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Quality management

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CONTENTS

1. TERMS, DEFINITION, BASIS OF QUALITY MANAGEMENT

Quality is an integral part of every product, process or service. It influences our lives without noticing. Quality can generally be displayed in two views:

- **Customer Quality** - It is a set of characteristics that the customer expects from the product or service or that exceeds his expectations.
- **Manufacturer - or supplier quality** - It is a technical set of product or service characteristics. Services are more about the unmeasurable parameters.

1.1. Definition of quality:

The quality of a product or service is defined as: A complex characteristic of marketing, technology, production and maintenance that satisfies the customer through the use of the product or service.

Feigenbaum defined the quality:

The customer does not decide on the quality of the technician or the marketing or management worker. The customer's decision is based on the experience with the product or service in relation to his requirements - which are distinguished between pronounced or not pronounced, conscious or suspected, technically justified or subjective.

Product and Quality

The product is the generally used term for the process output. The concrete output can be the material or immaterial product. Basic quality characteristics are distinguished for both products and services.

Product quality:

The technical execution of the product is assessed. It is desired that the use of the product is intuitive and simple and that it looks good. The product quality requirements consist of:

- Harmlessness.
- Controllability.
- Repairability.
- Maintenance.

- Reliability.
- Durability.
- Functionality.
- aesthetic effectiveness.

Quality of service:

Services are most often influenced by the provider or personnel. Services with their quality requirements are influenced by flexibility, suitable environment, professional qualification, proper handling, availability and reliability.

Quality management:

Quality management refers to organisational attitudes to activities with a focus on quality. A distinction is made between quality leadership and quality management. Quality management means operational management of activities in relation to quality, management ensures quality from a more complex and long-term point of view.

Quality management system:

The basis for quality management systems is provided by international standards, which define the requirements for the management of an organization with regard to quality.

1.2. ISO and standards:

ISO is an abbreviation for International Organization for Standardization. ISO is an international network of standards organizations that coordinates the ordering and publication of approved standards.

More than 16 500 standards have been published, which determine different requirements on the management system, products and services in different industries.

The standards are divided as follows:

- **System standards** - are applied in each area, they are standards that define requirements on the organizational management systems.

Important standards: ISO 9001 - Quality management systems.
ISO 140 01 - Environmental management systems.
OHSAS 18001 - Occupational health and safety management systems.
ISO 27001 - Information security management systems.

- **Technical standards** - are based on ISO 9001, but are more specified depending on the industry.
- **Technical standards** - determine the qualitative product and service requirements. These standards are used by manufacturers to prove to users and customers that their products meet exact standards.

There are other activities in the international environment that take quality support into account and have a legal or voluntary basis:

Accreditation - an official recognition of the suitability of the subject (laboratory, certification organisation) to carry out the specific activities (testing, calibration, product or quality system certification) or the activity at a verified level. In the Czech Republic only the Czech Institute for Accreditation Český institut pro akreditaci (ČIA o.p.s.). may grant accreditation. The Institute is a national accreditation body established by the Government which provides services in the state and private sectors.

ČIA carries out accreditation for the following subjects:

- Testing laboratories (ČSN EN ISO/IEC 17025:2005).
- Health laboratories (ČSN EN ISO 15189/2007).
- Calibration laboratories (ČSN EN ISO/IEC 17025:2005).
- Certification bodies that carry out the certification of quality systems, environmental management systems, information security management systems, food safety management systems and the sustainable forestry system (ČSN EN ISO/IEC 17021:2011).
- Product, process or service certification bodies (ČSN EN 45011:1998)
- Personal certification bodies (ČSN EN ISO/IEC 17024:2003).
- Inspection bodies (ČSN EN ISO/IEC 17020:2005).

Certification - a process that proves compliance of the system or product, possibly service, characteristics with the requirements (including technical) or specification. This means that the quality is proven at least as "**at the usual level**".

CE marking - comes from the Act on Technical Product Requirements (No. 22/1997 Coll.). The CE marking is therefore not a seal of quality, but shows that the marketed product meets the special requirements according to the law. The CE marking must be affixed as a label to products sold in EU countries. This only applies to products that are not covered by the so-called "New Approach" principles.

2. HISTORY AND FATHERS OF QUALITY MANAGEMENT

The first mention could already be found in Hammurapi's Codex, issued by King Hammurabi, which reads, for example: "*If a builder builds a house for a citizen, but does not carry out his work firmly, the house he has built collapses and thereby kills the owner of the house or his son, this builder or his son will be killed*".

In ancient cultures, one could also understand the privileges of being allowed to brew beer as requirements for quality management.

With the development of trade, the function of the inspector has become another aspect of quality management, especially where the weight and dimensions of the goods were checked. With the development of the industry, the concept of quality has changed significantly. The first independent quality departments were founded. The skilled employees check the equality of the certain delivered product criteria with customer needs, requirements and interests. These departments were often called "technical control department" and specialized in:

- Preparation of technical specifications.
- Product controls according to specifications.

Over time, highly developed countries have concluded that only the technical control does not always lead to the perfect fulfillment of customer needs and establish that the quality:

- is part of every stage of the manufacturing process,
- is related to physical and non-physical production,
- not only the products, but also the processes,
- is influenced by humans,
- is related to employee and company motivation,
- without scientific methods and attitudes.

2.1. Fathers of Quality Management

The increase in production after the First World War brought the emergence and development of statistical theories used in industrial practice. The American professor W. A. Shewhart has described the basis for controlling the manufacturing process using statistical theories in his book "Statistical Method from the Viewpoint of Quality Control". During the Second World War and the post-war period, manufacturers turned their attention to their own production and technical input and output control.

Have customer requirements for products and services started to grow significantly. Customers have also begun to consider other criteria such as appearance, reliability, economy and comfort. At the same time, customer service requirements have begun to rise. The Japanese strategists and managers have understood the market situation most quickly.

Dr. Edwars Deming

An American statistics specialist who was involved in the renewal of Japanese industry after the war and who distinguished himself in statistical quality management in Japan thanks to this activity. That is why the Japanese National Quality Award was called the "Deming Award". One of its core ideas, for example, is the opinion that the customer determines what is of high quality and what is not. Furthermore, he has continuously improved the quality of his products and services. He was basically against the "Zero Defect" movement. Thanks to Deming and the development of the basic improvement tool one can learn about PDCA cycle (called also as Deming´s quality tool). The instrument is a starting point for many ISO standards.

Prof. Josepf M. Juran.

Juran was Deming´s the closer co-worker in Japan and the founder of the research and consulting base for quality management, so-called Juran´s Institute. He said: "If the customer does not find a defect on the product, the product is of high quality". He also worked with the idea of **quality trilogy**, which consists of quality planning, management and assurance.

Prof. Kaoru Ishikawa

Ishikawa studied at Tokyo University, where he later worked as a professor. He was one of the members of the Japanese Union of Scientists and Engineers. Ishikawa is the author of the Fishbone diagram.

Dr Genichi Taguchi

He disseminated the static methods through a new attitude to experimental work in the pre-production stages of product and service design. His attitude is known as the experimental interpretation method.

Phil Crosby

Philip Bayard Crosby was of the opinion that quality care could be useful for the company but not loss-making. Between 1965-1979, he developed a quality system at a large international company ITT and founded a special training and consulting institute in the USA, which propagated complex quality management with an emphasis on the human factor.

Prof. Dr. Walter Masing

He was one of the professionals specializing in electronic management systems and is also one of the founders of the non-profit organization EOQ (European organization for quality), which awards the prizes.

Armand Vallin Feigenbaum

The idea of TQM came from Feigenbaum during his studies at the Institute of Technology in Massachusetts, where he finished the first edition of his book "Total Quality Management". He was also founding president of the International Quality Academy. He said that quality affects the entire industrial manufacturing process and control is required at all key points of the manufacturing process.

Prof. RNDR. František Egermaer, DrCs.

Egermaer was one of the fathers of quality management in the Czech Republic, who dealt with the application of static quality management methods, especially in Škoda Pilsen. He was involved in the establishment of the Czechoslovak Society for Quality.

PhD Dr. Anežka Žaludová

After the Second World War, Agnes Žaludová (born Waddell) was engaged in the application of static methods, especially in mechanical engineering. Since 1946 she worked in the State Research Institute of Mechanical Engineering. She was one of the founders of the Central Commission for Quality of the Czech Association of Scientific and Technical Societies ČSVTS (Český svaz vědeckotechnických společností), the Committee for Quality and Reliability and also the Czech Society for Quality ČSJ (Česká společnost pro jakost).

2.2. Concept of quality management in Europe and the world

Japan's success led other industrial societies to turn their attention to quality in the 1970s.

In the early 1980s, the International Organization for Standardization - ISO Technical Commission ISO/TC 176 - appointed the Commission to elaborate and present the ISO 9000 series of standards for quality management, which were approved in 1987. These standards became part of the national standard systems in the majority of industrially developed countries. They were revised in 1994, 2000 and 2008-9. The 2009 revision had a fundamental character and clearly focused the standard requirements on meeting customer needs and requirements and on process management and improvement.

Compliance with standard requirements is practically verified during the certification process, when specialized agencies control organizational activities and issue corresponding certificates. These certificates show the customers that the quality standards in the organization are respected and fulfilled. In order to achieve the company's success, other possibilities were sought.

Another way is the philosophy TQM - Total Quality Management. TQM is more a way of thinking about organizational goals, processes and people, including ethics and corporate culture than a guide to management performance.

At the beginning of the 1990s, the European Foundation for Quality Management (EFQM) introduced the Excellence Model, which serves as a recommended form for organizational management in the corporate sphere as well as in public services. The model can be used as a methodological tool for improving managerial practices and a summary of criteria for own assessment.

3.DIMENSION OF QUALITY, CUSTOMER ORIENTATION

3.1. The importance of the customer

A customer is the one who buys a product from us. Customers are divided into two groups:

- **External** - users, wholesalers, consumers, retailers.
- **Internal** - a department in a company (e.g. a customer of a warehouse could be the production in the company, since the output from the warehouse is taken by the employees from production).

To collect information on customer satisfaction, first select the external customer group. Of course, it is also possible to draw attention to the satisfaction of the internal customer group. In the first place in the system measurements are the measurements of customer satisfaction and loyalty. At the moment there is a high competition and companies are fighting for every customer.

Companies try to attract customers with extra services, news and innovations. The aim of the companies is to arouse the interest of potential customers in various ways. At present, customers want to have their desired products faster, better, cheaper and with a high number of additional services.

Companies naturally want to meet their customers' needs. This could ultimately lead to loyalty. A satisfied customer does not necessarily have to be a loyal customer and vice versa. So it does not mean that if a customer is loyal, he is automatically satisfied. It may be that the customer is simply limited by a greater distance of substitution products and services. An example of this would be a local shop in a small village, where the inhabitants regularly come because it is not worthwhile for them to go to the distant city for smaller purchases.

Customer satisfaction = a complex of feelings created by a difference between the requirements and the perception of the reality of the customer.

The customer only perceives the real value of what he has gained after shopping. The comparison of the original requirements with the real value then leads either to the satisfaction or dissatisfaction of the customer.

There are three states of customer satisfaction:

- **Customer satisfaction** - the value achieved exceeds the customer's needs and expectations (rare). One could also say that it is a condition where the product exceeds customer expectations.

- **Full Customer Satisfaction** - arises from a full match between needs and expectations. The customer feels that his requirements have been met by purchasing and using the product.

- **Limited satisfaction** - the perceived reality does not match the original customer requirements. The customer could be satisfied in a certain way, but the satisfaction is lower than in the above mentioned conditions.

The level of customer perception that can be measured determines the customer satisfaction rate. KZR = f(X), where KZR is a measure of customer satisfaction rate and X defines the difference between requirements and real value. A high customer satisfaction rate is a guarantee of customer loyalty. Many companies think that if they have not received any complaints, it means that the customers are satisfied. But this is not true, because a complaint is only the peak of the glacier of dissatisfaction. Only 4% of all dissatisfied customers complain.

The main reasons of the lower number of customers complained about:

- Convenience of customers - to higher decency, modesty and consideration,
- Too short a warranty period for some products and services,
- the fact that the cost of the complaint is higher than the price of a new product,
- a large distance between the place of purchase of the inferior product and the place where the defect occurred,
- the useful life of the product,
- the age of the customer (the most complained about by customers between the ages of 25 and 45), etc.

Customer requirements and satisfaction characteristics

The determination of customer requirements and satisfaction characteristics is critical to the correct results of customer satisfaction measurement.

The needs represent the benefits that a given product should provide (e.g. the need for transportation to work). Then there are also expectations and requirements, which refer e.g. to time, completeness, frequency, etc. (e.g. transport to work daily until a certain time).

For each product or service there **could be three requirement groups that influence the customer satisfaction rate** (according to Kan):

- **Bonbons** - a small group of requirements - The customer is not met or he does not use them, but it does not reduce his real satisfaction. On the contrary, the customer experiences something pleasant and special through the fulfilment and performance of these requirements.

- **Obviousness** - a large group of requirements related to the performance of the given product, e.g. a vacuum cleaner is expected to remove dust and dirt from the floor, etc.

- **Necessities** - a small group of requirements which are characterized by the fact that in the best case they do not lead to customer dissatisfaction. These requirements may be related to legislative requirements, such as noise level, etc.

Satisfaction characteristics = measurable and unmeasurable characteristics which ensure that customer requirements are met and which directly determine the perception rate of the given product or service.

In practice, two methods can be used to determine customer satisfaction characteristics:

- **Method of developing quality features** - active members do not represent real or potential customers, but they are employees of the company who produce and deliver the given product. Employees are asked to define customer requirements (or satisfaction characteristics). This requires an experienced facilitator who can use brainstorming, affine diagrams, or any other method.

- **Method of listening to the client** - working with a sample of current or potential clients. It is not important whether you are dealing with your own customers or customers of a competitor.

Methods suitable for listening to the client:

- **A discussion in focus groups** - a group of preferably 6-12 current or potential clients with whom a discussion is conducted with the help of a moderator. The aim of such a discussion is to identify a group of customer requirements or quality characteristics. The discussion should not last longer than two hours and the moderator should record all results of the discussion.

- **Individual interviews** - The questioner asks questions to individual participants according to pre-prepared schemes (questionnaires) so that at the end, if possible, a complete list of customer requirements (satisfaction characteristics) is

The interview should not last longer than one hour.

- **Questionnaire method** - is a typical method of indirect contact with all its advantages and disadvantages. The pre-printed questionnaire is sent to a sample from customers. However, the questionnaire structure should in any case enable a uniform evaluation of the data. At present, there are even companies on the market that create questionnaires for other companies. The Internet can then be used to quickly transfer information from customers to companies.

- **Critical Events Method** - this is the best way to determine customer requirements and customer satisfaction characteristics developed by Flanagan. The term "critical event" refers to a completely concrete statement of a customer, which refers to a positive or negative experience with the use of a given or similar product (it is not enough to say that the service was not helpful - it is necessary to talk about the specific behavior of the service).

Every critical event should have the following basic characteristics:

- it should describe the behavior of the given product or the behavior of the person providing the product,
- it should be specific, i.e. it should describe only one particular aspect of the behaviour,
- it should be clear in order to avoid a different interpretation,
- it should be based on someone's experience describing the event.

4. PROCESSES AND PROCESS SETTINGS

4.1. Process

Process = comes from the Latin word "Processus", where you can express its meaning with the words "proceed" or "develop".

A process is a totality of repeated activities, which start somewhere and end somewhere, but are nevertheless constantly repeated in space and time. A process creates added value and consumes resources (converts input into output).

The processes therefore do not only include an adjustment of the rules for the course of individual activities, but they also accept observance of duties and diversify the responsibilities or powers.

Every process involves

- its name so that it is clear what the exact process is.
- the purpose for which it was created,
- its owner, who is responsible for proposing, improving or monitoring an entire process.

Sometimes there may be a brief interruption when another process occurs in a current process. In order to improve the company and its processes, processes should be identified, measured and controlled.

PROCESS is therefore an activity that converts inputs into outputs. **Regulators** (regulators) are used and the probability of error has to be accepted (**disturbances**).

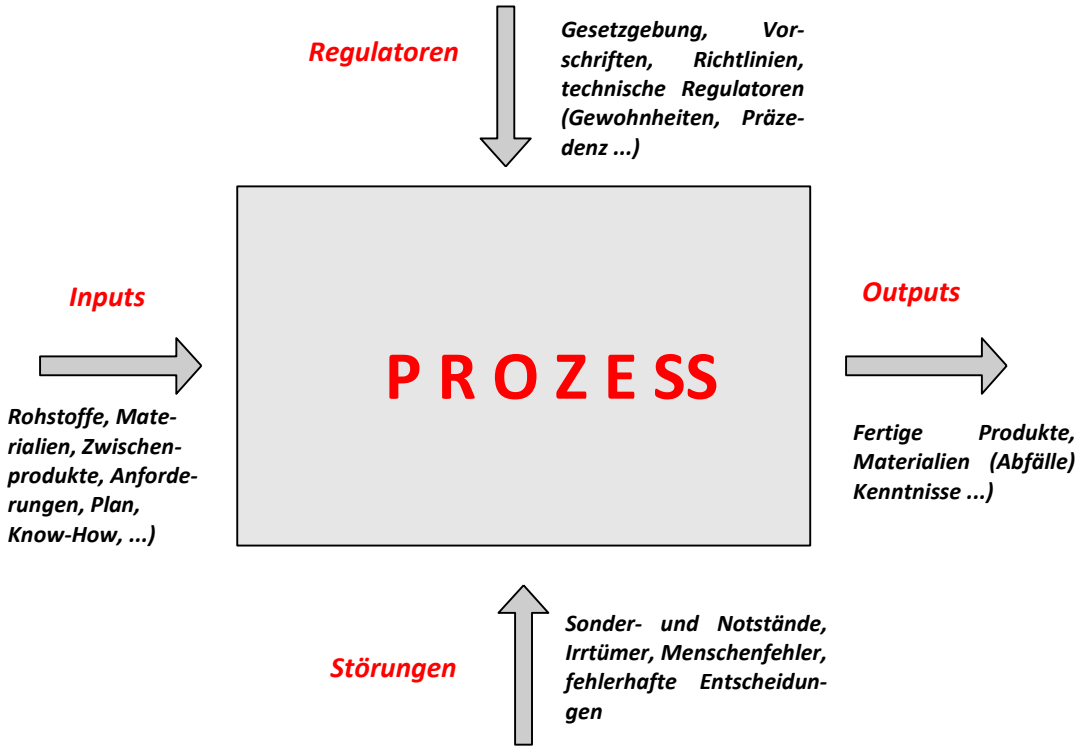

Bild 1 - Process
Source: Author

Controlling processes and activities in the organization is one of the basic activities of managers. Processes are carried out, observed, improved, shortened, sometimes extended, complicated or slowed down. Processes are omnipresent, no matter if they are good or bad and no matter if you leave your fate to them or if you control them with the help of process control or project management.

4.2. How to control the processes?

The control measures are different in different organizations and systems. The best thing is when "everyone is aware of what they should do", when processes seem to "**work by themselves**", or even better when the processes **improve** by themselves. However, this can only happen through a well organized, properly composed team of people with a common opinion and through properly working technologies. People and technologies influence the functioning processes the most. The basis of managerial work in controlling processes is therefore: a suitable selection of technologies and people, their organization, i.e. compilation of activities, technologies and processes, compilation of all activities into an organizational structure and assignment of activities to concrete employees at concrete workplaces. Daily work therefore includes coordination of activities and processes and solution and decision on special situations that occur. The ability of the organization to continuously improve processes plays a key role. This is not possible without people, because the suggestions and improvements themselves

should always come from people.

The control levels can best be described with the help of control levels according to the CMM model:

- **0 - not occurring control**: Processes and their control are quite chaotic
- **1 - Initial**: Processes are realized adhoc.
- **2 - Repeatable**: A certain discipline is observed, which is necessary for the execution of the repeated basic processes.
- **3 - Defined**: Processes of the organization are documented.
- **4 - Managed**: Processes are controlled and performance is measured using KPI.
- **5 - Optimized**: Processes are permanently improved, there is an innovation cycle for processes and control.

What settings are there for process control?

There are three basic settings for controlling **activities and processes in an organization**.

- **Function setting** (functional control) - this setting was already defined in 1776 by Mr Adam Smith and is based on traditional division of labour according to specialisation. It is based on the division of work into the simplest activities, so that these activities can also be carried out by unqualified employees. Functional adjustment leads to division of labour with a focus on simple tasks. And it leads to distribution of work between units divided according to their expertise (functions).

- **Process adjustment** (process control) - This adjustment focuses on the activity flows that cross the organisation - i.e. the processes. These are mainly repeated processes. Compared to the traditional vertical functional attitude, which is based on designs and changes in formal organizational structures, the process attitude is more horizontal - to the processes. In the 90s of the 20th century, process adjustment became a big hit. During this time, there was intensive discussion about processes and reengineering, among other things thanks to the introduction of modern information and communication technologies, which made thorough process changes in the organizations possible.

- **Project Setting** (Project Control) - This type of setting is used for projects. A project is a unique process in which an optimal solution can only be found during implementation. Compared to the process setting, which aims at repeated processes, the project management is aimed at unique processes.

5. DOCUMENTATION OF THE QUALITY SYSTEM AND QUALITY MANAGEMENT SYSTEM ACCORDING TO ISO 9001

In organizations there is a written form of various requirements or requirements for inclusion of information. The international standard ISO 9001 for quality control even includes the requirements for keeping internal documentation. It requires certain documents that are necessary as well as requirements for the content of the documented procedure. ISO 9001 requires a total of 6 documented procedures. These are the following procedures:

- Document management.
- Management of entries.
- Internal audit.
- Control of the non-compliant product.
- Improvement measures.
- Precautionary measures.

Procedure - is a specified way of carrying out an activity or a process. Processes cannot or do not need to be documented. If a process is documented, the term "documented procedure" is used. If the term "documented procedure" is used in any international standard, it means that it is required in order for the procedure to be established, documented, applied and mainly complied with.

The application of the documentation contributes to the following points:

- to achieve compliance with customer requirements and to improve quality,
- to ensure appropriate training,
- for repetition and pursuit,
- to ensure factual evidence,
- for effectiveness evaluation and continuity of the degree SJM

The scope of the documentation was not strictly determined and differs in terms of:

- the size of the organisation,
- the difficulty of the processes and their effect on each other,
- the professional skills of the employees,
- customer requirements.

The corresponding documentation can be kept either in printed or electronic form. The name of the documentation on quality is usually chosen according to the habits of a particular organization. The most common types are as follows:

- Quality manual,
- internal communications,

- Orders, instructions,
- Procedures,
- Forms,
- Work procedures.

Keeping documents includes activities that are necessary for the following points:

- approval of the documents from the point of view of adequacy of the documents before entry into force,
- review documents and activities related to the updating of documents prior to their re-approval,
- identification of changes in documents and current document versions,
- ensuring the accessibility of the documents in the place of use,
- ensuring legibility and easy identification of documents,
- preventing the use of outdated document versions if they have been preserved.

5.1. Guideline ISO/TR 10013 - Guideline for the documentation of the quality management system

The range of documented procedures includes the following:

- The structure and format of the documented procedure,
- Content of the documented procedure (name, purpose of the document, its subject matter, clarification of responsibility and competencies, job description, sample entries),
- Review, approve and control the documented procedure,
- Identification of the changes.

A documentation pyramid is considered a common occurrence. At each document level there are still forms, such as tables, which are used to create a protocol. Furthermore, the pyramid contains records that can be used for each level. The forms and patterns are used on the one hand to standardize the given record and on the other hand to simplify work, clarity and reporting. For example, an employment contract template allows a personnel officer to conclude new contracts, or a table template for a non-

product results in such a table looking the same for all shifts. The records promoted by the standard and the records defined by the company are used to search for specific information. Under Recording one could also imagine an entry in the information system.

Each pyramid level has its own forms and patterns from which later emerge records that serve the company. The first part concerns the whole company. The second part concentrates on the subdivisions of a company, on individual activities. The third part relates to the areas of expertise of the individual procedures.

Figure 2 - Quality Manual
Source:: Zvoneček, F., Zídková, H. – upravil autor
Legend: Quality manual, work rules of an organization, II.Process guidelines,documented procedures,Process descriptions, Guidelines III. Working procedures (technological instructions, Job descriptions, laboratory procedures, methodology,

5.2. Quality manual

It is a document in which the quality management system of the whole company is specified. This manual may include the following points:

- Short history of the company.
- Company declaration on the production quality policy.
- Declaration of the managing director about the personal responsibility for the quality of the company.
- Scheme of the organizational structure.
- Conception of the quality system.
- Scope and type of duties of the departments.
- Types of documents and documentation of procedures concerning the whole scope of activity.
- Number, course and type of updating.
- Types of control and testing and their scope.
- Method of processing control results, use of static methods.
- Quality recording.

- Internal controls.
- Improvement measures and their evaluation.
- Change slips, etc.

Guidelines (process descriptions)
Represents a complete set of actions that happen for one purpose. Often the guidelines can change the process descriptions. In the context of guidelines one usually describes also complete procedures, which include the obligation documents for individual procedures.

Working procedures
They can also be described as technological processes, activity descriptions or technical production processes: It is a clear description of what, how and who should do something. The given activity is described in detail.

6.INSTRUMENTS FOR QUALITY IMPROVEMENT

Juran described the improvement process, known as the "Quality Trilogy", which management uses as the triad of activities:

- **Quality planning** - processes from identification of customer needs to documentation release for the product (quality cycle can be used for definition).

- **Quality management** - a short-term and operational quality management, which maintains that the processes will not deviate from the planned level. It is important that everything runs as planned and there is no difference between documentation and practice.

- **Quality Improvement** - constantly reach new level of quality assurance through analyses, tools for improvement, inter-controls, customer feedback, incoming material control.

Currently, companies are struggling with various shortcomings, for example: passive complaints, production delays, etc. As the companies try to overcome the shortcomings, they return to the level already reached. The improvement depends on the detection of these defects and their elimination. The reasons for improvement can e.g. come from this:

- Customer satisfaction measurement.
- Complaint and difference analysis.
- Process and result process analysis (sales reduction, cost increase, customer loss).
- Market loss and market requirements analysis (comparison with the competition).
- Benchmarking results (comparison with the best on the market), results of internal and external audits (certification, customers), self-assessment.
- Discussions with employees.

Seven basic quality instruments:

- Development diagram.
- Data collection, basic requirements and organization of the data.
- Histogram.
- Cause-effect diagram (herringbone diagram).
- Pareto diagram.
- Scatter chart.

- Quality control chart.

6.1. Development chart

It is a universal tool and allows a description of any process:

- Development
- Manufacturing, technological process
- Project planning, management

The development diagram simplifies the extensive description of the procedures and operations in a graphical form so that the internal connections in the processes are understandable and the communication between the departments is better. It should be understood how the process works and at the same time it should discover the problems and where they arise. Development diagrams are easy-to-understand diagrams that show and explain individual steps in the problem or process.

6.2. Data collection

Data collection does not solve a problem, but is a prerequisite for the solution. There are different entry forms for the collection, mostly the form is used as instrument. This allows to record the information.

The entry is:

- needs as input for analyses.
- the proof.

The data collection serves for the analysis and at the same time for the formation of statistical overviews.

It provides the company with information about processes and problems and is used for monitoring and measuring processes and products (ISO 9001).

Basic data types:

- **Quantitative** (measurable) and **qualitative**.
- **a control result** - based on a random **selection control**.
- **simple won** or **tests** - time and financial demanding.

6.3. Histogram

There are different types of probability fission:

- **uniform splitting** - one can cite as an example dice throws. Here there is equal probability for all six numbers

- **normal splitting** - normal layering of real values at target value

The histograms help to assess the processes influenced by the random and precisely defined causes.

6.4. Cause-effect diagram

Ishikawa diagram is often referred to as herringbone diagram. It is a graphical form of relationship between cause and effect. For cause splitting, Shewhart's process view (machines, methods, environment, material, measurement, people) is used.

Diagram construction:

- Summary of all causes (brainstorming) - potential as well as current.
- Identification of the main categories.
  - Cause assignment to the decomposition - cause → Subursache.
  - Team assessment of cause and connection adequacy.
  - further causes.

6.5. Quality control chart

The quality control chart consists of a normal probability split. If the process has a normal probability fission (i.e. the histogram is in a bell shape), the control chart can be used. Static regulation is a preventive approach to quality management. The quality control chart is a basic graphical instrument of the statistical control process, which enables to assess the statistical process controllability. The statistically controllable process is a process that can only influence the random causes of variability. The quality control chart enables the effect of the random causes of variability to be distinguished from the precisely defined causes.

Variability of the manufacturing process is divided into two types:

- triggered variability by random causes,
- variability triggered by precisely defined causes:
  - unpredictable defined causes - do not represent a natural process flow and should be eliminated
  - predictable defined causes - their effect is determined by the physical core of the exact process (a tool is blunted by machining, a filter is clogged during filtration, etc.). Such causes can be limited or eliminated.

6.6. Scatter diagram

Shows dependency and confirms independence. The scatter chart helps to reduce the risks and to compare the interdependence of two phenomena.

The dependency is:

- stochastic
- functional (physics)
- Correlation coefficient - most used: Comparison of a graphical result transfer

The scatter diagram is an instrument of quality management that can clearly help, for example, with process management.

6.7. Pareto diagram

The diagram determines the most important problems. It is about a thought of Italian economist Vilfredo Pareto, who at the beginning of the last century found out that 80 percent of the national income is formed by 20 percent of the population. The rule 80 x 20 is also used somewhere else.

7. BENCHMARKING AND BRAINSTORMING

7.1. Brainstorming

Brainstorming is a group creative technique. An advertising employee Alex Faickney Osborn was the first to come up with the idea in 1939. It's about a situation when a group comes together, about new ideas about the area of interest. There are loose rules so that participants can think freely to create new ideas and solutions.

Brainstorming Definition:

- Generation process of new ideas.
- Conference technique in which a group tries to find a solution to a concrete problem with the help of the procurement of new ideas - Alex Faickney Osborn.
- Brainstorming helps to find new ideas with less effort.
- Brainstorming helps to generate new ideas that can be used in product, service and process development.

Most of all it combines individual and group brainstorming. The goal of brainstorming is to eliminate all limitations and stimulate new ideas:

- **pleasant atmosphere** - good climate, well planned meeting ...
- **Quantity is important** - the more ideas, the more likely they are to offer high-quality solutions.
- **no criticism** - no limitation, no criticism that can slow down ideas
- **all ideas are welcome** - imagination welcome, ideas out of frame, regardless of reality, logic, meaning
- **combine and improve already existing ideas** - "1+1=3", suggestions come from a team collaboration
- **mutual inspiration** - mutual stimulation and stimulation of new ideas
- **all participants are equal** - boss's idea is not better junior idea, the goal is the idea itself

Brainstorming step-by-step:

- **Group formation** - the good atmosphere is important. The room should be well lit and prepared, a refreshment and aids available. It is important to consider which employees should

  participate. If the employees are similar opinions, it brings less creative ideas. When everyone is in the room, it is important to name one person (mentor) who will write down all the ideas. All noted ideas should be visible to all participants.

- **Problem** - It is important to define the problem to be solved and to present all the criteria to be met. The goal of brainstorming is to create the most ideas. Everyone should contribute and have an opportunity to express themselves.

- **Discussion** - after an exchange of ideas in the group it is recommended to start a group discussion. The aim of the discussion is to develop ideas further. The most valuable aspect of group brainstorming is that you can connect or develop individual ideas. It is important that everyone participates actively and that no one criticizes ideas.

- **Take action** - when many ideas are collected, it is necessary to sort the ideas and find the best ones. An important step is an analysis. A few tools are used for this - such as affinity diagrams, which can help with an arrangement of ideas.

7.2. Benchmarking

Benchmarking is a method based on systematic measurement and comparison of specific indicators. It is possible to use the method at any management level and for different indicators. The basis is the comparison of selected indicators with other reference values that are either historical (older than 5 years) or can be compared with other reference subjects (with similar departments or organisations). The comparison is only relative. There are no bad or good indicator values.

The term benchmarking has been known worldwide since the 1980s and was helped by Xerox Corporation, which first used benchmarking as a management tool in 1979. Benchmarking is a component of successful American companies under Malcolm Baldrige National Quality Award and has become well known in Europe.

Benchmarking is an identification process "best practice" in relation to the product where the products and processes are included. The search for "best practice" can take place within the department or in other departments. The goal is to understand and

the current corporate or organizational marketplace in terms of best market practice and at the same time identify the areas and tools for better performance.

Successful application includes 4 principles:

- Understand the current business processes.
- Business process analysis.
- Compare your own business performance with others.
- Implement the steps necessary to close the performance gap.

Benchmarking is not a one-off matter. Benchmarking must be a constant activity and part of the ongoing improvement process to be effective. The goal is to keep pace with the competition.

In this method 4 questions have to be asked:

- What has to be compared.
- Who will be the partner/who has successful processes.
- How will the processes be realized?
- How do the processes realize the others?

Stages of benchmarking

- **Planning** - this phase is intended for a plan development of the realization of benchmarking. The key questions are:

    - What needs to be compared?
    - Who will be the partner?
    - What is the data collection method?
    - These phases form a basis for benchmarking.

- **Analysis** - collected data are analysed to provide the basis for data comparison. The questions are:

    - What services do the benchmarking partners offer?
    - What is your own performance compared to the others?
    - Why are they better?
    - What can you learn?
    - How can the instruction be used in your own company?

- **Integration** - In this phase, the objectives are formed that are further integrated into a model process. It must be shown that performance is significantly improved. The key questions are:

- How has management accepted the fund?
- Do the company objectives need to be adjusted based on the findings?
- Are the objectives communicated to all participants?

- **Action** - in this phase action plans to achieve the objectives decided in the integration phase are worked out. The key questions are:

  - Does the plan enable the objectives to be achieved?
  - How is progress monitored?
  - What is the plan for recalibrating the reference levels?

- **Principles** - to maintain legality and honesty, to respect confidentiality of information.

8.AUDIT

8.1. Audit definition

An audit is a systematic, independent and documented process for obtaining evidence and objectively evaluating it, the objective being to determine the extent to which the criteria of the audit have been met.

Internal audits regularly check the level of the current tax system. This means that they check the conformity with the requirements of the standard used and they should confirm that the documented tax system is appropriate and applied appropriately to the business processes. In the opposite situation, the inconsistency is determined and suggestions for improvement are presented and appropriate corrective and preventive measures are adopted. Internal audit is carried out at regular intervals so that possible measures can be applied and it is determined whether:

- it corresponds to a planned arrangement, to the requirements of this international standard and to the requirements of the quality management system established by the organization.
- it has been effectively applied and whether it is complied with.

It is necessary to determine the plan of audits, the creation of entries and the reporting of results. The audit plan should be determined with regard to the status and importance of the processes and areas. These together with the results from the audit of previous audits should undergo the audit, the results will be recorded. On the basis of these records, the management of an organization will then carry out improvement actions and eliminate inconsistencies and their causes.

Audit criteria - a set of individual policies, procedures or requirements used as references.

Audit evidence - Entries, findings of fact or other information related to or verifiable by audit criteria. Audit evidence may be qualitative or quantitative.

Audit Findings - Results of the evaluation of assembled audit evidence against audit criteria. The findings would be described as a match, non-conformance, or opportunity for improvement.

Technical expert - provides specific knowledge or expertise of the team of auditors.

Audit programme - is an audit, or a set of audits, scheduled for a specific period of time

aimed at a specific purpose.

Plan of the audit - description of activities and arrangement of the auditor organisation.

Auditor - a person who is qualified to perform audits.

8.2. Goals of the audit

The main objective of any audit is to establish facts and not errors. This means that an internal audit serves for an effective change that should help the organization to achieve the identified objectives, also taking into account the following points:

- Determine whether the particular organization has a quality system in place.
- Determine whether the documented quality system and its individual elements, processes, products or employees meet the requirements of the relevant standards or guidelines specifying the requirements for the quality system.
- Verify that the actual processes are running continuously and under all circumstances in accordance with the documented system.
- Verify that the implementation of the quality system is effective, i.e. that the quality system meets its main objective - i.e. the creation of conditions for meeting customer requirements.
- Providing a clear and accurate formulation of identified nonconformity, evidenced by factual evidence.
- Reaching proposals for measures or recommendations for improvement.

8.3. Types of audit

1) **Product quality audit** - aims at verifying the suitability to meet the customer requirements of the particular product. This audit serves mainly to determine the actual level of compliance with parameters of functionality, reliability, safety and technical level. Within the audit it is possible to check the packaging according to the customer's specifications and to check the mounting of all type plates.

2) **Process audit** - if the company uses a process approach that is the basis for the correct implementation of ISO 9001, the purpose of the process audit could be as follows: Detailed evaluation of the effectiveness, degree of innovation and suitability of the working procedures and processes resulting in the products. Individual processes - purchasing, sales, production, delivery, development, etc. - are reviewed.

3) **Management system audit** - the aim is to evaluate the level and effectiveness of the management system of the verifying company.

4) **Employee audit** - the company management could eliminate organizational obstacles by means of an employee audit, which prevent employees from improving the application of their skills and qualifications.

8.4. Auditor

An audit is carried out by a person (an **auditor**) who is fit on the basis of his abilities, experience and practice. An auditor must ensure the objectivity and impartiality of the process. An auditor cannot perform his work on his own. Each auditor should have certain skills:

- ethical - just, honest, reasonable

- open to opinions - willing to consider alternative opinions or views
- diplomatic - tactful in attitude towards people
- attentive - actively being aware of the environment
- sensitive - tries to understand the situations
- all-round - adapts to different situations in a ready to strike manner
- tough - aims to achieve objectives
- decisive - in time he reaches the conclusions based on logical consideration and analysis.
- Independent - he acts and acts completely independently.

An auditor should have knowledge in the following areas:

- audit principles, procedures and techniques.
- QMS documents and reference documents.
- Organisational situations.
- Appropriate laws, regulations and other requirements appropriate to the subject area.

8.5. Stages of the audit

Every audit has stages - from planning to defect removal. The individual stages of the audit are as follows:

- **Planning**

The basis for planning is the program of audits. This program is used for the submission of basic information to the persons who will be audited and to the auditors. The criteria may be established within the framework of the programmes.

- **Sources of auditing**

As with other processes or activities, auditing also requires the necessary resources, which top management should ensure to the appropriate extent, so that audits are taken seriously and carried out effectively. The sources for audits are as follows:

- **Organizational sources** - procedures for conducting an audit, preparation time for an audit, schedule for conducting an audit.
- **Human Resources** - the management representative, external and internal auditors.
- **Sources of information** - internal regulations, external regulations, results of previous audits, documents.
- **Financial sources** - funds for external audit, funds for ensuring professional aptitude.

- **Preparation**

The preparation for an audit is the longest but the most important part for an auditor. An auditor must study all documents related to the subject of the audit. These are mainly procedures, guidelines, laws, but also the results of previous audits. If the audit is aimed at evaluation in accordance with the legislation, the auditor must also know the relevant legislation.

- **Performance of an audit**

An auditor shall establish the facts so that he is able to decide in accordance with the requirements of the audit. He seeks evidence to support his conclusions. He takes notes of people he saw in the documents and records presented to him.

- **Conclusion of an audit and processing of the report**

The investigation will lead to the conclusion of an audit. The findings could lead to the following: Disagreement, agreement or recommendations. Disagreements can be divided into weighty (systemic) or small (deviation).

9. SIX SIGMA, LEAN PRODUCTION

9.1. Six Sigma

The **Six Sigma** concept represents the attitude towards management, the basic idea of which is the realization of activities with maximum profitability and maximum customer satisfaction through mastered and appropriate processes. This concept was developed by Motorola in 1980.

The Six Sigma concept can be presented in different ways, e.g. as a progressive approach to quality improvement, defect reduction and cost reduction, or as part of the corporate culture or attitude towards employees.

The following are some of the goals pursued by the Six Sigma concept:

- Satisfy customers and meet customer requirements effectively and effectively,
- to achieve competitive advantages,
- increase profitability, productivity and quality,
- to minimize the variability in product, process and service execution, to maximize the efficiency of the processes,
- Elimination of defects and waste to reduce costs,
- Reduction of operations and processes that do not increase the value estimated by the customer,
- To minimize the corrections and revisions,
- Achieve timely implementation and reduce the duration of the process,
- On the basis of information and objective data and not on the basis of assumptions.

The Six Sigma concept is based on the use of empirical data. The basic scale used in this concept represents the number of defects.

Defect - The occurrence of an unacceptable output, which may be a product that does not conform to the technical specifications.
The evaluation of the results, which were reached by observed transaction and manufacturing processes, also includes the evaluation of the yield.

The yield shows which part of the outputs in the process corresponds to the specific requirements. An ideal yield is 100%. Such a yield shows that all products are corresponding.

There are three types of yield:

- Partial yield.
- permeable yield.
- Total permeable yield.

If one reaches the quality Six Sigma, it means that one does not produce bad products. Through so-called Six Sigma projects the improvement of processes and the reduction of variability is achieved. Such a project can be implemented in 5 phases, which are marked as DMAIC:

- **Define** - Identifying problem areas and identifying the areas to which priority attention should be given.

- **Measure** - the aim is to obtain factual data characterizing the current state and the results obtained.

- **Analyze** - data analysis with the aim to identify and verify the key causes.

- **Improve** - Creating, testing and implementing solutions that address the key causes identified in the analysis phase. This modifies the process to reach an acceptable limit.

- **Control** - evaluating solutions and maintaining positive results through adequate control, standardisation and documentation of working procedures.

9.2. Lean Production

Lean or **Lean Management** is a very comprehensive management method. The term philosophy, which an organization (a company) must adopt, is usually used in connection with Lean. Lean is based on some basic principles. Primarily it is about the effort of an entire organization to constantly improve itself in all areas and to prevent unnecessary **waste**.

The second principle is to satisfy the customer's needs as best as possible, regardless of how you do it. Lean is used with many attributes. It depends on the area in which this philosophy is applied.

- Lean Production.
- Lean Manufacturing.
- Lean Administration.
- Lean leadership.

- Lean Marketing.
- Lean integration.
- Lean Programming.
- Lean Construction management.
- Lean Services.
- Lean Six Sigma.
- Lean Audit.
- and others.

Lean has its roots in Japan in the post-war period, mainly in the Toyota company. It emerged in the 50's of the 20th century as an alternative to mass production in an area that required high flexibility and lacked the finances for expensive investments. The roots of Lean (**Lean Production**) are linked to the **Toyota Production System (TPS)**.

The practical use of the Lean method: Lean is a method that builds on the culture of continuous improvement, employee support, concentration on value stream and increasing this value. It is synonymous with speed, simplicity, clarity, product and service creation without unnecessary activities and stocks, limitation of waste, balancing processes and connecting processes to customers.

10. TOTAL QUALITY MANAGEMENT TQM

10.1. Definition of TQM

TQM is an abbreviation of "**Total Quality Management**", which refers to a complex quality management system. The attitudes were conceived during the second half of the 21st century in Japan. Subsequently, TQM was disseminated in the USA and Europe.

The effort about quality improvement is not only applied to the manufacturing process, but also to the following areas for example: marketing, service, consulting, purchasing, packaging, financing, warehousing, targeted consulting on products that maximally satisfy customers. The basic idea is that every unit that brings added value is a result of customer or supplier performance on certain process operations.

10.2. TQM has some principles:

- Customer orientation - All activities and processes in the company. It is important to form them and to regulate them with regard to internal and external customer needs and wishes. The customer is everyone to whom the work results are sold.

- **Continuous improvement** - At present the main reasons of all positive changes are continuous improvement processes and reaching new level in the organization. Continuous improvement can help to ensure and maintain better competitiveness.

- **Supplier-Customer Process management** - each employee, department or unit provides certain services to internal and external customers.

    - **Internal customer** - is the following operation or process
    - **External customer** - is a buyer of goods or services

- **TOP management support** - binding manager integration. The task of TOP management is to support the appropriate environment where all employees are stimulated to be active and follow TQM principles.

- **Participation of all interested parties** - This principle is closely linked to TOP management support. The quality of satisfaction is influenced by each employee

use of the TQM principles concerns all, all methods, activities etc. Everyone must be aware that their work contributes to the viability of any organization.

- **Process management** - any activity carried out in the organisation, from a technological operation to a sales service. It is a set of interconnected processes.

10.3. TQM Structure

TQM has three main bases:

- **binding integration of managers** - quality policy, potential, organisation, training,
- **Quality system** - ISO, audit, customer requirements,
- **Quality instruments** - FMEA, SPC, quality costs, problem analysis, static methods

TQM building blocks

The principles are similar to those used in quality management according to ISO 9000. The principles are used daily in practice:

- Leadership based on goals,
- Customer orientation of the entire organization,
- Internal and external supplier-customer relationships,
- Programs of zero percent error,
- Work in processes,
- continuous improvement with measured quantities,
- Involvement of all employees,
- continuous training and education,
- regular management control.

10.4. TQM cornerstone

- **Customer orientation** - All activities and processes in the company. It is important to form them and take into account customer needs. The customer is everyone to whom the work results are sold.
  It is important to act in the same way with all customers. The present and future requirements must be considered. The requirements must be fulfilled and monitored flexibly and effectively so that the organization knows whether the customer is satisfied or not.

- **Continuous improvement** - Currently, the main reasons for all positive changes are continuous improvement processes and reaching the new level in the organization.

  At present the customers require the projects for the improvement concerning:

  - radical reduction of inconsistencies in deliveries
  - dissemination of product and service functions

- **Participation of all interested parties** - TQM is about everyone participating in the improvement process. All at their best.

- **Social consideration** - the companies that follow TQM are responsible for their own employees and their environment. It is important that the company monitors employee satisfaction and impact on the environment (region, nature, state).

Companies following this principle should also support their own activities with the support of regional health care, culture and sport, Caritas, environmental protection, etc. This principle is used in quality award programmes.

II. ASSESSMENT OF COMPLIANCE

Inconsistency - a specific requirement has not been met (i.e. the need or expectation that is determined has not been met)

Inconsistency entry - written description of the inconsistency, action and subsequent check (inconsistency and complaint log, entry in maintenance log)

Inconsistent products are products that are not in accordance with customer, certain regulatory or own requirements.

The organization must guarantee that a product that is in conflict with requirements is identified and managed so that it is not delivered or used. The responsibility and authority for action of the inconsistent product must be determined in a written procedure.

Principles of action:

- Accept actions to eliminate the identified inconsistency,
- authorisation for use or acceptance with one exception,
- authorisation of the measure to be used as originally planned.

Inconsistent product also means a service where the specific requirements for quality conformity are missing.

II.I. Characters of inconsistent product

The inconsistent product has the following characteristics:

- **Damaged packaging of the delivered or delivered goods** (damage to the goods must be caused directly by the damage to the packaging),
- **Inconsistency in quantity or type of goods**,
- **Inconsistency in delivery dates**,
- **Inconsistency in product requirements** (non-functioning, missing documents, wrong manual),
- **Inconsistency in related services** (service, proposal of new product),
- **other characteristics of the inconsistent product**.

The direct superior is responsible for the evaluation and agreement of the inconsistent products, for the documentation and notification of the employee concerned. In the evaluation of the disparate product, the type and scope of disagreement regarding the

are taken into account.
The inconsistent product or the above characteristics are usually identified by:

- Sales department,
- Commercial,
- Warehouse (during transfer or storage of goods),
- Service (during takeover, service provided - installation of equipment, service),
- IA (during the internal audit),
- Customer (when using or taking over),
- every employee at work.

If the employee detects or causes a discrepancy during the performance of the managed service, the discrepancy must be repaired according to the instructions of the superior law.

The inconsistencies concern suppliers and external work, own organizational activity or products delivered to customers. The documentation must include control and responsibility in order to avoid further use. It is obligatory to record the entries about the inconsistency character and to evaluate which measures (remedial or preventive measures) must be adopted. The product or material, which is not designated or the quality condition is unknown, should be accepted as inconsistent and acted upon in accordance with a specific procedure.

If the employee determines that the inconsistent product has been delivered and the customer is not aware of it (hidden discrepancy, defect due to use, etc.), it is important to adopt appropriate measures to mitigate inconsistency effects. It is recommended to inform the customer under certain circumstances what has happened and solve the situation to his satisfaction.

The conformity assessment is divided into modules containing a limited number of different procedures.

- The modules refer to the product proposal or manufacturing phase, or both phases. The basic modules and their variants can be combined between each other to form a valid procedure.

- The product is assessed in the product proposal and manufacturing phases.

- Each procedural regulation describes an effect and a content. It then shows whether the regulation provides a sufficient level of protection. Regulations also contain the criteria that determine the conditions.

11.2. Improvement measures

The remedial action is intended to eliminate the inconsistency identified so that it is not repeated.
The corrective action procedure shall be documented and shall resolve the following requirements.

Identification of identified inconsistencies relating to:

- Products, processes,
- Sources, suppliers and outsourcing work,
- products delivered to the customer,
- Customer complaints,
- Costs for quality notifications, etc.

The process of identifying inconsistencies and using the appropriate solution to the problem and the cause. The problem solving tools include:

- Failure analysis;
- Capability study;
- Correlation diagrams;
- Data collection;
- "fishbone" diagram (Ishikawa diagram);
- Histograms;
- Pareto analysis;
- Probability diagrams;
- Data stratification;
- graphical representation; etc.

Measures adopted must originate from an investigation and a proposal to solve the problem. Activities may include changes to the product, process, documentation, control, etc. or different combinations. It is also obligatory to carry out tests, controls or assessments to show that the actions really lead to elimination.

All inconsistencies do not lead to corrective actions. Therefore, it is necessary to evaluate the significance of inconsistencies in terms of distribution costs, inconsistency costs, product performance, reliability, safety, regulatory requirements, product and process influence on customers, all risks, customer satisfaction.

11.3. Preventive measure

The preventive measure serves to eliminate the potential inconsistency or undesirable situation so that no more arises.

The information sources for searching for potential QMS inconsistencies include:
Audit results, quality records, supplier performance evaluation, customer feedback, review, prior experience, SPC graphs and analysis.

The Quality Manual - It is an introduction to the quality system, mostly regarding the standard chapters.

- **Advantage** - clarity
- **Disadvantages** - same description on different places because the chapters form a system and connect to each other.

The organization must create and maintain a quality manual. This includes:

- Area of use,
- documented procedures established for the management system or the instruction to follow procedures,
- Description of the reciprocal process effect, often referred to as the process map.

12. RISK MANAGEMENT

The history of risks began at the beginning of 50 years of the 20th century. The big companies started to buy insurance cover according to actual risks. With the adoption of new conditions, this area of human activity developed into "risk engineering" oriented towards risk minimization. Today, risk management is a fully-fledged modern discipline belonging to the field of management knowledge and skills. Risk management is also one of the basic tools of management in the face of ever tightening legislative requirements. Practice shows that an underestimation of this discipline could lead to high financial losses and in extreme cases to an interruption of business continuity.

The aim of occupational safety management is to limit the risks to people's health and lives, the environment and property. These risks are linked to the performance of work activities.

12.1. Risk analysis

Risk analysis is a key activity of safety care and consists in:

- Detection of danger,
- Statement on the probability of occurrence of the risk and on the level of consequence.
- Decision on the acceptability of the risk.
- Adoption of corrective measures.

The procedure of risk assessment is characterized by constant search for dangerous sources, which could cause damage to health, property, environment, the whole process or quality deterioration of products/services.

It is always necessary to answer the following questions:

- What problems could arise?
- What is the probability of individual problems occurring?
- What effect will a problem arise have?

The goal of the risk analysis is the maximum reduction of the probability of a problem, conflict, accident or occupational disease arising. The goal is not to threaten the company's activities by losing the customer, the employees or the good reputation.

RISK = probability that an undesirable phenomenon will occur and its consequences due to dangerous action. Risk generally represents a probability of occurrence of undesira-

with undesirable consequences.

DANGER = Properties of machinery, equipment, environment or activities that may lead to the occurrence of undesirable phenomena.

12.2. Risk management

- Risk analysis,
- Risk assessment,
- Risk control.

Risk analysis - is the systematic use of available information to identify potential hazards and assess risks with a view to protecting the legitimate interests of society in terms of the protection of life, health, property and the environment.

Risk assessment - is a process in which the conclusion about acceptability of the risk is formed on the basis of a risk analysis and in which factors such as socio-economic aspects and environmental impact aspects are taken into consideration.

Risk management - is a decision-making process that leads to the management and/or reduction of a risk. It also includes the implementation of the decisions, their enforcement and the repetition of the assessment with the use of risk assessment results as input.

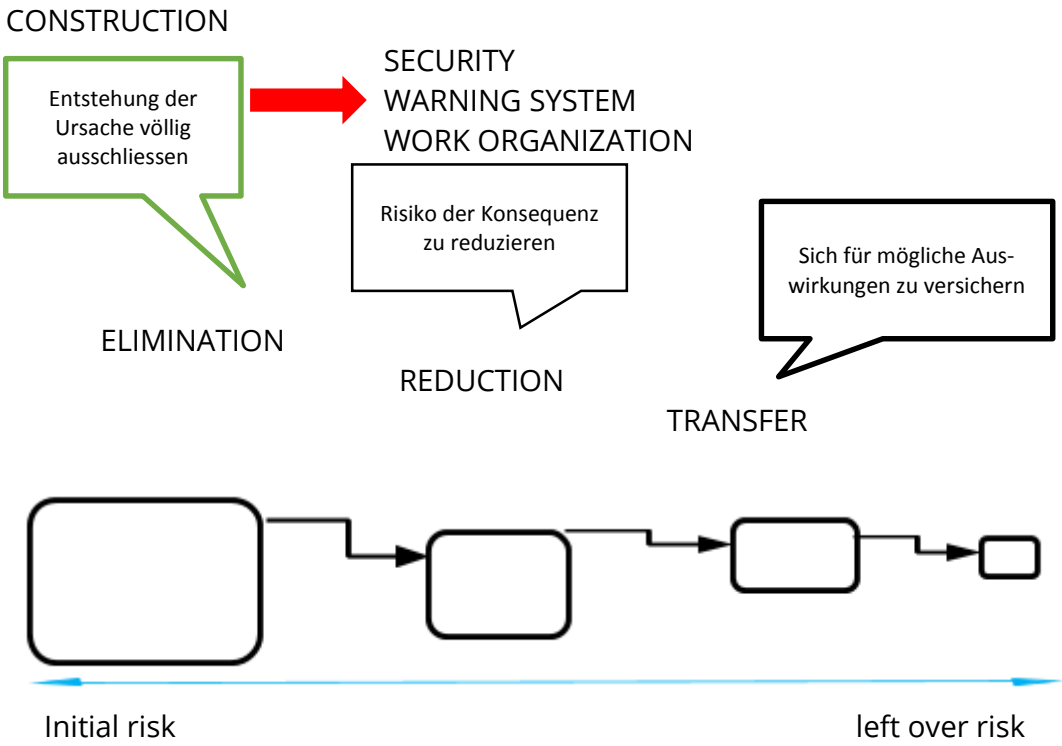

Figure 3 - Risk management process
Source: author

12.3. Principles of risk management

The knowledge of these principles supports the attitude to risk management with accountability:

- All business activities involve risks.
- Risks associated with personnel, environment, products and business infrastructure tend to interact with each other.
- Risks must be managed, not just analyzed and evaluated.
- Risk reduction is part of the corporate culture.
- Risk reduction can only be achieved through close collaboration between management.
- The effective application of risk management presupposes that the measures are systematically adhered to.
- A risk analysis is necessary to achieve economic growth and a successful assessment of the reliability of the organization.
- The best results of the risk analysis are achieved by the average teams.
- Correct project and strategic decisions help to prevent losses.
- Properly designed automatic protection is more reliable than human intervention.

- The level of residual risk accepted by the client must be respected.
- An important element of prevention is partnership with customers and suppliers.
- The effectiveness of the risk analysis should be supported by the qualification of the personnel.
- The understanding of risks is improved by the lessons learnt from damage.
- The support of continuous further training leads to the success of the company.

12.4. Quantitative and qualitative methods of risk assessment

Quantitative evaluation of the seriousness of the risks

The term "risk nature" usually refers to the determination of a probability of some loss or of a measure of threat to people.

In most cases the following formula is used to quantify the risks: **R = p * N**, where **R** is risk, **p** = probability of the occurrence of a dangerous situation and **N** represents the consequences caused (damage, losses).

Quantitative methods are mostly used in the following areas:

- Financial risks (insurance),
- Technical safety (threat to building structures)
- Security of information systems
- z. B. Methods RISK, Monte Carlo, Mark´s Model, Bayesovy analyses etc.

Qualitative risk assessment

The methods of risk assessment should ensure a maximum completeness and complexity of the activity analysis. On the contrary, the results obtained will be a limited application in practice.

The following methods, for example, are used to identify risks:

- Safety Rewiew (SR)
- Analysis using a checklist (Checklist Analysis -CA)
- Methods of relative qualification (Relative Ranking - RR)
- Preliminary hazard analysis (PHA)
- Analysis "What happens when..." (What-If Analysis - W-I)
- Study of hazard and operability (Hazard and Operability Analysis/Study - HAZOP)
- Failure Mode and Effects Analysis (FMEA) - analysis of the manner and consequences of failures

- Analysis of the fault tree (Fault Tree Analysis - FTA)
- Analysis of the Event Tree (Event Tree Analysis -ETA)
- Analysis of causes and consequences (Cause - Consequence Analysis - CCA)
- Human Realbility Analysis (HRA) - analysis of the reliability of the human element
- Hazard Analysis and Critical Control Points (HACCP) risk analysis

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