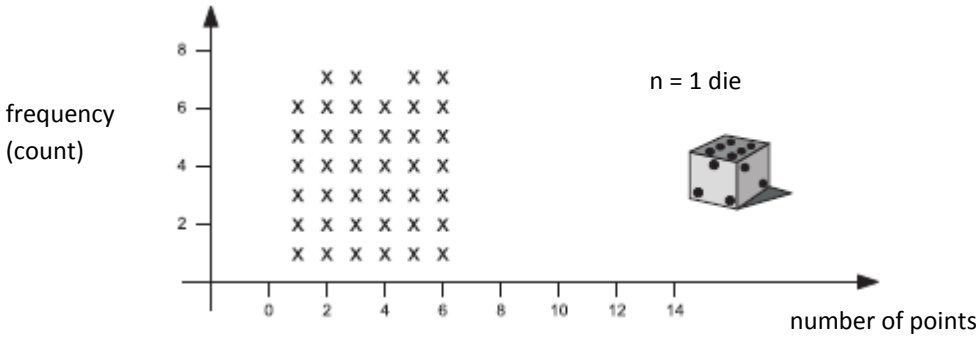
 edge peak	edge peak distribution peak-like cluster at one edge of the distribution; ´overloaded` class (at tolerance limit?); often prevention of tolerance violations; check (manipulation?)
* extremely skewed distributions (see above) appear as truncated	

2.3.4 Frequency distributions

The laws of large numbers and of probability allow for multiple events to be arranged according to patterns.

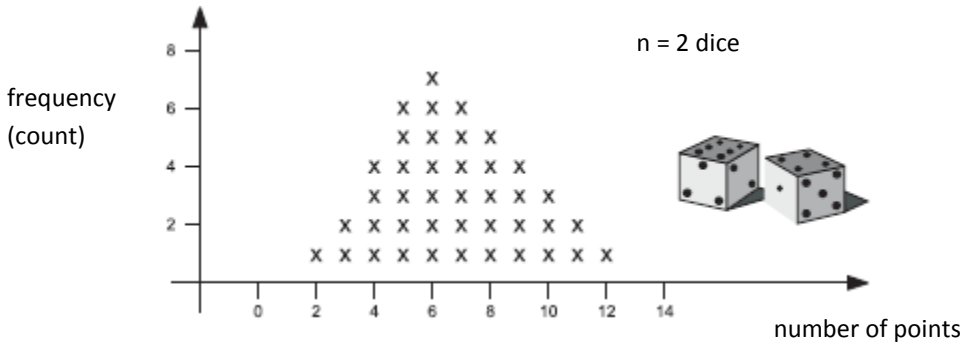
Throwing one die a large number of times will produce all numbers with about equal frequency. The correct graphical representation will show a plateau distribution (s. figure 2.21).
The frequency of the numbers 1, 2, 3, 4, 5 and 6 will show a rectangular distribution if each possible number – depending on the observed result – is entered as a symbol (dash, x, circle, point, etc.) in a properly prepared form.

Figure 2.22: Plateau distribution



The throwing of two dice and proceeding as above results in a triangular distribution

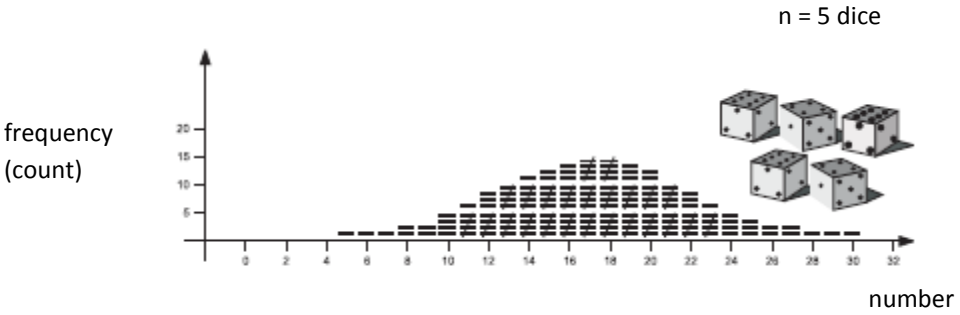
Figure 2.23: Triangular distribution



The practically most useful and most well-known form of distribution is the Gaussian or normal distribution, informally known as the bell-curve (K.F. Gauss – mathematician, physicist and astronomer, 1777 to 1855)

This distribution can be obtained by throwing several dice (see figure 2.24)

Figure 2.24: Normal distribution

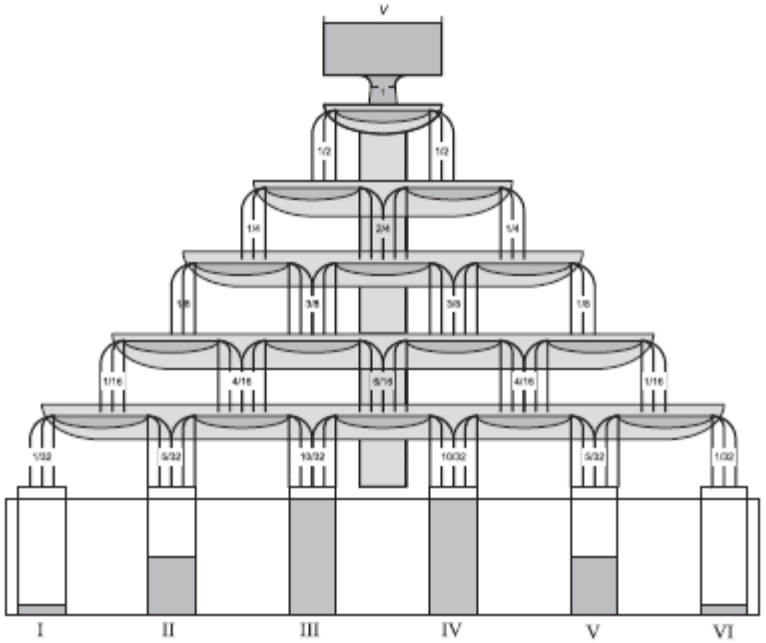


Roman fountain (bean machine) and the Galton box
A clear model for the emergence of the binomial distribution is the cascading arrangement of a number of water trays as in figure 2.25

In this so-called Roman fountain all the trays are initially completely filled with water. Each additional amount of water from the reservoir V causes the first tray to overflow equally to the left and right – as we assume – and into the next trays. This sequence is repeated for each row of trays.
If the overflow from the last row of trays is caught in uniform containers, the water level in these will clearly reflect the binomial probability distribution.

Binomial distribution (from lat. ´es binis nominbus` consisting of two parts): The simplest characterization of a result is the division into two distinct states.

Figure 2.25: Roman fountain



Example 2.2:
The water level of container IV of the ´Roman fountain` for a starting level of V = 200 l for the reservoir.

The expected level is given by the probability P of its occurrence and the total volume of water V.
With P_{IV} = 10/32 = 31% the expected water level is:
water level = $200 \bullet \frac{10}{32}$ = 62.5 l

Another well-known representational model is the bean machine or Galton box as shown in fig 2.26.

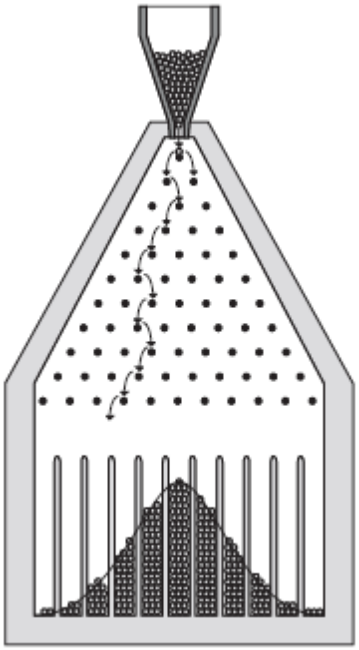
Basically, a ball is rolled down an inclined board where it hits the first pin and from there either goes to the right or to the left. Then it hits the next pin and is again randomly deflected and hits the next row of pins, etc.

The balls are collected in bins at the bottom.

A large number of balls in the middle, less right next to it, very few in the outer bins.

In practice, the bell curve will not always have an ideal symmetrical shape. The purpose of a statistical test is to determine whether a certain process is based on the normal distribution or another distribution, deviating from this ideal form.

Figure 2.26 Schematic representation of a Galton-box with pin rows, feed hopper and collection bins for the balls.



Making a conceptual leap and replacing the balls (trays) with the process parameters, which are to be determined, such as

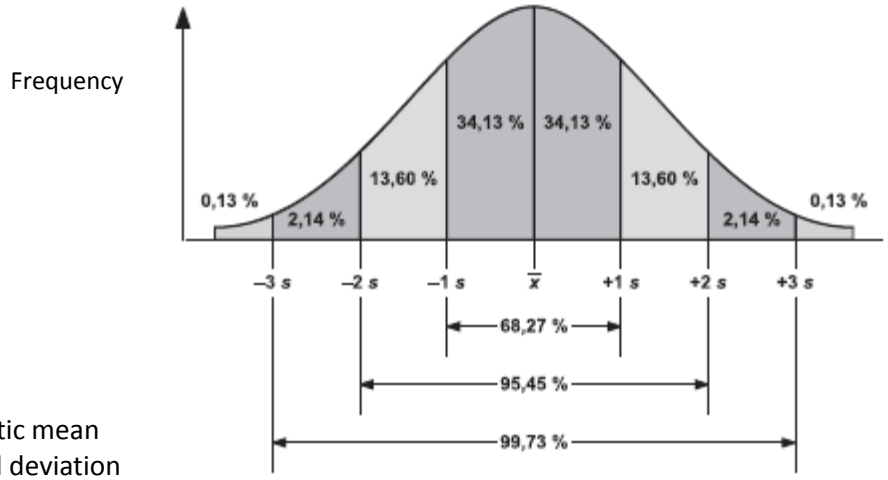
- hardness of a shaft
- diameter of a bolt
- paint coating thickness
- filling weight of packages
- viscosity of oils

leads to an explanation as to why such process parameters or trays of the Roman fountain follow the Gaussian normal distribution.

Characterization of the normal distribution
In 1832 Carl Friedrich Gauss drew up the ´error curve` that was named after him. He used it to depict observational errors for astronomical and other types of measurements in the form of a bell.

Symmetrical, a single peak, maximum at $\bar{x}$, ordinate divides the area under the curve in half (´mean` and median` are identical); the smaller the standard deviation, the narrower the curve, the curve asymptotically approaches the $\bar{x}$-axis, there is a direct correlation between the standard deviation s of a sample and the proportional area coverage of the curve segments.

Figure 2.27: Gaussian normal distribution



$\bar{x}$ = arithmetic mean
s = standard deviation

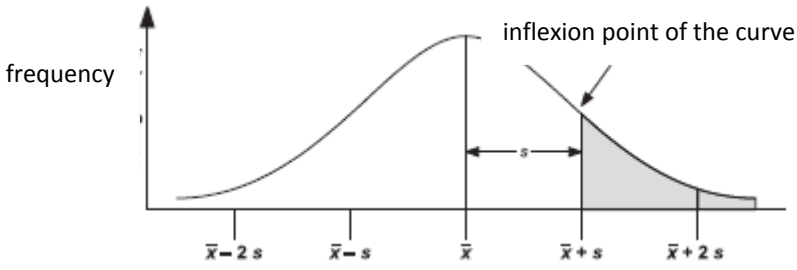
2.3.5 Details on the normal distribution

Every normal distribution is – as previously indicated- completely characterized by two parameters:

Mean $\bar{x}$
Dispersion **s**

The following representations clarify the relationship.
As can be seen, the normal distribution is symmetrical, centering on the mean $\bar{x}$. Also the breadth of the distribution is measured in multiples of s.

Figure 2.28: Normal distribution



To be precise, s is the distance from the inflexion point of the curve to the mean. The inflexion point is the point where the curvature changes from convex to concave.

Figures 2.29, 2.30, 2.31 show normal distributions with parameters $\bar{x}$ = 40, s = 10, x = 120, s = 10, x = 50, s = 20 (mm), respectively.

Note:	The distributions all have the characteristic bell shape. The parameters x and s only affect the positioning and breadth of the curves.

Figure 2.29: Normal distribution ($\bar{x}$ = 40)

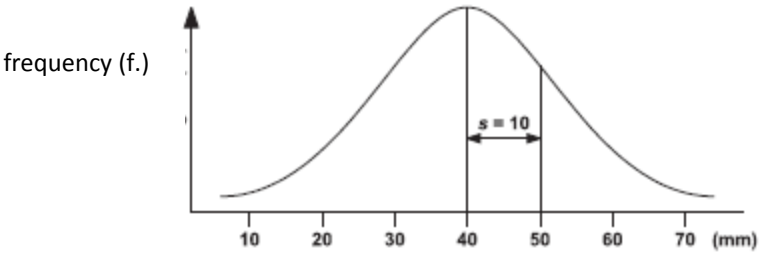


Figure 2.30: Normal distribution ($\bar{x}$ = 120)

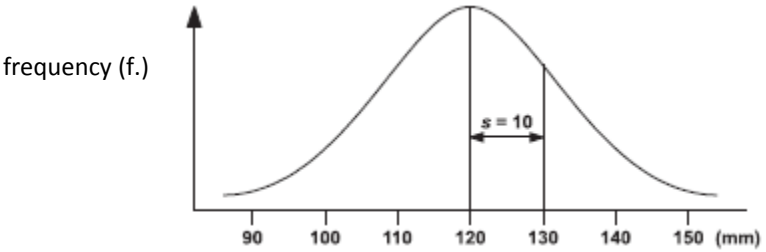
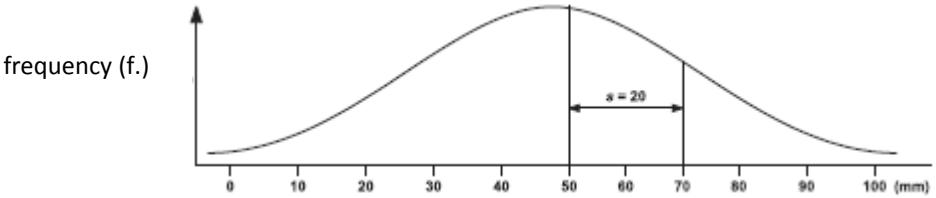


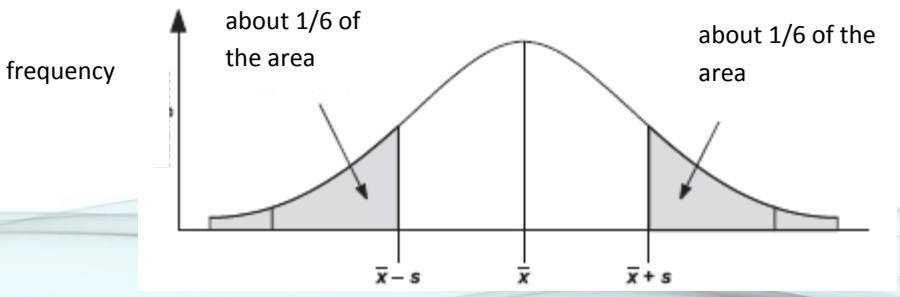
Figure 2.31: Normal distribution ($\bar{x}$ = 50)



Probabilities are measured according to the section of the area under the distribution-curve.
There is a remarkable rule that says that about a sixth of the measured values are more than one s (one standard deviation) above the mean.
That is to say, the area bounded by the curve, the axis and the vertical line at $\bar{x}$ plus s on the left side (s. figure 2.32) accounts for about a sixth of the total area under the curve.

It can be said: The probability of a measurement $\bar{x}$ being higher than $\bar{x}$ plus s is about 1/6.
Because of the symmetry of the curve this analogously applies to a sixth of all measurements being lower than x minus s.

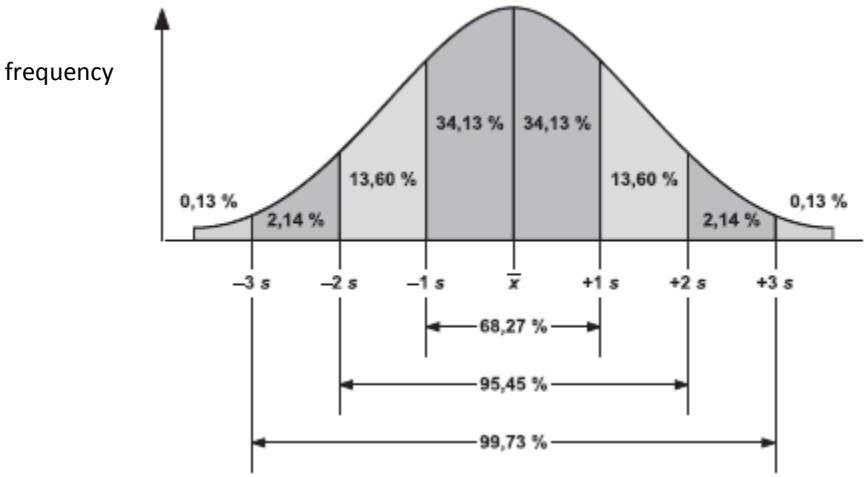
Figure 2.32: Area sections of the normal distribution



This fact has immediate practical applications. If one knows that the production results approximately follow the normal distribution, for example, with mean $\bar{x}$ = 51mm and dispersion s = 3, then the probability for the values being between 48 mm and 54 mm is 68.27 %.

For being between 45 and 57, the probability is 95.45 % and for values between 42 and 60 it is 99.73 %

Figure 2.33



Considering the deviation from the mean without specifying the direction of the deviation the following can be said: about 1/3 (= 1/6 + 1/6) of all measurements deviate more than 1 s from the mean in either direction and about 1/20 (= 1/40 + 1/40) deviate more than 2 s from the mean x in either direction.

When deviations in either direction are considered, the probabilities are called two-sided, otherwise they are called one-sided.

Figure 2.33 Results of a manufacturing process frequency

$\bar{x}$ = 51 mm
s = 3mm

How to calculate the mean and standard deviation

The following measurements were made with a packaging scale:
50 g, 45 g. 47 g, 51 g, 49 g.

Calculation of $\bar{x}$:

$$\bar{x} = \frac{x_1 + x_2 + x_3 + \ldots + x_n}{n} = \frac{\Sigma x_i}{n} = \frac{sum\ of\ all\ single\ values}{number\ of\ all\ single\ values}$$

$\bar{x} = \frac{1}{5} \bullet (50 + 45 + 47 + 51 + 49) = \frac{242}{5}$
$\bar{x}$ = 48.4 g

The mean is **48.4 g.**

Calculation of s:

$$s = \sqrt{\frac{\Sigma\,(x_1 - \bar{x})^2}{n-1}}$$

$$s = \sqrt{\frac{(\text{measured value 1}-\text{mean})^2 + (\text{measured value 2}-\text{mean})^2 + \ldots + (\text{measured value n}-\text{mean})^2}{number\ of\ measured\ values - 1}}$$

$$s = \sqrt{\frac{1}{5-1}\,[(50 - 48.4)^2 + (45 - 48.4)^2 + (47 - 48.4)^2 + (51 - 48.4)^2 + (49 - 48.4)^2\,]}$$

$$s = \sqrt{\frac{1}{4}\,(2.56 + 11.56 + 1.96 + 6.76 + 0.36)}$$

s = 2.4 g

The standard deviation is **2.4 g**.

Standard deviation, mean and other statistical parameters can easily be calculated using a statistics program on a computer.
For this purpose, consult the respective manuals.

Unfortunately, the key assignments for calculators are not standardized!

Calculation of x and s using a calculation scheme (using the same original values as above)

Number of measured value	**Measured value x_i (g)**	**Mean value $\bar{x}$ (g)**	**Differences x_i - $\bar{x}$**	**Differences squared $(x_1 - \bar{x})^2$**
1 2 3 4 5	50 45 47 51 49	$\bar{x} = \frac{\Sigma x_i}{n}$ $\bar{x} = \frac{242}{5} = 48.4$	50 – 48.4 = 1.6 45 – 48.4 = -3.4 47 – 48.4 = -1.4 51 – 48.4 = 2.6 49 – 48.4 = 0.6 etc.	2.56 11.56 1.96 6.76 0.36
5	Σx_i = **242**			**23.2** sum of squares

$$s = \sqrt{\frac{\Sigma\,(x_1 - \bar{x})^2}{n-1}}$$

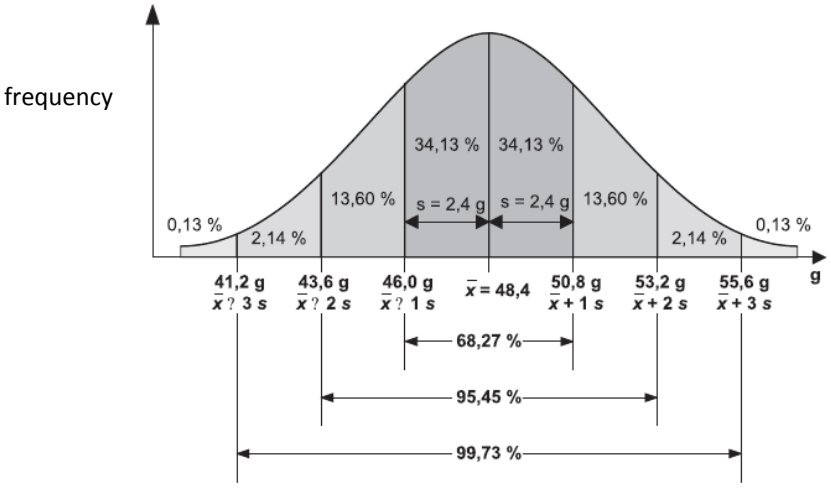
$$s = \sqrt{\frac{23.2}{4}} = \sqrt{5.8}$$

s = 2.4 g

The standard deviation is **2.4 g**.

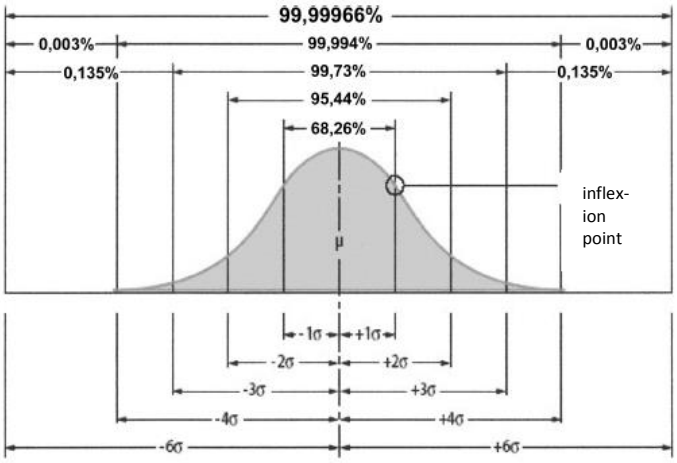
The resulting distribution is:

Figure 2.34: results of an example



$\bar{x}$ = 48.4g
s = 2.4 g

Figure 2.35: Percentages for the normal distribution ($\sigma \mathrel{\widehat{=}}$ s)

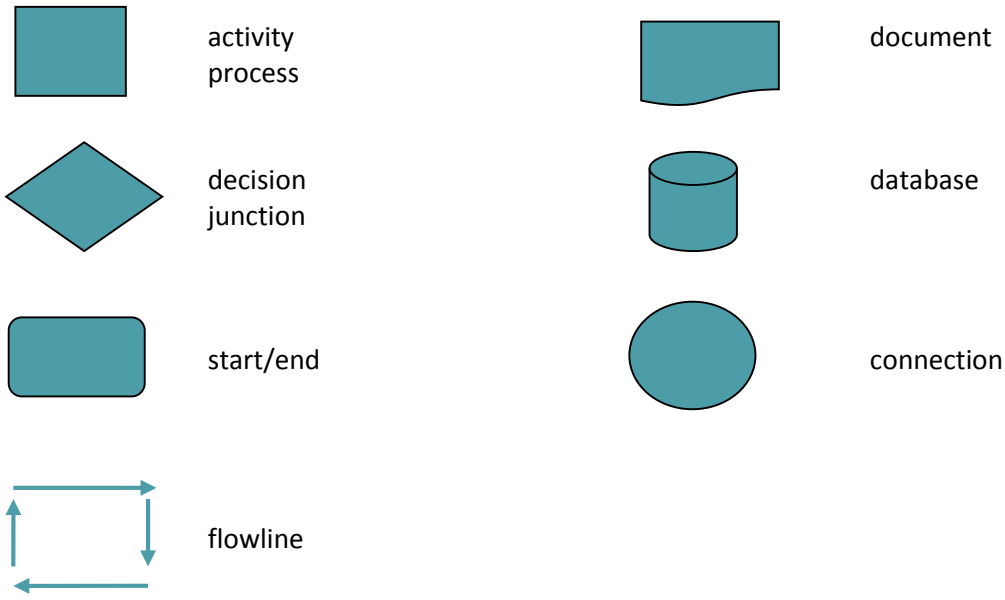


2.3.6 Flowcharts

The purpose of a flowchart is to make complex processes, with different responsibilities and tasks, clear and transparent.
The basic idea is to clearly and consistently represent information processing tasks.

Commonly used symbols

Figure 2.36: Commonly used symbols



Definition:

A flowchart is a diagram that represents a sequence of steps that lead to a specific result (a product, a service, a piece of information or a combination thereof).

Flowcharts facilitate process analysis and root cause analysis.

Therefore, flowcharts are often used in process analysis and root cause analysis and also as basis for the establishment of process-FMEA.

Two examples from quality management are represented in the following diagrams.

Figure 2.37: Flowchart for a sampling inspection based on quantitative criteria (example)

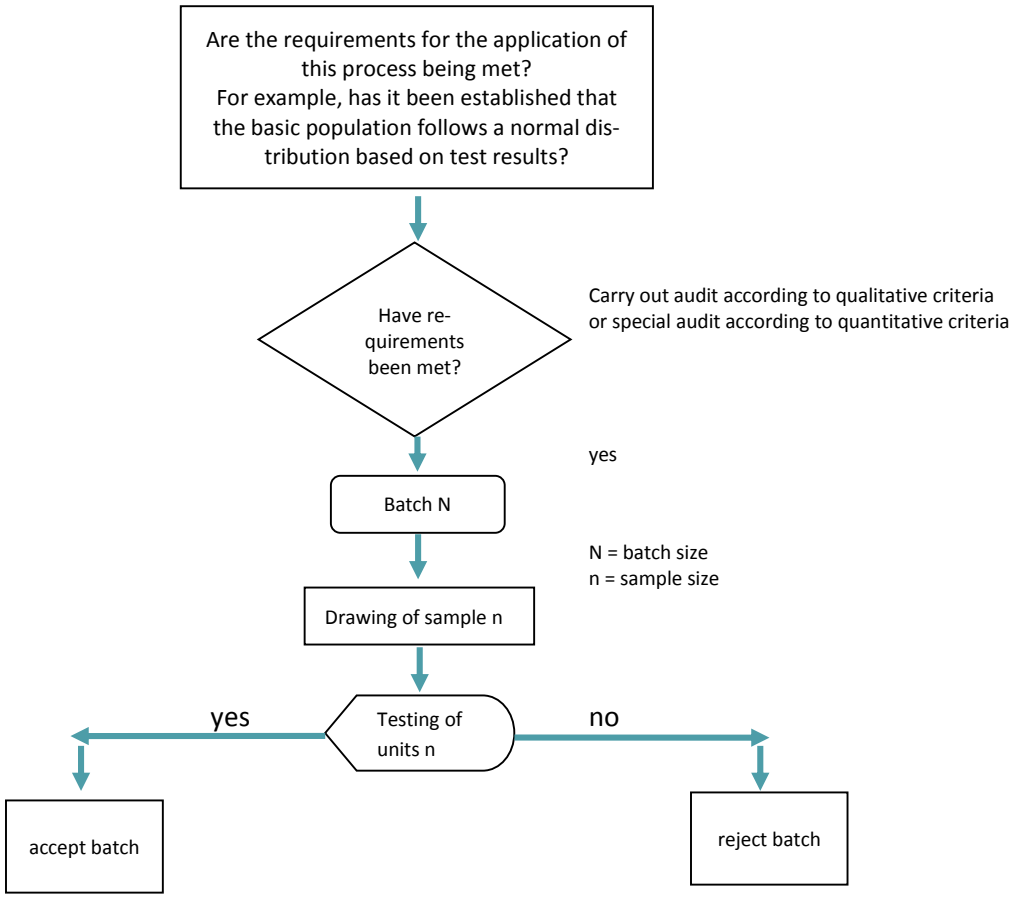
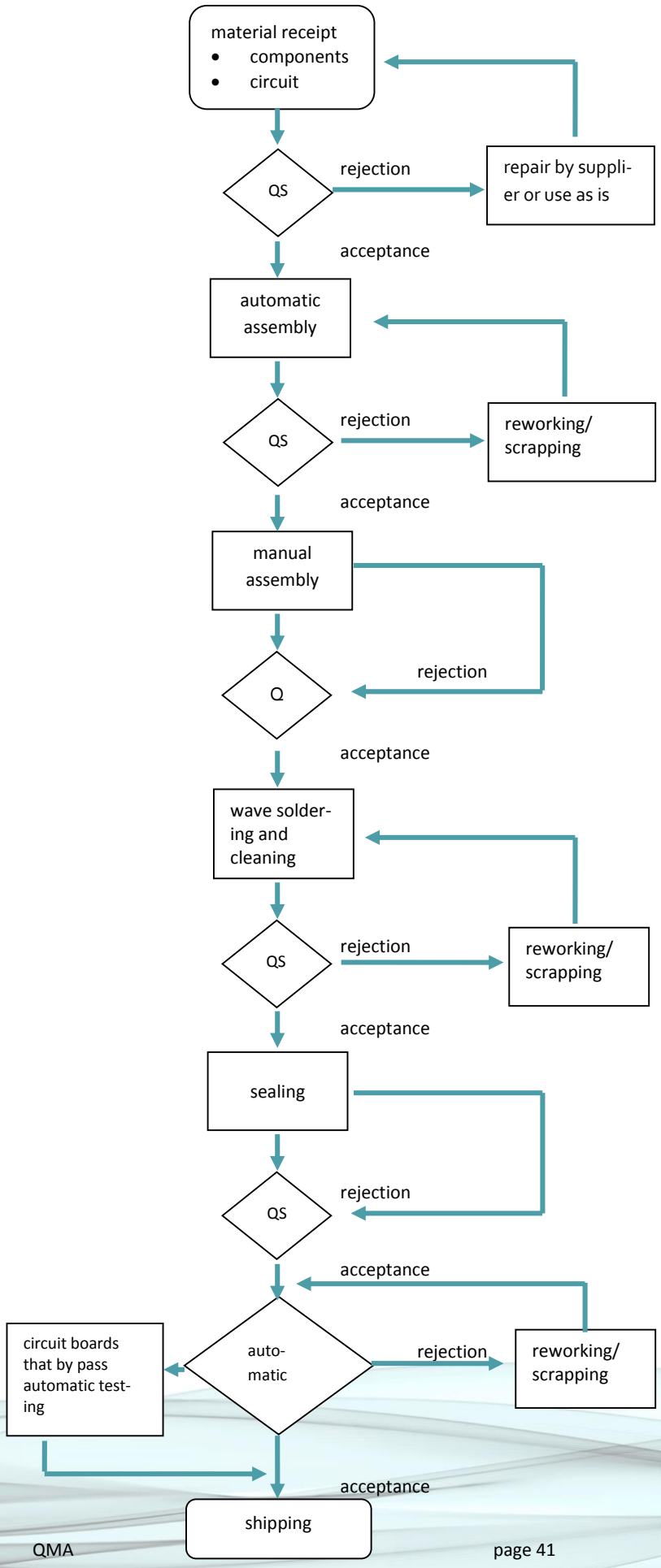


Figure 2.38: Flowchart – example from circuit-board production



2.3.7 Pareto analysis

Pareto analysis is another tool for effective root cause analysis

Pareto analysis uses a graphical representation of information to determine which out of a large number of factors have the largest impact, e.g. for cost considerations. Pareto had discovered that often only a small number of causes account for the majority of effect. This allows for prioritization in error rectification.

Definition:	Pareto analysis (ABC-analysis, Bradford distribution) gives a ranking of influences that, for example, affect a quality problem.

The few essential factors are recognized and consideration and decision-making can be focused on these.

Note: Pareto diagrams and charts always contain three basic elements:

1. All factors that influence the issue at hand, arranged in descending order according to magnitude of their influence.
2. Importance of each factor (numerical)
3. The cumulative percentage of the factors

In the context of the Pareto principle the 80: 20-rule is often mentioned. 80 % of problems come from 20 % of causes.

The so called 80: 20-rule states that 80 % of errors are caused (in most cases) by only 20 % of error types.

This list could be continued indefinitely. The numbers 80 and 20 shouldn't be taken too seriously. They are only approximate values.

The core of the Pareto principle states that more heavy-weighing causes have to be separated from less important causes.

Pareto-analysis allows for these main points to be easily identified and presented.

The process of such an analysis will be explained in the following.

- 1. step: Objective and time frame of the analysis are determined.
- 2. step: The required data is collected and sorted.
- In the last step the Pareto-diagram is drawn.

Figure 2.39 shows the sequence of these three steps using the example ´too many rejects`.

If one is not familiar with Pareto-diagrams, the effect might be surprising.
In fact, how strongly some errors affect the problem as whole can be clearly seen.

Pareto-diagrams form a strong basis for improvement measures.

Step 2: The number of occurrences for rejection types is recorded in Table I, below.

Table I:

Type of rejection	Absolute frequency	Relative frequency
A	32	4.35 %
B	111	1.49 %
C	48	20.16 %
D	7	0.95 %
E	71	9.67 %
F	311	42.37 %
G	9	1.22 %
H	117	15.94 %
I	14	1.90 %
J	6	0.82 %
K	8	1.09 %
sum	734	100.00 %

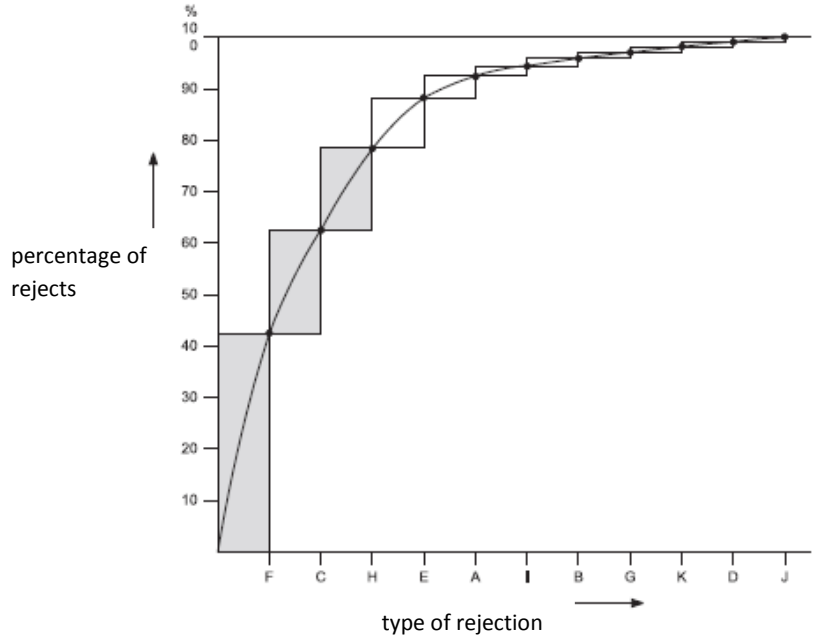
All entries in the table are sorted and percentages and cumulative sums are calculated and recorded in table II.

Cumulative sum = 42.37 % + 20.16 % = 62.53 %
62.53 % + 15.94 % = 78.47 %
etc.

Table II: Sorted data

Type of rejection	Absolute frequency	Relative frequency	Cumulative sum
F	311	42.37 %	42.37 %
C	148	20.16 %	62.53 %
H	117	15.94 %	78.47 %
E	71	9.67 %	88.14 %
A	32	4.35 %	92.49 %
I	14	1.90 %	94.39 %
B	11	1.49 %	95.88 %
G	9	1.22 %	97.10 %
K	8	1.09 %	98.19 %
D	7	0.95 %	99.14 %
J	6	0.82 %	100.00 %
			100 % rounded, since inconsequential

Figure 2.39: Pareto-diagram



Rejection types F, C and H cause nearly 80 % of all rejections.

Step 3: Draw Pareto-diagram

Example: ´too many rejects`

2.3.8 Cause-and-effect-diagrams

Cause-and-effect-diagrams are graphical representations that allow one to point out causes in a compact form that is both consistent and ordered.

Definition: Fishbone-diagrams are used for problem analysis. They help in finding the causes of dispersion patterns.

They are called:

- cause-and-effect-diagrams (for their purpose)
- fishbone-diagrams (for their form) or
- Ishikawa-diagrams (after their inventor)

This type of diagram was developed to illustrate the relations between ´effects` and all kinds of ´cause variables`. The cause or problem is on the right side of the diagram, while the important explanatory variables or ´causes` are listed on the left side of the diagram.

Cause-and-effect-diagrams are created to illustrate the different cause variables of a process through sorting out and demonstrating relations. In general, each effect may be caused by multiple variables from different categories. In the example above these main causes could be split into 7 (´7 M`) groups:

Management, measurement, material, man, machine, method, environment (s. image)

Cause-and-effect-diagrams are created via teamwork or brainstorming and can be universally applied, in particular

- to refine process improvements and to optimize quality, productivity, costs, etc.
- to analyze errors, complaints and other anomalies.

Figure 2.40: Fishbone-diagram

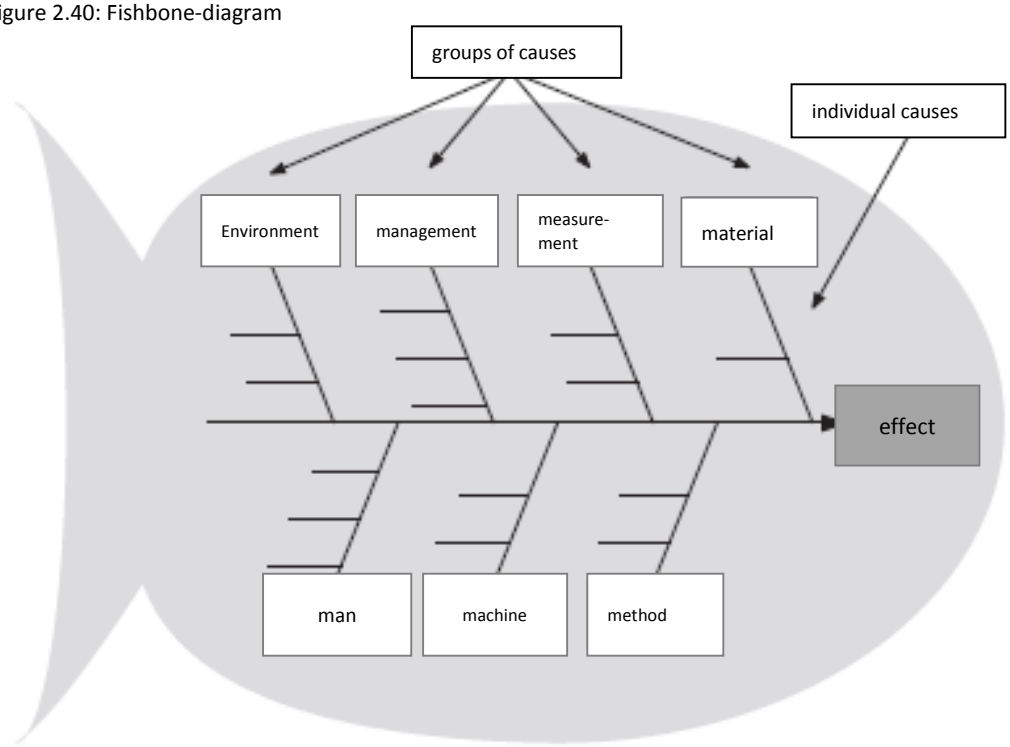
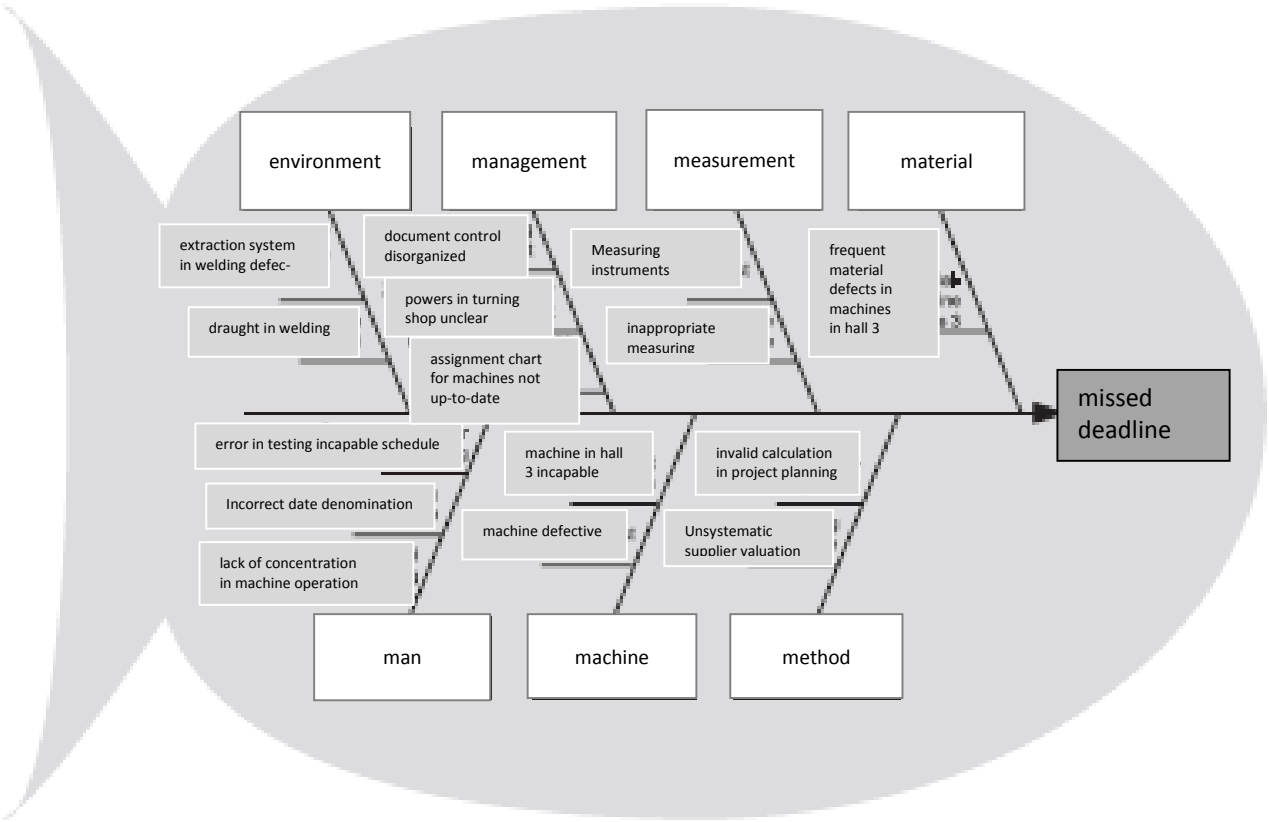


Figure 2.41: Fishbone-diagram (example)



2.3.9 Scatter plots (correlation diagrams)

A scatter plot can examine potential correlations between two variables and check for potential **cause-and-effect-relations.**
It cannot be proven that one variable has an effect on the other, but it can be determined whether a correlation exists and how strong it is.

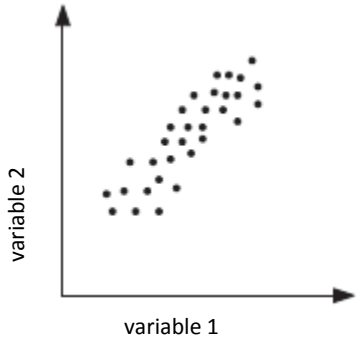
Definition:	Scatter plots show the relationship between two measureable or ordered characteristics according to type and strength.

In problem analysis they serve to determine cause and effect.

In scatter plots the x-axis represents the measured values of one variable, the y-axis those of the other.

A ´typical` scatter plot could look like this:

Figure 2.42: Scatter plot



Note that the recorded values form a dot pattern. The alignment and ´density` of the dots provide information about the strength of the relationship between variable 1 and variable 2.The closer the point cluster resembles a straight line, the stronger the correlation between the variables.
This orientation along a straight line reflects that each time one variable is changed the other one undergoes a corresponding change.

Note:
- Develop a technically sound hypothesis about the suspected relationship between the relevant characteristics.
- Collect suitable data pairs.
- Create the scatter plot.
- Determine the correlation from the graph and compare it with the theory.
- Discuss the original hypothesis and alternate explanations in the light of the findings.

Example:

1. Electronic components are not working properly. One assumes: Voltage output is increased by humidity and this causes malfunctions.
2. A test is performed on batches of 5 such components in a test laboratory. Humidity is increased gradually and the corresponding voltage output measured.

Designation: component xyz
Testing location: test laboratory
Measuring instrument: voltmeter

H	U	H	U	H	U	H	U	H	U
10	43.1 39.1 41.3 42.2 40.4	30	46.0 43.2 45.5 45.8 44.1	50	51.2 47.0 50.1 51.2 49.7	70	54.0 52.0 51.3 54.6 53.2	90	58.9 56.5 56.1 58.2 56.7
20	45.2 42.9 42.6 44.3 43.1	40	49.1 45.0 48.4 48.9 46.3	60	53.6 50.5 51.4 52.1 52.9	80	57.1 55.1 54.3 55.8 55.8	100	60.5 58.4 57.0 59.3 57.5

Table of paired data points
H = relative humidity (%),
U = voltage (mV)

3. Create the scatter plot

a) Determine maximum and minimum values for both characteristics (original values list) (s. Lesson

b) Determine which characteristic to put on the horizontal axis.
   - If a cause-and-effect-relationship is suspected, the suspected cause should be put on the horizontal axis.

c) Draw, scale and label both axes.
   - Make the axes about the same length (square drawing area)
   - For each characteristic set the lowest scale value just below the corresponding minimum value and the highest scale value just above the corresponding maximum value.
   - Determine the scale to increase from left to right and upwards, respectively.
   - Partition the axes.
   - Label the axes according to characteristics and units of measurement.

d) Mark the data points
   - Identical data pairs should be denoted by concentric circles (s. figure 2.43)
   - For grouped data use filled and open symbols.

e) Add title/header and additional information.

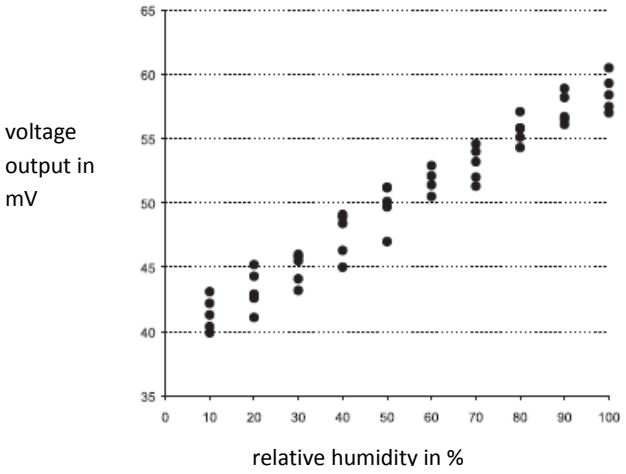


Figure 2.43: Test: components xyz

4. Analyze and interpret the scatter plot.
   The graph supports the original hypothesis. The increase in voltage between 10 and 100% humidity is nearly linear.

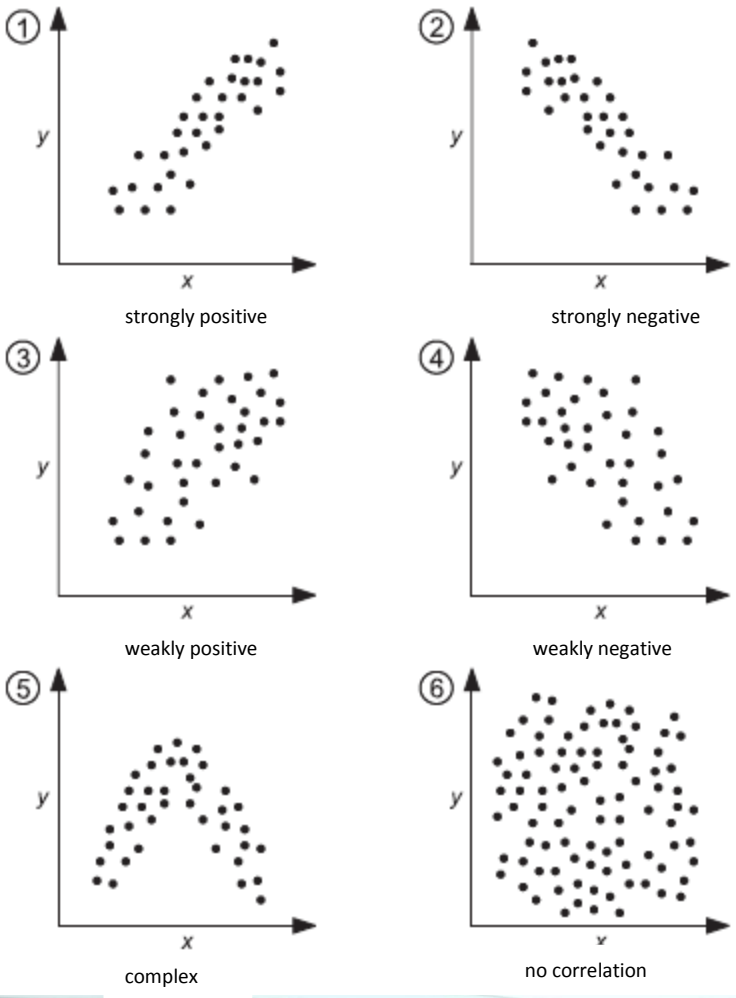
5. Make a decision
   - Check analysis for misinterpretations
   - Assess common factors and other possible interpretations for the form of the scatter plot
   - Decide on what action to take next

Further interpretations:

The following images show different types of correlation:
With increasing x ...

1. y increases notably: strong positive correlation
2. y decreases notably: strong negative correlation
3. y increases slightly: weak positive correlation
4. y decreases slightly: weak negative correlation
5. y seems to be dependent on x, but not in a linear fashion: *complex correlation*
6. y independent of x: *no correlation*

Figure 2.44: Types of correlation

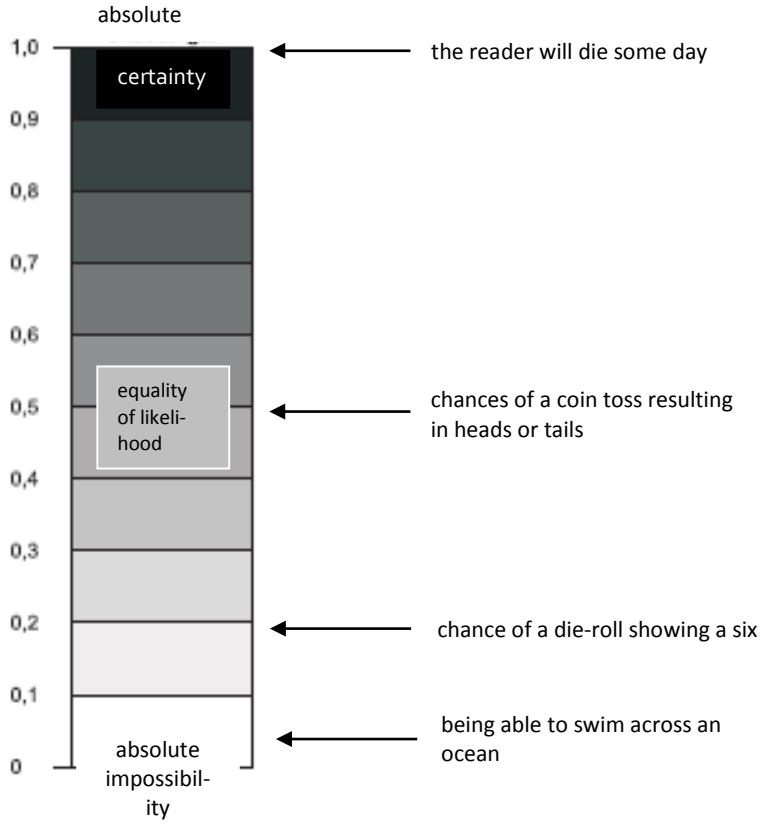


2.4 Probability theory

Probability theory and the probability scale

The probability scale

Figure 2.45: Probability scale



A person's physical death can be considered a certain event.

This absolute certainty is equated with 100% certainty or a probability of $P = 1.0$ on the probability scale.

A person never dying or swimming across an ocean is absolutely impossible.

This impossible event is assigned the probability of $P = 0$ on the probability scale.

All events that have some chance of happening fall somewhere between these extremes 1 and 0.

Examples:

a coin toss showing heads
a die rolling a six
winning the lottery, jackpot etc.

Definition:

Probability:
Probability is a number that characterizes the chance of a random event actually occurring. Every such random event is given a value in the closed interval from zero to one. The certain event is assigned the value 1; the impossible event is assigned the value zero.

One might ask the following question:
What are the chances of rolling a 1, 2, 3, 4, 5 or 6 on a six-sided die?

Or one might ask:
What are the chances of a coin toss coming up heads or tails?

Bernoulli`s definition reads:

$$P = \frac{number\ of\ outcomes\ favorable\ to\ the\ event}{total\ number\ of\ possible\ outcomes}$$

So the mathematical probability *P* is equal to the number of outcomes favorable to the event divided by the total number of possible outcomes.
P stands for the Latin word *probabilities* = probability.
P can only assume values from 0 to 1 or 0 to 100 %.

The simplest example is a coin toss. Let heads be the favorable outcome. Since there are only two possible outcomes the result is:

$$P = \frac{favorable\ outcomes}{possible\ outcomes} = \frac{1}{2} = 0.5 \text{ or } 50\ \%$$

A tossed coin is expected to come up heads with a likelihood of 50 %.

Example 2.3

What is the likelihood of rolling a 1?

Solution:
Only one outcome is favorable, that is the 1 (figure 2.46). Yet six numbers are possible. This results in:

$$P = \frac{number\ favorable\ outcomes}{number\ possible\ outcomes} = \frac{1}{6} = 0.1667 \text{ or } 16.67\ \%$$

Figure 2.46 Probability: die roll example

Die: Likelihood of rolling a 1?

P = $\frac{1\ favorable\ outcome}{6\ possible\ outcomes}$ = $\frac{1}{6}$ = 0.166
P = 17 %

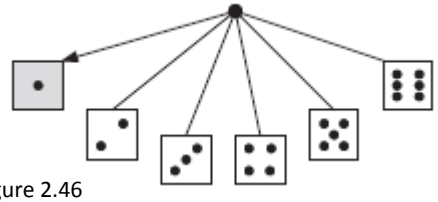


Figure 2.46

The rule of additivity is to be applied whenever the likelihood of an event *or* another event happening is sought.
The problem definition always contains an ´or`.

Example 2.4
What is the likelihood of one die roll either showing a 2 or a 5?

Solution:
The likelihood of rolling a 2 is $\frac{1}{6}$ (s.a.).
The likelihood of rolling a 5 is also $\frac{1}{6}$.
The likelihood of rolling a 2 or a 5 is, according to the rule of additivity (figure 2.47).

$P_{(2\ or\ 5)} = P_{(2)} + P_{(5)} = \frac{1}{6} + \frac{1}{6} = \frac{2}{6} = \frac{1}{3}$ = 0.33 = 33 %

Summation over individual likelihoods for ´either-or`-problems!

What is the likelihood of one die roll either showing a 2 or a 5?
$P_2 = \frac{1}{6}$ and $P_5 = \frac{1}{6}$

$P_{2,5}\ \frac{1}{6} = \ + \frac{1}{6} = \frac{2}{6}$ = 0.33

P = 33 %

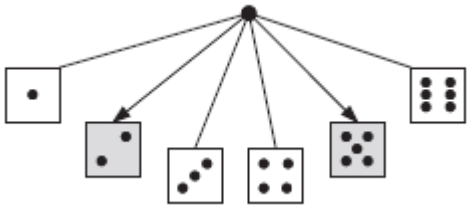


Figure 2.47 Rule of additivity: die roll example

The multiplication rule applies to likelihoods of one event and another event happening.
The problem definition always contains an ´and`.

Example 2.5:
What is the likelihood of one die showing a 1 on the first roll and a 6 on the second roll?

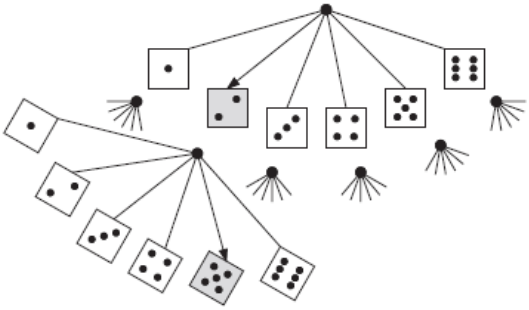
Solution:
The likelihood of rolling a 1 is $\frac{1}{6}$ (s. first problem)
The likelihood of rolling a 6 is also $\frac{1}{6}$.

The likelihood of rolling a 1 and then a 6 is, according to the multiplication rule the product of the individual probabilities (figure 2.48).

$P_{(1\ or\ 6)} = P_{(1)} \bullet P_{(6)} = \frac{1}{6} \bullet \frac{1}{6} = \frac{1}{36} = 0.0278 = 2.78\ \%$

Multiplication of individual likelihoods for ´and`-problems!

Figure 2.48: Multiplication rule: die roll example



What is the likelihood of one die showing a 2 on the first roll and a 5 on the second roll?

$P_2 = \frac{1}{6}$ $P_5 = \frac{1}{6}$

$P_{2,5} = \frac{1}{6} \bullet \frac{1}{6} = \frac{1}{36} = 0.028$

P = 2.8 %

Law of large numbers

When trying to prove the accuracy of the calculated likelihoods with die roll experiments, the outcome will be more accurate the more experiments that are conducted.

Only an infinite number of experiments would yield precisely the calculated likelihoods.

In practice this means: The more pieces that are extracted from a batch as a sample, the more precise the statement about the batch.

Extracting all pieces of a batch as samples yields absolutely certain (100 %) statements about the batch.

Example from statistical probability

The following example further clarifies the situation.

A shipment of 2500 parts erroneously contains 160 rejects.

What is the chance of finding one of the rejects with the first pick?

$P = \frac{favorable\ outcomes}{possible\ outcomes} = \frac{160}{2{,}500} = 6.4\ \%$

And what is the chance of finding one of the good parts with the first pick?

$$P = \frac{favorable\ outcomes}{possible\ outcomes} = \frac{2{,}340}{2{,}500} = 93.6\ \%$$

Adding both probabilities must yield 100 %.

2.5 Acceptance sampling in quality control

In the last chapters you learned about conducting tests and the range of tests. Where necessary, a complete audit (100 %-test) is to be conducted.

This, however, is the most elaborate and uneconomical kind of test. Often 100 %-tests are not even applicable, e.g. with matchsticks and other items that can only be used once, because they are used up during testing.

In these cases only sample testing can be conducted. With other products one will also limit oneself to sampling (s. correspondence course ´statistics`: sample types).

Sampling tests have the advantage of being less elaborate and thus lest costly.

They have the disadvantage of not being able give a precise overall picture (statement about the total population). Since quality control also has to take economic considerations into account, the efficient method of sampling testing is used as often as possible.

Sampling must follow this basic rule:

Note:	Sampling must be representative and random. That is: Parts must be selected randomly and indiscriminately. Each part must have the same chance of being selected for sampling. Parts must be selected from all positions and layers within a crate (batch). If multiple crates are presented for testing, a corresponding number of parts must be selected from each crate.

Loosely speaking, the larger the sample size, the more accurate the test.

Example 2.6:

batch size *N* = 1,000 sample size *n* = 50
batch size *N* = 1,000 sample size *n* = 315

Obviously, the second sampling (315) is more accurate. This sampling will find more errors than the smaller sampling (50), provided that all parts are equal and were produced under equal conditions.

Steps of a simple sampling plan

Before beginning with the sampling, the following must be specified:
1. How many units (parts) are to be tested (n)?
2. What number of defects or defective parts in the sample is acceptable (acceptance number c)?

The flowchart in figure 2.50 shows how the sampling process is executed.

The following terms and letter symbols are used:

N = batch size (e.g. number of parts in a crate)
n = sample size (number of parts to be selected)
x = number of errors found in the sample
c = acceptable number of errors in the sample
d = rejection number

AQL = test severity (acceptable quality limit); e.g. agreed upon beforehand with supplier.
The basis of every sampling is the test instruction that states not only the sample size, but also the criteria for any testing decisions.

Figure 2.49: Design of a test instruction for a simple sampling

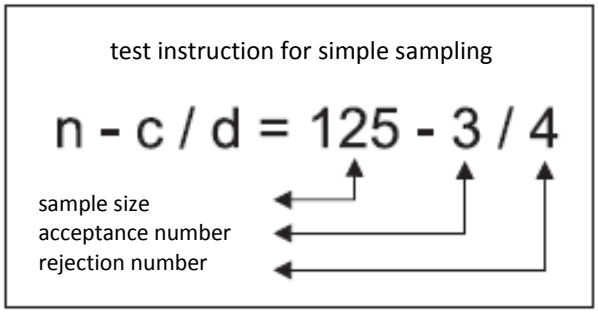
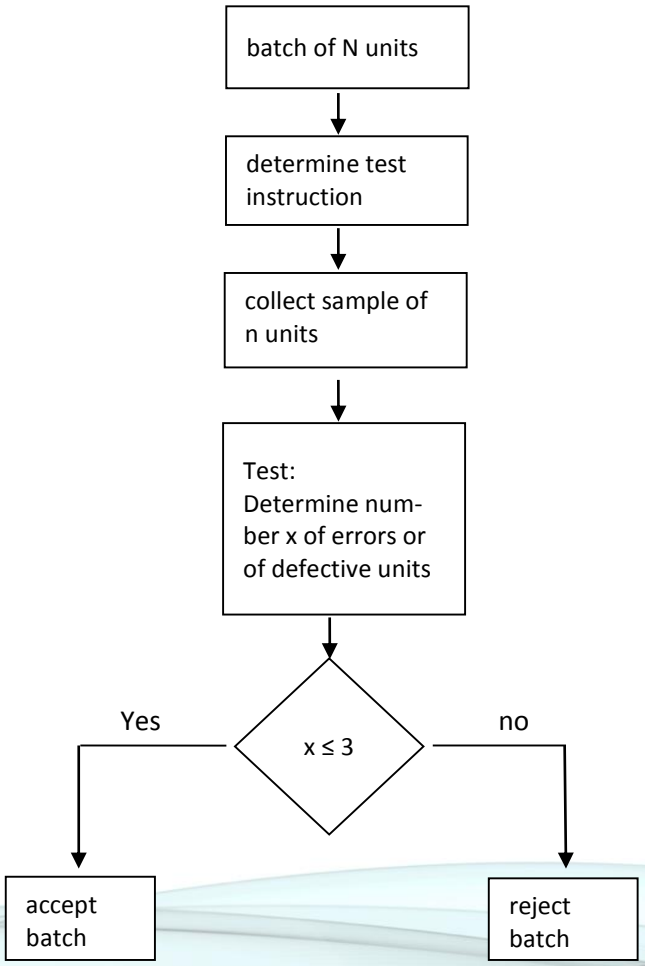


Figure 2.50: Flowchart of a simple sampling

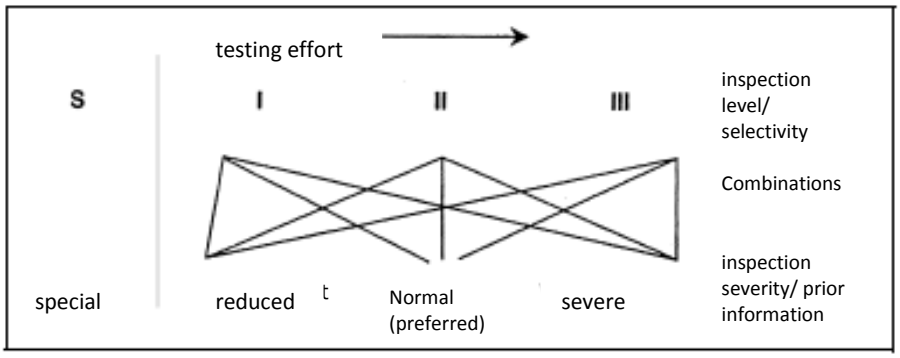


In practice, the rejection number d for simple samplings is often not stated, since it is usually c +1.

Thus the determination of a test instruction requires knowledge of:

- the inspection severity
- the inspection level
- the batch size N
- the AQL-value

Figure 2.51: Testing effort and principles of classification



Normally the code letter is chosen from the standard DIN ISO 2859-1, table 1 - column for inspection level II.
Inspection level I contains test instructions with low selectivity and inspection level III instructions with high selectivity.

Example 2.7:

A ´selectivity` of AQL 1.0 (general inspection level II) was agreed upon with a supplier. The shipment contains N = 1000 parts in one crate. The table provides the code letter J for *N* = 1000 and general inspection level II.

In this example, this means J = 80 (AQL c = 2, d = 3). Now 80 parts out of the 1000 are to be selected as samples. Then the 80 parts are tested according to the test guidelines and the errors (x) or defective units (parts) are counted.

If x is less or equal to c (2), the batch should then be accepted.
If the number x of errors found is greater than c (2), the batch should be rejected (d = 3).

In special cases, the simple sampling procedure for more severe testing is applied, e.g. for new suppliers or in the event of deteriorating quality.

Reduced tests are used with ´good suppliers`.

Figure 2.52: Code letters for sample sizes according to DIN ISO 2859 – part 1

batch size	special inspection severity				general inspection severity		
	S-1	S-2	S-3	S-4	I	II	III
2 till 18	A	A	A	A	A	A	B
9 till 15	A	A	A	A	A	B	C
16 till 25	A	A	B	B	B	C	D
26 till 50	A	B	B	C	C	D	E
51 till 90	B	B	C	C	C	E	F
91 till 150	B	B	C	D	D	F	G
151 till 280	B	C	D	E	E	G	H
281 till 500	B	C	D	E	F	H	J
501 till 1200	C	C	E	F	G	J	K
1201 till 3200	C	D	E	G	H	K	L
3201 till 10000	C	D	F	G	J	L	M
10001 till 30500	C	D	F	H	K	M	N
35001 till 150000	D	E	G	J	L	N	P
150001 till 500000	D	E	G	J	M	P	Q
500001 or more	D	E	H	K	N	Q	R

Figure 2.53: Simple sampling plans for normal tests; excerpt from DIN ISO 2859 – part 1

code letter	sample size n	acceptable quality limits														
		0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25
		c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
B	3															
C	5										0 1	0 1	0 1	1 2	1 2	1 2
D	8									0 1					2 3	2 3
E	13										1 2	1 2	1 2	2 3	3 4	3 4
F	20							0 1	0 1			2 3	2 3	3 4	5 6	5 6
G	32						0 1			1 2	2 3	3 4	3 4	5 6	7 8	7 8
H	50					0 1		1 2	1 2	2 3	3 4	5 6	5 6	7 8	10 11	10 11
J	80				0 1		1 2		2 3	3 4	5 6	7 8	7 8	10 11	14 15	14 15
K	125			0 1		1 2		2 3	3 4	5 6	7 8	10 11	10 11	14 15	21 22	21 22
L	200		0 1		1 2		2 3	3 4	5 6	7 8	10 11	14 15	14 15	21 22	↑	↑
M	315	0 1		1 2		2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑		
N	500	↑	↓	2 3	3 4	5 6	7 8	10 11	14 15	14 15	21 22	↑				
P	800		1 2	3 4	5 6	7 8	10 11	14 15	21 22	21 22	↑					
Q	1250	1 2	2 3	5 6	7 8	10 11	14 15	21 22	↑	↑						
R	2000	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑							

↓ Use first test instruction (i.e. n and c) below the arrow. If sample size is larger or equal to batch size, test 100 %.

↑ Use first test instruction (i.e. n and c) above the arrow.

c acceptance number

d rejection number

Figure 2.54: Simple sampling plans for severe tests; excerpt from DIN ISO 2859 – part 1

code letter	sample size n	acceptable quality limits														
		0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25
		c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
B	3															
C	5											0 1	0 1		1 2	1 2
D	8									0 1	0 1			1 2	2 3	3 4
E	13											1 2	1 2	2 3	3 4	5 6
F	20							0 1	0 1				2 3	3 4	5 6	8 9
G	32						0 1			1 2	1 2	2 3	3 4	5 6	8 9	12 13
H	50					0 1		0 1	1 2	2 3	2 3	3 4	5 6	8 9	12 13	18 19
J	80				0 1		1 2			3 4	3 4	5 6	8 9	12 13	18 19	↑
K	125			0 1		1 2		1 2	2 3	3 4	5 6	8 9	12 13	18 19	↑	
L	200		0 1		1 2		2 3	2 3	3 4	5 6	8 9	12 13	18 19	↑		
M	315	0 1		1 2		2 3	3 4	3 4	5 6	8 9	12 13	18 19	↑			
N	500	↓	↓	2 3	1 2	2 3	3 4	5 6	8 9	12 13	18 19	↑				
P	800		1 2	3 4	2 3	3 4	5 6	8 9	12 13	18 19	↑					
Q	1250	1 2	2 3		3 4	5 6	8 9	12 13	18 19	↑						
R	2000	1 2	2 3	3 4	5 6	8 9	12 13	18 19	↑							

↓ Use first test instruction (i.e. n and c) below the arrow. If sample size is larger or equal to batch size, test 100 %.
↑ Use first test instruction (i.e. n and c) above the arrow.
c acceptance number
d rejection number

Figure 2.55: Simple sampling plans for reduced tests; excerpt from DIN ISO 2859 – part 1

code letter	sample size n	acceptable quality limits														
		0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25
		c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d	c d
A	2															1 2
B	2															1 3
C	2										0 1	0 1	0 1	0 2	0 2	1 4
D	3									0 1					1 3	2 5
E	5							0 1	0 1		0 2	0 2	0 2	1 4	2 5	3 6
F	8											1 3	1 4	2 5	3 6	5 8
G	13						0 1			0 2	1 3	1 4	2 5	3 6	5 8	7 10
H	20				0 1	0 1		0 2	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13
J	32								1 3	1 4	2 5	3 6	5 8	7 10	10 13	
K	50			0 1	0 2	0 2	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13		
L	80		0 1			1 3	1 3	1 4	2 5	3 6	5 8	7 10	10 13			
M	125	0 1			0 2		1 4	2 5	3 6	5 8	7 10	10 13				
N	200			0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13					
P	315	0 2	0 2	1 3	1 4	2 5	3 6	5 8	7 10	10 13						
Q	500		1 3	1 4	2 5	3 6	5 8	7 10	10 13							
R	800	1 3	1 4	2 5	3 6	5 8	7 10	10 13								

↓ Use first test instruction (i.e. n and c) below the arrow. If sample size is larger or equal to batch size, test 100 %.
↑ Use first test instruction (i.e. n and c) above the arrow.
c acceptance number
d rejection number. If acceptance number is passed but the rejection number not reached, accept batch. In future, apply normal tests.

Definition:
AQL = **a**cceptable **q**uality **l**evel the maximum percentage of defective units (or maximum number of defects per 100 units) in acceptance samplings that can be seen as satisfactory average production quality.

If a buyer wants to establish a certain AQL-value for a defect, group of defects or defective units, this indicates to the supplier that the agreed upon sampling plan will lead to the acceptance of most batches delivered by the supplier. That is, if the quality level – as percentage of defective units – of these batches does not exceed the AQL-value.

For example, an AQL-value of 1.0 means that a shipment that contains just 1 % defective units and is tested according to test instructions for sampling plan ´AQL 1.0`, will most likely be accepted.

The specification of an AQL-value does not mean that the supplier has the right to knowingly supply even a single defective unit!

The applicable AQL-values are agreed upon by the contracting parties. On the one hand, they are based on the percentage of defective units or defects the buyer is willing to accept and, on the other hand, on the average quality level of the supplier's production process.

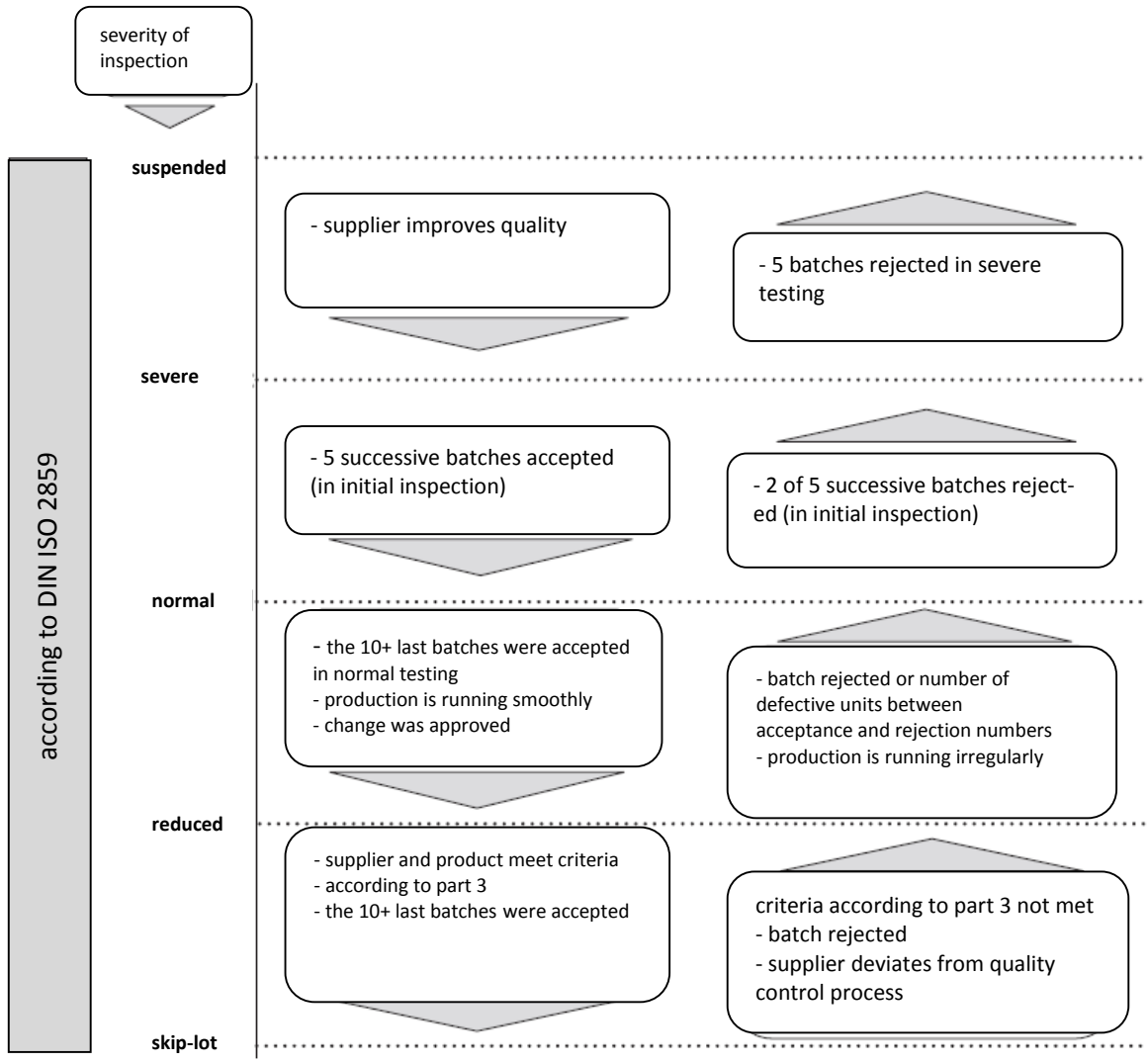
The figures below show when the normal sampling procedures should be changed to severe or reduced sampling procedures (figure 2.56 and figure 2.57).

As previously mentioned, the following alternatives are to be considered when determining the scope of an inspection.

- 100 %-inspection
- sampling, e.g.
  - with a standardized, published or in-plant sampling system
  - skip-lot
  - statistical process control (SPC)

In a 100 %-inspection all units of a test batch are tested. This is economical only for single or small batch series, or for medium or large batch series when using automatic testing machines.

Figure 2.56: Batch testing according to DIN ISO 2859



A sampling test with a standardized, published or in-plant sampling system uses tables of sampling plans. Nowadays, sampling systems in compliance with DIN ISO 2859 and DIN 3951 are primarily used.
The sampling test according to DIN ISO 2859 is expanded by skip-lot procedures that intermittently suspend testing for good test results. If the test scope is to be reduced further, due to good product quality, the question of whether to accept batches without any testing arises.

Skip-lot sampling tests:

Skip-lot stands for skipping lots or batches. In this case not every batch is tested, only a certain percentage of batches. The goal is to reduce the cost of testing, by forgoing the testing of a portion of the presented batches.

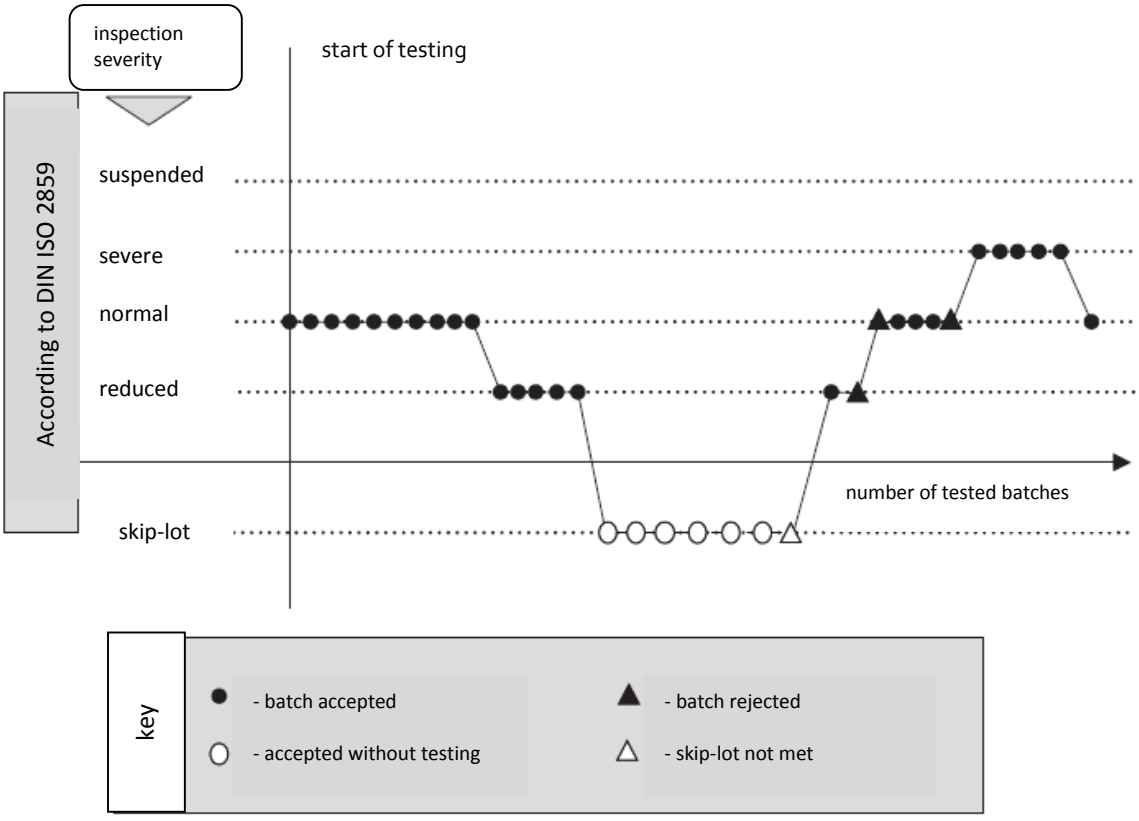
Its application requires a certain degree of trust in the quality management of the supplier and that the test does not concern errors that could endanger people or especially valuable goods.

Which arrangement best suits supplier and buyer has to be decided on a case-to-case basis.

The decision of whether to apply 100 %-tests or sampling tests primarily hinges on the type of defect which is being tested for. Critical defects require an automatic 100 %-test or, in the case of large quantities, at least sampling tests.

In the production of large quantities, statistical process control (SPC) is often employed. Samples of equal size are extracted from the process and tested at regular intervals. The results are documented in the form of control charts. The capability of the process is a requirement for SPC.

Figure 2.57: Example of batch testing according to DIN ISO 2859



Determination of a test site (´where`) primarily hinges on the test characteristics, the test equipment to be applied, production flow and the size of the parts.

Test sites can be measuring rooms, laboratories or inspection stations in, at or next to the production or assembly facilities. Determining the test site often also determines the test personnel (´by whom`). Tests in measuring rooms or laboratories are generally conducted by quality testing personnel, while tests in, at or next to the production facilities are conducted by the production personnel. The selection of testing equipment (´with what`) determines the optimal tools for testing.

For this purpose, the following should be taken into account:

- organizational circumstances, e.g. availability
- technical aspects, e.g. accessibility of the test site
- economical aspects, in order to minimize the costs of testing.

Testing equipment is selected by consulting an equipment selection matrix or testing equipment index. Nowadays, the equipment selection process for larger inventories of testing equipment is usually computer-aided.

By specifying an inspection text, additional information about the set inspection requirements is documented. This text is either added to the inspection plan or is part of an additional test instruction.

Complicated testing equipment or the testing of complex characteristics make inspection texts necessary.

Specification of test documentation is a prerequisite for the specific evaluation of the test results (´test data`). In particular, the external requirements, contractual as well as legal, are of significance.

Examples of this type of documentation are initial sample test reports or inspection charts.

Establishing data processing guidelines for test data ensures the utilization of that data.

Quality data feedback to preceding sections is of great importance (s. chapter Basics of Test Engineering).

The last section showed that a test instruction (n – c) is characterized by the sample size n and the acceptance number c.

The probability of acceptance is understood as:

The effect a test instruction has on the likelihood of a batch being accepted.

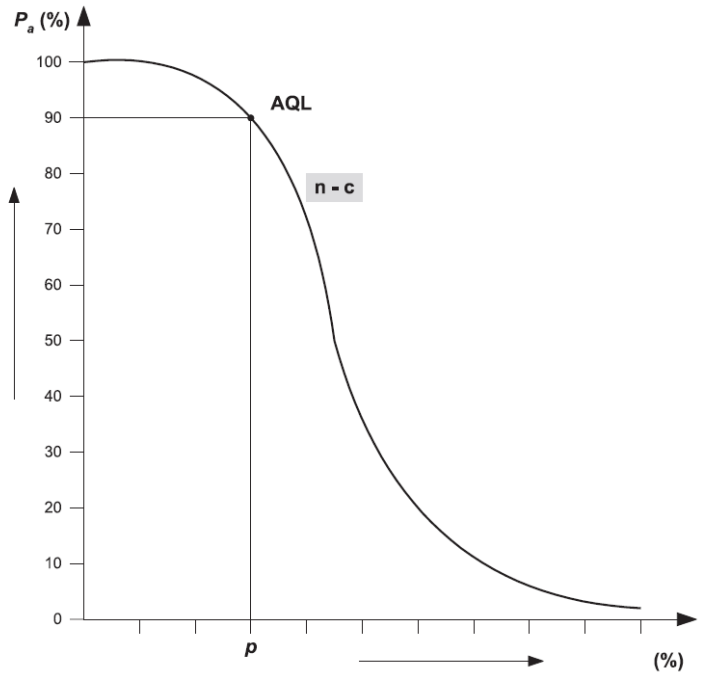
As long as the error count x does not exceed the acceptance number c, the batch will be accepted.

The probability of acceptance depends on the quality of the presented batch, i.e. the actual percentage of defective units in the batch.

The combination of the probability of acceptance P_a and the percentage of defective units p, in a batch, is called operating characteristic (OC).

The operating characteristic shows the correlation between the percentage of defective units and the probability of acceptance. Batches with a small percentage of defective units have a high probability of acceptance. The larger the percentage of defective units in a batch, the lower the probability of acceptance. Occasionally, however, batches with a percentage of defective units get accepted, or batches with a low percentage of defective units get rejected.

Figure 2.58: Operating characteristics curve



The operating characteristics curve shows the relation between the percentage of defective units in the batch before the test (p) and the probability (P_a) of the batch being accepted, under certain test conditions.

Percentage of defective units in the batch before the test in % symbol: **p**
Probability of acceptance in % symbol: $\boldsymbol{P_a}$

As stated earlier, the graphical representation of this relation, between the probability of acceptance of a batch and its percentage of defective units, is called operating characteristic (OC). Each test instruction (n – c) corresponds to a specific OC: The curve in figure 2.58 shows the operating characteristic for the test instruction.

n – c = **80 – 20**

For each test instruction n – c, the corresponding operating characteristic can be calculated. The operating characteristics presented here were created this way.

The other way round, test instructions can be derived from the acceptance probability of specific percentages of defective units.

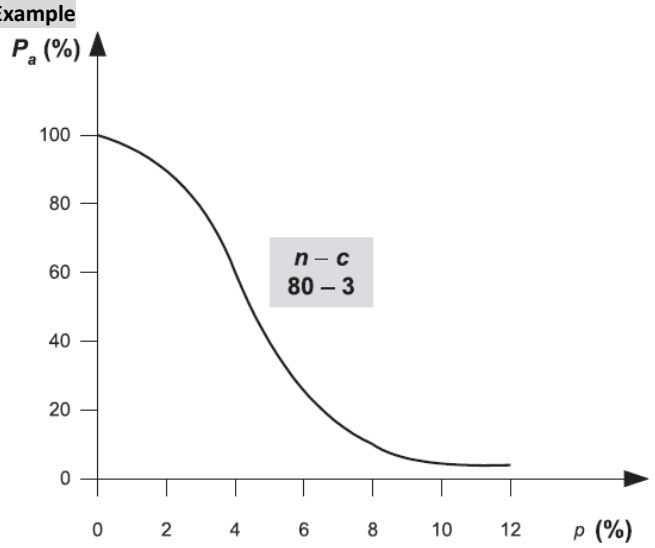
Example:
A shipment is tested according to test instruction n – c = **80 – 3**.

What is the probability of acceptance for a shipment which contains p = **4 %** defective units?

The following representation shows the operating characteristic (OC curve) of the test instruction (n – c) = (80 -3).

What probability of acceptance (P_a) is to be expected for a shipment which contains p = 4 % defective units?

Figure 2.59
Example



Solution:

A vertical line is drawn, starting at p = 4 %, until it reaches the OC-curve (80 – 3). From the intersection a horizontal line is drawn to the P_a-axis. The probability of acceptance is identified as P_a = 60 %.

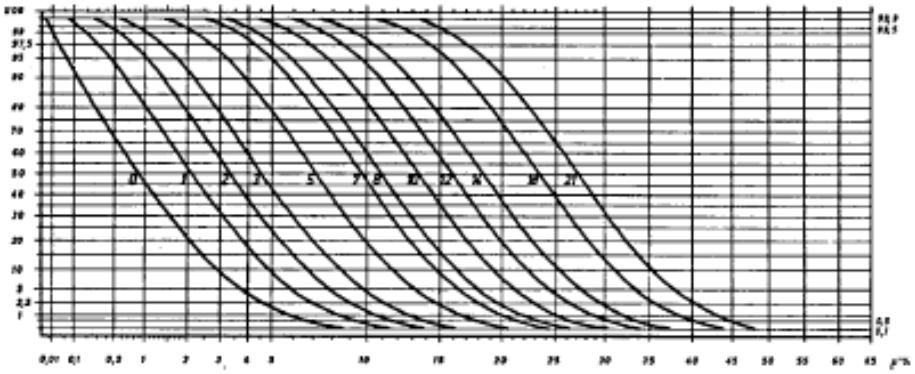
What is the probability of rejection?

The likelihood of the batch which contains 4 % defective units of being rejected, based on this test instruction, is
100 % - P_a = 100 % - 60 % = 40 %

The operating characteristic is a function of the sample size n and the acceptance number c. Changing one of these parameters, changes the shape of the OC-curve.

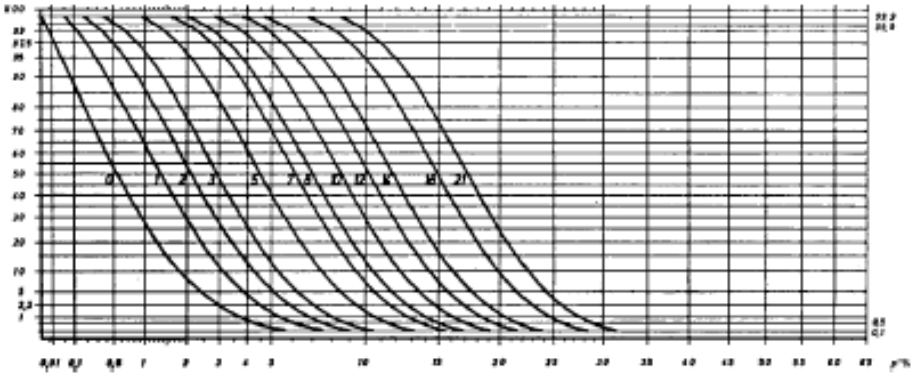
n = 80:

	$c = 0$	$c = 1$	$c = 2$	$c = 3$	$c = 5$	$c = 7$
P_a %	$c = 8$	$c = 10$	$c = 12$	$c = 14$	$c = 18$	$c = 21$



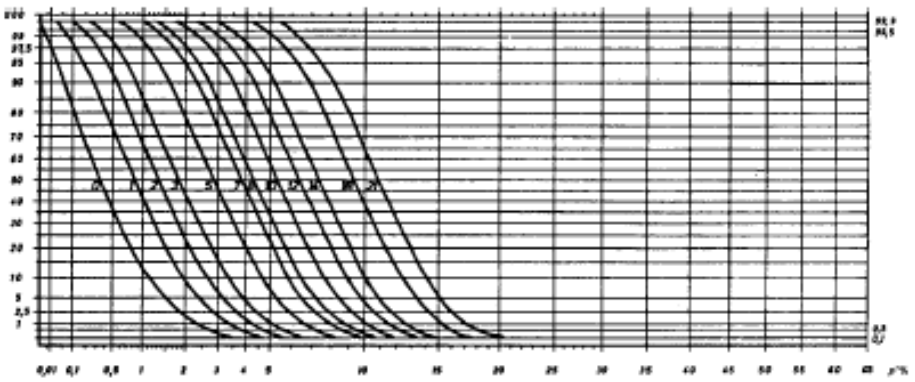
n = 125:

	$c = 0$	$c = 1$	$c = 2$	$c = 3$	$c = 5$	$c = 7$
P_a %	$c = 8$	$c = 10$	$c = 12$	$c = 14$	$c = 18$	$c = 21$



n = 200:

	$c = 0$	$c = 1$	$c = 2$	$c = 3$	$c = 5$	$c = 7$
P_a %	$c = 8$	$c = 10$	$c = 12$	$c = 14$	$c = 18$	$c = 21$



2.5.1 The confidence interval

Suppose the previously mentioned sampling of 80 parts yielded two parts with one defect each (x =2). The batch should be accepted. But this does not mean that the percentage for the sample can be projected onto the total population.

80 parts contain 2 defects
160 parts contain 4 defects
240 parts contain 6 defects

This is wrong!

Considering the best case, these two defects might have been the only ones in the shipment. In this case, the other 920 parts would be faultless. Considering the worst case, a lot more defects could be ´hidden` in the shipment. They just were not ´caught` in the sample.

To determine how many of the parts are really defective, the whole shipment (N= 1000) would have to be tested.

As has been shown, the effort to do this is too time-consuming in most cases, aside from not always being necessary.

As recipient though, we are still interested in how many more defective units might be in the shipment.

This is where the table of confidence intervals (95 % confidence) can help us.

Our example had a sample size of n = 80 and an error count of x = 2.

The corresponding confidence interval can be found in column (n = 80), line (x = 2) of our table. The interval is 0.3 % to 8.8 %. This means, for this sampling, our shipment (N = 1000) could contain between 0.3 % and 8.8 % defects.

For 1000 parts this would amount to between 3 and 88 defects, or defective units, with a confidence of 95 %.

Handling of rejected batches.

If a sampling test results in a batch being accepted, it can be forwarded from receiving control to production. In the case of in-plant tests, the next department can continue production.

If a batch is rejected, it first has to be ´freed` of defective units through sorting out, as far as possible. Only then can it be resubmitted for testing.

This task can be done, e.g. for the supplier of the parts, if he provides for the costs in the form of a discount. Otherwise, he would have to bear the costs of not only the sorting himself, but also transport to and from his location.

The defective parts that were found in the sorting process can either be reworked or, if they are unrectifiable, be discarded. In borderline cases a deviation permit for the defective parts can be obtained. This requires notification of and permission by all relevant company departments, e.g. assembly regarding reliability or production management regarding possible additional costs.

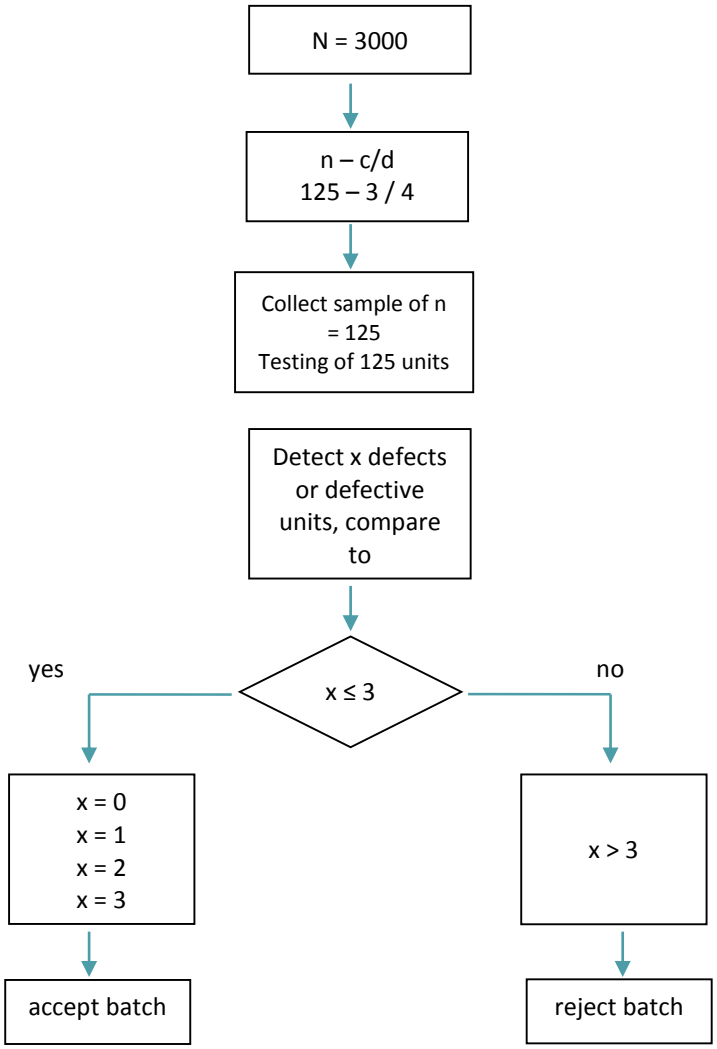
Table 2.8: Confidence intervals for percentage of defects (Clopper/Pearson)
(lower and upper endpoints in %; 95 % confidence)

	n															
x	**8**		**13**		**20**		**32**		**50**		**80**		**125**		**200**	
0	0.0	37.1	0.0	24.7	0.0	16.8	0.0	10.9	0.0	7.1	0.0	4.5	0.0	2.9	0.0	1.8
1	0.3	52.6	0.2	36.0	0.1	24.9	0.1	16.2	0.0	10.7	0.0	6.8	0.0	4.4	0.0	2.6
2	3.2	65.1	1.9	45.4	1.2	31.7	0.8	20.8	0.5	13.7	0.3	8.8	0.2	5.7	0.1	3.6
3	8.5	75.5	5.0	53.8	3.2	37.9	2.0	25.0	1.3	16.6	0.8	10.6	0.5	6.9	0.3	4.3
4	15.7	84.3	9.1	61.5	5.7	43.7	3.5	29.0	2.2	19.2	1.2	12.4	0.9	8.0	0.6	5.0
5	24.5	91.5	13.9	68.4	8.7	49.1	5.3	32.8	3.3	21.8	2.1	14.1	1.3	9.1	0.8	5.8
6	34.9	96.8	19.2	74.9	11.9	54.3	7.2	36.4	4.5	24.3	2.8	15.7	1.5	10.2	1.1	6.5
7	47.4	99.7	25.1	80.9	15.4	59.2	9.3	40.0	5.8	26.7	3.6	17.3	2.3	11.2	1.4	7.1
8	63.0	100.0	31.6	86.1	19.1	63.9	11.5	43.4	7.2	29.1	4.4	18.9	2.8	12.1	1.7	7.8
9			38.5	90.9	23.1	68.5	13.7	46.8	8.6	31.4	5.3	20.4	3.3	13.2	2.1	8.4
10			46.2	95.0	27.2	72.8	16.1	50.1	10.0	33.7	6.1	21.9	3.9	14.3	2.4	9.0
11			54.6	98.1	31.5	76.9	18.6	53.3	11.5	36.0	7.0	23.4	4.5	15.2	2.8	9.7
12			64.0	99.8	36.1	80.9	21.1	56.4	13.1	38.2	8.0	24.9	5.1	16.2	3.1	10.3
13			75.3	100.0	40.8	84.6	23.7	59.4	14.6	40.3	8.9	26.3	5.7	17.2	3.5	10.9
14					45.7	88.1	26.3	62.4	16.2	42.5	9.9	27.7	6.2	18.1	3.9	11.5
15					50.9	91.3	29.1	65.3	17.9	44.6	10.9	29.2	6.8	19.1	4.3	12.1
16					56.3	94.3	31.8	68.2	19.5	46.7	11.8	30.6	7.5	20.0	4.6	12.7
17					62.1	96.8	34.7	70.9	21.2	48.8	12.8	32.0	8.1	20.9	5.0	13.3
18					68.3	98.8	37.6	73.7	22.9	50.8	13.9	33.4	8.7	21.8	5.4	13.9
19					75.1	99.9	40.6	76.3	24.7	52.8	14.9	34.7	9.4	22.7	5.8	14.5
20					83.1	100.0	43.6	78.9	26.4	54.8	15.9	36.1	10.0	23.6	6.2	15.0
21							46.7	81.4	28.2	56.8	17.0	37.4	10.7	24.5	6.6	15.6
22							49.9	83.9	30.0	58.8	18.0	38.8	11.3	25.4	7.0	16.2
23							53.2	86.3	31.8	60.7	19.1	40.1	12.0	26.3	7.4	16.8
24							56.6	88.5	33.6	62.6	20.2	41.4	12.7	27.2	7.8	17.4
25							60.0	90.7	35.5	64.5	21.3	42.7	13.4	28.1	8.3	17.9
26							63.6	92.8	37.4	66.4	22.4	44.0	14.1	29.0	8.7	18.5
27							67.2	94.7	39.3	68.2	23.5	445.3	14.7	29.9	9.1	19.1
28							71.0	96.5	41.2	70.0	24.6	46.6	15.4	30.7	9.5	19.6
29							75.0	98.0	43.2.	71.8	25.7	47.8	16.1	31.6	9.9	20.2
30							79.2	99.2	45.2	73.6	26.9	49.1	16.8	32.5	10.4	20.7

Example 2.8

What is the test instruction for a batch of N = 3000 with AQL 1.0 normal inspection level (inspection level II)?

Figure 2.60: Test instruction



The appropriate test instruction can be read from a table of code letters for general inspections.

Batch size and inspection severity give the letter K = 125.
K and AQL 1.0 (normal inspection level) lead to 125-3/4. Collect a (random!) sample of n = 125 from the batch of N = 3000 and test it.

Count the number of defective units found in the sample.

Compare the number x of defective units with the acceptance number c = 3.

Solution:

The batch is to be accepted for c = 0 to 3
The batch is to be rejected for c = 4

2.6 Errors and error analysis

Error analysis is the dissection of occurring errors into their individual elements. The goal of this analysis is to make the link between their cause and effect transparent and to initiate remedial action.

The first question to arise is: What is an error?

Definition: An error is the non-compliance with a specified requirement

If the value of a characteristic is not within the predetermined limits, then it is in non-compliance with the specified requirements. An error is said to have occurred.

Or perhaps:

An error is an inadmissible deviation from the target state.

A product can have one or more defects. Therefore, a clear distinction should be made between the following terms:

- number of defects per unit (number of individual defects found for a single unit)

  and

- number of defective units (number of units found with one or more defects)

Error elements

Now we will learn about error elements.

Type of error

The designation of an error is its error type (name of the error), e.g.

- diameter error
- bending fault
- surface flaw
- cracks
- soldering defect

etc.

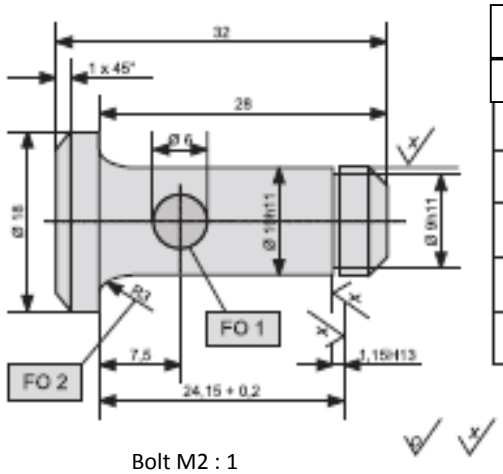
Error location

The error location is the position of the error on the work piece/part (figure 2.61)
It is not the location where the error occurred, e.g. in the turning shop.

Example:

Figure 2.61: Examples of error locations

error location 1 (F01)	bore	e.g. Ø 6 too large
error location 2 (F02)	radius	e.g. R 3 too small
.....	.....	.....



symbols for surface finish	
in diagram according to DIN ISO 1302	according to DIN 3141, line 2
=	
= R_z100	
= R_z25	
= R_z6,3	
= R_z1	

Bolt M2 : 1

Error cause

Every error that occurs has a cause.
Just as a disease in a patient has to be diagnosed before it can be treated, the cause of an error has to be known if one wants to avoid it.

Errors in production have to be reduced as much as possible because they cause additional costs (s. Q-costs).

Potential error causes are:

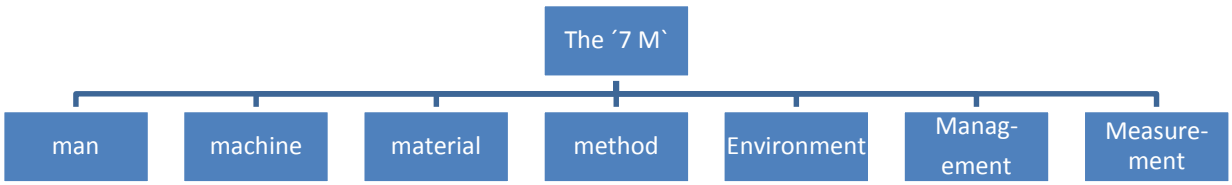
- shoddy tools
- inaccurate receiving inspections
- inadequate machinery and equipment
- faulty markings
- insufficiently trained and instructed personnel

etc.

In short, variations in quality, including errors, are affected by the so-called ´7 M`.
The ´7 M`

- man
- machine
- material
- method
- environment
- management
- measurement

Figure 2.62: The ´7 M`

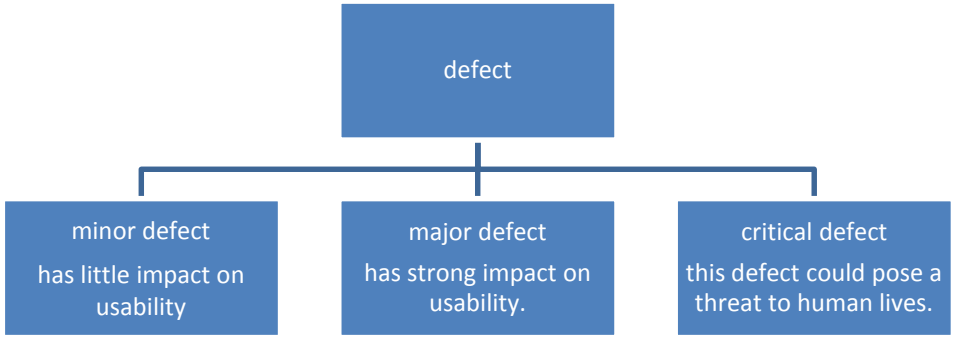


Each of these factors, positively or negatively, affects quality, to a larger or smaller degree; either individually or in combination (s. Chapter cause-and-effect-diagram)

Error classification

Ranking of errors according to their impact.

Figure 2.63: Defects



Defects are usually ranked according to different classifications.

The standard defines the following defect classes:

- minor defects
  Defects, that are expected, to not lower usability for the intended purpose in a significant way; or defects that only have a minor impact on the operation of the unit.

- major defects
  Non-critical defects are those that are expected to cause a breakdown of the unit or to significantly reduce usability for the intended purpose.

- critical defects
  Defects are those that are considered to have the potential to cause hazardous or unsafe situations for employees, maintenance workers or end users.
  Or they are defects that are considered to have the potential to hinder the operation of larger installations, like cars or medical facilities.

This classification is often further dived into subgroups, e.g. major defects A, major defects B, minor defects A, minor defects B.

2.7 FMEA

FMEA (Failure Mode and Effects Analysis) is an effective method of detecting potential errors and problems in design, manufacturing and assembly in time for prevention measures to take effect.

In short: FMEA = analysis of potential errors and their effects.

This Failure Mode and Effects Analysis was first put to use by NASA for the space program. Before the first moon landing, nobody could tell what kind of situation the astronauts could expect there. Therefore, possible situations were anticipated in scenarios and then thoroughly thought through. Whenever one of these (theoretical!) scenarios proved risky, preventative measures were taken to control the potential errors.

There are basically four types of FMEA:

1. system-FMEA (also development-FMEA)	Detection of potential errors in larger components of the overall system (mutual compatibility, interaction, cooperation)
2. design-FMEA	Detection of potential errors in components during the design phase (layout, material selection, dimensioning)
3. process-FMEA	Detection of potential errors in (future) production processes (machine parameters, work instructions, engineering ...)
4. management- or organizational-FMEA	Detection of potential errors

The basic questions that every FEMA asks, are:

´What happens if/when ...?`

A FEMA process searches for errors that could, but not necessarily have to, occur.

FEMAs should be established as early as possible in the product design phase, in order to detect potential errors, evaluate their impact and determine the likelihood of them actually occurring.

Complex processes, in particular, make the clear recognition of connections without a systematic approach very difficult.

Small causes may have large effects.

Establishing a FMEA at an early stage prevents unpleasant surprises and can be considered an effective tool for minimizing risks.

In most large-scale businesses it has become a matter of course to establish FMEAs for new products and facilities.

We will now only address process-FMEAs.

Objective and introduction

The objective of a process-related FMEA is to analyze all design characteristics with regard to projected manufacturing, assembly and test processes. This is done in order to detect weak points in process sequences and take corrective measures early on.

This involves a qualitative evaluation of systems, products or processes, with regard to breakdown of individual process steps.

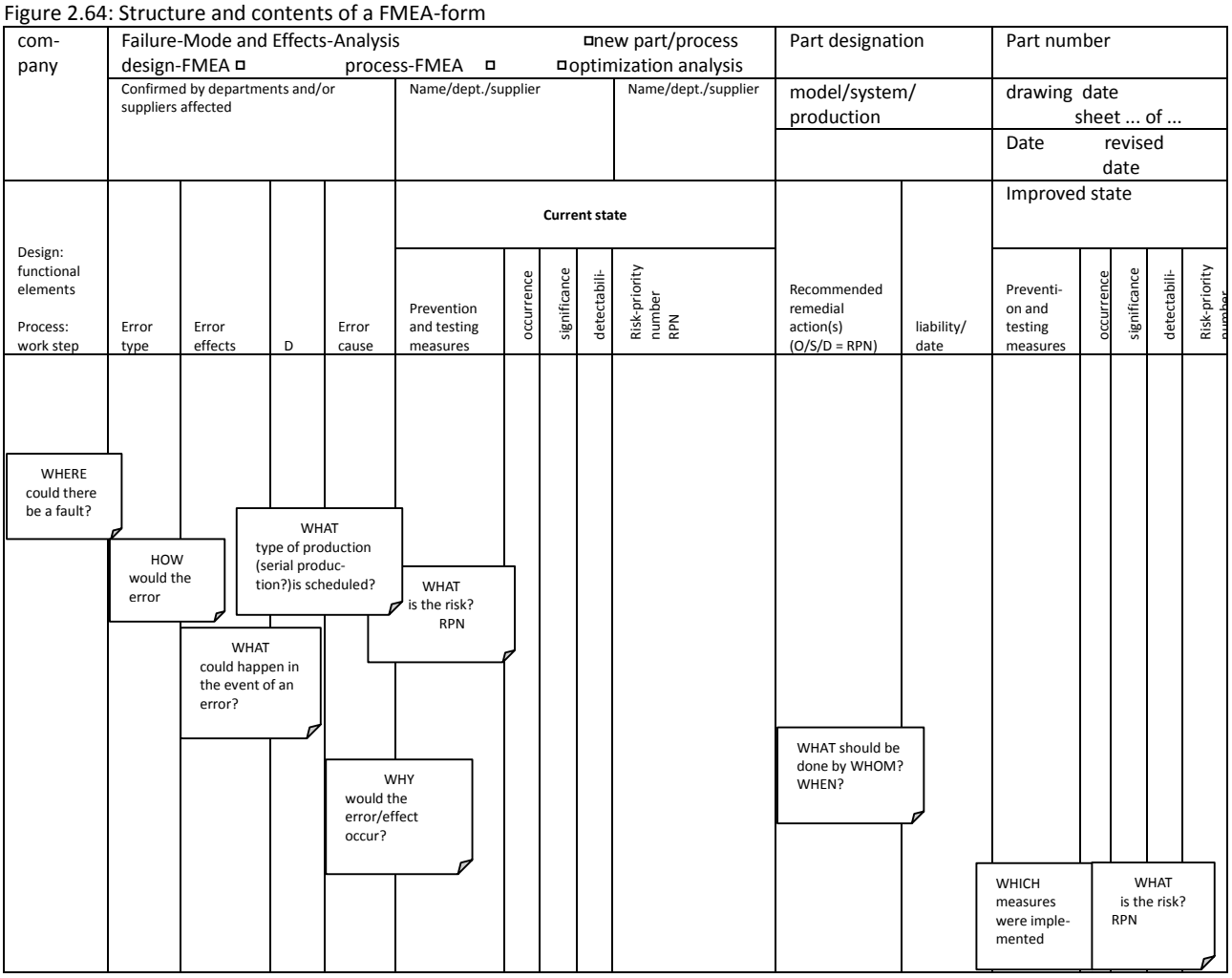
Essentially, the sequence of questions is always the following:

- What happens when a potential error actually occurs?
- What are the consequences of the error?
- How likely is the error?
- How can the error be recognized and avoided before it occurs?
- Which process characteristics are particularly suitable as control variables?

FMEA is an efficient tool for risk prevention, quality improvement and cost reduction. The procedure has been formalized to the greatest possible extent.

Figure 2.64 Shows a FMEA-form.

Figure 2.64: Structure and contents of a FMEA-form



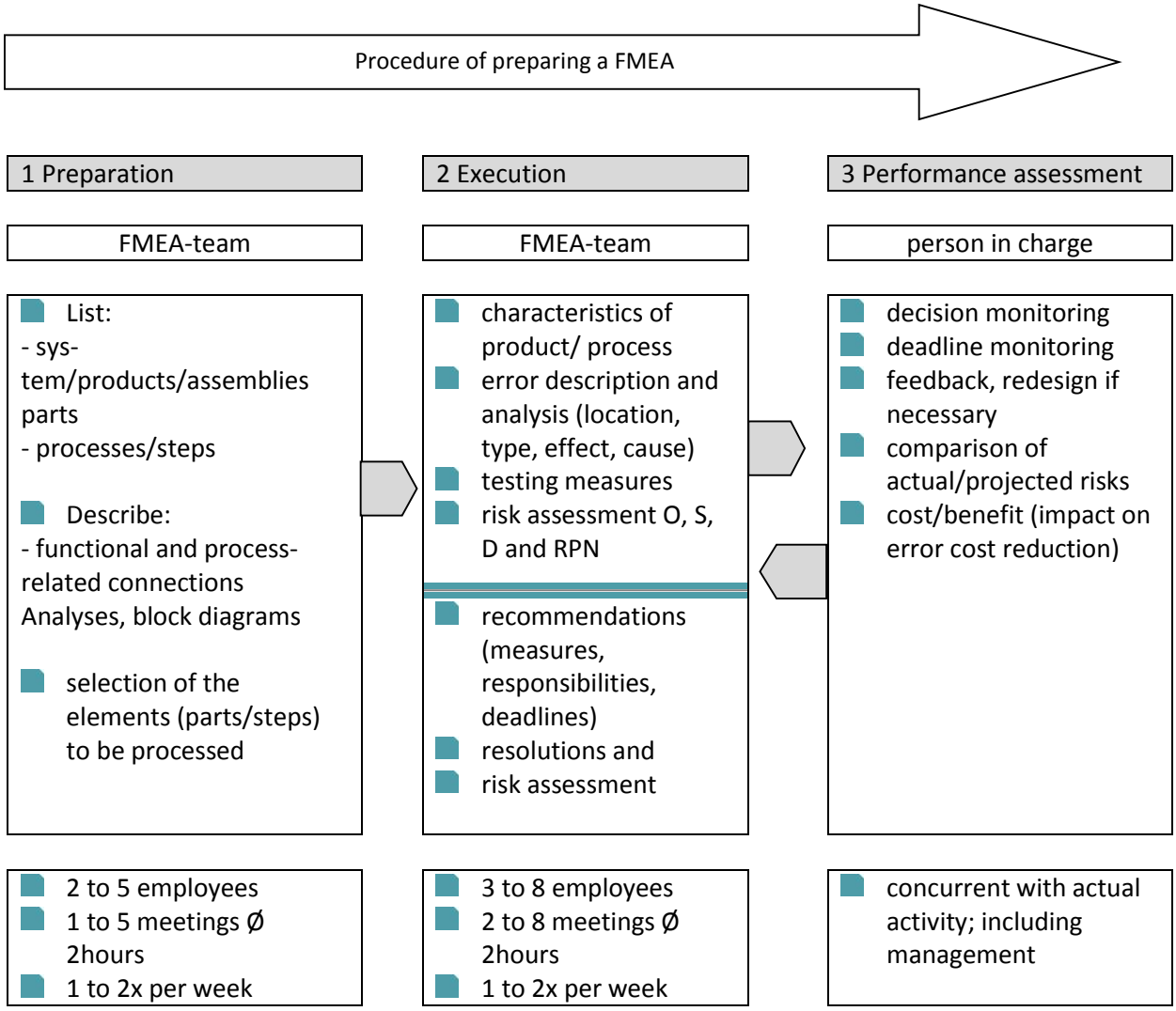
Error description	evaluation	Recommendations result checking	re-evaluation

Occurence		Severity (effects as seen by customer)		Detectability	
None	1	Imperceptible	1	High	1
very low	2-3	low impact	2-3	moderate	2-5
low	4-6	moderate impact	4-6	low	6-8
moderate	7-8	strong impact	7-8	very low	9
high	9-10	extremely severe impact	9-10	none	10

How does one proceed?

1. Preparation
2. Execution
3. Performance assessment

Figure 2.65: Procedure for preparing a FMEA



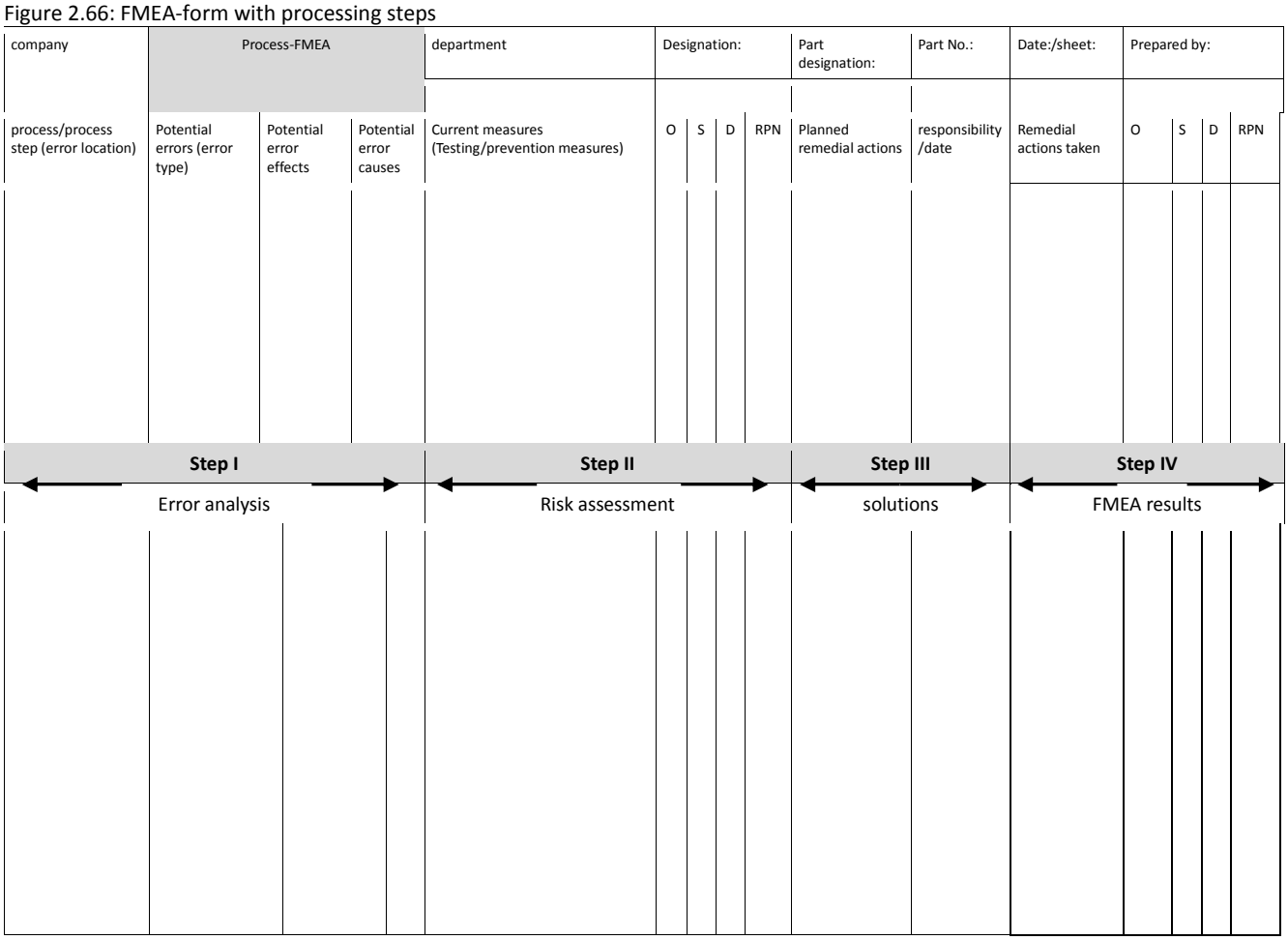
Process description of an FMEA

The form from figure 2.64 is the basis of the FMEA-process. The form meets general industry standards and could be easily applied to other industry-related situations.

The FMEA-process is carried out in 4 steps:

step I	error analysis
step II	risk assessment
step III	solutions
step IV	FMEA results

Figure 2.66: FMEA-form with processing steps



Step I
The first step is to carry out an error analysis.

For this purpose all steps of the process are listed in detail, and potential process errors are investigated for.

Then the potential error effects are examined and the potential error causes are explored.

These tasks already include the error analysis step of the FMEA. Questions about error location, error types, error effects and error causes are all answered in this important part of the FMEA.

Step II
The second step of the FMEA-process concerns risk assessment.

The question is what actions are currently being taken in the course of the process. Then the current risks for potential errors, shown by the preceding error analysis, their effects and causes are evaluated.

This evaluation includes the likelihood of a potential error occurring.

The next issue is the impact of potential effects of the errors. Finally, the likelihood of detecting a potential error is examined.

The rating is done on a scale from 1 to 10. The following classification can be applied to the likelihood of potential errors occurring:

unlikely = 1
very low = 2 to 3
low = 4 to 6
moderate = 7 to 8
high = 9 to 10

By multiplying the three individual ratings a risk priority number is derived (s. Tables ´risk assessment`).

Step III
The third step of the FMEA-process concerns the measures for the improvement of process quality, based on the analysis.

It is determined what has to be done and who carries the responsibility for the execution of the measures.

Step IV
In the fourth step of the FMEA an assessment is made after reasonable period of time.

The measures taken are evaluated in detail, just as in step II. The risk priority numbers are also recalculated.

If the risk priority numbers are considerably lower than the ones in step II, an improvement of process quality can be expected.

Figure 2.66 Shows these steps in the form.

O Frequency of occurrence
Tables: Risk assessment

rating score	comment
1	**no errors** Hardly any errors occur (likelihood ≈ 0) (unlikely)
2-3	**very low** rarely occurs, design conforms to a proven concept, and process is statistically controlled (x ± 4s → x ± 3s) (e-percentage 1/20000 to 1/2000)
4-6	**Low** occurs; comparable solutions show, that errors will occasionally occur (e-percentage 1/20000 to 1/200)
7-8	**Moderate** design and/or process are problematic; comparable solutions frequently led to errors (e-percentage 1/100 to 1/20)
9-10	**High** a high number of errors will almost certainly occur (e-percentage 1/10 to ½)

- The occurrence of an error refers to the cause of the error
- High rating scores indicate unreliable elements, or uncontrolled manufacturing processes
- The frequency of occurrence for an error can be lowered through changes
  - in design (construction)and/or
  - in the process.
- For O ≥ S, even low risk priority numbers require more intensive analysis.

S severity (effects, from the point of view of the ´customer`)

rating score	comment
1	**no error impact** The error has no detectable impact on the performance of the product or on further processing of the parts/material. The ´customer`, most likely, will never notice the error.
2-3	**low error impact** The error is insignificant and the ´customer` will only feel slightly affected. He will, most likely, notice only minor adverse effects on the system.
4-6	**moderate error impact** Will cause dissatisfaction in the ´customer`. The ´customer` feels annoyed by the error or is upset. He will notice the adverse effects on the system or the workability (reworking, impaired usability)
7-8	**severe error impact** Causes great annoyance to the ´customer` (non-operational product, or malfunctioning parts of the equipment) or non-workable parts. Safety concerns and non-compliance with laws are not yet covered by this.
9-10	**extremely severe error impact** Causes complete failure (9) of the product or might interfere with safety issues and/or compliance with laws (10).

- Error impact is oriented towards the effects of the error
- The same rating score is applied to all effects of one error
- For D-requirements (documentation/safety) S = 10.
- Concerning design-FMEAs, the end-user is considered to be the ´customer`.
- Concerning process-FMEAs, the next work-step which might be affected by errors is considered to be the ´customer`. In the worst case, this might be the end-user.
- Severity can only be influenced by changes in design (construction).

D Detectability (before shipment)

rating score	comment
1	**High** Errors that are inevitably detected in the current or next work-step (e.g. mounting hole missing). Detectability > 99.9 %
2-5	**Moderate** Visible error characteristics (base/part missing). Automatic screening inspections for simple characteristics (e.g. existence of a bore hole) Detectability > 99.7 %
6-8	**Low** Traditional testing (test, attributive or measured sampling) Detectability > 98 %
9	**very low** Error characteristics hard to notice (e.g. connectors only partially inserted) Visual or manual screening inspections (varies with individual) Detectability > 90 %
10	**None** Characteristic is not, or can not be, tested for (inaccessible, no way of testing, service life).

- Error prevention and testing measures for the design (construction), e.g. design review, experiments, plan approval, refer to detectability during the design phase.
- Design errors, detected by in-plant ´customers` (production preparation) are to be rated as D = 9. Errors, detected by external customers are to be rated as D = 10.
- Detectability in process-FMEAs always refers to serial inspections, or work steps matching an inspection.
- Errors that are only inevitably detected in the next-but-one or further work steps, are to be rated with D > 1 (for cost reasons)
- The detectability is the same for the same inspection severity.
- Detectability can be improved through changes in
  - design (construction)
  - processes (SPR)
  - inspections.

Column ´potential process errors`
This column concerns the errors that could occur in the process step.

It is of significant importance to consider every possible error.

One should list every conceivable error in the column ´potential process errors` on the form.

Initially, these potential errors are to be considered, regardless of whether they are especially likely, detectable in time or have serious consequences.

The following conditions can be considered especially prone to errors:
- voltage spikes in the power supply
- extreme fluctuations in temperature
- extreme variations in atmospheric humidity
- insufficiently trained personnel
- temporary staff
- high degree in variation of supplied materials

etc.

The recognizable effectiveness of a FMEA mainly depends on the extent to which potential errors under these conditions have been recorded.

Potential process errors should be described in physical terms.
Examples of typical potential process errors are:
- damages
- non-standard measurements
- missing characteristics
- incomplete
- too hard; too soft
- bent
- dented
- stuck

etc.

Column ´potential error effects`
The previous section asked which types of errors could occur. Now we ask which consequences can be expected if an error actually occurs.

This does not refer to the effects in the next process step, but to the viewpoint of the customer or end-user.

Each potential error has to be examined in detail for the negative effects it could have for customers or end-users.

Such process error effects can be clearly described in just a few words, e.g.
- reduced tool life,
- dust pollution,
- limited performance value,
- contaminated surface,
- limited electrical functionality,
- loud engine noises,
- unpleasant odors,
- reduced life time

etc.

Column ´potential error causes`

Here the question is asked as to the causes of potential errors.

This is by far the most difficult part of the FMEA. The true causes of potential errors are often hidden or obscured. Just as with actual diseases, symptoms can easily be confused with causes.

Finding the true causes requires sound expertise regarding the process step.

The following are potential process error causes:
- air temperature too high
- bearing clearance too large
- unbalanced
- tool sharpened incorrectly
- material composition is off
- oil temperature too high
- cutting speed to high

etc.

Column ´factors affecting the process, such as disturbance and control variables

The feedback principle that is the basis of nearly every process should be known from control engineering.

Nearly every process can be understood as a control system which has to be able to balance differences between regulating variables (a process indicator) and command variables (quality requirements).

To achieve this, deviations from the quality requirements are relayed to a controller. This controller then regulates the process via control variables (Fig 5.67 shows a control system).

Such control variables could be:
- rotation speed
- feed rate
- temperature
- time
- viscosity
- mixture ratio
- pressure
- lifting distance

etc.

Together, all these control variables can have significant influence on the result of a process.

A well regulated process is characterized by compensating for disturbance variables via feedback.

Disturbance variables can also have significant influence on the result of a process.

If disturbance variables get out of hand, process quality suffers.

The causes of process errors, identified during the FMEA-process, very often turn out to be disturbance variables. Sometimes they turn out to be previously unknown, control variables.
Unregulated control variables can act like disturbance variables.

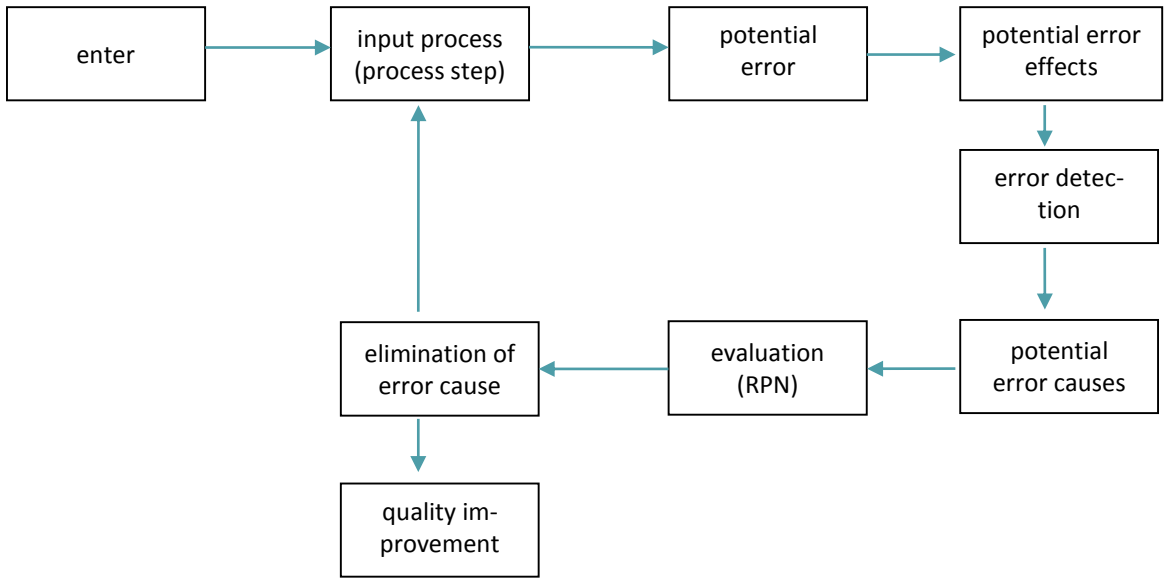
Possible disturbance variables are:

- moisture
- variations in temperature
- variations in pressure
- effects of heat
- dust and dirt
- vibrations

etc.

A detailed analysis of the cause of a process error will detect most disturbance variables and many control variables.

Figure 2.67: FMEA-process-correction-system



Column ´evaluation of process data`
In this step (step II) of the FMEA-process the risk assessment is conducted. Risk assessment concerns the current state.

Risk assessment is divided into the formulation of two questions:

1. How are things done now?
2. Where lay the risks?

On 1: Here the current state of affairs is analyzed. All measures for error prevention and detection of errors and error causes are to be fully documented.
This documentation of the state-as-is is so important, because the subsequent risk assessment relies on it.

On 2: Process risk is determined, based on three criteria. However, an absolute risk level is not defined. Rather a ranking of risks is determined, which should be as differentiated as possible.

The first evaluation criterion is the likelihood of a potential process error actually occurring. It is ranked on a scale from 1 to 10.

1 represents the ideal case. There are no problems in process control.
10 represents the worst case. Process errors occur with high frequency.

A more detailed scale for the likelihood of occurring, could look like this:

unlikely	= 1
very low	= 2 to 3
low	= 4 to 6
moderate	= 7 to 8
high	= 9 to 10

The second evaluation criterion concerns the impact of a potential error, assuming it actually occurs and has the corresponding negative effects.

The evaluation is based on the potential effects of an error, primarily those affecting the customer.

As with the first criterion, it is ranked on a scale from 1 to 10.

The third evaluation criterion concerns detection. The question is, how likely it is for an actual process error to be detected.

1	signifies that a process error will be detected 100 % of the time.
10	signifies that a process error, in all likelihood, will not be detected.

The determination of the risk priority number concludes the evaluation of the basic data.

The risk priority number (RPN) is determined by multiplying the likelihood of occurrence O with the severity of impact S and the likelihood of detection D.

RPZ = O • S • D (min. 1, max. 1000)

The risk priority number should never be seen as an absolute measure of risk, but rather as a kind of ranking of the risk.

Equally problematic is the notion of risk priority numbers as general threshold values for when to initiate remedial action.

To substantiate the necessity of remedial action, each of the risk factors O, S and D has to be carefully examined.

Column ´remedial actions`
The second before last step (step III) of a FMEA-process concerns measures for error elimination.

The main questions concern what is to be done and who should be responsible for the remedial action.

The main goal for the determination of corrective measures and improvements is the reduction and prevention of error causes.

This section will focus on the method of statistical process control (SPC). A detailed explanation of this method takes place later in this correspondence course (chapter SPC).

It should first be mentioned that the introduction of process control charts (x, s or R) represents a step that helps to prevent errors and, therefore, reduces the impact of their occurrence.

Correct application and a capable process (C_{pk} significantly larger than 1.3) can reduce the impact of occurrence to 1.

The introduction of such measures leads to improvements of quality.

Column ´improved state`
The last step (step IV) of the FMEA-process occurs only after the remedial action has been concluded.

Before analyzing the improved state, it is important to critically examine whether the measures that were taken have already had an effect.

If this is the case, any measures that were taken are carefully assessed with regard to the improved state.

The risk numbers are recalculated for the improved state. As in the second step, the likelihood of occurrence, the impact severity and the likelihood of detection (before shipping to customers) are determined.

The so recalculated risk priority number must be significantly lower than the risk priority number calculated before any improvements.

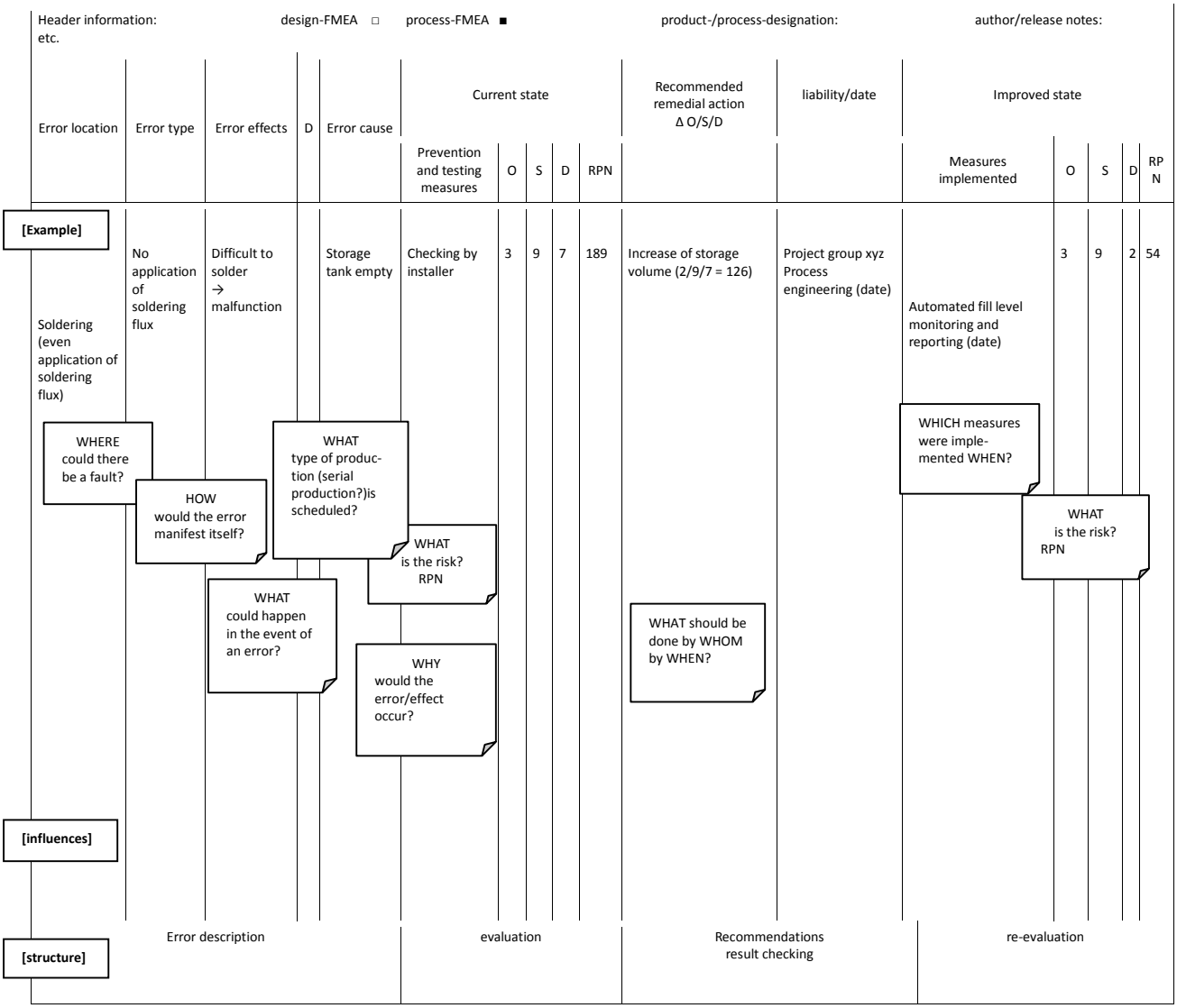
If this – based on the measures taken – verifies the minimization of risk, an improvement in quality can be expected for the process.

This concludes the FMEA-process.

Figure 2.68 shows a real life example.

This complete abstract does not claim full substantive accuracy, however. It only serves to demonstrate its foundation in reality (also see example ´soldering`) (with slightly differing structure and arrangement).

Figure 2.68: Example ´soldering`



2.8 Statistical process control (SPC)

Nowadays, customers demand that their suppliers not only have an organized quality control system (quality management) and provide standard samples, but they also demand, as part of an initial sampling, that the capability to stay within the required limits for highly important quantitative characteristics is verified.

Definition:
SPC should achieve nothing less than to reliably regulate the production process according to averages and variations of samples.

Machine capability: Measure of short-term influences on the product dispersion, mainly caused by the machine in question.

Process capability: Measure of influences on the process dispersion that are caused by interactions of humans, machines, material, environment, etc. (long-term influences)

Machine capability studies

A machine capability study is conducted whenever a new machine or a new tool has been introduced or a process has been shown to not be capable.

It is used for machine acceptance/-enabling tests or machine inspection.

To conduct a machine capability study a single large sample is taken from the machine. The parts from this sample are tested and the result is presented using cumulative frequencies (n ≥ 50).

Then the relative cumulative frequencies are entered into a probability plot (s. probability plot).

The interpretation of this graphical representation is conducive to the normal distribution of the sample (s. Chapter ´normal distribution`).

If a normal distribution is present, one can continue with the calculation of the parameters C_m and C_{mk}.

The parameter C_m is the ratio of the predetermined tolerance (UT-LT) to the dispersion ± 3s.

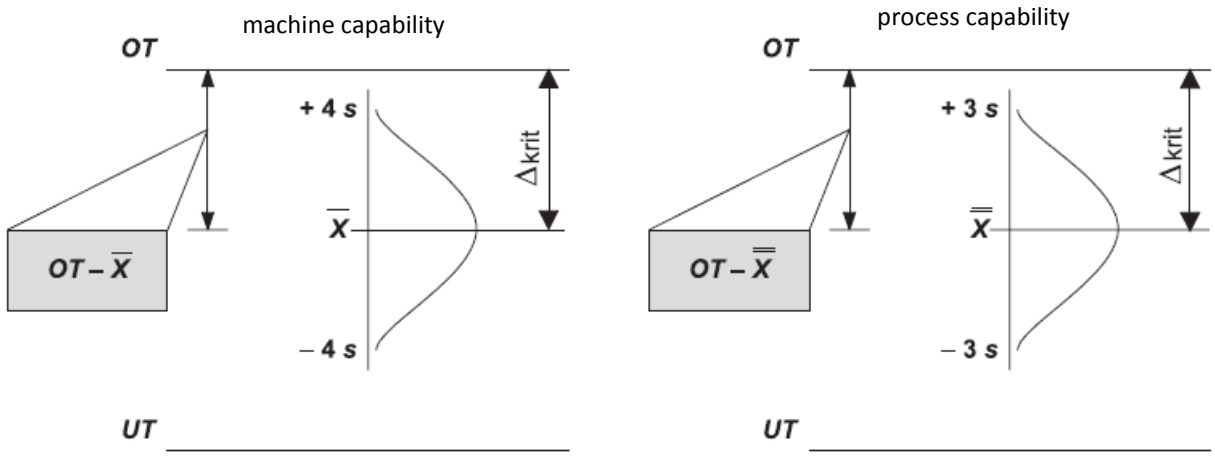
The parameter C_{mk} characterizes the positioning of the dispersion within the limits.

Machine capability requires at least all measured values within the ± 4 s-range to also be within the tolerance limits. This requirement leads to the condition for the parameter C_{mk} ≥ 1.

Machine capability studies are short-term studies.

They are characterized by the collection of single large samples of consecutively produced parts (n at least 50 parts / n > 50).
At the same time disturbances of the production processes should be kept at a minimum.

Figure 2.69: Machine and process capability



$$\bar{x} = \frac{sum\ of\ all\ individual\ values}{number\ of\ individual\ values}$$

$$\bar{\bar{x}} = \frac{sum\ of\ \bar{x}\ from\ all\ samples}{number\ of\ samples}$$

	machine capability index	process capability index
dispersion ratio	$C_m = \frac{UT-LT}{6s}$ $C_m = \frac{tolerance}{production\ disersion}$	$C_p = \frac{UT-LT}{6\hat{\sigma}}$ $C_m = \frac{tolerance}{production\ disersion}$
position	$C_{mk} = \frac{\Delta crit}{3s} \geq 1$	$C_{pk} = \frac{\Delta crit}{3\hat{\sigma}} \geq 1 \quad \hat{\sigma} \mathrel{\widehat{=}} s$
minimum requirement	$\Delta crit$ = minimal distance between average and tolerance limits (calculate using $\bar{x}$)	$\Delta crit$ = minimal distance between average and tolerance limits (calculate using $\bar{x}$)
verification	machine capability is commonly accepted as verified, if $C_m \geq 1.33$ and $C_{mk} \geq 1.0$	process capability is commonly accepted as verified, if $C_p \geq 1.33$ and $C_{pk} \geq 1.0$

Process capability studies
To conduct a process capability study, small samples are taken from a running process over a longer period of time (m ≥ 25 / n ≥ 5, that is, at least 125 parts)

This means, that a process capability study is a long-term study.

All disturbances, influencing the process, are recorded. The test for normal distribution of the actual values is the same as in machine capability studies.

If a normal distribution presents itself, the computation of the capability of the process can be conducted.

The parameter C_p reflects the ratio of (UT – LT) to the estimated value of the standard deviation $\hat{\sigma}$ ($\hat{\sigma}$ = s)!
The parameter C_{pk} indicates the positioning of the estimated dispersion within the tolerance limits.

Process capability requires all sample values within the ± 3 $\hat{\sigma}$-range to also be at least within the specified tolerance limits. Therefore the parameter C_{pk} should always be ≥ 1.

Example machine capability index

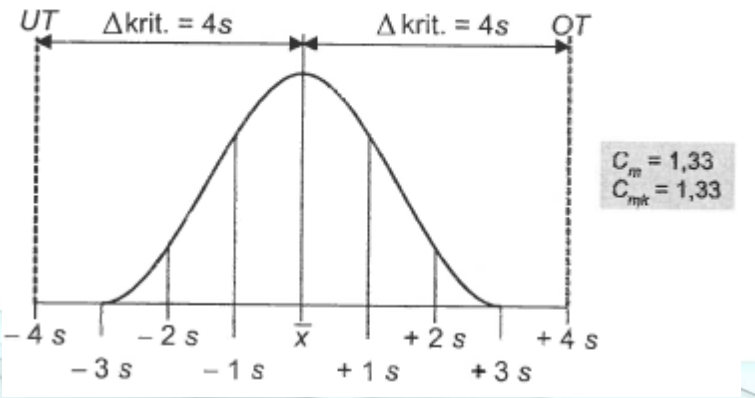
$C_m = \frac{T}{6 \bullet s}$

$C_{mk} = \frac{8s}{6s} = 1.33$

$C_{mk} = \frac{\Delta crit}{3s}$

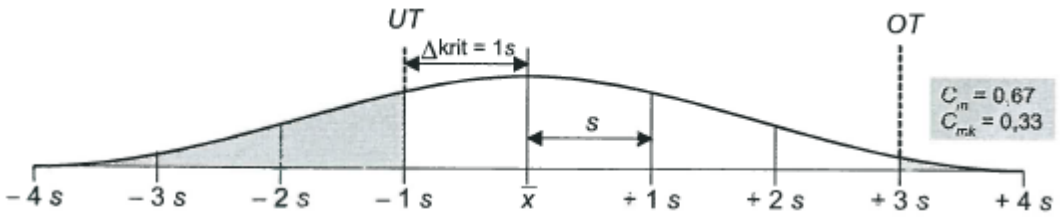
$C_{mk} = \frac{4s}{3s} = 1.33$

Δcrit = same



$C_m = \frac{4s}{6s} = 0.67$

$C_{mk} = \frac{1s}{3s} = 0.33$



Examples process capability index

$C_p = \frac{T}{6 \cdot s}$

$C_p = \frac{6s}{6s} = 1.0$

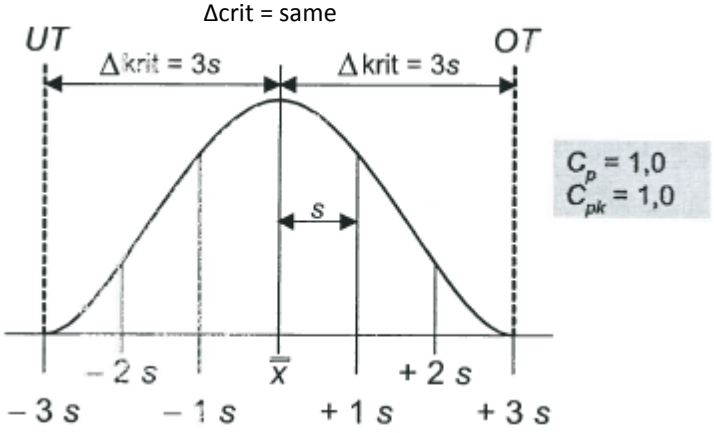
$C_{pk} = \frac{\Delta crit}{3s}$

$C_{pk} = \frac{3s}{3s} = 1.0$

$C_p = \frac{6s}{6s} = 1.0$

$C_{pk} = \frac{2s}{3s} = 0.67$

Δcrit = same



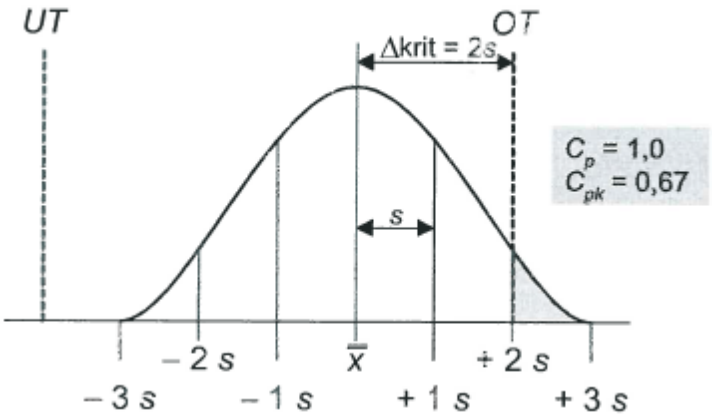
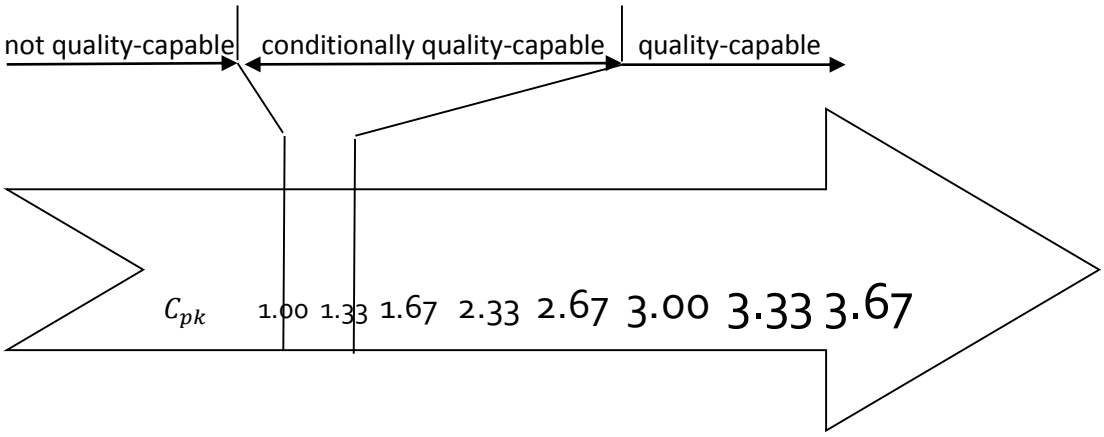


Figure 2.70: Process capability and constant improvement



There exist indices for the degree of capability and control. The scale is clarified in figure 2.72.
In general the following applies:

$C_{pk} < 1$ not quality-capable
$1 \leq C_{pk} \leq$ conditionally quality-capable
$C_{pk} > 1.33$ quality-capable

Table 2.9: Characteristics of machine and process capability

characteristic	**machine capability**	**process capability**
investigation period	short-term study, e.g. of a newly installed machine	long-term study
subject of investigation	components within a production facility	production processes, i.e. the interaction of people, machines, materials and work environment
sample	collection of a single, large sample (e.g. 50 parts)	collection of smaller samples over a longer period of time
goal	assessment of a machine regarding its capability	assessment of a process regarding its capability

A distinction is made between four separate process states:
1. The process is capable and under control.
2. The process is not capable, but under control.
3. The process is capable, but not under control.
4. The process is neither capable nor under control.

Process state 1 is without question the one to be achieved. It characterizes the process as both capable and under control.

Getting from the worst possible process state 4, (process neither capable nor under control), to process state 1 requires step-by-step quality improvements.

The step from 3 to 2 can only be achieved by systematic and meticulous work. The appropriate methods, namely the determination of process control, are not part of this section.

The step from 2 to 1 usually poses the greatest problems. It requires the further narrowing of the dispersion of the overall process.

Figure 2.71: A process under control and a process not under control

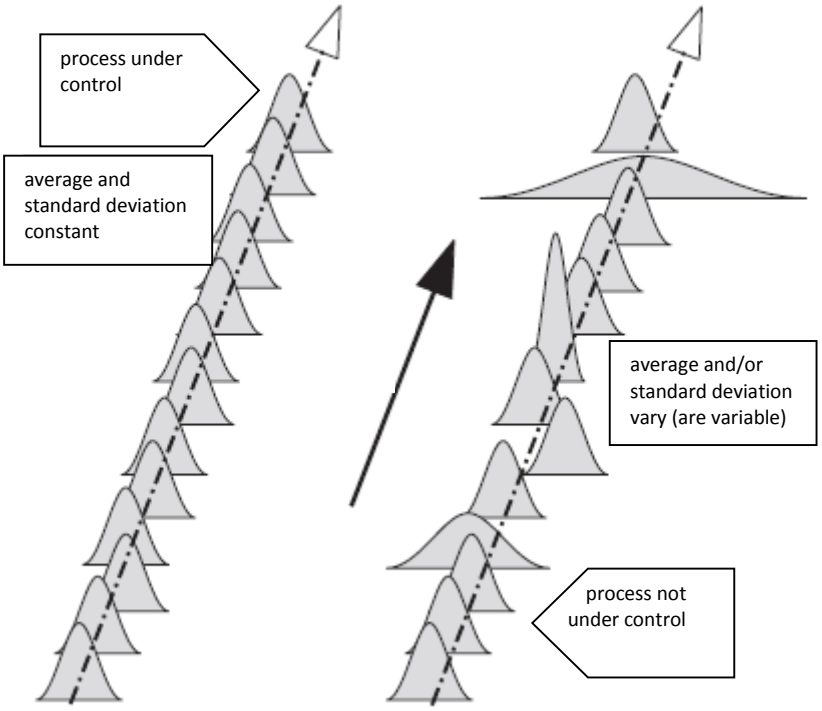


Figure 2.72: Progression of a capable and an incapable process

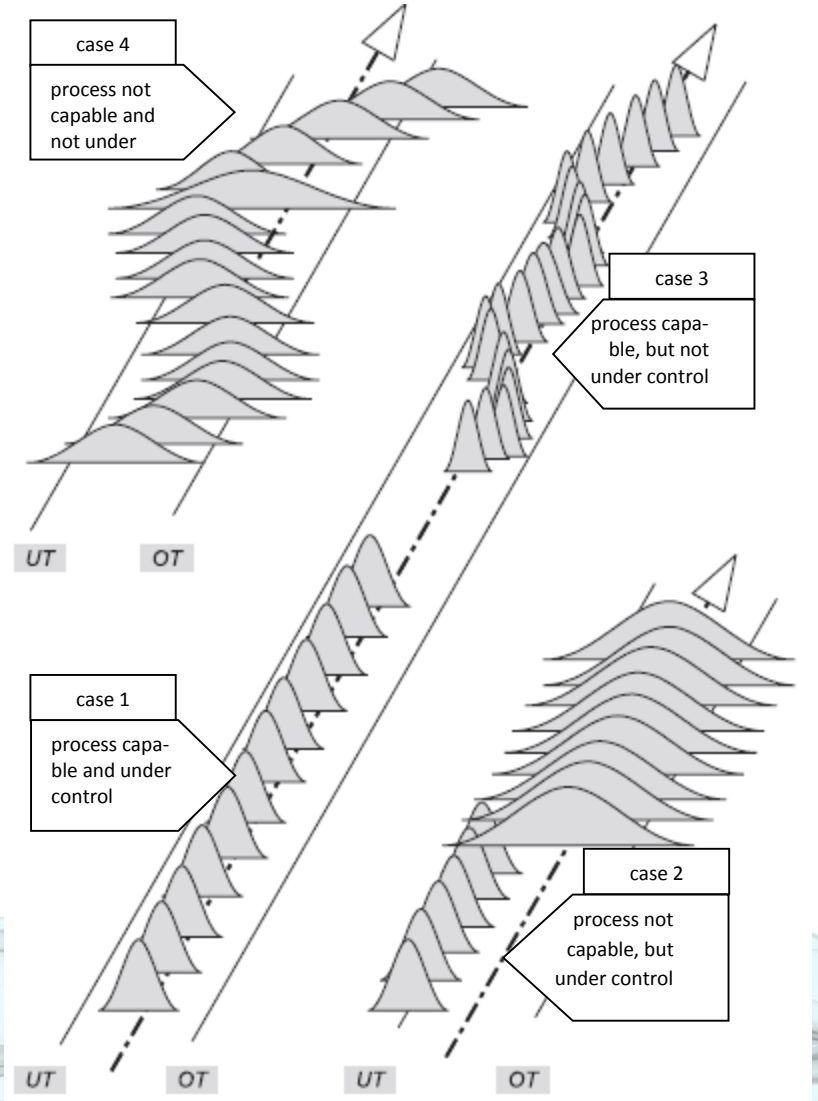
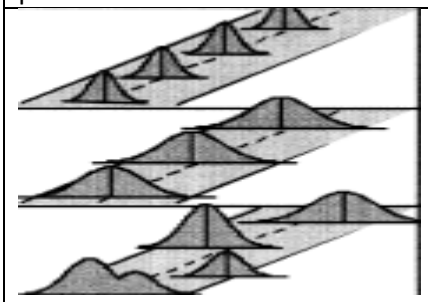


Figure 2.73: Assessment of processes

assessment of processes		
process result	capability parameter	significance for company
	> 1.33 process under control and capable	Excellent! Continue as before!
	< 1.33 process under control, but not capable	Begin sorting! (immediate measure) Analyze! (Find permanent solution)
	process neither under control, nor capable	No answer possible. Lacks basic structure.

Example:
A CNC-machine is supposed to mill an important groove.
The width of the groove has been established as the decisive quality characteristic for this work step.

The nominal width for the groove is 6mm and deviations of up to + 0.1 mm (T_o = 6.1 mm, T_u = 5.9 mm) can be tolerated.

A study of the short-term capability of the machine gave a C_{mk} of 1.4. This is indicative of a capable process.

A subsequent study of the long-term-capability using 30 samples of 5 drive-shafts each, taken over multiple days, showed these results:

- the medium average was:
  $\bar{\bar{x}}$ = 6.03 mm and
- the average standard deviation of the samples was:
  $\bar{s}$ = 0.02 mm

The C_p- and C_{pk}-values can then be calculated:

$$C_p = \frac{T}{6 \cdot \hat{\sigma}}$$

$$C_p = \frac{6.1-5.9}{6 \cdot 0.02} = \frac{0.2}{0.12} = 1.666$$

$$C_{pk} = \frac{\Delta crit}{3 \cdot \hat{\sigma}}$$

$$C_{pk} = \min\left\{\frac{6.1-6.03}{3 \cdot 0.02} ; \frac{6.03-5.9}{3 \cdot 0.02}\right\}$$

$$= \min\left\{\frac{0.07}{0.06} ; \frac{0.13}{0.06}\right\}$$

$$= \min\{1.166 ; 2.166\}$$ the lower value is chosen

So the process is long-term capable and can subsequently be regulated with a quality control chart.

2.9 Quality control charts (QCC)

Quality control charts are forms for the graphical representation of the results of tests of series of samplings from a running process. The results are measured values, or counts, that serve to regulate predetermined warning and action limits. (Statistical process control, SPC)

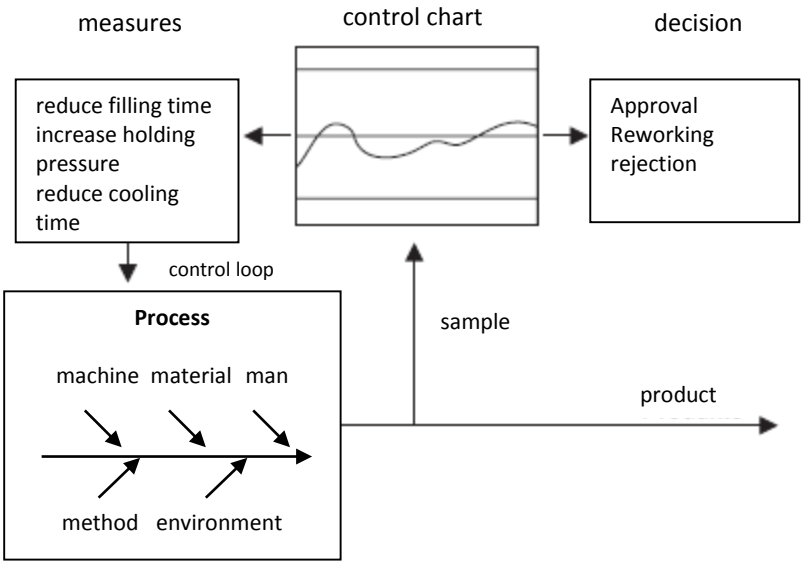
This subject can only be covered in a basic and simplified manner at this point.

The essential purpose of this representation is the assessment of the process regarding operational control, i.e. whether the dispersion is merely random.

Another potential area of application lies with the dispersion of serial production processes, aiming at the attainability of nominal values.

The example diagram shows the application of SPC to an injection molding process.

Fig 2.74: Application of SPC



Analysis of traverses on control charts
The natural operation of a production process, as shown on a control chart, is characterized by variations following the law of random chance.

Most values cluster around the average.

Therefore, most points on a control chart lie close to the center line.

Another characteristic for natural operation is the symmetry of the frequency distribution. Equal numbers of points (values) should lie to each side of the center line.

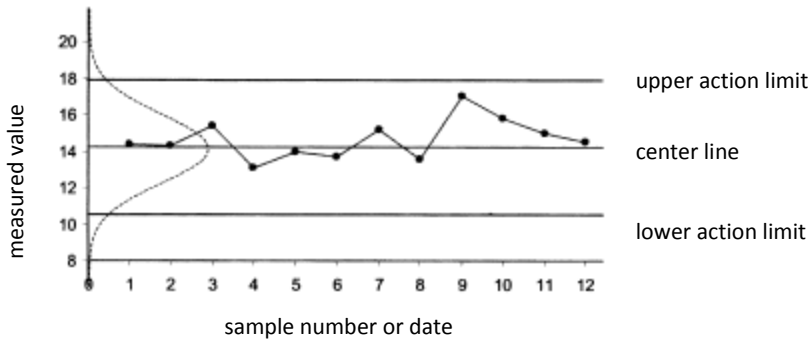
This results in the following rules for the natural traverse:

- Most points (values) lie close to the center line.
- Only a few points scatter and occasionally reach the action limits.
- No points (or only very few) lie outside the action limits.

If the traverse of the operation of a process fulfills all three of these requirements, it can be considered under control.

Definition:
Form for the graphical representation of measured values and counting results or derived statistical parameters. The results are acquired through periodic collection and testing of samples from an ongoing production process. They are calculated according to a statistical point of view and compared to the registered warning and action limits. Nowadays, the documentation of warning limits has mostly been given up. Figure 2.75 shows the schematic structure of a QCC.

Figure 2.75: Basic structure of a quality control chart with natural traverse



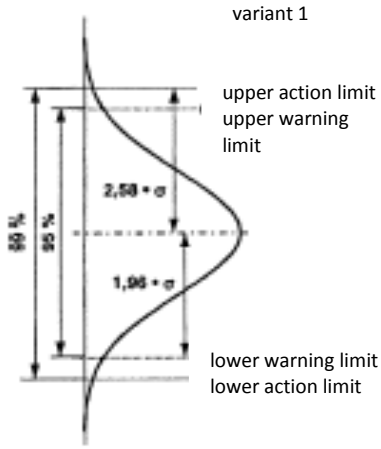
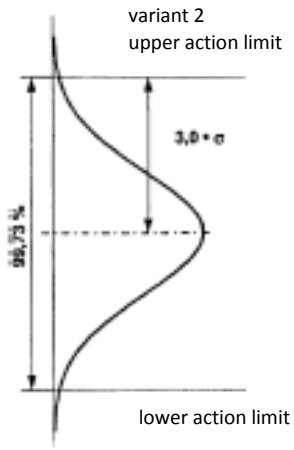
UAL = upper action limit
LAL = lower action limit

Table 2.10 Shows an overview of the main variants of quality control charts with the most common combinations as information.

Different specifications for the range of variation for warning and action limits

A limit of two or three standard deviations corresponds to a range of variation of 95.4 % or 99.73 %. The main principles of quality control charts are not affected by this, only some of the factors, in the calculation change. They can be obtained from the appropriate lists of tables or the specific requirements of vehicle manufacturers. Table 2.10 shows a comparison. Minor differences in the effect on the action limits can be seen (variants 1 and 2).

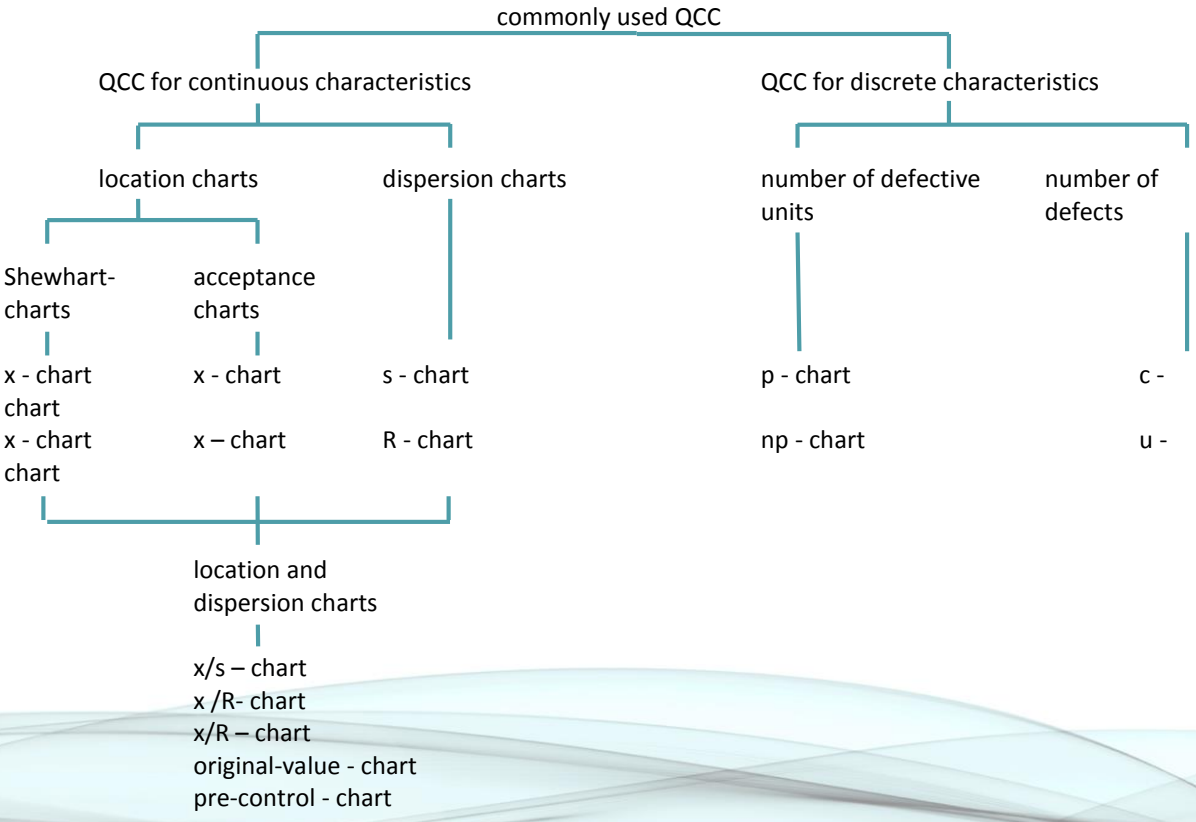
Table 2.10: Comparison of control limits based on different calculations

variant	1	2
warning limit	95 % RoV	omitted
action limit	99 % RoV	RoV = 6 • σ
		
RoV = range of variation		

Overview of quality control charts
Commonly used quality control charts.

Basically, any combination of quality control charts is possible. In practice, only some very few are used. Figure 2.76 shows an overview of the commonly used quality control charts.

Figure 2.76: Overview of commonly used quality control charts



Generally one differentiates between quality control charts for:

- measurable (variable or quantitative) characteristics / continuous characteristics
- countable (attributive or qualitative) characteristics / discrete characteristics

Measurable characteristics are usually tolerated and most often normally distributed.

Quality control charts for variable characteristics are used to prevent errors! Consequently applied, they may lead to ´zero-fault-production`.

Quality control charts for countable characteristics, on the other hand, are based on errors!

Quality control charts for continuous characteristics

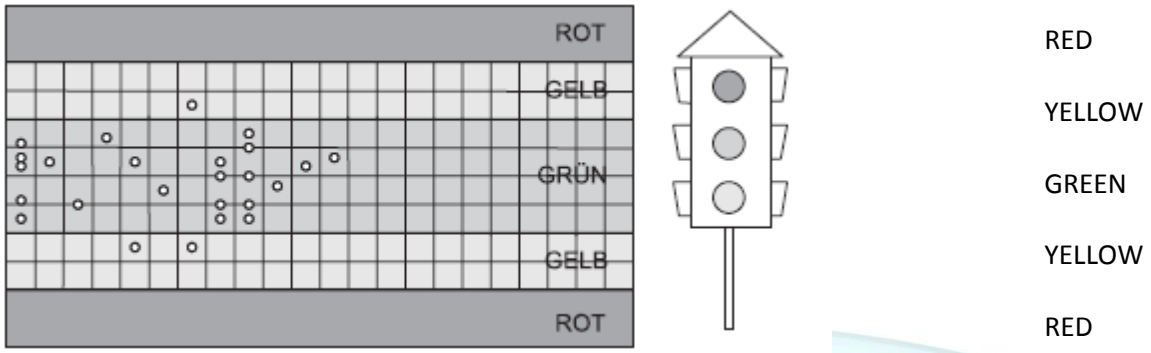
Quality control charts for the monitoring of continuous characteristic values in measuring tests, can be divided into single-track location charts (average or median charts) and dispersion charts (standard deviation or range charts), as well as combinations of these. The most commonly used QCC in the production sector is the x/s–chart. In the computer age, the advantage of easy determination of median and range are no longer relevant. Therefore, $$$/R-charts are becoming less and less important.

Shewhart-QCC
Shewhart-quality control charts are used if the satisfactory or controlled state of a process is to be maintained. Their function is to indicate if and when this state changes. For constant averages, the classical Shewhart-chart is used. If the averages randomly vary around a long-term constant value, the Shewhart-chart with extended range is used.

Acceptance-QCC
An acceptance quality control chart (or: modified Shewhart-chart) has its action limits calculated, based on the tolerance of the characteristic, the error percentage or the significance level. The last two values can be freely chosen. While Shewhart-charts show what the processes actually do, the tolerance limits of acceptance-QCCs show what the processes are supposed to do.

Pre-control-charts
The pre-control-chart (or traffic light chart) is a very simple acceptance-control-chart.
Here the specification limits determine the action limits. Because of the limited statistical significance they should only be used for controlled and capable processes. (Specification: document, which lists requirements, e.g. Design drawings and other documents)

Figure 2.77: Traffic light chart



Original-values-QCC
The original-values-chart (or x-chart) does not condense the measured values. They are entered directly into the chart. Since the decision whether to take action or not does not entirely hinge on the extreme values of samples, the single-track original-values-chart is also called the extreme-values chart.

Single-value-QCC and QCCs with sliding parameters.
Sometimes it is impossible or not expedient to use sample sizes n > 1, e.g. for destructive testing or slow production speed. In these cases, single-value-charts or control charts with sliding parameters can be used. The latter combines two, three or more consecutive measured values into a ´pseudo-sample` of size n = 2, 3, ... . The then calculated ´pseudo-parameters` are entered into the appropriate dual-track OCC. This allows the detection of dispersion patterns for individual values.

Quality control charts for discrete characteristics
QCCs for discrete characteristics require counted values, e.g. the number of errors. Depending on the area of application, the following QCCs are used (s. table 2.11)

Table 2.11: overview of quality control charts for discrete characteristics

discrete characteristic	applicable QCC
pass/fail; yes/no	- p-chart for the percentage of defective units (%) - np-chart for the number of defective units
number of errors per unit (part)	- c-chart for number of errors per sample - u-chart for number of errors per unit

For p-charts the percentage of defective units can be based on the assessment of one or more characteristics. Even if a unit has more than one defect, it is counted as defective only once. The number of defective units x of the sample and the sample size n determines the percentage of defective units p

$$p_i = \frac{x_i}{n_i}$$

This value is entered as %-information into the p-chart.
In contrast to the p-chart, the np-chart determines the number of defective units x in a set. The np-chart is to be preferred, if the sample sizes remain constant.

For a c-chart the number of all defects in a sample is counted (e.g. air bubbles in glass), in contrast to the number of defective units for the np-chart (e.g. glass pieces with bubbles). The c-chart requires a constant number of units per sample and is used in the following two situations:

- if the defects are distributed over a continuous production process.
- if the defects of a sample could have separate causes.

For the u-chart, the numbers of defects per unit of a sample are counted. The sample should contain more than one unit.

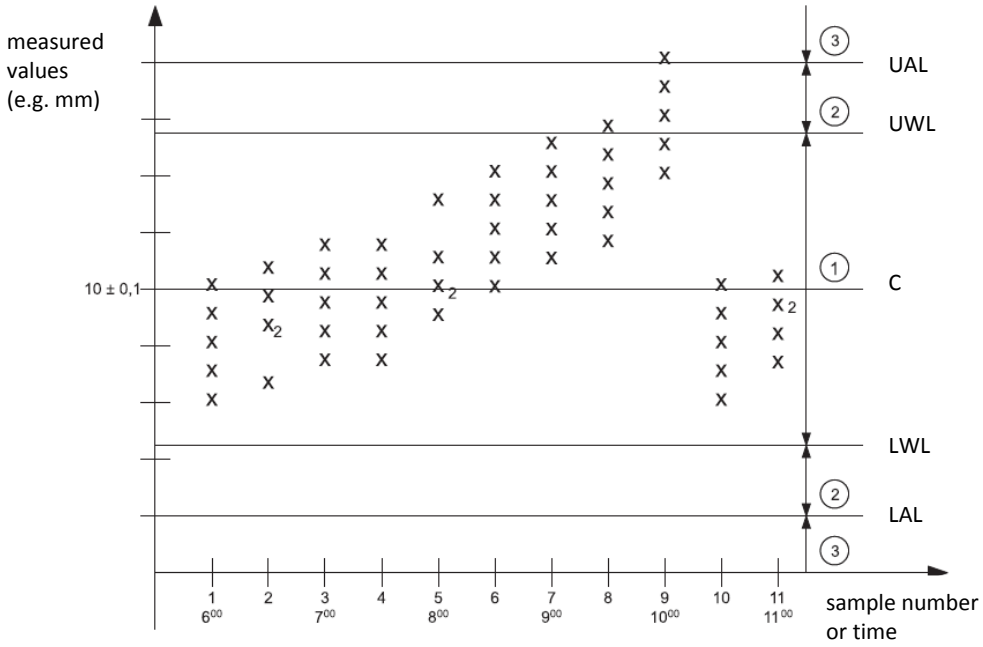
Quality control charts for discrete characteristics require relatively large sample sizes (rule-of-thumb: ≥ 50) and a large number of samples (rule-of-thumb: ≥ 20), in order to detect even minor process changes and make reliable statements about process stability. The sample sizes should also stay constant (a requirement for np- and c-charts) or vary by no more than ± 25 %.

We will limit ourselves to the representations of basic control charts in this section.

Quality control charts for measuring tests (original-values-charts)

For this type of control chart, the target is not to exceed or fall short of the given AL. To achieve this, parts are collected from the current production, as for the preceding control charts, according to the inspection instructions, e.g. 5/30, i.e. 5 parts every 30 minutes.

Figure 2.78: Control chart for the monitoring of measured values (original values)



UWL = upper warning limit
LWL = lower warning limit
C = center line
UAL = upper action limit
LAL = lower action limit

zone 1: Acceptable dispersion range for production process
zone 2: Take action if just one of the 5 measured values crosses the action limit
zone 3: Stop production: Determine and remove error cause. Readjust process and sort out the quantity produced since the last sampling.

Figure 2.79 Shows another example of a possible control chart (average-value-chart with standard-deviation-chart for the monitoring of location x and dispersion s).

Figure 2.79: Dual-track control chart for average and standard deviation

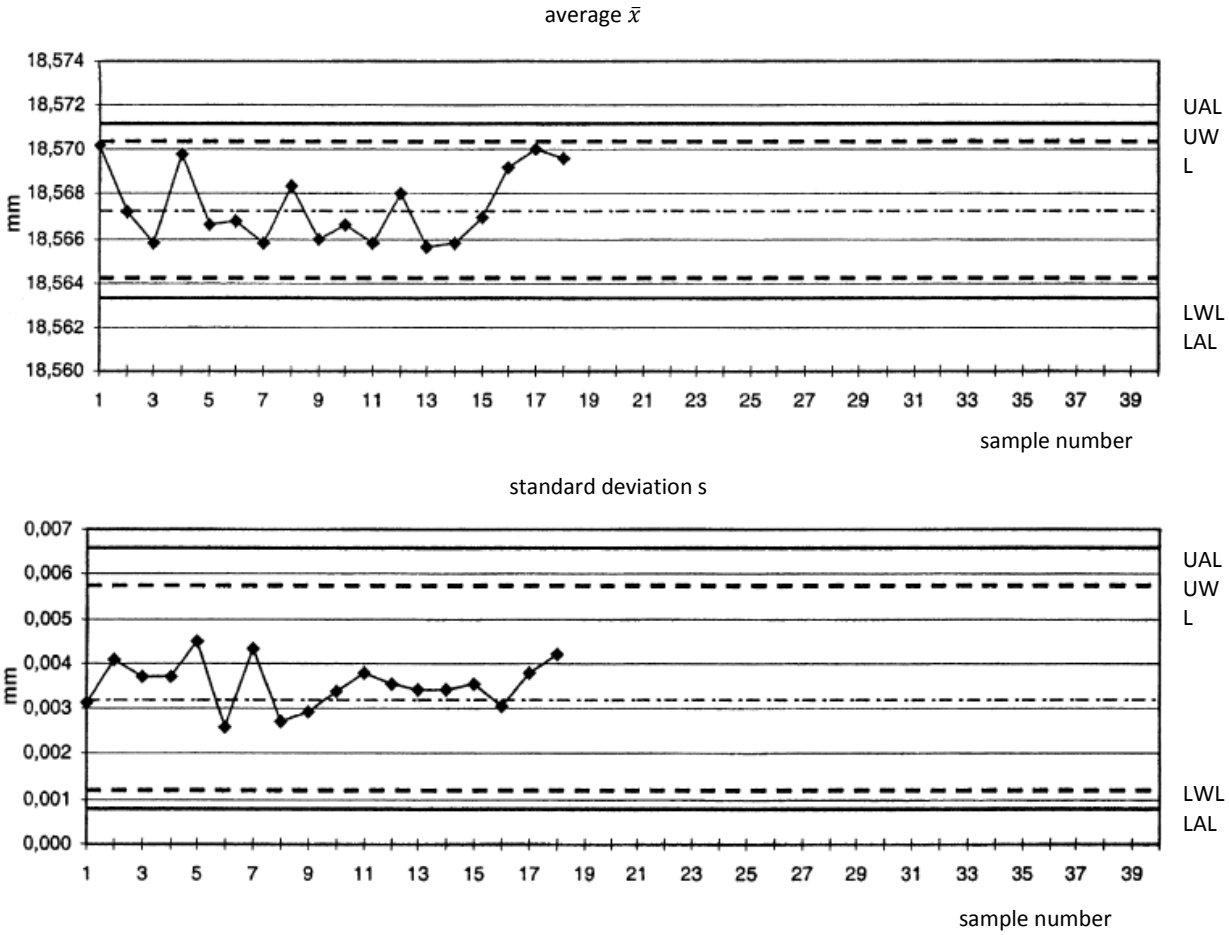
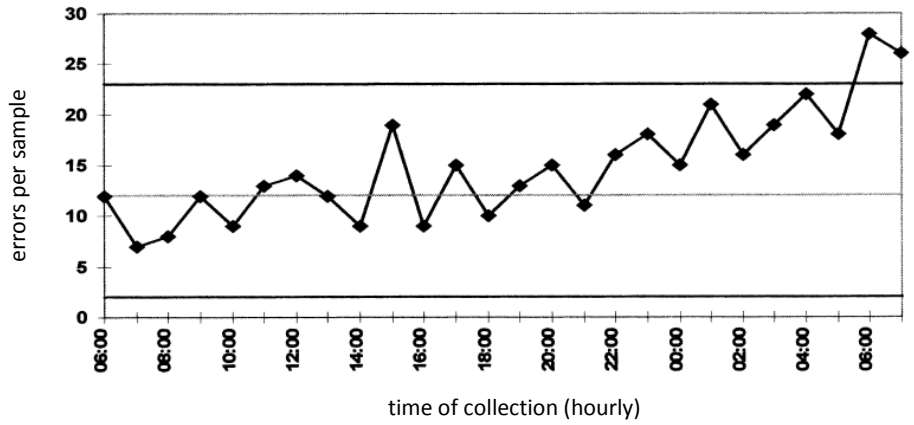


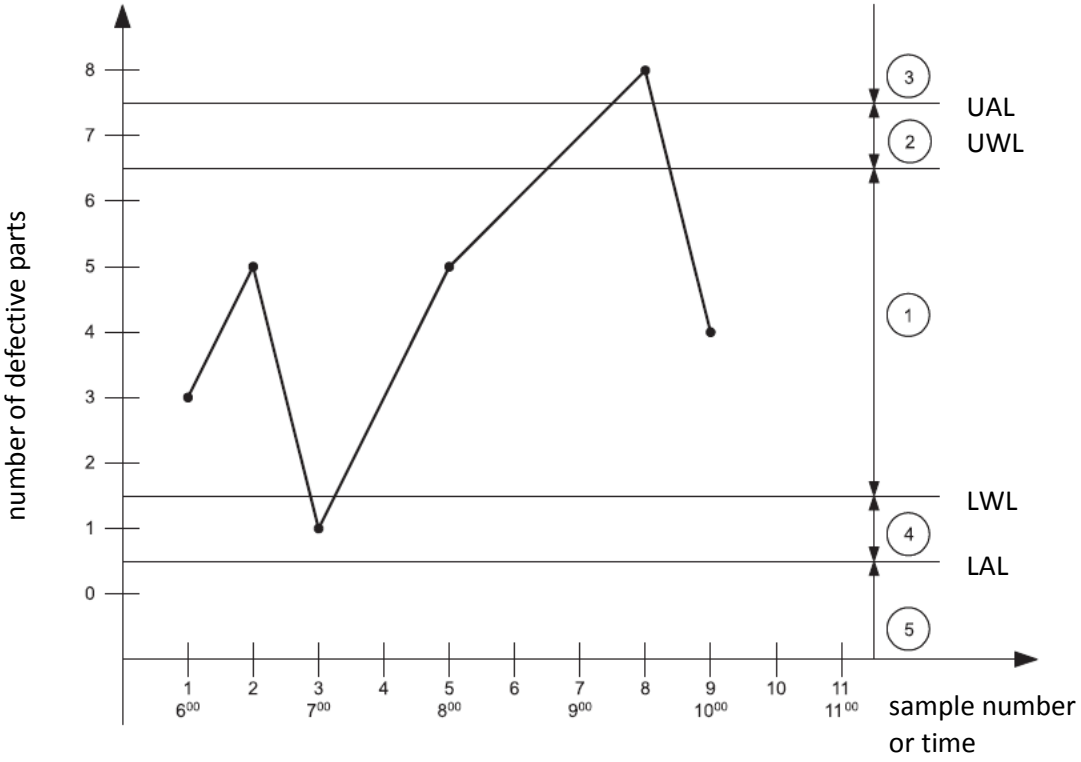
Figure 2.80: C-chart



Quality control charts for attributive testing
This type of control chart also offers different possibilities.
There are, for example control charts for the number of defective parts (x) and control charts for the percentage of defective parts (p).

First, we will take a look at the quality control charts for the number of defective parts (x) (figure 2.81). Samples are taken from the current production at regular intervals. The samples are tested and the results entered into the prepared quality control chart. When, how often and in what manner should be tested is determined by the inspection instruction for the part.

Figure 2.81: Control chart for the number of defective parts (x) (np-chart)

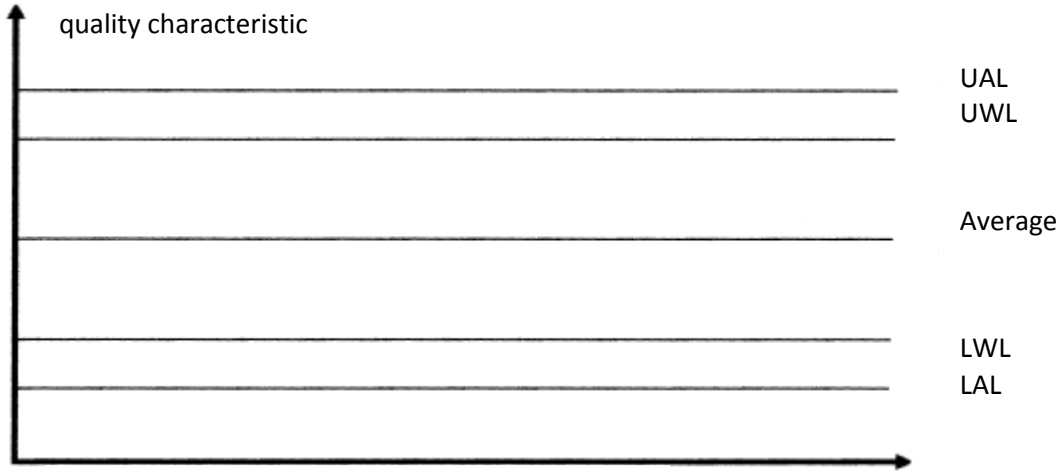


UWL = upper warning limit
LWL = lower warning limit
UAL = upper action limit
LAL = lower action limit

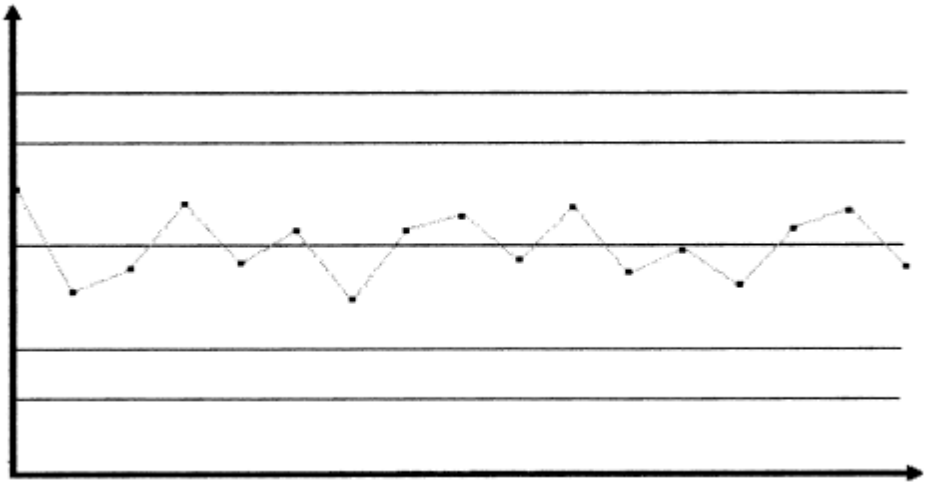
zone 1: acceptable dispersion range for the production process
zone 2: caution zone: test more severely (e.g. Additional samplings), since the production process might have deteriorated
zone 3: Intervene in production process: i.e. determine causes and eliminate them. Readjust process and sort out the quantity produced since the last sampling.
zone 4: caution zone: test more severely (e.g. additional samplings) since the production process might have improved (determine cause for improvement)
zone 5: Production process has improved. Determine causes and maintain them, if possible.

´Capable and controlled processes`

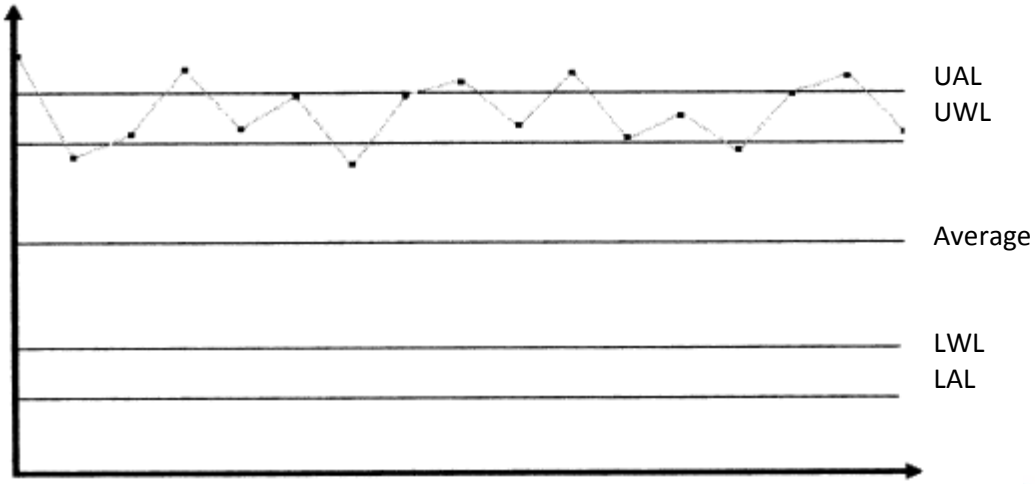
Figure 2.82



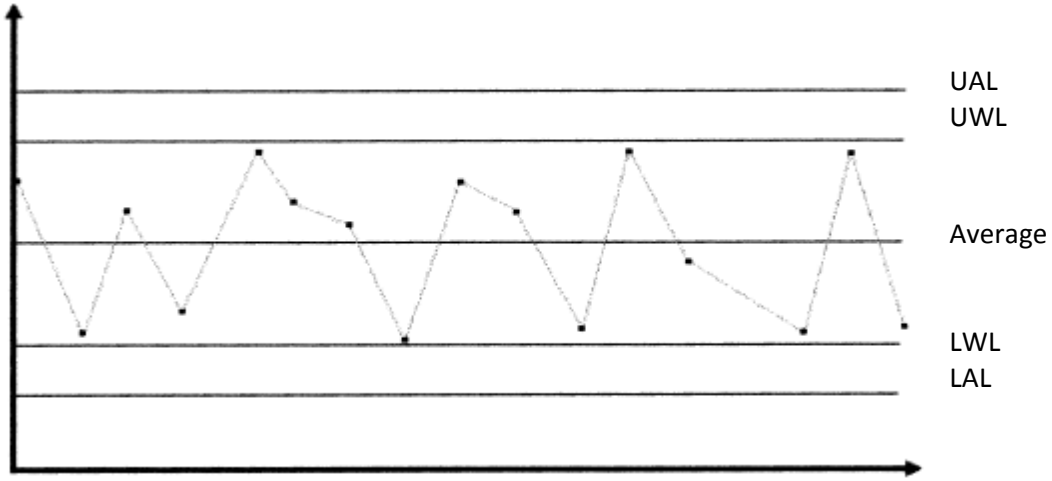
UAL	=	upper action limit	UWL	=	upper warning limit
LAL	=	lower action limit	LWL	=	lower warning limit



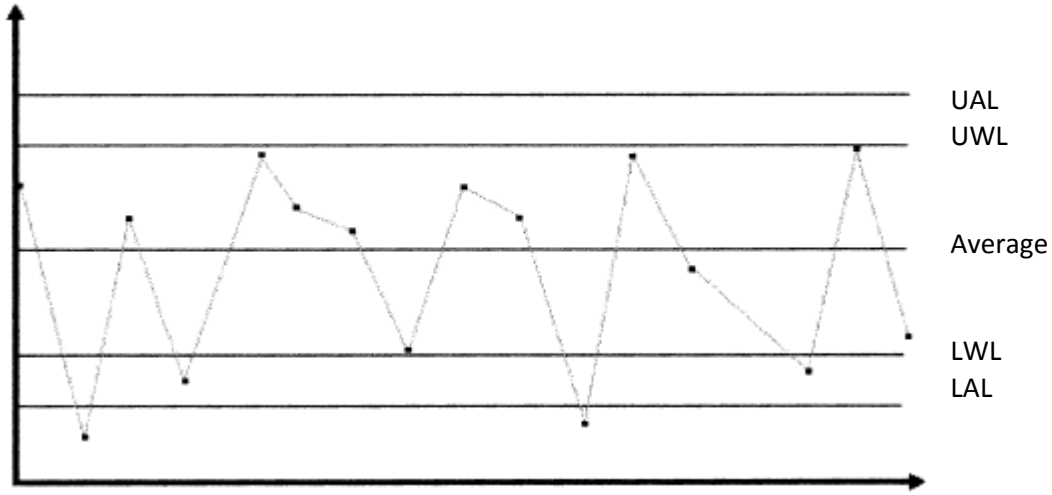
low dispersion (Cp high) = capable process
position centered relative to tolerance limits (Cpk high) = process under control



low dispersion (Cp high) = capable process
position shifted upward relative to tolerance limits (Cpk low) = process NOT under control



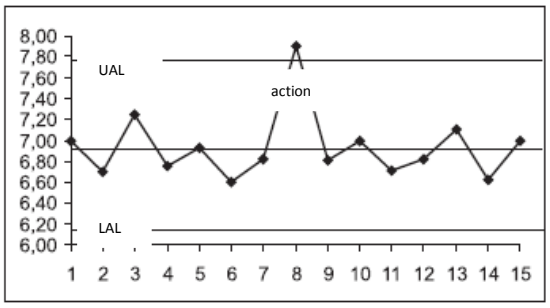
high dispersion (Cp low) = process NOT capable
position centered relative to tolerance limits (Cpk high) = process under control



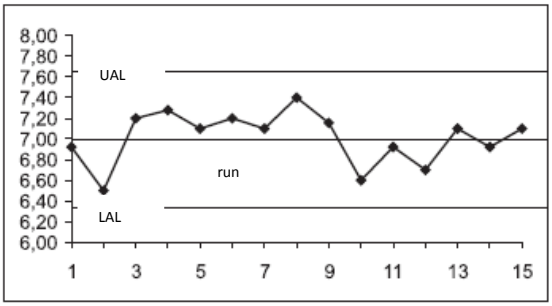
high dispersion (Cp low) = process NOT capable
position shifted upward relative to tolerance limits (Cpk low) = process NOT under control

Stability criteria

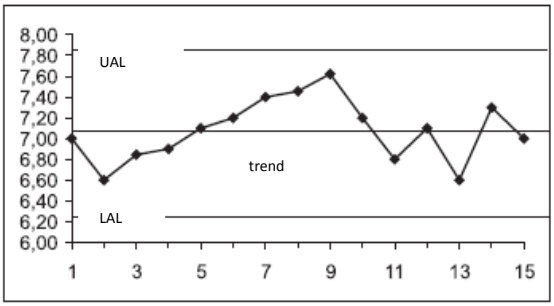
Action limits exceeded
Here the cause can be assumed to be a systematic deviation. The cause has to be analyzed and appropriate corrective measures have to be taken.



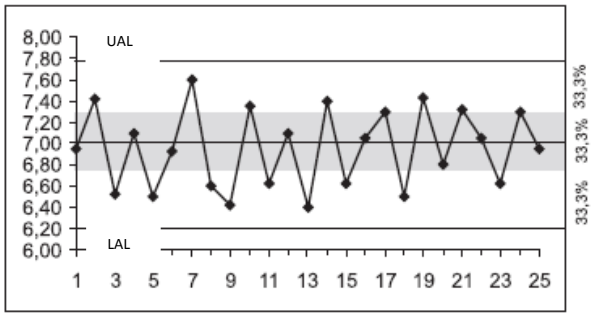
Run
More than 7 consecutive parts above or below the center line



Trend
More than 7 consecutive parts in rising or falling order.



Central third
More than 90 % of the values lie within the central third between the action limits. 40 % or less of the values lies within the central third. Application of these rules has the following requirements:



Normally distributed basic population without fluctuations of the average value. The action limits are derived from the 3 limits of the distribution. At least 25 samples have to be presented for testing.

2.10 Quality audits

Regardless of how well it was designed, every quality control system has to be tested again and again.

A quality audit is the review of a QM-system or its parts. A distinction is made between system-, process and product-audits (s. figure 2.83).

Weak points are revealed, improvement measures suggested and the effectiveness of measures monitored.

Definition:
A quality audit is (lat. ´audire` = to hear; i.e. ´quality hearing`) a systematic and independent evaluation. It assesses whether the quality-related actions and their results meet the preset requirements and standards. It further examines whether the necessary actions were implemented in an economic and efficient manner and to which degree the implementation of the measures is suited to achieve the preset business goal.

Reasons for initiating a quality audit could be:

- customer requests
- customer complaints
- certain quality problems
- routine audits at regular intervals
- new business strategies or goals
- introduction of new products or processes
- relocation of the production process
- training of other sections regarding quality control
- safeguarding the quality capability of a product
- awarding of important contracts to sub-suppliers
- quality cost control, economization
- ratio of testing, prevention and error costs is unfavorable

Figure 2.83: Purpose and basis of different types of quality audits

Quality audit					
System audit		Process audit		Product audit (product oriented)	
purpose	basis	purpose	basis	purpose	basis
Assessment of the effectiveness of a quality control system, through determination of whether the necessary components exist, based on the knowledge of the employees and testing of the practical application of the individual components that make up the quality control system. Also quality functions of other departments, such as development, manufacturing, purchasing, sales.	QM-manual, quality control instructions, contract documentation, management guidelines.	Assessment of the effectiveness of quality control, through evaluation of the knowledge of the employees, adherence to and suitability of certain procedures.	Documentation for the implementation, monitoring and evaluation of the process, personnel qualification requirements.	Assessment of the effectiveness of quality control, through evaluation of a certain number of end-products and/or parts.	Quality guidelines, inspection and production documentation, inspection and production tools, as required by the production process.

Other types of audits are:

- Supplier audit
  Names the affected organizational unit. Nowadays, most often constitutes a system audit. Process or product audits are also possible.
- Internal audit
  The assessment is conducted under the businesses supervision, within its own organizational structure. May be a system, process or product audit (s. figure 2.83).
- External audit
  The assessment is conducted not under direct supervision of the business and not within its own organization (s. supplier audit).
- Follow-up audit
  A check-up on previously documented deviations and, where appropriate, assessment of whether the corrective measures agreed upon have been implemented and are effective, may be a system, process or product audit.
- Re-audit
  A routine and recurring audit. Also assesses deviations documented in previous audit, that were not subject of a follow-up audit,

Basic procedure of an audit

- Preliminary actions
  - management decision and procedure initiation
  - selection and training of auditors and supervisors
  - preparation and announcement of the audit plan
  - determination of a questionnaire
  - preliminary briefing of the persons concerned
  - organizing of the individual audits
  - preliminary assessment of the documentation
- actual implementation
  - questioning and examination
  - evaluation of audit, announcement of results
- follow-up
  - determination of improvement measures
  - implementation and monitoring of improvement measures
  - scheduling of further audits

A complete description of the QM-system is a requirement for a system audit. The preliminary assessment of the appropriate documentation, which is sent or presented to the head of the audit, is of significant importance. This provides first insights without necessitating the elaborate questioning of personnel. In the worst cases, this might conclude an audit with negative results.

Not every step of this procedure has to be processed for every system audit. Depending on internal regulations, a management decision or the questionnaire might be valid for a longer period of time, for example. The details differ for internal and external audits. On the other hand, certification audits conducted by external bodies have other particularities. Therefore, an adjustment to the specific situation is necessary.

To keep the system in order, the use of check-lists and forms for the entire process and all associated documents is recommended.