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MODULE I

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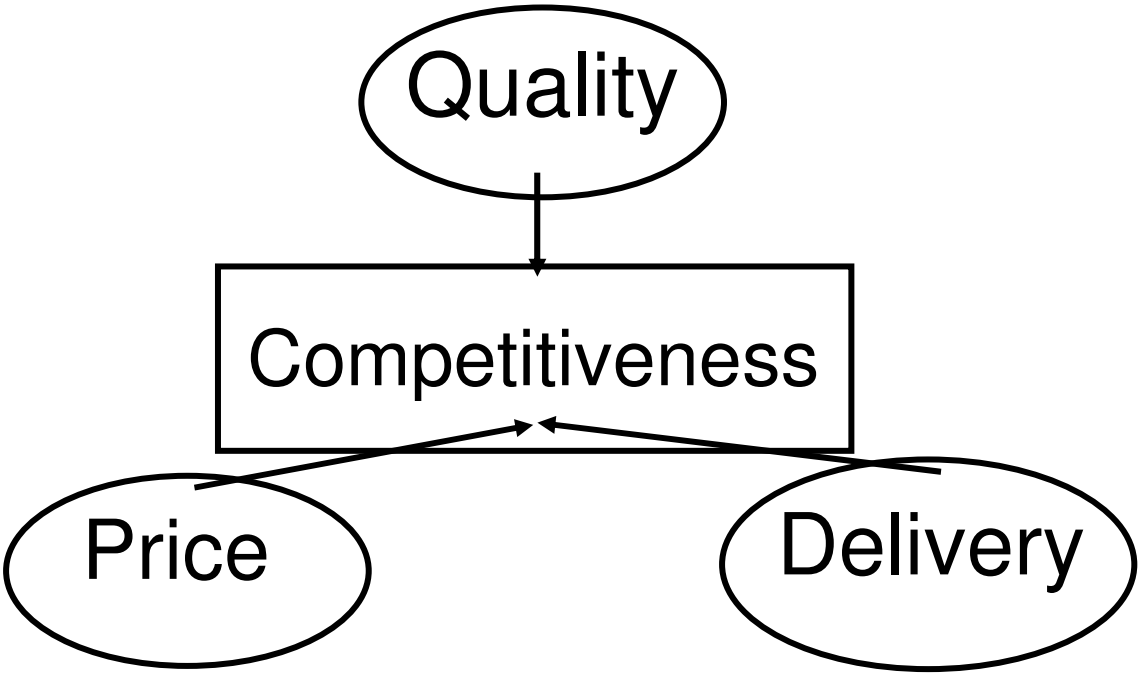
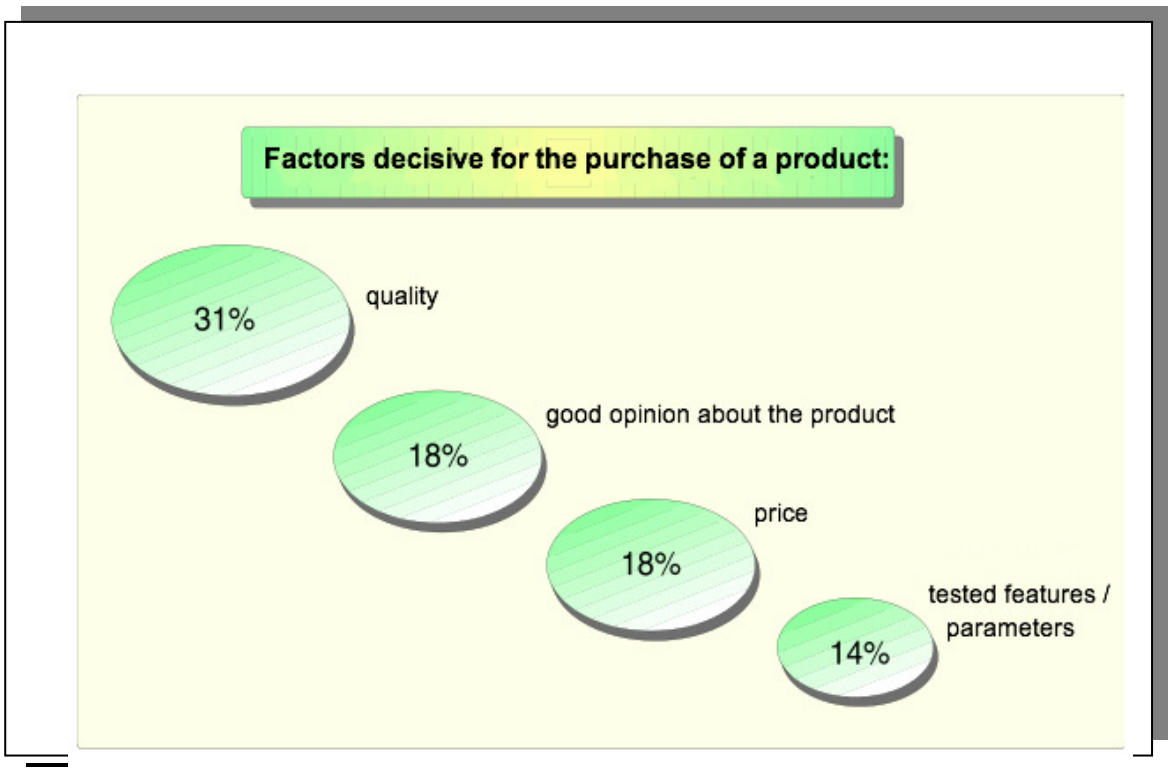
Importance of Quality in Modern Economy.

Key Strategies of Management Based on the Quality Criterion

1. The role of Quality in the Company Management





COMMON FEATURES OF COMPANIES WHICH SUCCEEDED WITH THE QUALITY OF PRODUCTS

- ***Quality is regarded as a strategic objective and appropriately managed***
- ***Deep involvement of the directors is regarded as a key element***
- ***Training in quality at all levels***
- ***Change of the corporate culture to a pro-quality one including all employees***
- ***The leading thought of the strategy is constant focusing on the customer***
- ***Quality management integrating:***
  - ***production and marketing,***
  - ***actions requiring the cooperation of different departments,***
  - ***technologies and meeting the customer requirements***
- ***Quality management regarded as a process requiring constant improvement***

Culture and not the product. Increasingly, in order to defeat their competitors, companies are faced with the necessity to promote their culture or brand and not only their products. Such companies as BMW or Sony sell the image which is called ***"quality"***

A British retail chain, the Body Shop, sells an image of being "environmentally friendly". However, such a message will be convincing to the customers only when an appropriate culture flourishes throughout the company. Japanese managers are taught about it throughout the whole period of their professional career; in Western business schools there are still difficulties in teaching this concept. But they must learn about it.

Robert Haas
Director General of Levi Strauss
(The Economist, 2.03.1991 r.)

IF YOU DO NOT INVEST IN QUALITY, YOUR DAYS ON THE MARKET ARE NUMBERED.

Michael Dove
Director Express Lifts
Northampton

2. Importance of Customers

CUSTOMERS:

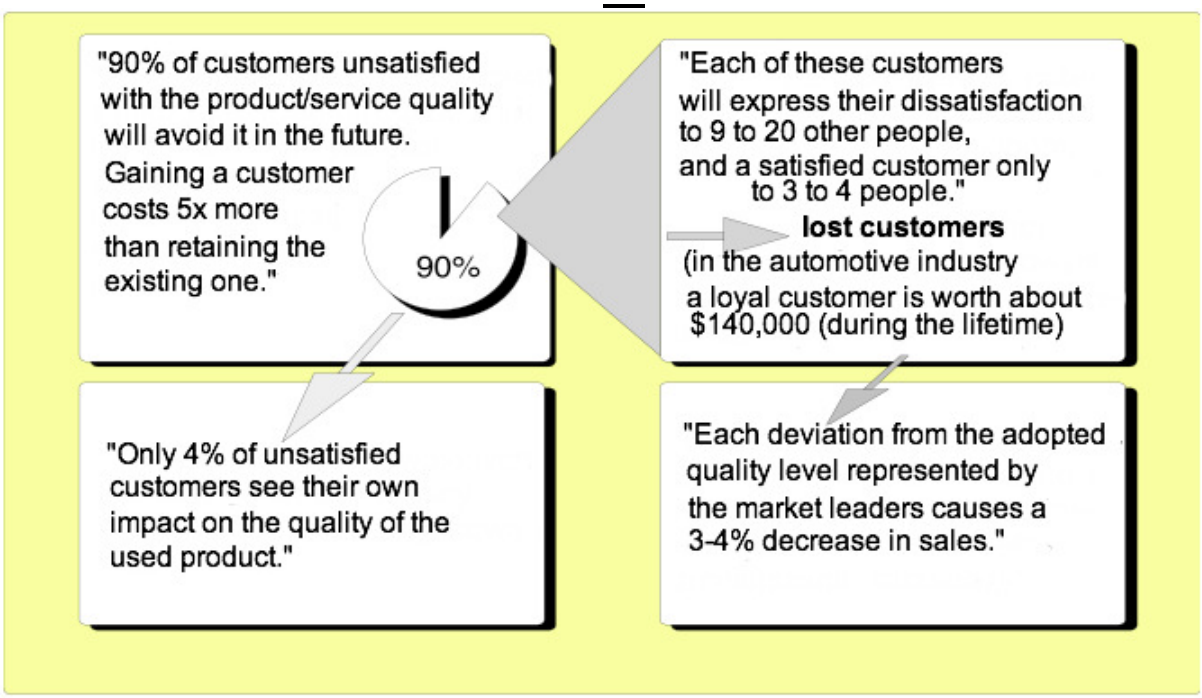
❤*Are the most important persons in each activity.*
❤*Are not dependent on us. It is us who are dependent on them.*
❤*Do not disturb our work. They are its objective.*
❤*They do us a favour when they come.*
We **do not** *do them courtesy servicing them.*
❤*They are a part of our organisation and not persons from outside.*
❤*They are not only a part of the statistics but true humans who feel and react as we do.*
❤*They come to us with their needs and wishes, and our task is to satisfy them.*
❤*They deserve as much kindness and attention as we can give them.*
❤*They are the essence of each business. We would not exist without them.*

BASIC QUESTIONS OF CUSTOMERS:

❤*What can I expect when I buy a product?*
product or service specification
❤*Is it what I expected?*
compliance with the declared characteristics
❤*Does it meet my expectations at all times?*
reliability of the product
❤*How much do I have to pay?*
value of the product in relation to the price
❤*When will I get this?*
delivery (fast and timely)

Meeting the requirements of the customers means listening to them and reacting to what they request and what has been established.

Impact of quality on the behaviour of customers



A confirmation of an appropriate quality of the product is the fact of its purchase by the customer. And therefore, quality should be related to their requirements and expectations - also not fully conscious ones. In this sense, quality is a relative category. The same product may be accepted by one customer and rejected by another as not meeting the requirements. Hence the necessity and importance of identification of customer requirements. It is obviously within the sphere of marketing activities.

The problem of poor quality is often neglected, which justifies a small percentage of observed deficiencies or mistakes and little "visible" costs connected with that. However, it is necessary to pay attention to the fact that easily noticeable costs of shortcomings are a part of the poor quality. As a rule, such factors as e.g. loss of reputation, non-conclusion of potential contracts or frustration of employees are not measured or difficult to measure. Mistakes made at all positions - also executive ones - bring considerable losses and their sum may constitute 20÷35 % of the company's sales value.

3. Definitions of quality and its aspects

Terminological standard ISO 9000:2005 defines the concept of **quality** in the following way:

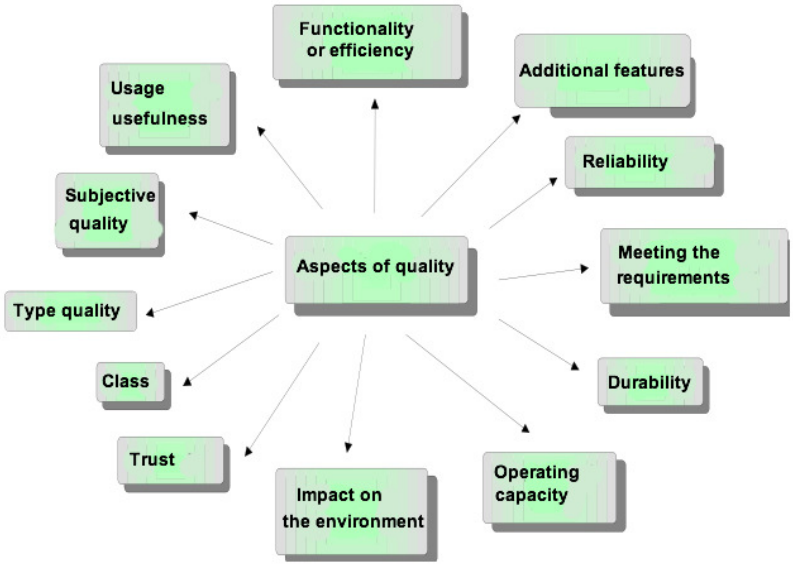
Quality – the degree to which a set of inherent characteristics fulfils the requirements.

Other definitions:

Quality

- **NO ERRORS** (P.B. CROSBY)
- **COMPLIANCE WITH THE REQUIREMENTS** (K. ISHIKAWA)
- **QUALITY IS INVERSELY PROPORTIONAL TO THE VARIATION** (D. MONTGOMERY)
- **QUALITY IS THE THING, THE LACK OF WHICH MEANS LOSSES FOR EVERYONE** (G. TAGUCHI)

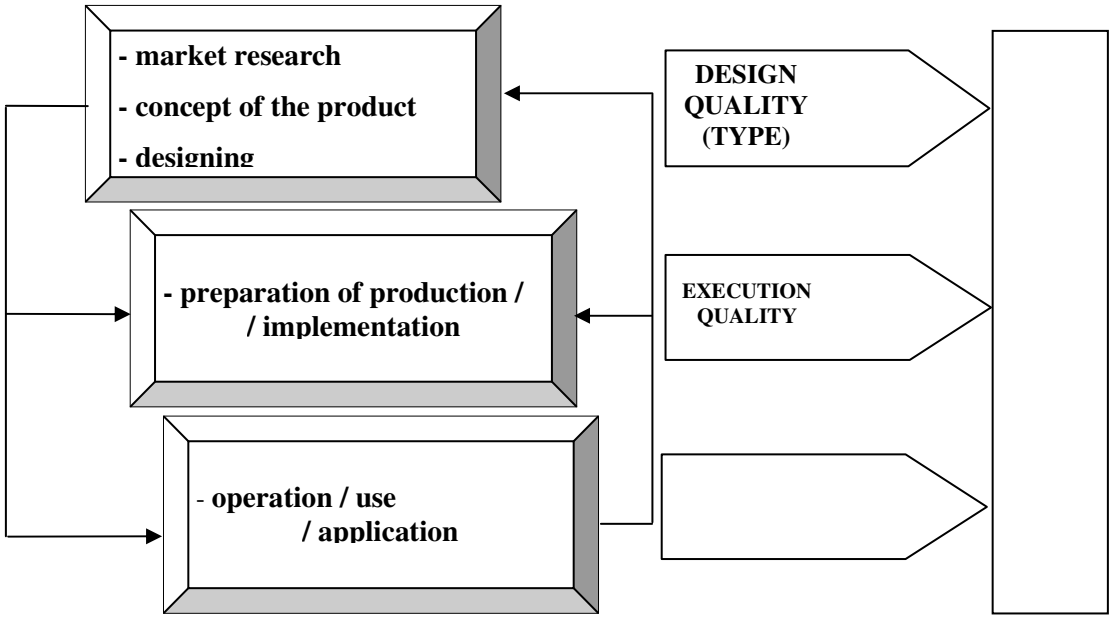
QUALITY is everything what is understood by the customer under this concept.



QUALITY INCLUDES:

- **Knowledge of the customer needs**
- **Design and planning to meet the customer needs**
- **Using optimum equipment and materials in production/implementation**
- **Clear and precise instructions for the implementation**
- **Timely delivery**
- **Production without deficiencies**
- **Efficient support services**
- **Using information from the operational phase (feedback)**

Quality of a product/service is a result of a series of actions constituting the so-called life cycle of the product. What is clear from the figure below, each organisation must take into account the importance of all the stages of building quality, and special attention should be paid to the processes preceding the direct production/implementation of services (i.e. determining the requirements, concluding a contract, planning the implementation) – constituting the so-called type quality. It is during these activities when a decision is made whether all the requirements have been "built in" the product and whether it will have a chance to satisfy the customers.



4. Other concepts connected with quality

Quality management
coordinated actions concerning **organisation** management and its supervision in relation to **quality**

System
a set of mutually connected or mutually influencing elements

Management system
a system for establishing the policy of objectives and achieving them

Quality management system
a management system for leading the organisation and its supervision in relation to **quality**

Quality policy
general intents and focus of the **organisation** concerning **quality,** formally expressed by the **top management**

The concept of **quality management** is a result of many years of gaining knowledge and experience through organisations around the world which had to meet the growing demands of customers and competition. The quality management philosophy puts the customer first, and then all the areas of organisation functioning are subjected to meeting their expectations.

Quality management is based on:

- establishing and continuous updating of the quality policy and quality objectives of the company,
- planning to achieve these objectives,
- current monitoring of the processes influencing quality and
- continuous quality improvement in the company.

Each company is a specific system in which appropriately configured elements - **people, machines, materials, methods and environment -** implement missions and subsequent goals determined by the management.

A system based on setting the policy and quality objectives and focusing on their implementation, in accordance with the management idea is called the **quality management system**.

It is a system, and not a single employee, who is responsible for the effects of the company's activity. A human is only an element of a better or worse configured system.

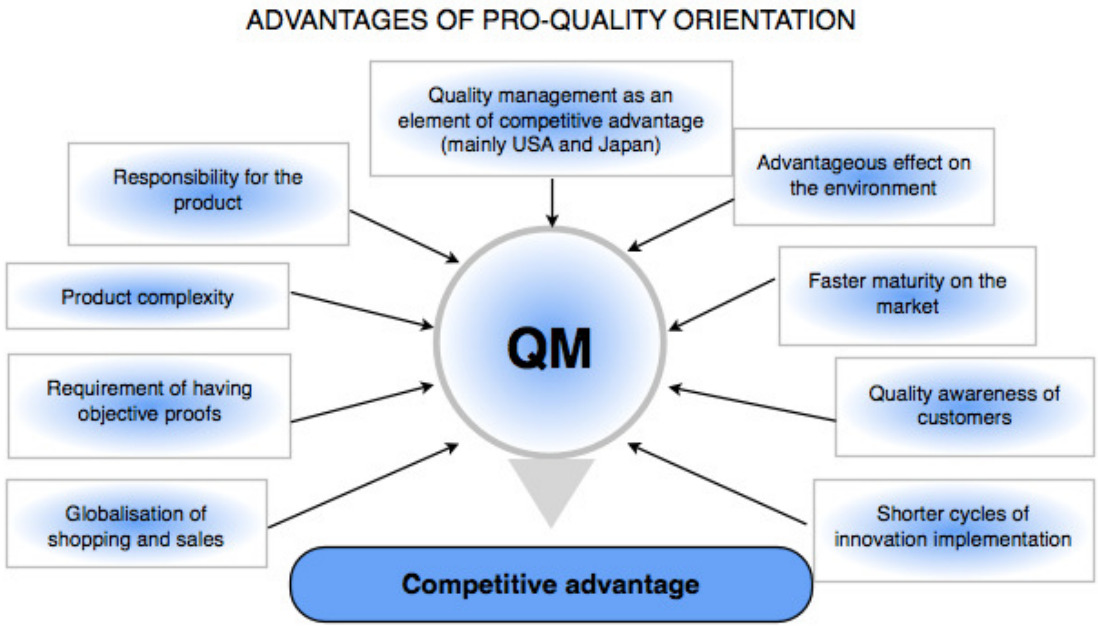
The **management of the company** is responsible for the proper configuration of the aforementioned elements and it bears the main responsibility for the broadly-understood quality by which the organisation is characterised.

5. Measures of quality

PRODUCTION QUALITY CRITERIA

1. ***Quality costs***
2. ***Defects (***work performed not in accordance with the specification*)*
3. ***Improvement (***work requiring improvement***)***
4. ***Discards (***wasted work***)***
5. ***Losses (***work performed again***)***
6. ***Downtime (***delays in work***)***
7. ***Delays in deliveries (***work performed after the set deadline***)***

*8. SURPLUSES (*work unnecessary*)*



6. Experts ("gurus") of quality and their views

Expert	Dominating element
P. Crosby	No deficiencies
W.E. Deming	14 points of management System of profound knowledge
A. Feigenblum	Total Quality Control
K. Ishikawa	Quality wheels Cause and effect diagrams Company-Wide Quality Control
J. Juran	Trilogy of quality (planning, steering, improvement)

TQM MODEL according to JURAN

QUALITY PLANNING

- Determine who your customers are
- Determine the needs of the customers
- Develop the product design which would meet the needs
- Develop production processes able to ensure that the product has the required features
- Convert plans into action

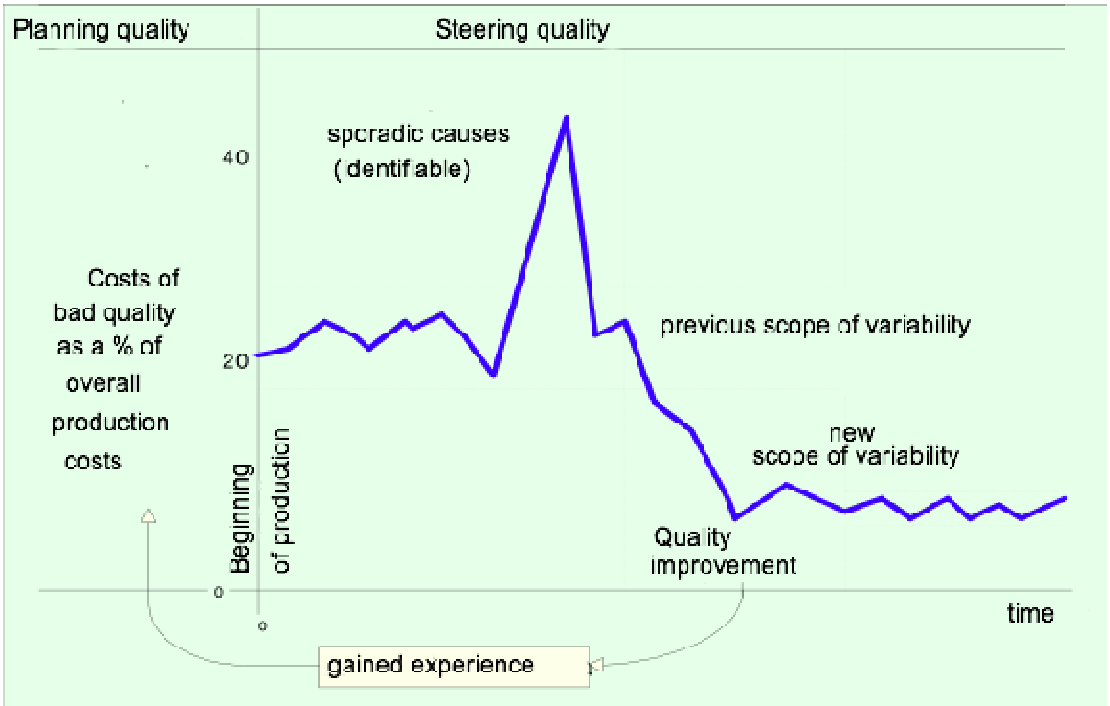
QUALITY CONTROL

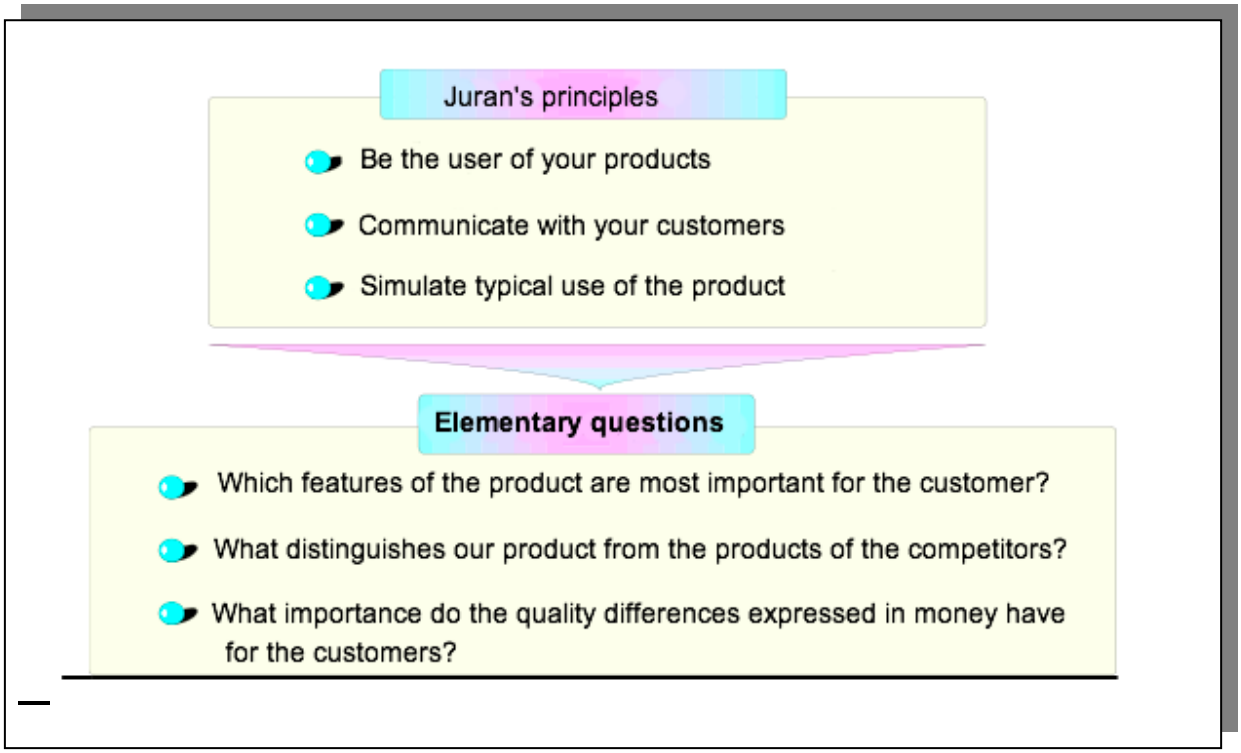
- Examine the actual product characteristics
- Compare the assessment results with the requirements
- Correct discrepancies

QUALITY IMPROVEMENT

- Create an appropriate infrastructure
- Define specific roles in enhancing quality
- Appoint task forces
- Create appropriate opportunities for the work of teams (resources, training, system of incentives)
- Implement the prepared solutions, distribute and strengthen them

J. Juran's Quality Trilogy





JURAN: 10 steps of quality improvement

1. Realising the need and opportunity to improve quality
2. Determining the continuous improvement aims
3. Creating an organisation which will help in the implementation of these aims through the establishment of a quality council, identifying the problems, selecting the right design, creating teams and selection of coordinators
4. Training of all employees
5. Assignment of problem tasks
6. Informing about the progress of works
7. Expression of recognition
8. Announcement of results
9. Record of success
10. Inclusion of improvements to the normal activity of the company, which ensures the enthusiasm of employees

7. Deming's philosophy

System of Profound Knowledge

1) System approach
2) Variation theory
3) Forecasting theory
4) Selected topics in psychology

Fourteen conditions of effective management

Condition 1 - Consistency in reaching the purpose

The purpose, mission of the management in relation to the enterprise should be articulated and disseminated not only among the employees of the company but it also should be known to its suppliers and customers. The existence of a company mission is necessary for both the management and the employees to plan their future tasks.

Condition 2 - Adoption of the "New Philosophy"

The essence of this "New Philosophy" is the rejection of past practices of uncritical acceptance of the quality level achieved in the past. The philosophy of quality improvement is the cheapest method of productivity improvement as the relation of the derived factors to the input factors. Deming provides in this place the so-called chain reaction:

Condition 3 - Finish with the dependence on mass control

Although the existence of control activities n the company is necessary, we have to remember that quality cannot be "fully controlled" - it is necessary to build it in the process or product. By giving an employee the opportunity to get to know the surrounding system thoroughly and equipping them with appropriate methods, it is possible to significantly reduce the need to apply the inspection control.

It is also necessary to remember that even the most advanced inspection systems never give 100% of certainty of capturing irregularities.

Below there is a simple criterion which allows for making a decision when it is necessary to apply full control, 100% and when it is enough to apply random, statistical control.

If $w^* = \frac{K_1}{K_2} \leq \overline{w}$ - do not apply 100% control, decide for random control
(control costs more than the possible loss)

If $w = \frac{K_1}{K_2} \geq \overline{w}$ - apply 100% control

where: K_1 - the cost of control of one element,

K_2 - costs (losses) caused by the occurrence of a defect at further stages of the production process or at the customer's,

$\overline{w}$ - average defectiveness found in a batch of products (e.g. on the basis of the control cards).

A contemporary alternative for the product control is the active process control as a result of which this product is created, using statistical devices such as control cards and enabling active shaping of quality.

Condition 4 - <u>End with the practice of making decisions exclusively on the basis of the price, reduce costs reducing changeability in the processes</u>

Always remember about the regularity:

Price + Cost of Use = Total Cost

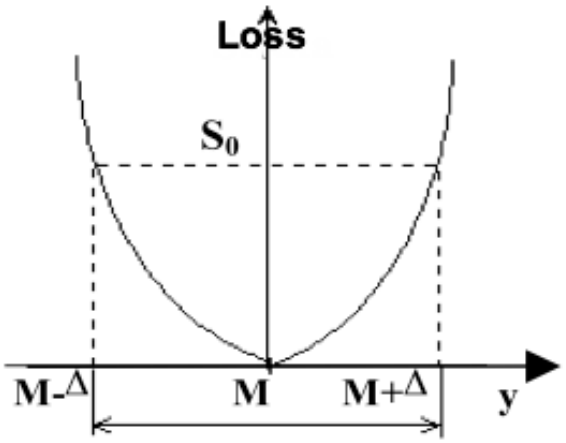
The purpose of the contemporary purchasing department is often a difficult work of searching for the answer to the question - In what case (i.e. for which supplier, product, service) <u>the total cost will be the lowest from the point of view of our company</u>?

If e.g. buying a car tyre are we interested only in the price or e.g. the lowest cost for the mileage guaranteed by the manufacturer?

A useful thing at this point is a new perspective on the issue of quality presented by G. Taguchi in the form of the so-called quality loss function.

Taguchi defines quality in a controversial way (at the same time setting its measure) as a <u>social loss caused by the product after it is submitted to the recipient.</u>

It is therefore necessary to calculate or estimate this loss, hereinafter referred to as <u>the quality loss</u>.



$$S(y) = k(y - M)^2$$

where: $k = \frac{S}{\Delta^2}$ - ratio of qualitative losses,

M - desired value of the parameter y,

M±⊗ - the so-called functional limits for the parameter y, i.e. the value of the feature at which the product will not function or will be perceived as defective, in 50% of cases,

S_0- cost of replacement or repair of product

As it can be seen, this approach is completely different from the traditional Taylor's approach on quality taking the tolerance on the performance of a product (everything that is in the range of tolerance is equally good, regardless of whether the value of one characteristic is close to the desired value or close to one of the tolerance limits) as a basis for its assessment.

Deming compares the two views on the cooperation with sub-suppliers:

Traditional way (bad)	**New way (good)**
- short contracts	- long-term contracts and relationships
- selection on the basis of the lowest price	- seeking to determine total costs
- treating each other as enemies	- constant quality improvement
- mutual distrust	- partnership, constant exchange of information
	- mutual adaption to the needs

Deming believes that you should strive for lowering the number of suppliers, maintaining contacts with those who want good cooperation and understand that they are an element of the manufacturer's system. The greater the number of suppliers e.g. of a given semi-finished product, the better the overall variability of the final quality.

Condition 5 - Constant improvement of the system

The task of the management is to create a climate in which each employee will be willing and able to introduce innovations and improvement of processes, products and services. The management must remember that the experience shows that 90% of the responsibility for the system is on the part of the leadership.

According to Deming, the desire of employees to self-realisation through the action for the sake of the company was destroyed by such rating systems as MBO, where the employee promotion in the company hierarchy usually takes place at the expense of the career of another employee (the loose/win philosophy instead of win/win).

At this point it is known recalling the well-known cycle of continuous improvement PDC(S)A - Plan (plan a change or an improvement) - Do (try the planned solution) - Check(Study) (check, analyse the results) - Act (introduce the change, make it a new standard for improvement).

Condition 6 - Adopt modern methods of increasing qualifications of all employees

The task of the management is to recognise the training needs of the employees. Deming suggest the use of control cards in order to recognise whether a given employee requires training (the employee's results indicate the existence of the special reasons, about statistical instability of the process implemented by this employee) or it is necessary to do the so-called "breakthrough" in the system which is within the competence of the management.

Condition 7 - Adopt modern leadership methods

A contemporary manager should be a leader. According to Deming, a good leader should have the following characteristics:

- recruits employees fairly and with great caution,
- strives to have subordinated who draw satisfaction from their work,
- is an advisor and a consultant but not a judge,
- uses objective data to understand the results of their subordinates,
- understands the impact of the work of their group on the company objectives,
- cooperated with the representatives of the preceding and subsequent phases after the one implemented by their own team,
- strives for the improvement of the processes implemented by their team,
- creates an atmosphere of trust in the team,
- does not expect perfection but learning from mistakes,
- acts in such a way that the subordinated implement what is expected without a feeling of coercion or humiliation,

Deming often emphasised that it is not enough to try to do our best - unfortunately, often it would be better to do nothing, it would not lead to the system destabilisation. Good intentions must always be accompanied by appropriate knowledge and understanding of the relevant processes.

Condition 8 - Eliminate fear

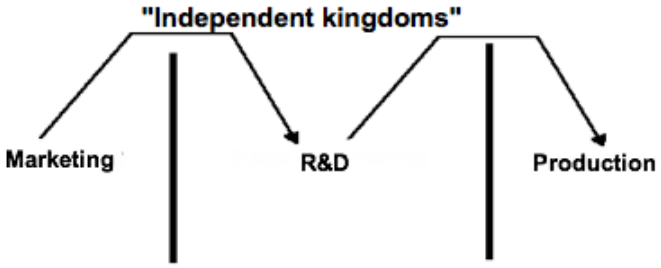
At this point Deming quotes his friend who said that " if you cannot oppose your boss, he is not worthy of you working for him." Communication by the subordinates of their different opinions is extremely important, of course, with the assumption of mutual respect.

Management by Objectives (MBO) is called by Deming the Management by Fear. Within the framework of this method, decisions are made on the basis of various indicators, usually ad hoc, without the mode understanding, as a result of which they were defined (without the so-called operational definition of a given size) and without the understanding the essence of variability of the system.

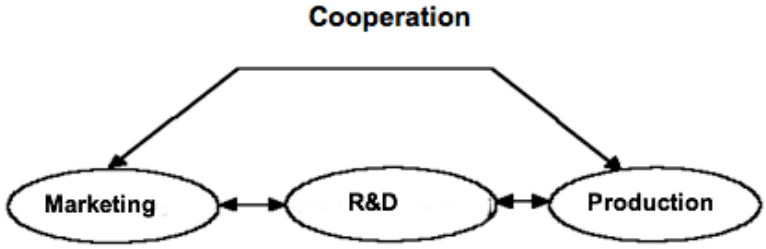
Deming contradicts the concept of the MBO with Management By Planning, win which the subject of interest is the process, the method of implementation and not the result itself. It should be remembered that the numerical objectives usually become the object of "the game" between the management and the employees for whom these objectives were determined. An employee, realising that further objectives are set at a higher level than the present ones, even if they achieve results better than the assumed ones, try to hide this fact at all cost. There is also the mentioned fact of system sub-optimisation for your own needs. Obviously, it is all happening at a loss for the entire company.

Condition 9 - Eliminate barriers between particular activities of the company

Faulty management at most companies has led to the formation of the so-called "independent kingdoms," sharing information on the basis of "flipping it over the wall."



Such an approach where individual departments compete with each other, optimising only their own subsystem should be replaced with a model based on mutual cooperation, constant exchange of information aiming at the optimisation of the entire system of the enterprise. Such techniques as e.g. Simultaneous Engineering, QFD, FMECA or even various forms of brainstorming, all conducted in interdisciplinary teams may be of assistance here.



Condition 10 - Eliminate slogans, appeals and arbitrary objectives

Deming promotes a view that while employees mist be communicated the different aspects resulting from the mission and objectives of the company, it should be remembered that if they are not adequately familiar with these objectives and trained in the way of achieving them, any slogans and appeals have a counterproductive effect. Employees are well-informed about the situation of the enterprise, seeking the confirmation of different declarations in the actual activities of the management. If they see that apart from slogans the management does not contribute anything substantial to improve the system - they become distrustful, frustrated and embittered.

At this point it is necessary to remind that if the actual condition of the enterprise system indicates its stability, action from the part of the management is necessary to introduce substantial improvements. The supervisors often require from their subordinates something that is impossible to achieve in these conditions (the system is not qualitatively fit). A highly helpful tool in this respect are control cards which allow for distinguishing a stable and unstable system (process).

Condition 11 - Eliminate thoughtless standards of work and quantitative objectives for employees

It is another reference to the ruinous practices of the MBO. Determining the quantitative objectives to employees or departments of the company and basing the system of rewards and punishment on it is a practice which dates back to the so-called scientific management proposed by F. Taylor in the early twentieth century. Taylor based his theories on the assumption that employees are inherently lazy, thoughtless and hostile to the management whose role is to introduce discipline and drill as the main methods of motivation. An employee or a department which operates in a system based on numerical objectives, having achieved these objectives, strives to keep the ways of achieving them secret (sub-optimises the system). Whereas, if the objectives cannot be achieved and it is known that an adequate gratification will not be obtained, there is no point in thinking about the possibilities of improving their own processes (the losses of the company are then very big).

The environment in which quantitative targets are applied without the use of the principles of the Comprehensive Knowledge System is an environment in which the employee will not help the management for fear of continuous "raising the bar." The management should assume the role of the leader who helps, explains, trains, asks his subordinates for opinion and can admit not knowing something, and not of a controller who seeks "a gap where the hedge is whole."

Condition 12 - Create conditions so that the employees would not be ashamed of what they do

Deming cites here numerous examples (known to us all) when the company system takes the pride of the employees from the performed work. For example, an

employee whose employment is interrupted due to tools of low quality (ordered by the purchasing department because of the low price) asked by Deming sarcastically why he is worried about this situation, if he is paid for the downtime, he answered that money would not compensate for his nerves and a gradual loss of enthusiasm. At this point, Deming criticises also annual employee assessments. Usually neither the superiors nor the subordinates like to do that. Deming asks - why do we wait the whole year to realise that the employee needs help?

Condition 13 - Create conditions for versatile development of employees

This condition is about creating opportunities for willing employees not only to increase strictly professional skills (see condition 6), but also a broadly understood development of their personality, e.g. by allowing for the continuation of the scientific career, learning foreign languages, sports, music, etc. A well educated employee who has a rich personality is the best investment of a company and its most valuable asset.

Condition 14 - Create an efficient structure within the framework of the top management, which will enable the company transformation - systematic, consistent implementation of the above 13 conditions

The transformation of a company must be a process initiated and actively supported by the top management!!!

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MODULE II

Total Quality Management (TQM) Models of Excellence

1. The essential concepts, principles and conditions of TQM

The philosophy of the Total Quality Management (TQM) is now perceived in the highly developed countries of the world as the most effective way of conducting any production and service activity.
The BS 7850 standard defined the TQM as:

"The management philosophy and the practice of an enterprise aiming to use its human and material resources in the most effective way to achieve the set objectives."

In the terminological ISO standard from the family of 9000 norms, *total quality management* is defined as:

"The way of managing an organisation is concentrated on quality, based on the participation of all the organisation members and targeted to achieving a long-term success owing to the customer and the benefits to all members of the organisation and the society"

The abbreviation TQM may be translated as follows:

Total - each person in the company is involved for a broadly understood quality (if possible also the customers and suppliers),

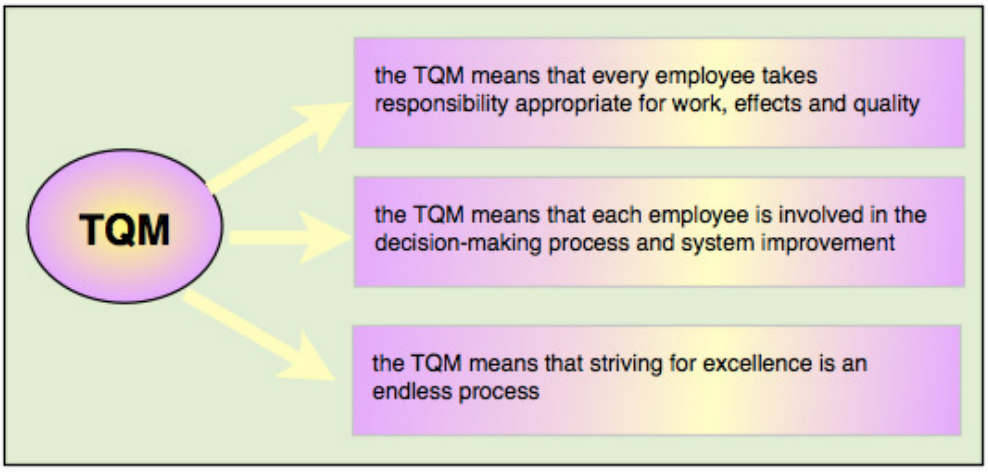
Quality - requirements of customers are fully met (see the definition of quality),

Management - the management of each level, especially the highest one, supports and actively participated in the implementation of the pro-quality culture in the company.

UNIVERSAL QUALITY:

- culture of the company which allows for the production of goods and services at the required quality level;
- effective integration of people at all levels of organisation in order to constantly improve the supplied products and services which meet the needs of the customer.

The statement that without the adoption of this management style, a production enterprise or a service institution will not be able to compete in its market is supported by numerous facts.



TQM takes the following as its guiding principles:

- creating the awareness and involvement of all the employees, and above all, the chief executives, for the sake of quality,

T Q M

OBLIGATIONS OF THE MANAGEMENT:

- **commitment - each action is directed towards the customer and quality,**
- **leadership - the example of leadership shows the way,**
- **good orientation - determine the problem and way of its solution,**
- **ability to work in a group - show that everyone has a part in creating,**
- **determining the qualitative tasks - clear formulation and consequent implementation,**
- **motivating - appreciate and recognise the contribution of each person,**
- **involving everyone - by creating a climate of common work and objectives,**
- **prevention - by the implementation of the responsibility of everyone for their work,**
- **sharing the customer requirements – through an efficient information system.**

MANAGER	**LEADER**
directs the staff	trains them
uses the function of authority	triggers voluntary action
causes anxiety	arouses enthusiasm
often says "I"	often says "WE"
looks for the guilty	looks for the way to success
knows how to work	gives an example of work
says: "Please do this"	says: "Let's do this"

LEADERSHIP IS:

- ❑ **determining the vision and direction in which we aim,**
- ❑ **convincing others to follow us.**

- striving to identify and meet the requirement of the internal and external customer (each employee has their customers and suppliers),

CUSTOMER

a person or organisation to which we submit the results of our work

Every company, department, employee is a customer and supplier

- A is the supplier for B
- A and B are customers
- B is a supplier

Basic Questions of the Supplier:

1. Who is my customer?

2. What does my customer need form me (goods, services)?

3. What are the expectations of my customer (objectives, tasks, requirements expressed as a quantity)?

4. What do I offer them at present (product, service - main features)?

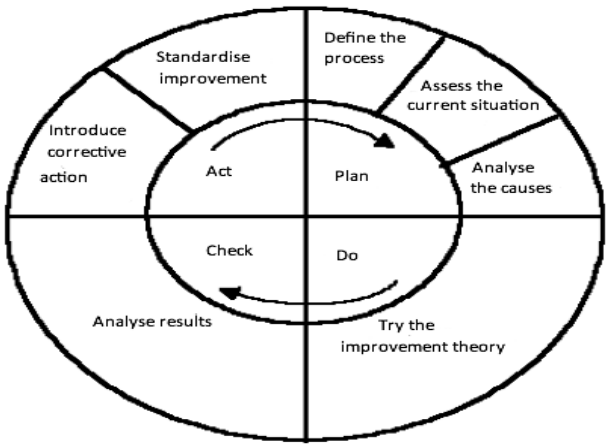
5. What expectations I do not meet?

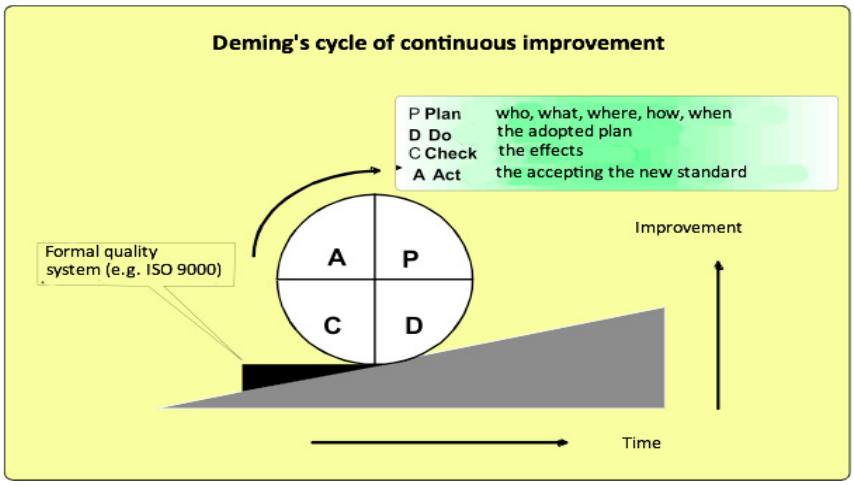
6. What can I do to fulfil the expectations of the customer (what parameters, activities, processes, components do I have to change)?

7. What corrective action will I take (what, who, when, where, with what, ...)?

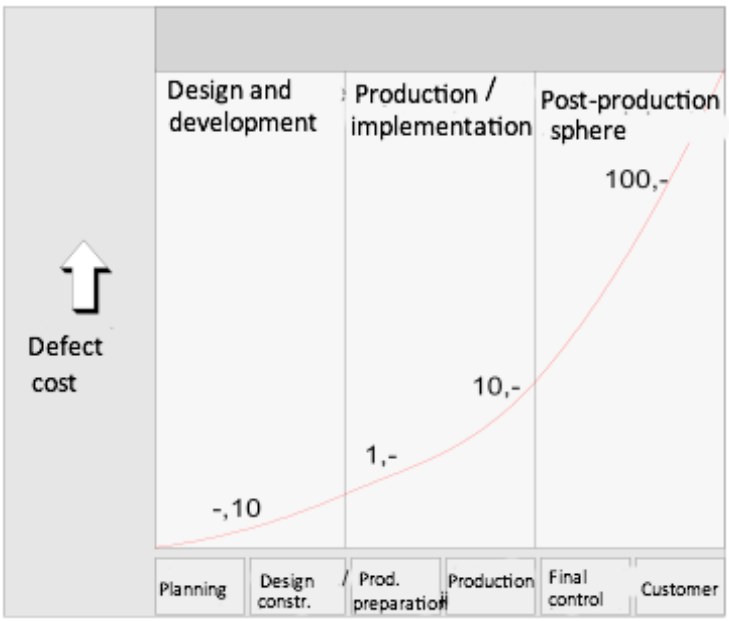
- continuous improvement of all actions in accordance with the so-called Deming cycle, including a constant cost reduction (perfection and not a set acceptable level); the synonym of the principle of continuous improvement is the Japanese philosophy of Kaizen which is valid not only in business activity

DEMING CYCLE



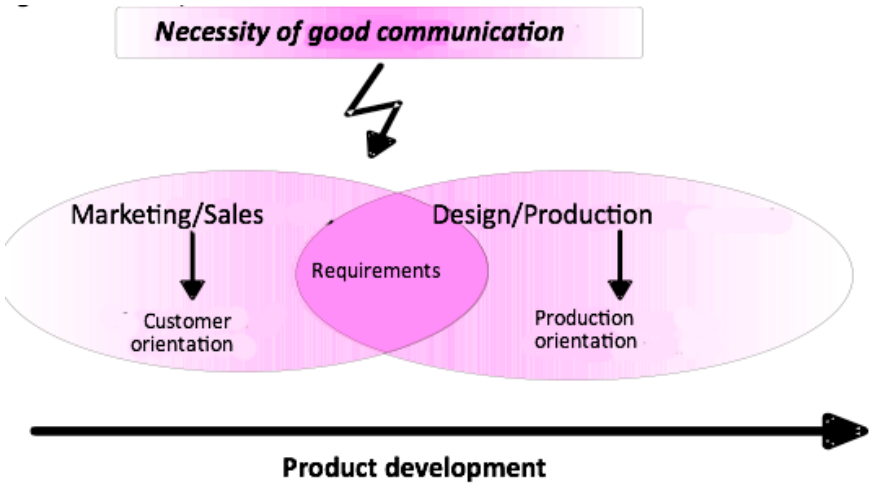


- performing the tasks right the first time, on time and every time,
- preventing problems and not only their ad hoc liquidation,



Importance of the moment of taking pro-quality action

- team approach to problem solving (everyone is responsible for quality), determining the group of leaders,

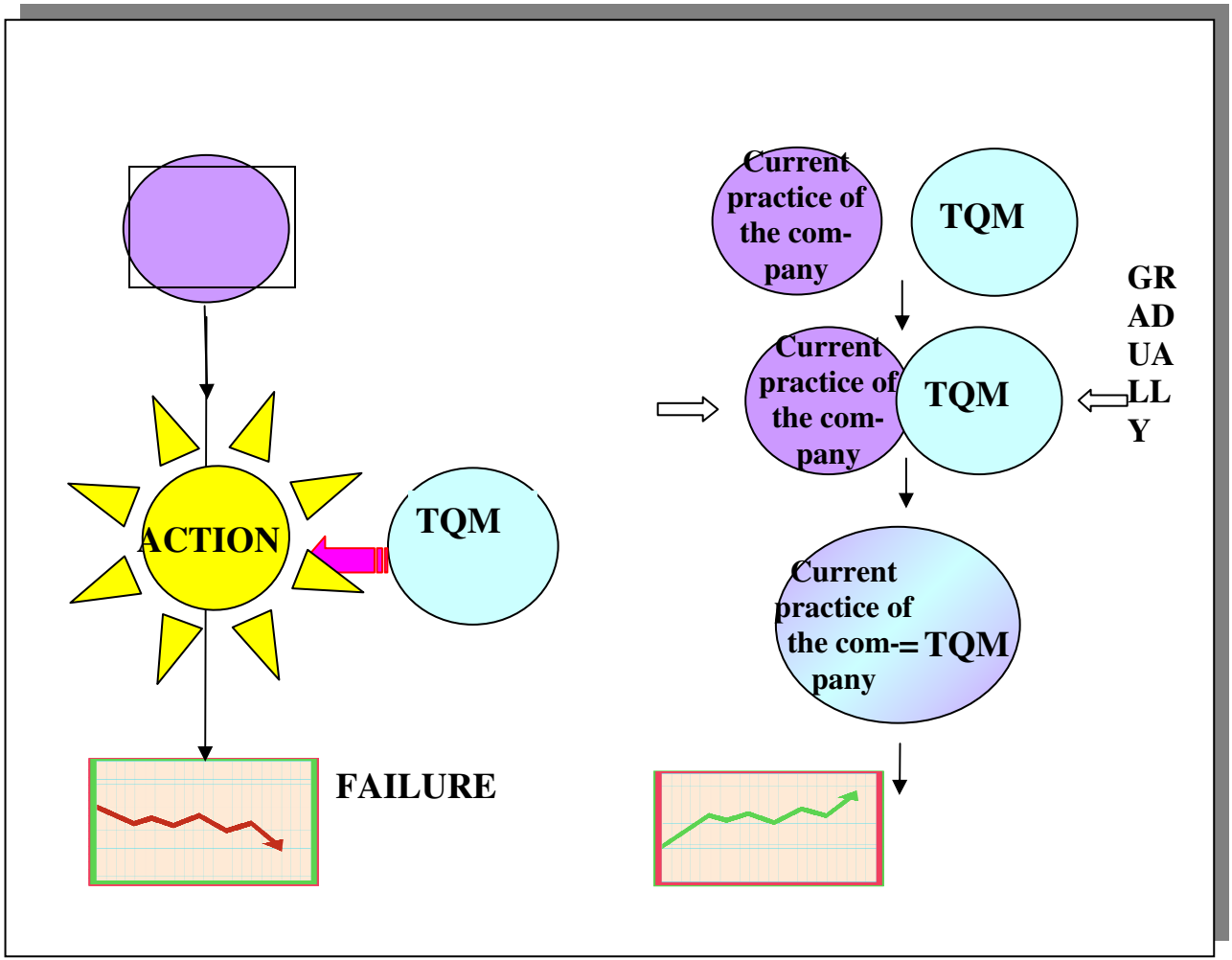


- investing in the development of employees; people are the greatest asset of the company and their efficiency and quality of work depends on good governance.

The process of continuous improvement according to the Deming cycle (often called the P-D-C-A cycle, from the English words Plan-Do-Check-Act) assumes that each improvement of the process should become a standard to be introduced to the new cycle. The new standard is therefore introduced basically to be revised and replaced with a new one. The Japanese believe in the principle that each standard must be revised and changed. At the same time, the standardisation of improvements in a process may serve as an inspiration to other actions, hence it is advisable to conduct in-house dissemination of positive experience and sharing comments on the errors.

The main problems associated with the process of TQM introduction are:

- improper distribution of responsibility for quality - responsibility is delegated only to certain departments (e.g. the Quality Department) or employees, quality does not become a universal matter,
- expectation of quick results - although they are desired as a motivating factor, you should not strive for them at all costs,
- belief that quality is created during production, żand that it can be controlled - it is caused by the lack of awareness of the influence of own work on the results of a given organisation.



OTHER BARRIERS FOR THE IMPLEMENTATION OF MANAGEMENT BY QUALITY AND PRODUCTIVITY

- belief that achieving a better quality and productivity leads to a significant increase in costs,
- assignment of responsibility for the implementation of the system, programs and processes only to one person, with small involvement of the management and all employees,
- assumption that the implementation of the normative quality system is sufficient for increasing the value of products and services while it constitutes only the first step in this direction, since it does not guarantee a change in the human mentality and the culture of work,
- belief that quality is created only in production is forcing people to a more productive work,
- directing the efforts towards copying the systems of other companies,
- no consequence, frequent changes, too much improvisation of activities,
- no assessment system and control of the work progress to maintain the operations.

2. Seven basic sins of management interfering with the pro-quality transformation of the company according to Deming.

Fourteen conditions of effective management constitute the basis for a company transformation. However, it is necessary to remember about the most important obstacles which may prevent the transformation or thwart its effects. W.E. Deming indicates the following seven basic sins in management.

1) Lack of consistency in the pursuit of purpose and its unity

Deming refers here to condition 1, stating that the lack of a uniform objective and the lack of consequence in its implementation leads to unpredictable results. Deming believes that too many managers think only of solving the current problems, not planning the future. The mission and objectives of the company should be appropriately disseminated and translated into the missions and objectives of a lower level - department ® team ® employee.

2) Emphasis on short-term profits

Deming criticises the pressure characteristic to the exchange market to make companies show a profit consistently. An inevitable variability occurring in all the processes, including the economic situation, is not taken into account, and instead the basis are such elements as "creative" accountancy, using the tax law, fluctuations and differences in the exchange rates. Deming gives an example the Japanese steel industry during a world recession. Instead of dismissal of thousands of employees as in the case of the American steel industry, the Japanese, understanding the cyclical nature of the economic situation, used the recession time to best prepare for the moment when it ends. They modernised the technology (continuous casting), sent specialists to determine the future requirements of the customers, lower the wages (without reductions), and when the recession was over, they took over the world steel market.

3) Periodic assessment, annual reviews of performance reviews

It is a clear reference to condition 8, 10, and 11. Deming quotes the equation:

X + Y + XY = work results

where: X - impact of the employee, Y - impact of the system, XY - impact resulting from the mutual impact (interaction) of the employee and the system.

If the employee assessment is made on the basis of the outcome of this equation, one should ask the question: Is it possible to solve this equation with two unknowns?

4) Large fluctuation of the management

Here also Deming uses the Japanese example where the employees usually remain loyal to one company. In the western culture, a frequent change of jobs is indeed a canon of a manager. Deming warns, because the believes that it is not conducive to team work, necessary for the correct devel-

opment of the company. He calls the situation of frequent change of jobs among executives the White Knight Syndrome which includes:

1) locate the area, the company in which there is chaos,
2) come as a saviour,
3) conduct numerous, often superficial or even very harmful (to confirm involvement),
4) show effects (short-term profits),
5) collect awards,
6) leave before long-term problems arise

5) Leading an enterprise only on the basis of "visible" financial data

Deming emphasises the importance of the words "exclusively" and "visibly." The financial data inform about what has happened in the past and are not appropriate for predicting the future apart from understanding the essence of the system in which they ate created. "Visible" financial data – results of the activity of the system, do not exhaust the essence of quality problems in the enterprise, they are only the tip of the iceberg. Many factors which we are aware of are impossible to grasp in the form of financial data. These are e.g. losses on account of customer dissatisfaction (not concluded potential contracts, loss of customer loyalty), effects of customer dissatisfaction or low motivation to work caused by bad management.

Such data should be analysed in connection with the variability analysis in the system in which they originate. Only then it is possible to identify unidentifiable areas of classified data. The key to the improvement is the knowledge of processes in the company by the management and striving to reduce variability in these processes. Management based on the end results only is disastrous for the company (the so-called *management by results*).

6) Excessive health costs

Deming refers here to the specificity of the American health insurance system in which enormous resources are wasted just because commonly used medical procedures and standards are applied, which assume that the needs of patients are identical. The health insurance costs make the prices of American products non-competitive (e.g. medical costs in an automotive company constitute about 10% of the car price). In order to reduce this onerous burden, Deming once again recommends to the management (including the medical staff) systemic assessment of the patient treatment as as an appropriate tool for this purpose, he recommends the cards of statistical process control .

7) Excessive legal costs

Deming emphasises the importance of authentic relationships between the supplier and the customer which cannot be replaced by the legally best contracts. Only trust gained as a result of long-term contacts based on understanding between the supplier and the customer are a guarantee of mutual benefits. Instead of paying horrendous amounts to lawyers, it is necessary to build trust.

3. Quality Awards

Appreciating the role of the TQM in the development of the world economy and the desire to emphasise the importance of the quality issues on the powerful European Union market were the foundation of the work for the European TQM model. This model was published by the European Foundation for Quality Management (EFQM) as a basis for granting the European Quality Award. This award has been granted since 1991 to enterprises conducting their activity in the EU countries. It is necessary to note that such awards have been granted for a long time in Japan (Deming Award) and the USA (Baldrige Award).

QUALITY AWARDS

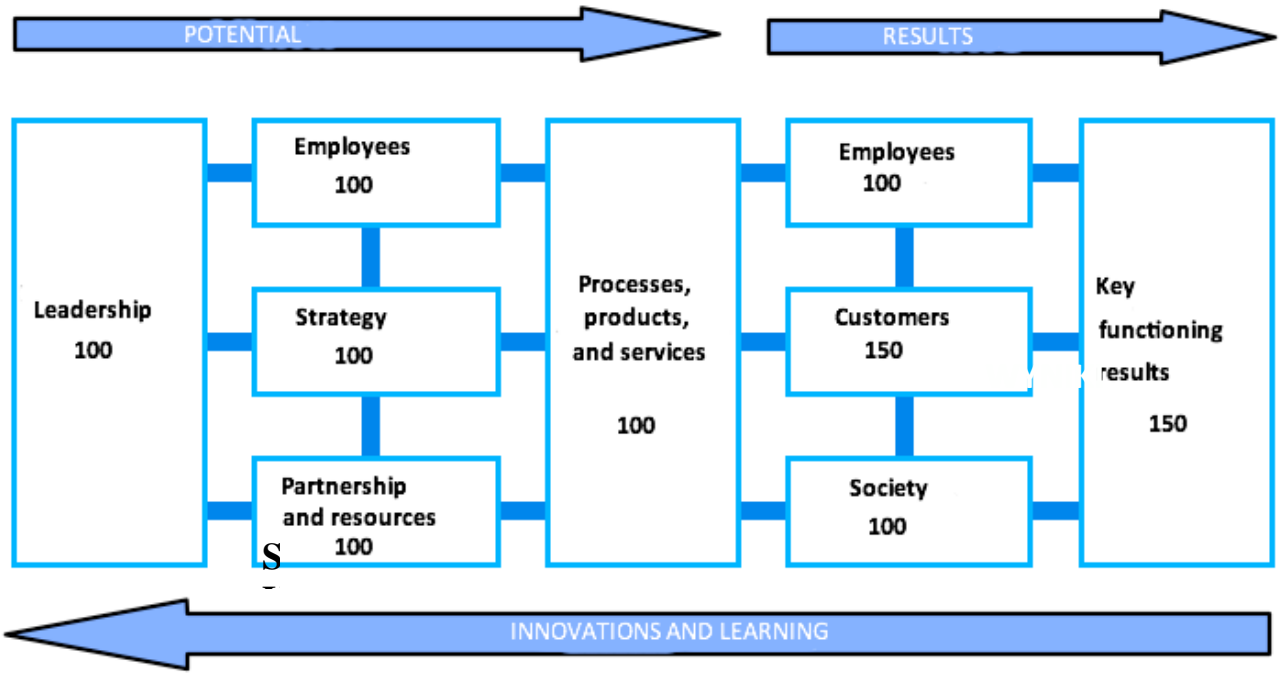
1951 - The DEMING Award (Japan)

1987 - Malcolm Baldrige Award (USA)

1991 - European Quality Award

1995 - Polish Quality Award

The European TQM model is presented in the diagram below.



As we can see, the elements constituting the basis of the model have been divided into two groups:

1) **Potential (driving forces) and**

2) Results

It results from the diagram that:
- **certain results of the organisation**,
- **customer satisfaction**,
- **employees** and
- **influences the society** are achieved by

the leadership of the top management of the enterprise which determines and introduces the **policy and strategy** of the enterprise and **manages people, partnerships, resources and processes**, leading to the success as a result.

European Quality Award

- **Category of large enterprises**
- **Category of small and medium-sized enterprises (<250 employees)**
- **Category of Public Sector**

POTENTIAL

Leadership

The way leaders create and enable implementation of the mission and vision, develop values necessary for achieving a long-term success and implement them through appropriate actions and behaviours, as well as show personal commitment in creating and implementing the organisation management system.

1a. Leaders create a mission, vision and values, and perform the role of the model excellence culture
1b. Leaders are personally involved in the creation, implementation and constant improvement of the organisation management system.
1c. Leaders are involved in the contacts with customers, partners and the society representatives.
1d. Leaders motivate, support and appreciate the organisation employees.

Strategy

How the organisation implements its mission and vision through a clearly formulated strategy directed to all the persons interested in the functioning of the organisation. In what way this strategy translates into an appropriate policy, plans, assumptions, objectives and processes.

2a. The policy and strategy are based on the present and future needs and expectations of all the persons interested in the functioning of the organisation.
2b. The policy and strategy are based on information obtained as a result of the activity results assessment, research and information obtained by learning and own creativity.
2c. The policy and strategy are created, revised and updated.
2d. The policy and strategy are reflected in the structure of key processes .
2e. The policy and strategy are made public and implemented.

Employees

How the organisation manages the personnel, develops knowledge and releases the full potential of its employees at the individual level, team level and the level of the whole organisation. The way the organisation plans such activities for the support of its policy and strategy and the effectiveness of the processes.

3a. Organisation plans human resources, manages and improves them.
3b. Organisation determines, develops and reinforces the level of knowledge and competence of employees.
3c. Employees are involved in the actions and entrusted with relevant competences.
3d. Employees and the organisation conduct a dialogue with each other.
3e. Organisation cares for its employees, rewards them and expresses appreciation.

Partnership and resources

The way the organisation plans and manages its relationships with the external partners and internal resources in order to implement the policy and strategy and ensure the process effectiveness.

4a. Organisation manages the relationships with external partners.
4b. Organisation manages finances.
4c. Organisation manages buildings, equipment and materials.
4d. Organisation manages technology.
4e. Organisation manages information and knowledge.

Processes, products and services

How the organisation determines its processes, controls and improves them so as to support the policy and strategies of the organisation and contribute to the full satisfaction of the needs of the customers and other organisations and ensures more and more value.

5a. Organisation systematically determines its processes and controls them.

5b. Organisation develops processes in accordance with the needs, introducing innovations in order to satisfy the needs of customers and other entities interested in the functioning of the organisation and ensures increasing value.

5c. Organisation designs and manufactures products and services on the basis of the needs and expectations of the customer.

5d. Products and services are produced, provided and covered by the service.

5e. Organisation develops its relations with the customers and controls them.

RESULTS

Customers

Everything what the organisation achieves in relations with its external customers.

6a. Measures of perception

Depending on the objective of the organisation, the measures of perception by the customer **may** concern:

- general image:
  - availability;
  - communication;
  - flexibility;
  - pro-active behaviour;
  - reacting.
- products and services:
  - quality;
  - value;
  - reliability;
  - novelty of projects;
  - deliveries;
  - impact on the environment.
- sales and after-sales service:
  - skills and behaviours of employees;
  - advice and support;
  - literature for the customer and technical documentation;
  - handling complaints;
  - training concerning products;
  - response time;
  - technical assistance;
  - warranty and guarantee conditions.
- loyalty:
  - willingness to further purchase;
  - willingness to purchase other products and services from the organisation;
  - willingness to recommend the organisation to others.

6b. Indicators of the activity results

Depending on the objective of the organisation, the measures of perception by the customer **may** concern:

- general image:
  - number of compliments from the customers and nominations to awards;
  - place dedicated in the press.
- products and services:

- competitiveness;
- percentage of defects, errors and returns;
- guarantee and warranty conditions;
- complaints;
- logistic indicators;
- life cycle of products;
- innovation in design;
- time of introduction to the market.

- sales and after-sales service:
  - demand for training;
  - handling complaints;
  - response time.
- loyalty:
  - time of duration of relationships;
  - effective recommendations;
  - frequency of placing/ value of orders;
  - value in the life cycle;
  - number of complaints and compliments;
  - customer retention.

Employees

What an organisation achieves in its relations with employees.

7a. Measures of perception.

The measures of perception by the employees **may** concern:

- motivation:
  - career development;
  - communication;
  - delegating powers;
  - equal opportunities;
  - involvement;
  - leadership;
  - opportunities of learning and achievements;
  - recognition;
  - ……
- satisfaction:
  - functioning of administration;
  - employment conditions;
  - facilities and services;
  - conditions of safety and health at work;
  - security of employment;
  - remunerations and additional benefits;
  - friendly relationships;
  - …….

7b. Indicators of the activity results.

Internal indicators for the employees **may** concern:

- achievements:
  - requirements concerning qualifications in comparison with the possessed qualifications
  - performance;
  - degree of training usefulness and development activities to meet the objectives.
- motivation and involvement:
  - involvement in the work of improvement teams;
  - active participation in the systems of applications;
  - levels of training and development;
  - measurable benefits from team work;

- satisfaction:
  - levels of absenteeism and morbidity;
  - levels of accidents;
  - complaints;
  - trends in employment;
  - personnel rotation;
- services provided to the employees of organisations:
  - sound administration of human resources;
  - effectiveness of communication;
  - speed of response to requests;
  - evaluation of training.

Society

What the organisation achieves in relations with the local, national and international community.

8a. Measures of perception.

Depending on the objective of the organisation, the perception measure by the society **may** concern:

- acting as a responsible citizen:
  - disclosure of information concerning the society;
  - equal opportunities
- involvement for the community in which the organisation operates:
  - involvement in education and training;
  - support for health benefits and social care;
  - supporting sports and recreation;
- measures in order to reduce and prevent the nuisance and harmfulness of organisation activity and/or throughout the whole life cycle of its products:
  - health and accident risk
  - noise and odours;
  - threats to safety;
  - pollution and emission of toxic substances.
- submission reports from the activity supporting the protection and maintenance of natural resources:
  - selection of means of transport;
  - influence on the environment;
  - reduction and elimination of waste and packaging;
  - use of substitutes for natural resources and other input materials;

8b. Indicators of the activity results.

Internal indicators for the society **may** concern:

- conduct in the case of changes in the employment levels;
- place dedicated in the press;
- contacts with the authorities in such issues as:
  - certification;
  - settlements;
  - import/export;

Key results of the activity

Everything what the organisation achieves in relation to the planned results.

9a. Key results of the activity.

Depending on the aim and the assumptions of the organisation, they **may** concern:

- financial results including:
  - price of shares;
  - dividends;
  - gross margin;
  - net profit;
  - volume of sales;
  - budget implementation.

- non-financial results including:
  - market share;
  - time of introduction to the market;
  - quantity;
  - measures of success.

9b. Key indications of the quality results

These are the operational measures applied for monitoring, understanding, expectations and improvement of the key results of the organisation activity. Depending on the purpose and objectives of the organisation and its processes, they **may** concern:

- processes:
  - -effectiveness;
  - assessment;
  - improvements;
  - cycle times;
  - indicators of defectiveness;
  - performance;
  - time of introduction to the market.
- external resources, including partner relations:
  - results of the supplier's activity;
  - prices of the supplier;
  - number and added value of partner relationships;
  - -number and added value of innovative solutions concerning productions and services introduced by the partners;
- finances:
  - cash flow positions;
  - balance positions;
  - depreciation;
  - costs of maintenance;
  - return on equity;
  - net return on assets;
  - assessment of credit worthiness.
- uildings, equipment and materials:
  - indicators of defectiveness;
  - trading stocks;
  - using media
  - degree of wear.
- technologies:
  - innovation indicator;
  - intellectual property value;
  - patents;
  - royalties.
- information and knowledge :
  - availability;
  - consistence;
  - appropriateness;
  - timeliness;
  - value of intellectual capital.

4. Methods assessment within the EFQM model

RADAR is an acronym of the English words: **R**esults, **A**pproach, **D**eployment, **A**ssessment i **R**eview, it reflects the requirement of the EFQM Excellence Model referring to what should be included in the criteria of potential and results.

1. Potential criteria

Approach refers to the objective(s) and targeting the activity to each sub-criterion, along with determining and establishing the most effective process(es) leading to the achievement of these objectives. The words "certain" and "integrated" refer to the excellence of the **approach**.

Certain

"Certain" concerns the scope in which the approach:

- refers to the relevant aspects of a given sub-criterion,
- is based on reasonable grounds, e.g. through the presentation of the set objective and direction;
- it focuses on the needs of the relevant groups directly interested in the results which are to be achieved, along with well defined and developed processes for achieving these results.

Integrated

"Integrated" concerns the scope in which the described approach supports the policy and strategy, and it is connected with other approaches wherever applicable.

Implementation indicated the application in practice of what was defined in the approach. The implementation in a sustainable and systematic way gives the policy and strategy their real dimension in the daily practice, at all levels of the organisation activity.

The words "Systematic" and "Full" – refer to the excellence of the implementation of the described approach.

Systematic

"Systematic" determines the scope in which the implementation of the approach is managed in a systematic way.

Full

"Full" determines the full scope in which the approach was implemented in the relevant areas – i.e. at the relevant levels and organisation cells.

Assessment and revision refer to the way in which measurement and monitoring of the approach are conducted, how the organisation learns and analyses the results of such actions to identify, determine priorities, plan and implement improvement. The words "Measurements", "Learning" and "Improvement" refer to the excellence of the **assessment and revision** of the described approach.

Measurement

"Measurements" determine the scope in which a regular approach measurement of the approaches, approach implementation and the achieved results are conducted wherever appropriate. The applied measures should usually be listed in the relevant sub-criteria of results.

Learning

"Learning" determines the scope in which such activities are connected with learning, such as: benchmarking, estimates and assessments are applied to help identify and share the best applied practices and improvement opportunities.

Improvement

The key result of the Assessment and Revision stage are the improvement activities aiming at strengthening the strengths and improving the weaknesses which were identified during the process. "Improvement" determines the scope in which the measures as well as the information obtained during the activities connected with learning and creativity is analysed and then applied for identification, determining the priorities, planning and implementation of improvements. Improvements should reflect innovative thinking wherever appropriate.

Elements	Points / Attributes	0%	25%	50%	75%	100%
Approach	**Certain:** - approach is based on solid, rational foundations - there are well defined and created processes - approach is focused on the needs of the directly interested persons	No proofs or not confirmed	There are some proofs	Proofs	Visible/clear proofs	Exhaustive proofs
	Integrated: - approach supports the policy and strategy - where appropriate, the approach is connected with other approaches	No proofs or not confirmed	There are some proofs	Proofs	Visible/clear proofs	Exhaustive proofs
	Scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

Elements	Points / Attributes	0%	25%	50%	75%	100%
Implementation	**Full:** - approach is fully implemented	No proofs or not confirmed	Implemented in about 1/4 of the relevant areas	Implemented in about 1/2 of the relevant areas	Implemented in about 3/4 of the relevant areas	Implemented in all of the relevant areas
	Systematic: - approach is extended on the whole organisation structure	No proofs or not confirmed	There are some proofs	Proofs	Visible/clear proofs	Exhaustive proofs
	Scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

Elements	Points / Attributes	0%	25%	50%	75%	100%
Assessment and review	**Measurement:** - regular measurement of approach effectiveness and implementation is conducted	No proofs or not confirmed	There are some proofs	Proofs	Visible/clear proofs	Exhaustive proofs
	Learning: - activities connected with learning applied for identification of the best models and improvement possibilities, and the exchange of experience in this scope	No proofs or not confirmed	There are some proofs	Proofs	Visible/clear proofs	Exhaustive proofs
	Improvement: - results of measurements and learning are analysed and applied for the identification of improvements, setting priorities, planning and implementation	No proofs or not confirmed	There are some proofs	Proofs	Visible/clear proofs	Exhaustive proofs
	Scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

Total scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

2. Criteria of results

Each of the words: "Trends", "Objectives", "Comparisons" and "Causes" refers to the **perfection** of the presented results.

Trends

"Trends" refer to the sets of data for a given period of time, concerning different parameters applied for measuring the results. A positive trend is the one which indicates a general tendency of improvement. The following sequence of numbers: 3, 6, 10, 9, 12, 11 and 14 will constitute an example of a positive trend. Of course, the results of the activity in the case of some parameters, may be good already at the beginning of the trend. In such cases, the organisation will seek a way to maintain the achieved good results of activity.

Objectives

The objectives refer to the objectives of the organisation. Each presented trend of results it is necessary to provide the internal objective – also as a trend in the progress of time.

Information presented in the criteria of results should also include a justification for the set objectives in such a way to be able to make an assessment whether these objectives are ambitious and groundbreaking. It should be possible to find the relationships between the objectives and the potential criteria – an example here may be the criterion concerning the policy and strategy.

A favourable comparison with the results of the target objectives means that the presented trend of objectives is generally achieved or exceeded.

Comparisons

"Comparisons" refer to the comparisons with the external organisations – with concrete organisations, average results in the industry or such organisations which are regarded as "the best in their class." The term "the best in its class" indicates that the achieved results are the best of their kind – a given organisation may of course represent another type of activity of the organisation subject to the assessment. If the last one is an organisation acting in the area of the whole country, the term "the best in its class" may relate to other organisations acting within the same area. If the

assessed organisation aspires to the category of activity on the world market, seeking something which is "the best in its class" should be wider.

Causes

"Causes" concern the scope in which the results are a consequence of a concrete approach(es) or constitute the ultimate area in which it is necessary to conduct an assessment of the excellence of results. Combining the results with the causative factors (potential) makes it possible to obtain a balanced view on the relationship between the cause and effect.

The word "Scope" refers to the scope of the presented results.

Scope

"The Scope" of results indicates the extent to which they cover the relevant areas. The results should be grouped, for example into product groups, categories of employees and provided for all the departments and organisational units taken into account in the assessment. Moreover, the scope should encompass all relevant aspects of the criterion.

Moving to the assessment of the scope of results, it is necessary to adopt a holistic view of the assessed organisation. Additionally, the relationship between the results and the methods of approach descried in the potential criterial should be clearly visible. It will affect the number of points awarded for the scope.

Elements	Attributes / Points	0%	25%	50%	75%	100%
Results	**Trends:** - trends are positive and/or good results of action are permanently maintained	No results or information not confirmed	Positive trends and satisfactory results in some areas	Positive trends and/or permanently maintained good results of action in many areas, at least for 3 years	Very positive trends and/or permanently maintained excellent results in most areas, for at least 3 years	Very positive trends and/or permanently maintained excellent results in all areas, for at least 5 years
	Objectives: - objectives are achieved - objectives are appropriate	No results or information not confirmed	Favourable and appropriate in some areas	Favourable and appropriate in many areas	Favourable and appropriate in most areas	Excellent and appropriate in most areas
	Comparisons: - comparisons are conducted with other organisations, they indicate that the results are better than the average ones in the industry and from the results of organisations regarded as "the best in their class"	No results or information not confirmed	Comparisons in some areas	Favourable in some areas	Favourable in many areas	Excellent in most areas and "the best in their class" in many areas
	Causes: - results are the effect of the approach	No results or information not confirmed	There are some results	Many results	Most results	All results. Leading position will be maintained
	Scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

Elements	Attributes / Points	0%	25%	50%	75%	100%
	Scope: - results relate to the relevant areas	No results or information not confirmed	Some areas taken into consideration	Many areas taken into consideration	Most areas taken into consideration	All areas taken into consideration
	Scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

Total scores	0 5 10	15 20 25 30 35	40 45 50 55 60	65 70 75 80 85	90 95 100

In the case of each sub-criterion, it is necessary to provide:

1a. Strengths

1a. Improvement areas

1a. Issues for the clarification during the visit

SUMMARY TABLE OF SCORES

1. "Potential" Criteria

Criterion number	1	%	2	%	3	%	4	%	5	%
Sub-criterion	1a		2a		3a		4a		5a	
Sub-criterion	1b		2b		3b		4b		5b	
Sub-criterion	1c		2c		3c		4c		5c	
Sub-criterion	1d		2d		3d		4d		5d	
Sub-criterion			2e		3e		4e		5e	
Sub-criterion										
Total										
		÷ 4		÷ 5		÷ 5		÷ 5		÷ 5

Awarded points					

Note: The number of awarded points for each criterion is the arithmetic average of points awarded to particular sub-criteria. If the applicant provides convincing proves that one or more sub-criteria does not concern his organisation, it is justified to calculate the average on the basis of the assumed criteria. To avoid confusion (in the case of a "zero" result), these sub-criteria which are not applicable here should be marked with the "NR" symbol in the above table.

2. "Results" Criteria

Criterion number	6		%	7		%	8		%	9		%
Sub-criterion	6a	x 0.75=		7a	x 0.75=		8a	x 0.25=		9a	x 0.50	
Sub-criterion	6b	x 0.25=		7b	x 0.25=		8b	x 0.75=		9b	x 0.50	
Awarded points												

3. **Calculating of the total scores**

Criterion	Awarded points	Coefficient	Final scores
1 Leadership		x 1.0	
2 Policy and strategy		x 0.8	
3 Employees		x 0.9	
4 Partnership and resources		x 0.9	
5 Processes		x 1.4	
6 Customers		x 2.0	
7 Employees		x 0.9	
8 Society		x 0.6	
9 Key results of activity		x 1.5	
Total number of awarded points			

- Enter the points awarded for each criterion (in part 1 and 2 above).
- Multiply the points awarded to each criterion by the corresponding coefficients to obtain the final sores of criteria.
- Add up the final scores of criteria to obtain the total number of awarded application points.

Apart from the European Union, a few countries (including Poland) have recently established its own quality awards.

5. Japanese experience

QUALITY IS SOMETHING WHAT CAN BE IMPROVED

We will win and the Western industry will lose and you cannot do anything about it because the source of your failure is in yourselves.
For you the management idea is based on the implementation of ideas developed in the heads of the heads with the hands of the employees. For us *the essence of management is to mobilise and unite the intellectual potential of all company employees.* Only owing to the combination of all in one powerful mind, the company is able to confront the limitations and the rapid changes taking place on the contemporary market.

Therefore, in our large companies train the employees two to four times longer than in ours. Therefore, our companies support the internal exchange of experience and information. Therefore, we constantly ask everyone for proposals and we expect our educational system to provide a larger number of persons with university education as well as intelligent, educated graduates of high schools, because they are the soul of the economy.

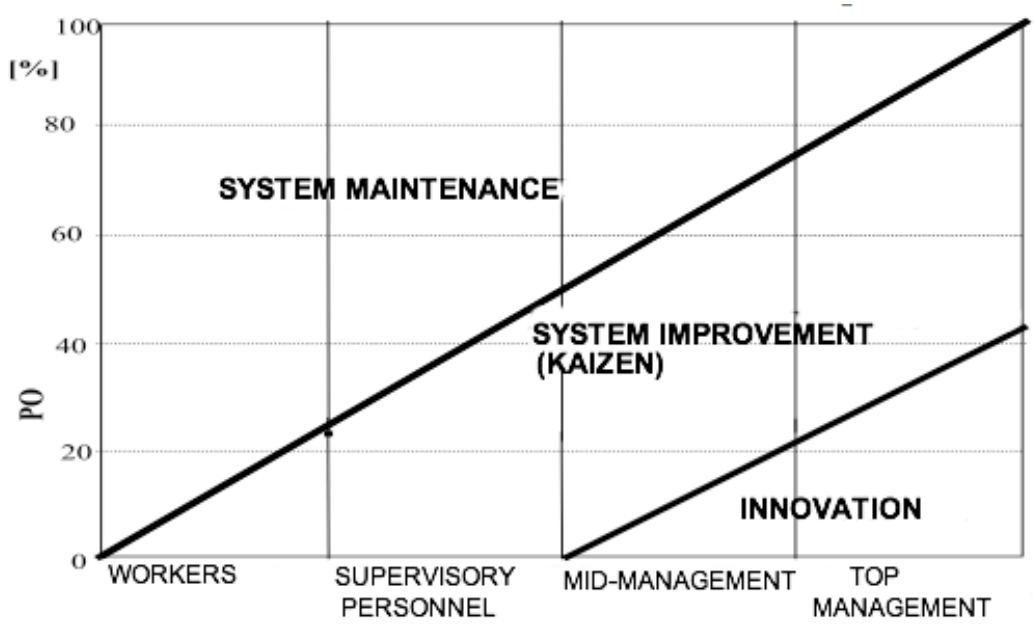
Your socially oriented directors often have good intentions, they think that they have to care for the people in their companies. We are realists and we think that people have to take care of their companies which pay them a hundredfold for their sacrifice. Thus, in the long run we care more about the social good than you.

Konosuke Matsushito

Employees of Toyota (40 000 workers) reported 687000 improvement proposals in one year.

	KEIZEN	INNOVATION
Effect	Long-term and long-lasting but devoid of drama	In short term but dramatic
Conduct	Small steps	Large steps (leaps)
Course in time	Still growing	Intermittent and discontinuous
Changes	Gradual and continuous	Nagłe
Involvement	Everyone	A few selected "masters"
Approach	Collectivism, group efforts, systemic approach	Absolute individualism, individual ideas and efforts
Implementation	Maintenance and gradual development	Fragmentary activities and redevelopment
Brilliance	Conventional knowledge, consistency in the arts	Technological revolution, new theories
Requirements to apply	Small investments are required but a large effort for the maintenance	Large investments are required but a small effort for the maintenance
Targeting of efforts	towards people	towards the technology
Assessment criteria	Processes and efforts for better results	Results for the profit
Benefits	Works better in a slowly growing economy	Is better suited for a rapidly growing economy

Japanese model of functions in the enterprise



QUALITY CONTROL FEATURES IN JAPAN according to *J. Juran*

- Mass training programmes in the area of quality
- Annual quality improvement programmes
- Playing the leading role by the top management in the area of quality

Characteristics of the Japanese management model

lifetime employment
seniority system (payroll)
reducing the differences in the material status (better contact)
team work (broad specialisation, "people first", motivation in the team)
loyalty and identification with the company

"I thought that in Japan there are two religions: buddhism and shintoism. Now, I discovered the third – KAIZEN." *William Manly, Pres. of Cabot Co.*

We often here an opinion that the Japanese are masters at adapting someone else's ideas. This statement, not without acridity, brings a great deal of truth. The role of E. Deming and J. Juran in the creation of the power of the Japanese economic model is not questioned by anybody. However, it is untrue that no own methods or pro-quality activity models have been developed in this country jest. Some of the Japanese achievements include:

1) Quality Circles

It is probably the best known feature of the Japanese quality management model. The quality circles began to form in Japan in the early 1960s as a development of the concept of K. Ishikawa, an eminent specialist in the area of quality. He stated that both the superior and the worker are not able

to solve problems connected with a given job or process on their own, but through cooperation they are able to effectively overcome these problems. This obvious principle found a fertile ground in the Japanese economy.

Quality circles (currently more than 250.000) are 8-10-person teams consisting of employees who voluntarily join them and meet regularly to solve the current problems or find improvements. Members of the quality circles are trained within the scope of the problem solving methodology and the use of statistical methods. It is estimated that about 15% of all the employees in Japan participate in the works of the quality circles. Despite the attempts to reproduce the model of the Japanese quality circles in the USA and in Europe, they have not worked in such an extent that was expected. The reasons for this are attributed to the cultural distinctiveness (the Japanese systems of education emphasise harmony and team work, the Western ones create individual initiative and creative skills) and the model of employment at a Japanese company (in the Western model it does not matter whether someone works hard – the lack of results leads to lower incomes and status; the Japanese management model is people-oriented, a gradual understanding of the essence and the improvement of processes leading to the improved results).

2) Just-in-time (JIT)

It is a production strategy which requires from the management such organisation of the production process to be able to perform all tasks just in time. In the classical model, each process (operation) "pushes" a part of material (semi-finished product) through further stages of production, regardless of whether the next process has performed its previous task or whether another "delivery" is needed. If certain problems arise in a given operation, the material from the previous process is gathered, creating unnecessary stocks. In the JIT model the course of the process is controlled by the last operation. Production on the previous position is completed only with the number of taken products. When a problem arises, the whole process is stopped and all the operators try to eliminate it (owing to appropriate training). A characteristic feature of the JIT model at Toyota is the *Kanban* – a card submitted in a plastic envelope, which determined the demand of a given station for workpieces and raw materials necessary for production in the near future. It simply prevents the formation of shortages and overproduction of certain elements. There are two types of *Kanban cards - kanban of collection* (specifies the amount of products which is to be collected in the next process (operation)) and *kanban of production order* (indicates the number of elements which was to be performed in the previous process). At Toyota, there have also been certain initiatives to minimise the shifting time and machine setting time (a known example of reducing the time of resetting the bodywork works within the last 20 years from 3 hours to 3 minutes or the reduction owing to small improvements developed within the framework of Quality Circles, the time of resetting the presses producing bumpers in a plant in the USA from 90 to 22 minutes within one month!!!). The most important advantage of the JIT is the fact that there are no stocks in the system. Stocks are often the cause of production losses, unnoticeable and underestimated. Due to its sensitivity to faulty production, the JIT uses the methods of statistical production control. The defectiveness of production should not exceed 100 ppm (parts per million), i.e about 0.01% .

Elements of the JIT strategy:

- *flexibility in determining the series size* – another operation which "controls" the production amount of the preceding operation,
- *reduction of process switching times* – employees from the neighbouring positions help in the "conversion" of the equipment,
- *implementation of the TQM principles* – especially important here is the adoption of there recipient and internal customer model, striving for error elimination, application of techniques of statistic process control,
- *flexibility of the production process,*
- *simplification of the procurement procedures* – it is particularly important to establish close relationships in the supply chain, mutual trust, knowledge of possibilities,

3) Excellence against the AQL

It is a Japanese slogan expressing a contrary philosophy deeply-rooted in the industrial Western countries, forms of quality assessment based on the acceptable quality level. The principle aims to eliminate variability in the use of products of through its constant reduction.

An IBM branch in Windsor, Ontario, ordered in one of the Japanese companied the delivery of parts, determining the permissible level at 3 pieces per 10,000 units.
The delivered parts were accompanied by a letter in which the Japanese explained:
"For us, the Japanese, it is difficult to understand the American business practices. However, to every 10,000 parts we added three defective parts which we packed separately. We hope that it is sufficient for you."
(according to *Toronto Sun*)

3) Poka - Yoke

One of the ways leading to this objective is the Poka-Yoke system designed and developed at Toyota by Shigeo Shingo. It is based on supplying the contractors in appropriate technologies and working methods so that they performed the work in the only possible way - the correct one. This system is called an immunity to stupidity or thoughtfulness. For example, a person assembling sub-assemblies every time, used the body from the courts, uses a special container in which there is an appropriate number of connecting parts. This prevents overlooking during the assembly.

The Poka-Yoke methods:- identification of elements (weight, size, shape),- the sequence of technological and assembly operations (e.g. remaining connecting parts),- detection of deviations from the set values (counters; elimination of unnecessary parts - two openings, three screws; detecting critical conditions – signal of exceeding a certain parameter).

The use of Poka-Yoke and the so-called source control, allows for the elimination of the need to apply receiving control of products.

4) The 5-S Practice

The name 5-S is an acronym of five Japanese words:

- SEIRI - separate the unnecessary parts and get rid of them.
- SEITON - arrange the necessary things in a way that is convenient to use.
- SEISO - clean the workplace thoroughly and clean the tools.
- SEIKETSU – be neat and clean, avoid dirty working environment.
- SHITSUKE – maintain a high level of discipline and work ethics.

5-S means in practice the attention to the order, diligent management. In Japan there is a perception that this practice is one of the most important elements of management of the contemporary enterprise. If the introduction of the 5-S principles is not undertaken, it is impossible to implement any systematic action among employees in order to facilitate the work, not to mention the TQM.

The essence of the 5-S practices is presented in the table:

5-S	Definition	Improvement
SEIRI	Sorting things into necessary and unnecessary. Removal of unnecessary things.	- reducing the inventories, - better use of working space, - prevention of the loss of items
SEITON	Appropriate placement of all necessary things for more efficient use.	- shortening the time for searching for the necessary things, - improvement of work safety
SEISO	Removing dirt, pollution from the workplace.	- maintenance and improvement of machine efficiency, - easiness to assess the workplace condition, - environmental protection.
SEIKETSU	Maintaining neat and clean conditions in the workplace.	- improvement of work quality, - elimination of accident causes,
SHITSUKE	Abiding by all the rules in the workplace	- lowering the number of mistakes due to inattention, - observance of the adopted procedures, - improvement of human relations.

How to implement the 5-S practice:

1) Selection of the area. It is necessary to choose the area in which the effect will be most visible. Often in the first place, the works cover the employee rooms (e.g. changing rooms, canteens, washrooms, etc.)

2) Taking photos of the places which require arrangement. Such photos will be used to show positive changes occurring at a given place.

3) Conducting actions of colourful labels. It is about marking unnecessary things by means of specially prepared colourful tags, stickers and labels. Within this stage it is necessary to:

- determine the usefulness criteria of a given item (e.g. time of not using it),
- prepare colourful labels, tags, etc. with the information such as: the name, type of thing, number, reason for inclusion in the group of unnecessary items, department (place), proposed action, date of labelling, tag number,
- indication and marking of unnecessary things with tags (it is better to mark too many things than to leave an unnecessary thing),
- computer inventory of the marked items (a global revision, better decision-making possibilities),
- removal of unnecessary things or moving them to designated zones r,

4) Thoroughly clean the vacated places. It is a basis for keeping these places clean then.

5) Introduce special markings e.g. for communication roads, dangerous places, installations, social rooms, containers for products (this may be performed simultaneously by the Poka-Yoke function). It mainly aims at improving safety and facilitating the work by relevant associations.

6) Introduce an identification system of all the sites in the enterprise; each place in the enterprise should have its own unique address (building> floor> room> square (e.g. with the side of 2x2[m])>shelving> shelf).

7) Place all the things in an easy to use way to: easily spot them, easily take them for use, easily put in place after use u.

8) Introduce marking of shelves etc. as the place for the return, with the indication of the permissible minimum and maximum numbers,

9) Conduct general cleaning of tools, machines, aids,

10) Perform the division of the cleaning tasks machines and equipment and the workplaces among the employees, where appropriate, determine the cleaning systems,

11) Put the cleaning supplies in places which are convenient for use,

12) Initiate joint activities and mutual assistance of the employees in cleaning and organisation; it is advisable to start from the social rooms, since an employee changing or eating meals in an unpleasant environment will not accept the need to maintain order in the workplace,

13) Prepare checklists with the participation of employees and introduce them to continuous use, it allows for full implementation of the agreed principles; relying solely on the memory does not protect against omitting some important activities,

14) Introduce constructive criticism and enforcement of the principles, order, cleanliness by the management, as the first step in the creation of the desired habits. It is necessary to do everything so that critical remarks would not be treated as a form of personal attack.

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MODULE III

Quality Management Systems. Structure of ISO Standards Series 9000. Requirements of ISO 9001. Process Orientation. Audit as a Tool of Diagnosis and Improvement. Certification and Accreditation

Normative Systems of Quality Management. Series ISO 9000

Introduction

Introduction of formalised management system in a variety of organisations has been one of the most characteristic phenomena in the world economy in the recent years .

Publishing the first edition of the standards from series 9000, ISO in 1987, the International Organisation for Standardisation did not expect that their popularity would be so big. At the time of the preparation of this study in the world, the certificates of compliance with ISO 9001 were held by approximately 1,100,000 organisations in at least 160 countries. In Poland this figure was at the level of 15000.

The success of the standards concerning quality systems inspired business communities to develop the concepts of the environmental management systems and gave rise to considerations on the mutual relations between different aspects of management in the organisation, their integration and ensuring mutual compatibility. It has become even more important that the system of workplace health and safety management (SWHSM) has frequently been enumerated as an additional module of such an integrated system (SZBHP).

Currently, other formalised systems are being introduced commonly, including mainly:

- knowledge management,
- financial management,
- management of social responsibility in the organisation
- protection of data and professional secrecy.

A phenomenon closely connected with the introduction of universal quality management systems is their adaptation for the purposes of particular industries z: automotive (ISO/TR 16949), telecommunications (TL 9000), aerospace (AS 9000), medical (works within the framework of ISO/TC 210).

Benefits for all organisations connected with the implementation and certification of quality systems may be divided into two categories: external and internal ones.

External benefits

1) Meeting the requirements of individual customers, business partners as well as the national and foreign market

A certificate for the quality management system ceases to be a tool for gaining competitive advantage and it gradually becomes the determiner of the minimum level acceptable by the demanding customers and markets. The number of organisations which require the implemented systems of quality management from their suppliers and sub-suppliers is growing at a rapid pace. Having a certified quality system constitutes a prerequisite to maintain the supplier position and this the existence of many, especially smaller companies. Whereas the certificate obtained by the company – the customer, gives the supplier a sense of stability and credibility within the framework of the cooperation.

2) Compliance with legal requirements

As shown by the European experience, it is much easier for the organisations functioning within the framework of certified quality systems to fulfil the requirements connected with the obligatory certification of their products. In a situation of a transition to the European New Approach Directives and marking a number of products introduced to the market with a CE marking, the aforementioned fact will be of great significance for our manufacturers. The quality system requires the organisation to ensure the knowledge of the current legislation and other official requirements connected with the activity of the company. This is conducive for maintaining compliance with them now and in the future.

3) Reducing the activity risk

By introducing a process-oriented quality management, the probability of making mistakes is lower in the key activities for the quality.

Banks, insurance companies and investors base their decisions on risk management. Therefore, the systemic approach to the problem of minimising the potential threats places the enterprise in a favourable situation towards the aforementioned entities.

The criterion of "quality credibility" is applied in the case of orders finance from te EU resources. The certificate of conformity with ISO 9001:2008 is also an essential argument in applying for public procurement.

4) Social benefits

For the local communities, to improve their quality of life, the important fact is that an increasing number of offices of the local government (municipal, community, district,

marshall and provincial offices), secondary schools and universities, hospitals and other health care units, and even police and tax authorities decide to implement the quality systems compliant with ISO 9000 standards. Implementation of the quality system in such organisations brings a number of benefits to the local community, such as the improvement of service efficiency, transparency and harmonisation of rules of conduct on various matters, effective response to complaints, or being guided by the quality criteria of the suppliers of materials, parts and equipment, as well as subcontractors of various services.

Internal Benefits

1) Improvement of management efficiency, organising the organisation, reduction of qualitative losses

The aforementioned pillars of quality management on which the requirements of ISO 9001:2008 are based, constitute a mechanism which gives the company a **possibility** of a constant improvement of the offered products or services. This is achieved by:

- appropriate awareness and involvement of employees at all levels,
- continuous improvement of the applied operating and and supporting processes and the implementation of new, more effective ones,
- optimisation of the selection of suppliers of materials, semi-finished products and services,
- increasing the effectiveness of the used infrastructure.

2) High employee motivation

Modern quality management systems create an appropriate framework for the empowerment of employees and reasonable allocation of tasks for which they can take full responsibility.

Another aspect having a positive influence on the level of life quality of the employees is a high level of professional satisfaction in connection with the functioning within the framework of an orderly organisation, respect for common, clearly defined rules, cleanliness and order in the environment, pride because of well done work and the quality results of a company. It has been found that this organisational order translates directly into a sense of security, mental health stabilisation of employees and their families.

The system of training and improving the skills of the staff can enhance the factors mentioned above, effectively increasing the motivation.

3) Openness to other normative management systems

Implementation of a quality management system is treated by specialists as the beginning of the way towards integrated systems taking into account such aspects as environmental protection, occupational health and safety and social policy, financial management and information security. These aspects included in the organisation strategy and appropriately managed take the economy closer to the vision outlined within the framework of the TQM philosophy.

The model which should be applied in this context in accordance with the recommendations of ISO 9004:2009 id the self-assessment of the organisation, e.g. based on the criteria of the Excellence Model of the European Foundation for Quality Management (EFQM). This model, including the Model of the Polish Quality Award which is based on it, enables the assessment of the level of being near the quality excellence, and thus determines the **level of the quality reserve** in the organisation. Many large and small organisations (also in Poland) proved that the formalised management systems may be a great tool for the implementation of the main postulate of the founder of the modern quality doctrine, W. E. Deming – random reduction and elimination of a determinable variability in the key processes taking place in the organisation. This postulate does not mean a constant striving for limiting variability (dispersion) of activity results and the elimination of the reasons for the lack of stability of these results. It is a way worthy of special recommendation, since it proves that in all conditions it is possible and necessary to act better than it is commonly expected. Then and only then it is possible to count on continuous success.

What main reasons guide the organisations which decide to implement and certify quality systems? Here are the most common answers to this question:

- increasing competitive advantage (often - staying on the market!),
- meeting the requirements of markets/national and foreign customers,
- meeting the legal and administrative requirements in the EU Member States and other highly developed countries,
- arrangement of work in the company (through clear procedures, instructions),
- reduction of losses (the so-called poor quality costs),
- making the first step towards the TQM (total quality management).

Obviously, the aforementioned advantages occur in the places where the systems have been implemented in a thoughtful manner, with the participation and acceptance of a wide

range of employees, in accordance with the chief principles of quality management and not to obtain the proverbial document.

The Family of ISO 9000 Standards

Standards of the ISO of series 9000 are applicable not only independent of the industry to which the manufactured product or service can be included but also **regardless of the organisation size**. Standards ISO 9000 include the standards developed by the Technical Committee ISO TC 176 – *Quality management and quality assurance.*

The core of this series of standards constitute the documents presented in Table 1.

Table 1

Basic norms constituting the family of ISO 9000

Symbol of international standard	**Standard name**	**Symbol of a corresponding Polish Standard**
ISO 9000:2005	*Quality Management Systems - Fundamentals and Vocabulary*	PN-EN ISO 9000:2006
ISO 9001:2008	*Quality Management Systems - Requirements*	PN-EN ISO 9001:2009
ISO 9004:2009	*Managing for the Sustained Success of the Organisation. A Quality Management Approach*	PN-EN ISO 9004:2010

Standard ISO 9001 is the basis of certification of the company quality management system. Standard ISO 9004 in connection with ISO 9001 constitutes the so-called **coherent pair**. **Standard ISO 9004 does not constitute requirements** but only presents recommendations concerning increasing the company effectiveness, exceeding the "minimum" of the requirements of ISO 9001. **Standard ISO 9000 is a glossary** of the key concepts from the scope of quality management system as a source indicating their relationships.

In addition to the basic three standards, we should also mention some other important documents performing an auxiliary role in the ISO 9000 family. They are summarised in Table 2 together with the corresponding documents translated into Polish and available within the distribution network of the Polish Standards.

Table 2

Selected standards and auxiliary documents of ISO 9000

Symbol of international standard or other ISO document	**Document name**	**Symbol of a corresponding Polish Standard or a document in Polish**
ISO 10012:2003	*Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment*	PN-EN ISO 10012:2004
ISO 10015:1999	*Quality Management – Guidelines for Training*	PN-ISO 10015:2004
ISO/TS 16949:2009	*Quality Management Systems – Particular requirements for the application of ISO9001:2008 for automotive production and relevant service part organisations*	ISO/TS 16949:2009 (translation into Polish from 2009)
ISO 19011:2011	*Guidelines for Auditing Management Systems*	PN-EN ISO 19011:2012 (original)
ISO 9001 for Small Business – What to do – Advice from ISO/TC 176	*ISO 9001 for small companies – published in 2011*	Guide published in Polish in 2011

ISO 9001 and 9004 standards are based on **eight principles of quality management.** These principles closely relate to the basic assumptions of the philosophy of total quality management (TQM). This fact makes the quality system not only a tool ensuring the stability and reproducibility of the product but it becomes the mechanism promoting progress and economic development. The quality management principles are presented in the terminological standard ISO 9000. Są to:

1) **Focus on the customer:** organisations depend on customers and thus have to recognise their current and future needs, meet the customer requirements and strive to exceed those expectations.

2) **Leadership:** leader determine the common objectives, courses of action and an appropriate organisational climate. At the same time they should create conditions through which employees will be able to join the implementation of the set objectives.

3) **Involvement of employees:** people at all levels are the key element of the organisation and achieving the full involvement of the staff allows for the full use of their skills fro the benefit of the organisation.

4) **Process approach:** the desired result of activity is achieved in a more effective way when the resources and activities related to achieving this result are treated and manages as processes. **Systemic approach to management:** identification, understanding and management of a system of mutually connected processes to achieve a certain objective contributes to increasing efficiency and effectiveness of the organisation.
5) **Continuous improvement:** a constant element of an organisation is continuous improvement.
6) **Decision-making based on facts:** effective decisions are based on a logical or intuitive analysis of data and information.

Mutually beneficial relationships with suppliers: mutually beneficial relationships between the organisation and its suppliers increase the mutual ability to create added value and development. Reference to the above principles and their practical implementation demonstrate an effective system of quality management in a company.

Requirements of ISO 9001

ISO 9001:2008 (and also its Polish equivalent PN-EN ISO 9001:2009) consists of the *Introduction* and 8 chapters.

The *Introduction* determines the possibilities of the standard application, presents the idea of a quality management model in a synthetic way on the basis of the process approach and with reference to the classic cycle of continuous improvement. To this end, there is a figure constituting an interpretation of the quality management system. The chapter also presents a justification for the application of ISO 9004 to improve the functioning of the organisation, constituting the so-called coherent pair with ISO 9001. The chapter also shows an increase in the compatibility of ISO 9001 with the standard including the requirements for the environmental management system – ISO 14001.

Chapter 1 *Scope of the Standard* specifies the purpose for which the organisation can implement the requirements included in this standard and determines the possibility of exemption from some of these requirements cel. Chapter 2 of the standard os cited as the primary document connected with ISO 9001 - the terminological standard ISO 9000, and chapter 3 explains the meaning of such concepts as the organisation, a supplier and a product.

The requirements concerning the quality management system are presented within the framework of the five main chapters of them most important standard from the practical point of view - ISO 9001:2008:

Chapter 4. Quality Management System.

Chapter 5. Management Responsibility.

Chapter 6. Resource Management.

Chapter 7. Product Implementation.

Chapter 8. Measurements, Analysis and Improvement.

Groups of requirements (chapters) contained in ISO 9001, in dynamic terms of the quality management cycle in any organisation are presented in Fig.1.

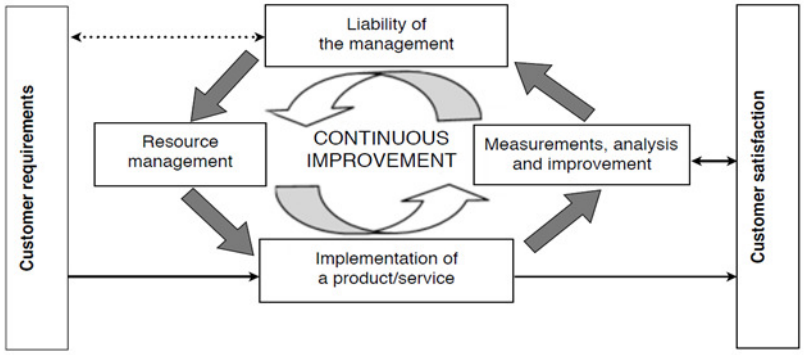

Fig. 1. Dynamic structure of the quality management systems according to ISO 9001:2008

All the requirements of ISO 9001:2008 will be discussed in detail in the next part of chapter 6.

Quality management system (chapter 4 of the standard)

Section 4.1 of ISO 9001, in spite of its unassuming name (i.e. *General Requirements*) serves as a foundation in relation to the remaining elements of the quality system. It is often said that section 4.1 is "ISO 9001 in a nutshell." The requirements provided here constitute the framework for understanding what an effective pro-quality process management of organisation should be based on.

Ref.4.1a. ***Determine the processes necessary in the QMS of a company (including the processes implemented by the subcontractors).***

Products and services are created as a result of many processes which are implemented in an organisation. The quality of outputs of an organisation depends on the quality of processes. At this point it is worth mentioning the basic definition of the process:

Process - a set of interrelated or interacting activities which transform the input state into the output state

The implementation of processes is the performance of the daily duties by the employees in the company. Every process is powered by different "inputs", e.g. materials, information, money, resulting in a variety of "outputs" (products, services, information which in turn feed other processes.

Along with receiving an order from the customer ("input") a whole sequence of action starts, e.g. its registration, feasibility studies, contract preparation, its verification and approval, supply of the necessary materials, parts and services, production of the ordered product or service implementation. This procedure is finished with the delivery of a product or service to the customer ("output"). It is similar in the case of other activities, connected both directly with the customer service, and with management, procurement, maintenance of the infrastructure, etc., e.g. long-term and short-term planning, selection, training and motivation of employees, cooperation with the suppliers of goods and services, cooperation with the providers of products and services, maintaining the internal computer network of the company.

Thus, the processes which are necessary in the quality management system are not only the activities which create a typical cycle of *product implementation* – from obtaining the order to the delivery of a product/service to the customer (including the customer service). These are also the *management services,* e.g. long- and short-term planning, human resource management, *supporting,* e.g. administration, finance, maintaining of the infrastructure and the procurement. ISO 9001 requires to include activities such as: management reviews conducted by the management, internal audits, all measurement processes, corrective and preventive activities in the processes within the quality management system.

Ref.4.1b. ***Determine the direction and mutual relationships of these processes.***

It is necessary to determine the sequence and interconnections between the identified processes. The best solution is the graphical form showing the relations between the processes. It is also necessary to remember that usually the process structure is complex even in the smallest companies - main processes consist of sub-processes which in turn consist of actions, activities, etc..

Ref. 4.1c. ***Determine the criteria and methods necessary to ensure that both the course and supervision of these processes are effective.***

The set process structure of the company is the basis for the creation of efficient supervision methods of its components.

Planning the criteria and methods ensuring effective implementation and the supervision of processes within the process structure of the quality system should be entrusted to the most competent people, most familiar with a given process, the so-called process owners. It is them who in consultation with the management and the persons participating in the process should determine, i.a. which measures and their limit states will be used to monitor the activities or what process monitoring method will be the most effective one.

Ref. 4.1d. ***Ensure the availability of resources (including information) necessary for the course and supervision of these processes.***

Effective process implementation obviously requires different resources. These include the employees, infrastructure, working environment and the necessary information. ISO 9001 includes the requirements concerning the resource management in chapter 6.

Obviously the company management bears the primary responsibility for ensuring the resources which are necessary for the implementation of the set goals.

This section refers also to the information necessary to the process implementation. It is mainly about documents in different forms – both the internal ones and the ones of the external origin.

Ref. 4.1e. ***These processes should be supervised, and measurements and analyses s should be conducted in them.***

Everything what was planned in relation to the process management should be implemented. The stage of implementation of the processes planned earlier verifies the efficiency of the solutions applied earlier. Therefore, the participation of the possibly largest group of employees (including the management) in the design of the process system. Only then one can expect an authentic involvement in the implementation and the use of this stage

to improve the adopted concepts. Monitoring, measurements and process analysis are the elements which constitute the essence of the requirements of chapter 8 of the standard, including the practices necessary in the quality system, allowing for maintaining the proper implementation of the activities but also their improvement.

Ref. 4.1f. ***Implement actions necessary to achieve the planned results and improve the processes.***

A consequent implementation of the objectives for particular processes included in the quality management system provides for the development of the company and, as a result, improving the quality of the offered products. Continuous improvement includes activities based on striving for improved meeting of the requirements that change rapidly along with the development of the market, technology, customer awareness, the law, etc. The management should put emphasis on setting the measurable, ambitious goals in the key areas to improve the customer satisfaction. Along with the company development, both the measurable processes and the tasks within which they are adopted should be updated.

Requirements concerning the documentation

Documentation of the quality system (section 4.2 of the standard) should be adequate to the needs and expectations of the organisation. A decisively smaller amount of documentation will be necessary in a small company than in a large, multi-departmental enterprise. Although there is a certain group of documents which have to be prepared obligatorily, it should not pose difficulties even in a sole proprietorship. It should be noted that in the implementation of the system a mistake of applying an excessive formalisation of activities is frequently made.

About the form of the system documentation and its supervision in the company decides, apart from the applicable requirements of ISO 9001:2008, a number of factors, among which the most important ones are:

- organisation size,
- specificity of the implemented processes,
- personnel qualifications,
- access and the ability to use the information technology by the employees.

According to ISO 9001:2008 the QMS documentation includes not only documents developed in relation to the system implementation, i.e.:

- **quality policy** which determined the entirety of quality objectives of the organisation adopted by its management;
- **quality book** – a document which provides consistent information about the quality management system in a company;
- **quality plan –** a document which describes what elements of the quality system are applied for a given product, project or contract. They are very useful in companies with a production with little repeatability, e.g. in relation or investment equipment, metal structures, investment, design and assembly services, etc.;
- **procedure** - an operating document determining clearly the procedures and conditions of supervision of the process implementation which is usually at the lowest level in the process hierarchy; where necessary, instructions are developed which constitute a detailed description of actions encompassed with the procedure,

as well as others, such as regulations, legal regulations, schedules, programmes, flow diagrams, databases, standards, instruction manuals and others which are or should already be applied in the company.

The records are a specific form of documentation, confirming certain facts, actions in the company. Therefore, they are a source of knowledge about the management system and should be evaluated on an ongoing basis to ensure that all decisions concerning the company are made rationally. Owing to these entries it is possible to assess whether the processes are effective in their current form, i.e. lead to the implementation of the assumed objectives. The records are also an objective proof that a specific requirement, e.g. determined in a standard, included in a contract or resulting from the legal regulations, has been met.

Making the inventory of the records conducted in the company and assigning them to appropriate actions, it is necessary to indicate which of them may include especially valuable data, enabling the process improvement. It may allow to improve the system of conducting records in the future, ensuring not only completeness, but also efficiency in the implementation of company objectives.

Providing adequate supervision over the documentation is one of the six areas for which it is necessary to establish a documented conduct procedure.

The supervision over the internal documents consists of:

- determining their form and appearance to ensure legibility and easiness of use,
- identification of documents (records of particular copies, numbering, marking, dating, etc.),
- assessment and approval of documents by authorised persons before the release,

- ensuring the access to the documents to all authorised persons (dissemination of document copies),
- determining the way of introducing changes and authorised persons,
- periodical documentation reviews, update and further approval,
- withdrawal of outdated, damaged or unnecessary versions of documents,
- determining the way, place and time of documentation storage,
- developing a list of documents which are subject to archiving and its time,
- making archived documents available to authorised persons,
- determining the principles of business secret.

Similarly to the documents, it is obligatory to develop a **documented procedure** concerning the supervision over the records. In accordance with the standard requirements, it should specify the way of:

- identification (marking),
- access,
- storage of records and
- disposing (archiving time).

The records should be clear. The way of their storage should prevent from damage and ensure their availability.

The period of storing the records in the case of the lack of external requirements (legal regulations) is determined individually, in accordance to the needs. In this context it is necessary to analyse in what cases they are useful, i.e. take into consideration e.g. the time of product operation, possibility to use the records in legal proceedings concerning the liability for the product (proofs) or the time between audits, where the records constitute a confirmation of the performed actions, etc.

Responsibility of the management (chapter 5 of the standard)

This section determines the elements constituting the proofs of involvement of the top management of the company in the construction, functioning and improvement of the QMS.

The role of the top management is to communicate the role of the customer in the organisation to the employees and ensure that the organisation tries to get to know, understand and meet the customer requirements.

A company striving to fulfil and even exceed the customer requirements should understand the necessity of continuous contact with the customers, listening to them and a continuous adaptation of its actions. The customer orientation also means that all decisions, initiatives

and changes in the organisation should be made taking into account their impact on the level of product or service quality.

Moreover, the management should establish and communicate the quality policy of the company to the employees. In accordance to section 5.3 of ISO 9001:2008, this quality policy should be:

- adjusted to the objectives of the organisation,
- include obligations to fulfil the requirements and constant improvement,
- communicated and understood in the entire organisation,
- subject to reviews.

The next part of the requirements of chapter 5 of ISO 9001 determined the obligation to set concrete, measurable objectives established for particular functions or processes in the organisation. The objectives must include those which directly refer to the level of meeting the requirements by the products/services provided by the company to its customers. The examples of the measurable objectives for various processes are the following:

- Defectiveness of the process reaches the value below ….% within …years.
- Complaint indicator at the level not higher than … by the end of …. .
- Not less than …% of deliveries will be made within …. days.
- Introduction in …. a new service to be implemented within a period not longer than....
- Maintaining the level of stocks not larger than … in the period of ……. .
- Development of a project of a new service in a period not longer than … .

The set quality objectives should be accompanied by the plans of their achievement which determine the necessary resources and measures.

ISO 9001 imposes on the management the obligation to ensure that the responsibility and entitlements are determined and communicated in the entire organisation**.**

It results from this requirement that:

- particular persons in the organisation should know the scope of their duties and entitlements, and be aware of their impact on quality,
- an appropriate scope of entitlements, which allows for the fulfilment of the set obligations, should be assigned to particular persons,
- the scope of duties should be understood well,
- each person in the organisation should be aware and feel responsible for achieving the quality objectives.

In order to present the company organisation in a simple way, usually there is an organisation scheme of the company in the quality book although the standard does not impose such an obligation.

Moreover, this standard requires also the appointment of a **management representative for the QMS**. This person should have certain responsibilities and entitlements to:

- establish and maintain the quality management system,
- submit reports on the functioning of the quality system and determining the needs within the scope of the necessity to introduce improvement changes in it,
- maintain the awareness of the customer role among the employees.

The management representative manages the actions connected with the system maintenance and provides the top management with the information allowing for making strategic decisions on the further development and introducing changes in the quality system.

A significant obligation of the management is to ensure an efficient flow of information in the organisation, i.e. creating appropriate channels of information flow and encouraging and motivating the employees to use them possibly to the fullest.

One of the basis means of quality improvement provided for by ISO 9001:2000 is a management review (section 5.6 of the standard), referred to in full as the quality management system review conducted by the managers**.**

Management reviews should encompass the holistic assessment of the system condition and its efficiency in relation to the quality policy and the assumed detailed objectives, as well as establishing the directions of changes and system development. At the same time, they are an expression of involvement of the management in quality and a conformation of its importance in the company.

It is traditionally assumed that reviews should take place at least once a year, whereby for young (implemented) systems it is necessary to plan more frequent reviews. Moreover, the frequency of reviews should be dependent on the specificity of the company, dynamics of changes in the company (the more changes, the more frequent the review should be), differentiation of customers and intensity of contacts with them, etc.

A good preparation of the review is the basic condition for achieving its objectives. Since the review should include an in-depth analysis of the system state, all the information describing this condition should be collected. The sources of information are i.a.:

- external and internal audits conducted in the enterprise,

- opinions submitted by the customers,
- assessment of the market and competition,
- analysis of process implementation, control, complaints, guarantees, service work, etc.,
- analysis of the extent of implementation and efficiency of corrective and preventive measures,
- analysis of cooperation with suppliers,
- financial results,
- analysis of changes in the company.

The effect of conducting a review should be finding the possibility of improvements in the quality system through such actions as:

- update of objectives and the quality policy,
- introduction of changes in the organisation, processes, procedures, manufactured products/provided services,
- the necessity to provide appropriate resources to ensure the correctness of all processes.

Resource management (chapter 6 of the standard)

Chapter 6 of the standard includes the obligations concerning the resources used in the processes included in the quality management system. Section 6.1 *Ensuring resources* determines in general the role of resource management in the quality system. The remaining requirements concerning human resources – company employees (section 6.2 of the standard), the infrastructure – rooms, equipment, installations, devices, tools for the implementation of products/services (section 6.3 of the standard) and the environment (conditions) of work (section 6.4 of the standard).

In relation to staff management, ISO 9001 standards boil down to the following two elements:

The key issue for the market success of every company is ensuring an appropriate personnel implementing the works which influence the quality of products/services of the company. The standard enumerates four aspects of the staff quality:

- **education –** knowledge gained in the institutions established for this purpose, including schools, universities (e.g. colleges),
- **training –** process of professional preparation, the aim of which is the adaptation of knowledge and skills of employees to tasks resulting from the company

organisation and performance technology (e.g. specialist authorisations, courses of machine operation, in-house auditor course),

- **skills –** additional qualifications useful at work (e.g. knowledge of foreign languages, computer skills, driving licence, team work skills),
- **experience –** knowledge about the means, ways and objectives of action, which is gained by the employee at work (period of service),

On the basis of the abovementioned criteria, it is necessary to select staff and plan its development. It is nothing new - recruiting and assigning new tasks to the employees, the management commonly applies these criteria.

The actions concerning employment and increasing the competences of the personnel should be efficient - therefore, it is necessary to **assess the usability** of various kinds of taff improvement forms. A solution here may be a questionnaire filled both by the employee who returns from training, and after some time by their superior, who may assess the influence of the training on the work results on the basis of observations. It is also necessary to be able to demonstrate the staff competence - so, as required by the standard, it is necessary to store all the evidence (records) concerning education, trainings, skills, experience, etc, e.g. in personnel records of employees.

Achieving the required quality of products or services is possible, provided that an adequate supervision over the company **infrastructure** is ensured, i.e.:

- buildings and installations, including water, electricity, industrial gases, etc.,
- production equipment such as: machines, tools, external and internal means of transport,
- computer hardware including: IT network, computers, printers, software,
- communication equipment such asL telephones, fax machines, radiotelephones.

A special infrastructure element, clearly separated in the standard is the control and measurement equipment, such as: patterns and measurement equipment, calibration and testing programmes (section 7.6 of the standard).

In practice, the infrastructure supervision boils down to:

- determining the equipment needs,
- supervision of purchasing equipment and consumables,
- keeping records of the equipment,
- ongoing and periodic maintenance,
- planning inspections and repairs,

-conducting systematic analyses and suitability assessment of the equipment,

-ensuring the availability of the relevant instructions and documentation, as well as proper operator training, etc.

Supervision should also concern all the contracts of the company concerning waste disposal, water, gas, electricity supply, etc.

For a correct implementation of products/services it is also necessary to maintain a proper **working environment**. Therefore, it is necessary to be familiar and apply the regulations which govern the parameters of the working environment (lighting, noise, dust, etc.), appropriate for a given position. It is also often related to the regulations concerning hygiene, occupational health and safety, fire protection, and thus it also includes equipment for a proper maintenance of the working conditions, such as: ventilation, dust removal, heating, neutralising devices, etc.

Therefore, the supervision over the working environment includes mainly:

- establishing a list of facilities in which monitored environmental conditions are required,
- clarification of the requirements concerning the environment in particular processes or their parts,
- ensuring the necessary equipment to maintain the required conditions (e.g. thermometers, hygrometers, manometers) and appointment of staff to maintain and control these conditions,
- determining the value of parameters constituting the criteria of process environment monitoring and ensuring adequate means of measurement,
- determining the required records and the manner of their storage.

Product implementation (chapter 7 of the standard)

Chapter 7 of ISO 9001 includes the requirements concerning the typical elements constituting the cycle of product or service implementation.

These elements are:

- planning (section 7.1 of the standard),
- customer-related processes (section 7.2 of the standard),
- design and development (section 7.3 of the standard),
- purchasing (section 7.5 of the standard),
- production and service provision (section 7.5 of the standard),

- supervision of the monitoring and measurement equipment (section 7.6 of the standard).

Only within this chapter of the standard it is possible to **exclude from the scope of quality** those requirements which are not reflected in the specificity of the company.

These exclusions cannot restrict the ability of the company to provide products/services which are compliant with the requirements of the customers and possibly the legal regulations.

The product/service implementation processes should therefore be **planned**. Within the framework of planning, it is necessary to determine:

- objectives connected with the quality of product/service which the company intends to achieve,
- human and material resources necessary for manufacturing products/implementing services,
- method of performing services or manufacturing products (technology),
- methods of measurement, control, verification,
- required records from the process implementation.

Practice shows that especially small companies have problems with establishing activities involved in the planning if the product implementation.

Planning of the process implementation has two aspects. The first one is connected with the assignment of appropriate resources to the intensions for a given period. These are all kinds of substantive and financial plans, the company budget, business plans, etc.

The second dimension of planning is connected with determining the ways and sequences of proceedings within the framework of implementation, i.e. appropriate procedures, programmes or schedules.

Customer-related processes concern the stage of **marketing activity** and include **contracts** with customers. These activities in the quality system are supposed to verify:

- Are the requirements of the contract determined and equally understood by the company and the customer, not to make mistakes at the beginning, due to which the company may lose a lot?
- Is the organisation able to meet the customer requirements and meet the deadline specified in the contract?
- Have the principles of customer communication been determined?

Therefore, it is necessary to know **the requirements (of the customer and other types – mostly of legal regulations)** and make sure that the company is able to fulfil them before it proceeds to the product implementation. The aim is not only to achieve compliance of the product or service features with the requirements but also to fulfil the expectations in relation to the delivery and possible after-sales service.

The standard requires that:

- before placing an offer to the customer,
- before the company undertakes to deliver a given order,
- before a contract is signed between the company and the customer

conduct a review of appropriate documents, possibilities and competence, making sure whether;

- all the requirements concerning the product are known,
- there are no differences between the offer concerning the products or services presented in an advertising folder, on the Internet, etc. and the actual implementation, as regards e.g. the time, place and way of provision,
- the company is able to deliver the declared order.

An example of simple review activities in the case of the sales of catalogue products may be the assessment of the state of stocks in the warehouse by the seller, e.g. through the control in the IT system, assessment of processing capacity by the production supervisor, etc.

Appropriate **records** made on the basis of the review are stored. These include business notes from the talks with the customers, drafts of offers and contracts signed by competent persons, letters, faxes and e-mails concerning the arrangements with the customers, etc. The last fragment of this section of the standard concerns the establishment of appropriate forms of information exchange with the customers. The essence is not only to inform the customer but also process and use the feedback in order to improve quality.

In the case when a company must determine the **specification** (a set of parameters, features, characteristics) of the manufactured products or implemented services, it is necessary to think about ensuring a proper course of the process of their design/development so that the effects of design were fully compliant with the **requirements**.

Design and development works are the most important actions in the implementation process, since they shape the desired form and characteristics of the product. Further

operating tasks are only based on the implementation of the arrangements adopted at the stage of design.

It is necessary to emphasise that ISO 9001 treats the concept of design (preparation from the beginning) and development (introduction of the essential changes in the current project) in the same way, especially as regards the methodology of supervision of such processes.

The design and development supervision in the standard includes the following elements:

- **planning** of design and development works - similarly to all the actions which are of key importance for quality, also this one requires planning,
- **input data** for the design, i.e. documented features and parameters of the designed product/service expected by the recipient, including legal requirements,
- **output data** from design - a documented form of results from the design process, usually in the form of the prototype documentation or preliminary project – e.g. advertisement design – a computer file, "design" of a new cake type – recipe,
- **project review -** the number and scope of the reviews depends on the character and the complexity of the project,
- **project verification** - comparison of the obtained output data from the design with the appropriate input data through simulations, calculations, comparisons,
- **project validation** - checking the effects of design in the real conditions – testing the product prototype, test version of software, trial cruise of the newly built yacht, etc.,
- **project changes** - may result from such factors as, i.a. customer wishes, improvement of the product and the manufacturing technology, changes in the law, verification, validation results, etc.; these changes may be supervised similarly to the changes in other documents of the QMS.

All the aforementioned activities within the framework of design and development **must be documented with appropriate entries**.

The form of these entries will depend on the project type, e.g. for complex projects these may include a packages of drawings or gigabytes of computer files, volumes of analyses and test results, whereas in the case of simple ones – a note signed by the participants, including the Director's decision or a decision of an authorised person concerning further stages of the projects, combining the aspects of a review, verification, validation and consistence of the introduced changes.

A fragment of chapter 7 on **purchasing** determines the principles of ensuring a proper quality of supplies **essential to meet the customer demands through the products or services of the company.**

ISO 9001 requires here:

- a detailed specification and approval of requirements prior to their submission to the supplier,
- selection of a supplier who is able to meet the determined requirements,
- subjecting both the supplied products and the system of their production to the quality assessment.

The basic methods of assessment of suppliers/subcontractors are:

- experience from the previous deliveries,
- notes resulting from the control of product samples, enclosed results of inspections, attestations and possible opinions of other users,
- surveys of potential suppliers,
- audits of the supplier.

Even if a not very strong market position of the company does not give the change of enforcing certain action of the supplier – e.g. a monopolist, it does not exempt this company from conducting assessment of this supplier. It may help the company to determine such actions which prevent a negative influence of this supplier on the quality offered to the customers.

The examples of the assessment criteria may be: **punctuality**, **completeness and level of compliance** of a delivery with the order specification, determined in a scale, e.g. 1-5.

It is necessary to remember about the whole sphere of *outsourcing* subject to the requirements of this section – actions not performed by a given company, but supervised by this company.

The first fragment of section 7.5 defines the notion of manufacturing/implementation of products/services in supervised conditions, constituting the framework in which the company should place its approach to the management of this area of activity.

The enterprise must develop and conduct **supervision over the process of manufacturing products/providing services** in a way ensuring the desired quality of execution. This system should guarantee that:

- the production materials meet the set requirements,

- machines, devices, tools and other means of production ensure the achievement of the required parameters and are efficient and supervised,
- employees are competent – have appropriate knowledge, experience and training,
- the scope of responsibility is defined, the information necessary for the implementation is developed and available (procedures and working instructions),
- revitalisation processes are properly monitored,
- processes in which results and are difficult or impossible to verify after their completion (the so-called special processes requiring validation) subject to strict supervision (qualification).

In the subsequent sections the standard presents other requirements which should be met to achieve the desired outcome of the process of production/implementation. These include:

1) **validation of processes**, whose results are difficult or impossible to determine immediately after the end of the process,
2) obligation to ensure **identification, determine the status** and if required - **identifiability** for products or services,
3) supervising the **customer property**,
4) **securing products** at all stages of implementation.

Ref.1

In the processes in the case of which the expected results are difficult to control, (the so-called special processes), a greater formalisation of supervision and extended records, i.e. validation (validation, qualification**) –** a concept that has been provided previously when discussing the principles of the design/development process supervision.

Examples of processes requiring eligibility can be processes such as heat treatment, painting, welding. Whether the result of such a process is correct or not, it occurs usually with some delay.

In each case it is necessary to know and apply the specific procedures and values (states) of certain parameters without the compliant with which it is hard to think of the result desired by the customer. Special attention should also be paid to the resources used in such processes – both technical ones and appropriate competence of the people who conduct the process.

Ref.2

Identification is an adopted system of marking products/services, allowing to distinguish them during the process of implementation from concluding contracts/orders to the delivery to the customer. Identification may be conducted by means of:

- carriers of information accompanying the products or containers with products (e.g. labels, tags, cards of material circulation, markings on the backs of binders),
- numbers, bar codes minted, printed or placed on the product in a different way ,
- placement in a specific location, zone (e.g. designated zone for defective prodicts),
- documentation accompanying the product or service, etc.

The standard requires also setting the product/service status informing about the conducted measurements, control or monitoring. The point here is for example to protect oneself against a situation in which the product passes to further stages of production but it has not been controlled after the previous operations yet. The most commonly used is one of the following methods:

- marking, including appropriate colour coding,
- tags, stickers and labels,
- permanent records accompanying the product,
- located on selected areas or labelled containers.

Determination of the **control status and research** indicates moreover whether the products such as raw materials, semi-finished products, parts or customer documentation being the subject matter of the implemented service:

- meet the requirements (have been approved after inspection or testing),
- fail to meet the requirements (detected non-compliance),
- have not been controlled or approved yet.

Identifiability - is a specific way of marking which allows to reconstruct the history, application or location of a given product or service for example in terms of :

- used materials and parts in the process of production,
- production conditions,
- contractors,
- data concerning storage, packaging and transport, etc.

Identifiability of the product should be ensured in relation to the relevant:

- drawings, e.g. drawing number,
- specification, e.g. material specification number,
- other documents, e.g. orders, approvals, inspection protocols, etc..

The standard formulates the requirement of conditional identifiability - "if it is requires…**",** and therefore it should be implemented in the case of necessity arising from the contract or as the fulfilment of legal requirements. Such requirements are closely connected with the sphere of activity and result from the legal regulations, e.g. medical devices, defence industry or result from the customer requirements reserved in the contract. Attention should be paid to the fact that in some situations the markings on the product or service may perform at the same time the identification role, determining the status and identifiability.

Ref.3

The standard requires the company to ensure full responsibility also for the product delivered by the customer. This notion is, as usual, understood very broadly in the standard – material, component, equipment, but also intellectual property, such as i.a. a project, software, documents and even personal data of the customer.

Elements not compliant with all the quality requirements, regardless of their origin, cannot be used for manufacturing the products/provision of services. Hence, in relation to the product delivered by the customer, the company is obliged to:

- conduct the control to test the product,
- store it in a manner protecting it against damage and loss of property,
- possible operation of the product in accordance with the instruction of the manufacturer,
- informing the customer of possible damage, loss, loss of property, etc.

Ref.4

The basic issue is to find out whether and within which scope this requirement concerns the activity of a given company.

A company, if it is applicable in its case, has to ensure that all the transport needs concerning packaging and storage of products will be implemented in a way that protects them against damage or destruction and in accordance with the customer requirements and/or legal regulations. Therefore, it is necessary to take into account the monitoring of the storage conditions (e.g. time, temperature, humidity), selection of appropriate packages both for internal and external transport and the manner of delivery (duration of delivery and adjustment of the vehicle). It is necessary to ensure full product identification and shipment condition.

Often, especially in the case of small organisations, it happens that certain activities covered by this section of the standard are recommended to the external companies (e.g. transport companies). In such situations it is necessary to ensure that the subcontractor has the necessary information on the requirements which they are supposed to meet. Such a subcontractor should obviously be verified in accordance with the requirements of section 7.4 of the standard.

Results of measurements received from many measurement devices should be reliable. In order to achieve it, it is necessary to supervise (section **7.6 of the standard**) the whole equipment used for monitoring and measurements (even private devices of the employees!). This means in practice:

- determining the measurement needs and the resulting needs concerning the equipment,
- determining the necessary measurement accuracy resulting from the requirements for the tested parameters (i.e. tolerance imposed on a given parameter); for example, in terms of the measurement of the length and angle measurement it is assumed that the required measurement accuracy should not be lower than 10÷20% of the size of the tolerance field of the measured parameter,
- determining the records and identification of the measurement equipment (e.g. a computer list of control and measurement equipment, forms),
- determining the procedures and frequency of calibration or regulation of instruments,
- application of the method of determining the equipment status (e.g. sticker with the date of the next control, computer records concerning checks, etc.),
- necessary records confirming the implementation of the calibration and verification procedures,
- the adopted rules of safe use and storage of the measurement equipment,
- the adopted rules of importance assessment concerning measurement performed with the equipment which proved to be inconsistent with the requirements.

In connection with the advancement of the measurement technology, it is also necessary to supervise the software used for monitoring and measurements.

The scope of supervision may vary, dependent on the role of the device and the influence of the measurement results on the product. For example:

- a weight in a store, a tachograph - legalisation in the Office of Weights and Measurements,

- micrometers – testing the accuracy of indications by means of supervised size blocks,
- measurement tapes, indicators, gauges- periodic inspection of condition, comparison with the reference standards.

The tests and calibrations must result in records – evidence of their making – calibration and validation protocols, notes, etc. A big help within the scope of the meteorology issues and supervising the control and measurement equipment is ISO 10012:2003.

Small companies for which it would be uneconomic to maintain standards and measurement equipment used during calibrations, may outsource a part of these activities to larger organisations, guaranteeing adequate reliability and connection with the national and international standards. Such a company becomes a supplier, requiring a procedure in accordance with clause 7.4 of ISO 9001- *Purchases*.

it is necessary to remember that the devices for **monitoring the conditions** in which a given process takes place – temperature, humidity, pressure, noise, dust, etc. - should also be supervised.

Measurements, analysis and improvement (chapter 8 of the standard)

For an effective management of the company it is necessary to provide relevant and appropriately formulated information concerning:

- the quality of products/services,
- extent of meeting the objectives,
- process effectiveness and the effectiveness of the process and the quality management system itself.

Knowledge of this information allows for making informed decisions relating to the quality of products/services, changes in the course of processes and the improvement of the overall system.

Requirements included in chapter 8 concern the sources and methods of obtaining the aforementioned information. The chapter includes five subsections which will be discussed in a system known already from the previous chapters of the standard.

Therefore, appropriate **measurements and monitoring** of the conducted processes (section **8.2 of the standard)** should be conducted in a company. According to ISO 9001:2008, measurements and monitoring must concern:

1) **satisfaction of the company customers**,
2) compliance with the requirements and the efficiency of the quality management system in the implementation of the adopted quality policy and the resultant objectives - owing to the conducted **internal audits**,
3) **processes** encompassed with the quality management system,
4) compliance of **products/services** with the requirements,
5) **suppliers,** as discussed earlier with requirement 7.4 of the standard concerning *Purchasing***.**

Ref.1

The fact that the customer purchases products or services does not mean that they are satisfied with them and that they purchase them in the future. Knowing, what the customer thinks of the company products and contacts with it, it is possible to meed his expectations in a better way.

No universal method has been developed so far to measure the customer satisfaction level, since each customer requires a different approach. Each company may easily identify a set of information from which the right conclusions can be drawn for the analysis.

When determining the methods of customer satisfaction surveys is the identification of all customer groups with which the company has to deal. Certainly individual customers will have a bit different preferences than large organisations. For example, a small renovation company meets other expectations in the case of the work in a small private flat than carrying out repairs in a school gym.

Of great importance is not only the way information is conducted but also the use of such information. A frequent mistake made when designing surveys is asking questions which indeed allow for obtaining a certain image of the organisation in the eyes of the customer but usually the one whose analysis is not constructive for the company itself.

Ref.2

To implement the objectives set by the company, the quality management system which was implemented should function in accordance with the prepared arrangements included in the documentation – quality book, procedures, instructions, regulations, plans, schedules, etc. and be **effective** in the achievement of the set objectives. This system should also be **constantly improved** in accordance with the basic quality management principle.

An important tool for checking the conformity, effectiveness and quality improvement system is **the internal audit,** also called the first party audit.

Hence, the objectives of the internal audit are:

- determining the compliance or non-compliance of the elements of the quality system with the determined requirements,
- possible revision of the compliance with the requirements resulting from the legal regulations,
- determining the efficiency of the implemented quality system in the implementation of the adopted policy and quality objectives
- enabling the improvement of the audited activity of the quality system process;

Internal audits are conducted by the company on its quality system by the in-house, trained auditor(s) or by means of a hired auditor.

In practice, there are two types of internal audits: planned and **special**. The latter may be initiated in relation to such circumstances as:

- significant changes in the system,
- decreasing quality of products,
- special demands of the customer.

The standard requires planning the audit dates and their programme.

The inspection of the quality system during the audit is based on collecting data through talks (interviews), review of documents and observation of actions and conditions in areas which the audit concerns Any observations which are regarded by the auditor as irregularities are recorded in the prepared forms. It is necessary to test the compliance of the applied practice with the requirements of the **standard**, the aforementioned arrangements included in the system **documents, customer** requirements and other requirements, including mainly the **legal requirements** concerning the conducted activity.

The importance of the in-house audit for the efficient functioning of the quality system is emphasised by the fact that in accordance with the requirement of ISO 9001:2008, the principles of its planning and conducting must be included in a **documented procedure.**

The most essential part of an **audit report** is the list of noticed **non-compliances.** A non-compliance is a failure to fulfil the requirements included in:

- contracts,
- standards concerning the quality system,
- the quality book,
- procedures, operating instructions, regulations.

The occurrence of non-compliance may have three reasons**:**

1) documents of the system fail to meet the requirements of standards/regulations.
2) the developed procedures have not been put into practice correctly.
3) practice is ineffective, i.e. the required result/aim is not achieved

An audit is finished upon the submission of a report to the audited party.

The decision what action needs to be taken to remove **the results of non-compliance** (make a **correction** of a mistake) and eliminate the causes conducting **corrective actions**, is made by the persons managing the area or process (process owners) which was subject to the inspection.

If these actions were efficient, the auditor confirms it with a signature in the proper place of the non-compliance card and the procedure is closed.

The assessment of efficiency of actions taken as a result of the audit is also required If, as a result of verification of corrective actions initiated earlier, the auditor finds that the measures do not bring the expected results, an appropriate annotation should be made and the non-compliance should be determined again.

Ref.3

Owing to an appropriate quality of processes in the quality management system, it is possible to achieve an appropriate quality of the results - products or services. Therefore, the standard introduces the **obligation of monitoring the processes** which are included in the quality system and in those in which it is necessary - **to conduct measurements** of values influencing their effect. Clearly, the aim of process monitoring is a broadly understood **prevention**, influencing the correct course of the process which should lead to the set objective.

The concept of monitoring is especially important in the case of service companies in which it is often difficult to separate the process of service provision and the result of this process itself.

Monitoring the process means for example to review the stored documents to gain knowledge on the state of stocks (the sales process), get to know the number of complaints filed for a given service within one month, entered in appropriate records (customer service) or measure the temperature of food heat treatment.

The method and way of monitoring of the process is recommended to be determined in a guide of a given process – a document including all the necessary items for the management of a given process.

Wherever it is possible to determine a measurable aim for the process (in the aforementioned process guide we adopted the name - **task)** – monitoring (measurement) is based on the analysis of a **measure** (parameter), in which the aim is expressed. Such measures may be for example:

- **number,** e.g. of complaints, defective deliveries, errors in a document,
- **time** of implementation, e.g.. of a delivery to the customer, introduction of a new service, repair,
- **costs,** e.g.. of losses on defective products, guarantee repairs,
- **concrete technical values,** e.g. temperature, pressure, hardness or many types of indicators, e.g. profitability, quality, e.g. defectiveness.

To conduct effective monitoring (measurements) of processes and use the obtained results for improvement, it is necessary to ensure credible **sources** from which knowledge is derived about the process. These sources include records (e.g. of complaints), financial documents, computer databases, collected protocols of measurements and other records.

If the monitoring and measurement results of the processes indicate problems occurring in them, it must constitute the basis for taking corrective actions (problem removal – section 8.3 of the standard), and as a result also corrective action (removal of problem causes -section 8.5.2 of the standard).

Ref. 4

Control of products/services should be planned in terms of the place, time, way of conducting and the criteria of approval, rejection, repair of a product/service and obviously the persons responsible for conducting the control. First, it is necessary to determine **the records confirming the fact of conducting control** along with its results which confirm or do not confirm meeting the requirements for the products/services. The standard requires also to determine the responsibility for the actions connected with the approval or rejection of a product in the records.

It is necessary to remember that monitoring a product/service is not necessarily a measurement of a physical value. It is also a visual, random inspection, confirmation of the acceptance protocol by both parties, etc.

Before a product/service is submitted to further stages of implementation, including ultimately to the customer, it is necessary to ensure that the product underwent the inspection successfully. Depending on the specificity of our actions, it is necessary to conduct inspections both between the operations and final control of products/services. It is also worth

mentioning that in the area of services often the monitoring of a process of the service implementation also performs the function of monitoring the service itself.

Small enterprises should consider the possibility of application of **self-control** by the employees very carefully, to eliminate unnecessary doubling of inspection activities by other persons. This form of activity verification proves effective in the case of small teams of people, since the employees know their customers and internal suppliers very well.

A non-compliant product (section 8.3 of the standard) in accordance with ISO 9001:2008 is a product which fails to meet the requirements established at a given stage of implementation and should not be sent to the customer, used further or submitted to further stages of implementation.

In the case of a production company it is relatively easy to identify a situation in which a non-compliant product or semi-finished product is manufactured but in the sphere of services it is not always so clear.

A non-compliant product may be e.g. a badly made print at a photographer's, training which did not fulfil the expectations of the participants, or a TV set which was supposed to be repaired at a service point but still does not work.

Products which are non-compliant may be identified as a result of:

- complaints of customers,
- monitoring and measurements of products or services,
- in-house audits.

The company must take action appropriate to the type of non-compliance in relation to the products/services which are not compliant with the requirements. These may be for example:

- repair, e.g. re-cleaning of badly cleaned garments, re-painting of an inaccurately repaired part of a car body,
- conditional approval after the consultation with the customer, e.g. associated with the reduction of prices,
- liquidation, e.g. of improperly prepared cosmetic product harmful for the health.

ISO 9001:2008 imposes the obligation of developing a documented procedure , determining the responsibility and the rules of conduct with non-compliant products. Removing a defect, mistake, irregularity which occurred in the product or service, is described with the term of **correction**.

Research results analysis (section 8.4 of the standard):

- customer satisfaction,
- internal audits,
- monitoring and measurements of processes, products and suppliers,

may be conducted with the application of various methods and techniques which present the problem in a broader context and provide a basis for the rational use of this data.

It is supposed to enable the improvement of actions, elimination of mistakes, both those which already occurred and those which may occur. Simple diagrams, tables, appropriately prepared forms, spreadsheets or databases can be used successfully for conducting such analyses. This script includes a description of many methods which may be used for the data analysis at different stages of the product implementation process.

The final fragment of the ISO 9001 requirements (section 8.5) consists of three subsections concerning the improvement of actions included in the quality system.

Continuous improvement is a consequent action based on achieving the objectives which change with the development of the market, technology, customer awareness, regulations, etc.

For improvement, ISO 9001:2008 enforces the use of such elements as:

- quality policy and quality objectives,
- management reviews,
- results of customer satisfaction surveys,
- audits,
- data from the measurements and monitoring of processes and products,
- conducted corrective, remedial and preventive actions.

The essence of the last two sections of ISO 9001:2008 is indicating the necessity of adopting the set, documented method of corrective action by the companies and their prevention. Corrective actions aim at eliminating the non-compliance not to occur again and this it is based on the elimination of causes of non-compliance. In the aforementioned example of the assembled product, such an action will be e.g. employee training concerning the assembly method and a development of a graphical instruction showing the key stages of the process.

Preventive action in intended to eliminate the problem not to occur again. An example of a preventive action is designing methods of assembly, ensuring such tools and process implementation so that an employee, even being totally distracted, could not

erroneously assemble a product. This type of action is called the source control, since the non-conformity is eliminated at the source, before it could even emerge. Please note that such an activity reduces not only the losses on account of the mistakes, but it eliminates costs connected with control. It is not necessary when a mistake just cannot be made.

The most obvious reason to take preventive measures in the analysis of data obtained from different processes, including the ones concerning customer satisfaction.

Implementation of the Quality Management System and its Certification

An initial analysis of needs concerning the implementation of the quality system in an enterprise may take place through personal insight, consultations or external training. After taking a decision on the implementation, it is necessary to determine which company resources will be required for the implementation and which the company can afford. Such an analysis should be conducted with the participation of persons experienced in this scope. The typical stages of implementation of the quality management system are provided and characterised below:

1. **Appointment of a project coordinator** reporting directly to the Board and having his full support. He may also appoint a group of **team leaders** (**process owners**), representing particular sectors (company processes), constituting the **Team for the System Implementation**. Such a person is likely to perform a function of a management representative for the system.
2. **Transfer of a complete and reliable information** on the objective of the system implementation **to the whole staff**.

   Without such information this initiative becomes for the employees another action, a "wonderful" idea of the management which is necessary to face and wait passively till the end. It is, of course, an extremely inappropriate situation and therefore it cannot be admitted already at the beginning of the implementation.
3. **A detailed analysis of needs by the Implementation Team.** It is necessary to identify "bottlenecks" and priorities through:
   - development of an **action plan** (sequence, implementation time, resources - **budget**)
   - setting specific targets for a subsequent evaluation of progress,

- ensuring that the members of the Implementation Team have: the relevant knowledge (trainings), access to persons and data in different departments, financial resources and administrative support**.**

4. **Work of the members of the Implementation Team** in organisational units in order to determine:
   - the requirements in force and assumed objectives,
   - hierarchy, course of processes and their mutual relations,
   - monitoring and process measurement methods, products, customer satisfaction, the management system itself (audit) and the suppliers, which should be conducted,
   - competences and responsibility of employees whose work has a direct impact on quality (including quality specialists),
   - indicating areas to conduct improvement measures,
   - determining the mechanisms for the collection and storage of data regarding processes,
   - determining the mechanisms of corrective and preventive action,
   - audit schedule and system review,
   - principles of use of system documents (books, procedures, etc.).
5. Ensuring **full participation** in the creation of the system for employees at different levels, helping the employees in a possibly extensive **preparation of own procedures,** e.g. within the framework of the quality circles, process groups, documentation teams.
6. Sharing the **current information on the progress** of the project – continuous **appreciation of the role of people in the system.** In order to maintain the staff involvement it is necessary to sacrifice certain resources - meals, bonuses, awards, etc.
7. **Ensuring support and information to employees**. It is essential to listen to the opinions of employees about the system; reaching a broad consensus and not enforcing ready-made solutions. Only then it is possible to achieve the identification of employees with the system when regard it as "their own", as something in the creation of which they participated actively.
8. **Introduction of the system in stages, in harmony with specific conditions** of different departments. It is not necessary to implement the system simultaneously in the whole company. This task may be broken down into stages to **show the first positive effects** already at the beginning of the system functioning. Therefore, it is

also worth selecting those areas or processes where it is possible to expect favourable experience.

9. **Practical implementation of mechanisms** of conducting records, auditing, revisions and improvement. System implementation is first of all the adoption in practice of the proposed solutions in the prepared system documentation (quality book, procedures, process maps, the necessary records, etc. It may occur at the beginning that some of the designed forms of conduct (e.g. a procedure) are not easy to apply in the everyday practice or ineffective from the point of view of the objective which was set in front of them. A good occasion for the verification of such situations are the internal quality audits. In the course of their conduct, attention should be paid to the broadly understood efficiency of the adopted solutions. Where the solution proves to be ineffective, it is necessary to implement corrective action, removing the cause of the problem. Before the certification audit, it is necessary to conduct a management process review conducted by the managers. The first review will be the proof how the managers understand the objective of the system and how they intend to improve it.
10. **Submission of an application for the certification audit.**

After the implementation of the system, conducting the first series of internal audits and finishing the after-audit actions and a review of the system by the management, it is possible to report the system as ready for certification.

The most important criterion for the selection of the certification authority is its credibility for the customers of the company and other interested parties. So when the company cares for the credibility of the system for its foreign customers, then it selects a certifying authority having an **accreditation** (formal recognition of competence) of a foreign accreditation authority. On the market there are also certification authorities specialising in granting certificates of conformity in a given industry and having recognition among the customers of this industry.

The course of the management system certification procedure applied by the largest national authority for the certification of the quality management systems - Polish Centre for Research and Certification (PCRC) – is presented in Fig. 2. This procedure maybe regarded as typical, also for other authorities certifying management systems.

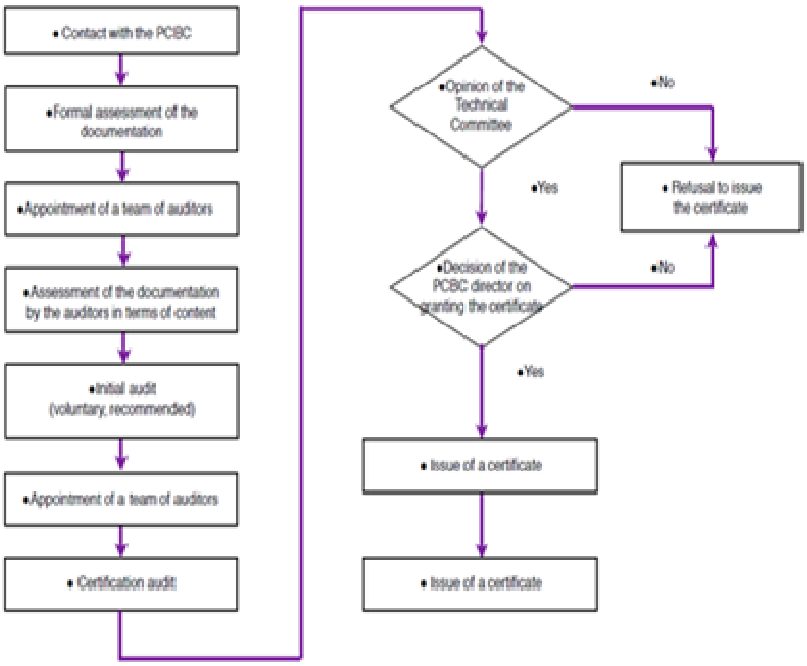

Fig. 2. The certification procedure of the management system applied by the PCBC

The certificate for the quality system is valid for 3 years, after this period, the certification audit is carried out again. During this period, the certifying authority supervises the management system of the enterprise conducting control audits (usually 1-2 per year).

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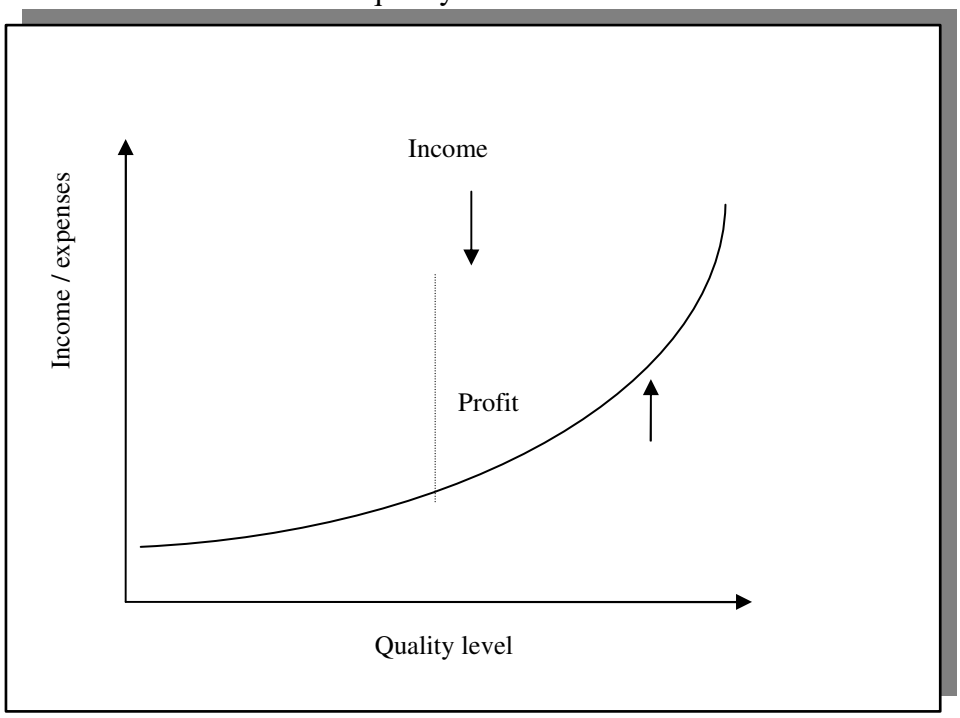
MODULE IV

Economic Aspects of Quality. Quality Costs, their Types and Use in Management Systems. Legal Aspects Connected with Quality. Assessment of Compliance in Accordance with the New Approach Directives (CE Marking)

Introduction

The quality level of products influences on the one hand the amount of earned incomes, and the amounts of the costs incurred on the other hand. Therefore we can speak of the income and cost function of quality.



When the quality level increases, we can expect an increase in the income from the sales of this product but only to a certain limit. This limit is determined by:

- the market size,
- the purchasing power of the market,
- the prices of competitive and substitute products

and whether the buyers consider the higher quality level as satisfying their real needs.

The costs of obtaining quality grow proportionally to the increase in the quality level only to a certain level. After exceeding this level, there is usually a rapid increase in the costa of obtaining quality which makes further increase in the quality unprofitable.

To determine the quality which is economically optimal we have to make reference th to indicator of quality to the costs of obtaining it (quality costs).

The quality costs are the expenditure incurred for the implementation of measures related to obtaining a proper quality of production. Quality costs should constitute a constant element of the quality management system. On the basis of the information of the incurred costs, the management makes certain decisions on increasing the intensity of action where it is effective or a reduction in such action which causes losses. Each decision, and thus every action is connected with cost generation. The idea is to make decisions on the basis of complete and up-to-date decisions.

Reasons for quality cost calculation

1. Knowledge of the quality costs allows for the identification of quality-related and organisational problems.
2. Knowledge of the cost structure allows for the selection of priorities in the corrective action to optimise operations.
3. Expressing the states in numbers facilitates communication.
4. Adequate presentation of the amount of the costs incurred has a strong motivational effect, it makes employees sensitive to errors.
5. Constant tracking of quality facilitates management, improves quality service organisation, ensures the possibility of constant supervision.

Efficient and effective management with the use of quality cost accounting requires keeping the records, analysis and optimisation.

1. Identification and types of quality costs

The records of quality costs are only possible when we can identify those costs, answer the question: which cost is the cost of quality? The standard PN-ISO 9004-1 distinguishes three approaches to the collection, presentation and analysis of data concerning the financing of quality aspects:

Three approaches to the cost data

1. **Approach "quality costs"**
2. **Approach "process costs"**
3. **Approach "quality loss"**

Approach 1 "quality costs" – divides the costs associated with quality into those which result from conducting activities within the company and those which are related to the external activity; costs of prevention and assessment are among the investments, whereas damage is considered a loss. The total costs in this approach are divided into:

1. prevention costs, i.e. costs of measures aimed at avoiding damage, including the costs of:

- planning the quality of new ans updated products j,
- ensuring the required quality of materials and raw materials,
- planning quality and managing quality,
- training within the scope of quality,
- conducting motivational and propaganda actions for quality,
- market research in order to understand the needs and requirements of users,
- control of processes,

2. quality assessment costs, i.e. the costs of checking whether the quality requirements have been met, including the costs of:

- testing and control of input materials,
- testing and control of own products.
- organisation of testing and control,
- maintenance of control equipment on standby,
- analysis of test results and control,

3. costs within the organisation, i.e. the costs of failure to meet the requirements for products, detected before they are delivered, including the costs of:

- irreparable failures,
- alterations and repairs,
- further control and confirmatory tests,
- searching for the causes of interference,
- re-qualification of products to a lower class,

4. costs of damage outside the organisation, i.e. the costs of failure to comply with the requirements for products, detected after these products are delivered, including the costs of:

- customer complaints,
- technical service for the users of defective products,
- processing of returned goods,
- contractual penalties,
- exchange of products under warranty,
- withdrawal of products from the market
- legal liability for defects.

Approach 2 "process costs" – connected with the analysis of compliance and non-compliance costs with the assumption that both categories may be a source of savings. Such an approach is convenient to be applied in the case of the process approach to the quality system regulation. The efficiency of the system achieves here an additional, direct dimension – the cost dimension, whereby the categories of costs are defined in the referenced standard in the following way:

Compliance costs: costs of meeting all the determined customer needs with a simultaneous correct course of the process

Non-compliance costs: costs caused by the improper course of a given process

Approach 3: "quality losses" – this approach focuses on the internal and external losses resulting from poor quality, whereby we determine tangible and intangible losses. According to Fujio Cho, the head of Toyota: "The losses in the activity of a company include everything apart from the minimum required equipment, components, materials, space and employee time which are necessary for generating the product value."

Types of losses

1. Losses caused by overproductions.
2. Losses caused by the waiting time.
3. Transport losses.
4. Losses during the process.
5. Losses resulting from excessive stocks.
6. Losses caused by excessive traffic.
7. Losses due to product defects.

Both tangible and intangible losses may be classified as:

- internal losses,
- external losses,
- losses on account of missed opportunities.

The causes of damage in the enterprise may for example be the following s:

1. Losses related to the equipment:

- excessive equipment - unused or very rarely used machinery, tools, computers; their amortisation, maintenance, ageing, etc.

- damage of machinery and equipment resulting from a negligent, untrained use or the use which is contrary to the purpose: the costs of repairs, downtime, tests after repairs overhauls, as well as withdrawal and purchase of new devices of the same type.
- idle runs resulting from the lack of rhythm in the processes, lack of materials, inadequate training of employees: labour, energy, amortisation costs, etc.,
- shortages of equipment and the consequent need to purchase services or lower the quality of products through the execution of maladjusted equipment, in the long run: costs of additional labour, costs of services,

2. Losses connected with the use of space:

- too large area of warehouses causing excessive rental, heating, lighting and personnel costs,
- too long transport roads making the process time longer, exceeding the costs of internal transport, increasing the personnel costs,
- too long ways of information flow which influences a longer time of information flow, increases the probability of error in the message and delays the decision-making process.

3. Losses connected with the staff:

- excessive employment causing too high costs of remuneration, influencing lowering of motivation, commitment to work and at the same time reducing the quality of work effects and increase in the costs of shortages,
- under-utilisation of skills and abilities which affect excessive growth of remuneration, delaying or preventing the development of the company, reducing motivation,
- deficiencies in employment - inability to accept more orders, loss of potential earnings, increasing competition, accumulation of works causing lowering their effects,
- intentional adverse action - increased costs of material, energy, remuneration, service, etc., and also the possibility of losing profits,
- absences - additional employment on commission or overtime due to absenteeism, costs of additional supervision, loss of rhythmicity,
- shortages of skills mean the possibility of material, labour, energy, repair costs, etc.,

4. Losses connected with materials and their deliveries:

- delayed or incomplete deliveries - loss of rhythmicity, exceeded deadlines of work completion and the necessity to pay penalties and/or lower the price,
- defective materials causing additional material costs and/or costs of additional service, contractual penalties, discounts, etc..
- unrhythmic deliveries - causing disturbances in the production, failure to meet deadlines and thud excessive costs of remuneration, service, as well as penalties and discounts,
- additional deliveries - not provided for in the plans, influence the increase in the overall costs and invalidity of effectiveness indicators, causing excessive costs of remunerations, storage, no rhythmicity of production,
- excessive stocks influencing the personnel and space costs of storage,
- bad material specifications causing an increase in the material and personnel costs, resulting from the necessity of re-ordering, transport, receipt and storage,
- lack of the necessary materials causing downtime in the processes and thus an increase in the personnel costs,

5. Losses connected with the process organisation:

- lack of appropriate information in the workplaces causing errors and/or downtime, and at the same time an increase in the personnel, material, energy, service costs, etc.,
- wrong order of operations influencing the formation of defects, and at the same time increase in the personnel, material, energy costs, etc.
- additional operations, unexpected operations affecting the obsolescence of plans and schedules, and at the same time the personnel, energy service costs, etc.,

6. Losses connected with the execution:

- erroneously performed operations - necessity to improve or scrap, influencing the increase in all the production costs,
- too long preparation of operations and their performance - influencing the increase in labour, energy and service costs,
- mess at workplaces causing the extension or repeated operations, increase in the use of the means of production.

7. Losses connected with the management:

- wrong decisions causing an increase of all costs incurred by the company,
- poor motivation or lack of incentives lowering the quality of work and thus influencing the remuneration, material, service costs, etc.,
- wrong allocation of responsibility and overlapping of competence influencing the inability to decide in a correct and timely way,
- conflicts disrupting the proper, planned rhythm of work,
- too numerous and/or too long meetings affecting the growth of remuneration, energy and/or delegation costs,
- lack of plans and/or changes in the plans - influencing the loss of rhythmicity of works and increase of all the costs in the company.

Internal losses

- excessive staffing,
- ineffective machines,
-defective materials,
- excessive stocks,
- corrective positions,
- untrained personnel,
- failure of machinery and equipment,
- no rhythm,

External losses

- warranty repairs,
- returns,
- ineffective enforcement of debts.
- penalties for delays in implementation,
- interest for late payment

Lost opportunities can only be estimated; it is very difficult but it is worth to know them. This could be for example:

- losses due to erroneous decisions,
- loss of customers,
- missing a market or product range niche,
- improper use of production capacity (including people),
- delayed introduction of the new product, inflexible organisational structure
- ineffective participation of tenders.

Studies conducted in GB revealed that about 4% in relation to the sold value constitute the losses which we are able to recognise. The remaining ones constitute the hidden part of the "iceberg" and accordance with the estimates they amount to about 30-50%.

3. Records of Quality-related Costs

The presented approaches are in accordance with the standard ..." are regarded as useful but not mutually exclusive; similarly to their adaptations and combinations." Regardless of how the costs connected with the quality will be identified and grouped, it is necessary to conduct the records in order to enable their analysis and optimisation. This requires the introduction of special balance or off-balance accounts, since the quality costs are usually not recognised by the normal accounting system of the company.

Methods of keeping records of costs

* **Fixed system**
* **Quick one-time cost diagnosis**
* **Random records of costs**

The application of a constant, uniform method of cost registration allows for conducting analyses of their trends and fast reactions in the case of the occurrence of sudden deviations. At the same time, a too formalised accounting system may not react to the changes in the environment, since it is often too inflexible. We must also reckon with a long, costly and labour-intensive period of preparation and implementation of the system. The structure and layout of the developed and implemented constant system of quality cost accounting system are organically connected with a concrete enterprise and cannot be applied in any other enterprise. In many American and European enterprises such systems were implemented in the 1980s but with time it appeared that their effects do not compensate for the expenditures and therefore they were withdrawn from such rigorously conducted records.

A quick one-time diagnosis of costs is most often conducted with an internal audit of quality system. Thus, the assessment of the system efficiency gets an additional dimension - the cost dimension. The amount of the incurred costs is in this case determined in a certain approximation, which is quite sufficient for their analysis and assessment. The results of quality cost records conducted in this way may be used for the assessment of the potential opportunities of the company to conduct a motivational action under the slogan "We sleep on a goldmine," but above all they are a prelude to further work. A quick cost diagnosis is most often conducted with the participation of external consultants.

An introduction of a random quality cost records requires a separation of areas in which it is necessary and possible to keep accurate records. it can be done on the basis of a quick one-time diagnosis or through the analysis of accounting data. For the remaining activity the records are kept in a random way. It is usually the currently applied system of quality cost records. It is a flexible and less time- and cost-consuming but the trust towards it may be built only after some time of its using.

Methods of obtaining data on costs

- introduction of new report types,

- division of data available on bookkeeping accounts,

- aggregation of data from different accounts,

- estimating.

All these ways are used in practice. The introduction of new types of reports and the pooling of data from different accounts require detailed clarification of the actions taken within the scope of quality, since all the costs incurred during their implementation will be recorded as quality costs. These may be for example:

- separating a group of commissions for the removal of defects revealed after the delivery and a development of a form for recording costs of these commissions ,
- preparation of cards of reparable and irreparable defects,
- summing up the recruitment costs, the costs of training of newly employed persons and costs of the procedure connected with the leaving of employees in order to obtain data determining the personnel rotation costs.

The division of data available on the bookkeeping accounts requires stating which part of the action, the costs of which have been recorded on a given account, concerns the quality. For example, in one of the enterprises is was assumed that 30% of activity costs of the technological department constitute the costs of research, analyses and removing the causes of defects, in another one the costs of places of preventive activity cost generation have been separated from the overall costs .

Estimating the quality costs concerns first of all those costs which do not have a direct reflection in the existing bookkeeping records. The estimation of costs incurred is usually based on the analogy or the opinions of specialists. An example here would be estimating the costs of erroneous product installation.

Difficulties in the records

- **connected with unproductive work**
- **bad recognition of the reality**
- **structure of overall costs**
- **too extensive system**
- **misunderstanding of the system**

In the course of keeping records of quality costs we may be faced with numerous difficulties and make mistakes in the calculations. Especially difficult is keeping records of the quality costs incurred during non-production work (e.g. in designing and management). It is also necessary to recognise the reality e.g. in the common understanding the word "scrap" refers not only to products which are so defective that they have to be disposed of but also it is used to describe chips, waste materials, risers, etc. Therefore, we cannot count all these material costs with the costs of deficiencies. Also, the information about numerous returns from the customers does not necessarily mean that the product is defective. Sometimes returns are caused for example by surpluses at the distributor who miscalculated the inventories. A great difficulty is to determine what part of the overall costs constitutes the quality cost. They are sometimes very high and it is logical to take them into consideration. The starting point in estimating these costs should be the determining of the "normal activity level," and then the records of deviations from this level. However, it is necessary to pay attention to the fact that a part of deviations may be caused by factors being outside the enterprise, e.g. strikes in other companies or a change in the legislation. A common mistake made in the entry of quality cost records is also its excessive expansion causing the "information noise." Too many types of costs and accounts does not help in assuring quality but it causes darkening of the image.

A properly functioning quality cost recording system should:

- be known and accepted by all those who provide data (primarily by employees of the accounting department),
- ensure the acceptance of the calculated amounts because only then it is possible to count on cooperation and use quality costs for motivating,
- apply a uniform way of filling in forms, since it allows for the use of a common "language" by all the departments within the enterprise,
- be introduced with the use of a guide developed especially of a given employment establishment, including the applied definitions, ways of keeping records and providing information,
- providing as much information as it is really needed in order to ensure quality.

A thought out and carefully carried out records of quality costs is a prerequisite for an effective analysis and optimisation .

4. Analysis of the recorded costs

Recording the costs allows for getting to know their amount, however, it does not answer the question whether this amount is appropriate for a given plant. It si necessary to provide certain outlays for activities connected with quality but the point is that these outlays should possibly be as small as possible. Therefore an analysis of the recorded costs is necessary.

Types of analyses of registered costs

- according to places of cost generation,
- according to products and product groups,
- in relation to the plan,
- in time,
- according to the relationships between cost groups.

- in relation to other measures of company activity.

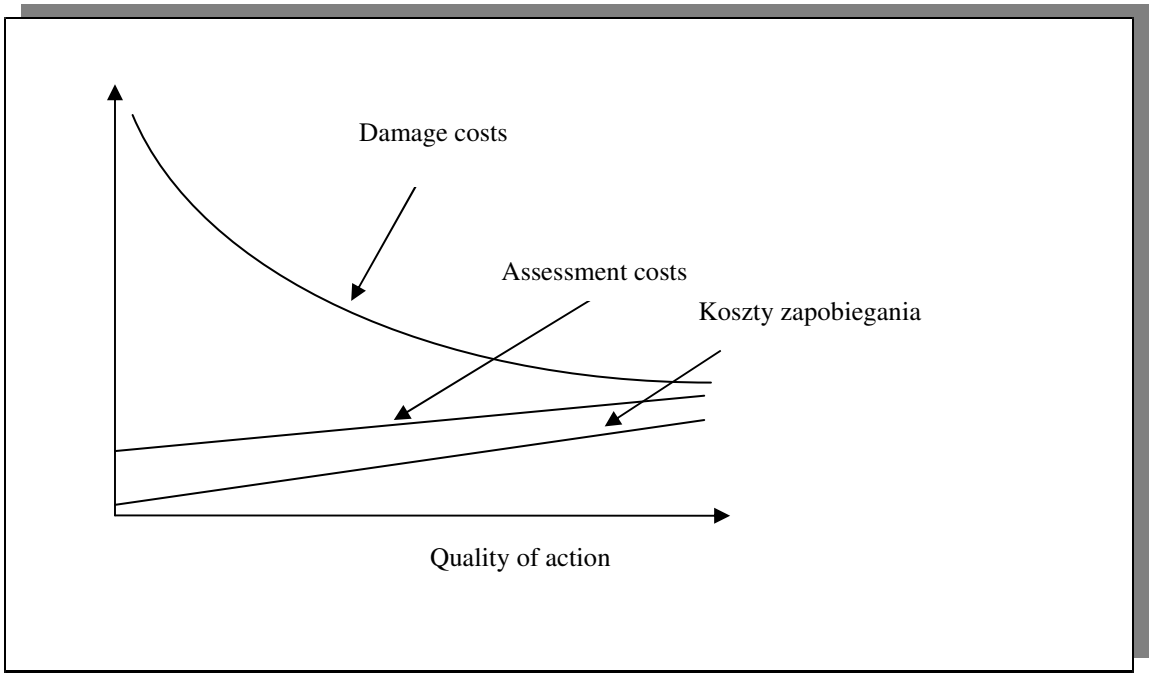
Cost analysis according to the place of formation and products uses a fact stated in many enterprises that unnecessary cost (losses) are not evenly distributed. They are generally distributed in such a way that a few basic factors are the cause of a large percentage of losses connected with quality. The phenomenon of such an unevenness is favourable to the management because it allows for directing the efforts towards weakening the actions or eliminate these factors. Upon their identification they - and only they - become problems which require solution. With a limited number of problems the costs of preventive activity are relatively small. However, since these problems concern the main part of the losses, there is a large possibility to limit the costs.

Recording quality costs in a longer period allows for their planning, and thus the analysis of deviations in relation to the plan. Each deviation is then a signal of an irregularity in conducting activities or in planning and it should lead to taking steps to improve the situation. Such an analysis ultimately leads to the improvement in the efficiency of performance.

An analysis of the recorded quality costs in time is based on tracking their trends with a simultaneous reference to the chances and the nature of the conducted pro-quality activities. Such an analysis should confirm the correctness of the decisions about the direction, scope and intensity of measures.

It is particularly helpful to connect the cost analysis in time with the analysis of the relationships between the kinds (types) of costs.

Proper relations between the types of costs and quality of action



The increase in the prevention costs should be the result of an extended substantive range of preventive measures. If the increase in these costs is reflected in a simultaneous decrease in the costs of damage or a decrease only slightly shifted in time and accordingly larger, it is beneficial for the enterprise. An increase of assessment costs in time may be the result of an extension of the control tasks, as well as the necessity of an additional product selection. However, a moderate increase in the quality assessment costs is favourable for an enterprise, since in most often affects a substantial decrease in damage costa, and as a result, influences the reductions in the overall manufacturing costs.

Analysing the changes in the costs of quality according to their types, we can also state whether an enterprise conducts an active or a passive pro-quality activity. If in a longer period, the relationship between the prevention and assessment costs and the damage costs is constant, it is a sign that the company is passive. Whereas a decrease in the damage costs with a simultaneous increase in the preventive activity costs and/or quality assessment costs, shows the activeness of the enterprise within the scope of quality. Each increase or even maintaining the same level of damage costs is a proof that the undertaken measures are ineffective.

Optimisation of Costs Connected with Quality

Optimisation of quality costs is determining the amount of outlays which are actually necessary to ensure an economically optimal quality of products and services.

If it is obvious that it is necessary to incur certain costs to ensure the required quality, it raises the problem of finding methods that allow to determine the optimum amounts. It is impossible to look for analogies of other companies, since the cost information is usually kept secret. In addition, each enterprise has a different technical, human and financial potential and due to these differences the data becomes incomparable. Optimisation of quality costs may be conducted only if an enterprise implemented and verified a system of their records and analysis which corresponds to its specificity.

Optimising costs means:

1. **Determine the standard level**
2. **Estimate lost opportunities**
3. **Select the best solutions**

When the quality costs are well identified, there is a large temptation to eliminate them, however, it is necessary to consider the consequences. Sometimes a partial (fragmentary) elimination of costs may lead to their global increase. The fundamental issue in trying to optimise the costs of quality is the ability to determine the costs connected with each of the conducted actions with each of the conducted.

It is necessary to analyse the measures which are taken to ensure quality and the assessment of its level. It will allow for strengthening these measures which result in lowering the total costs and eliminate those which require outlays but do not bring the expected benefits.

The optimisation (elimination) of deficiency costs should concern the whole activity of the enterprise. It is necessary here to determine the model level of measures or determine such measures and in what scope they should be introduced in the enterprise, and then check how they take place in the reality.

Optimising quality costs it is necessary to:

1. **Refer to specific actions**
2. **Analyse trends**
3. **Strengthen effective action**
4. **Eliminate ineffective action**
5. **Be careful not to optimise in part**

Determining the optimum level of action which is appropriate for a given enterprise and determining the necessary outlays on the one hand and the records of the costs actually incurred on the other hand will allow to estimate the lost opportunities as a result.

Cost optimisation may be performed by:

- the application of new technological solutions (new devices, technologies),

- introduction of changes in the process organisation,

- conducting motivational actions among the staff.

A special role in the process of cost optimisation through the elimination of losses is played by the level of employee awareness.

Levels of awareness in solving the problems of losses

1. **I do not know what a loss is, I do not know that my actions lead to the generation of losses.**
2. **I know that I am causing some losses but I do not know their extent and mechanisms of formation**

3. **I know what losses arise, I am able to observe and analyse them.**
4. **I have the tools and skills which enable me to eliminate losses**

The first of the above levels occurs in enterprises which do not conduct the quality cost account, the second one occurs in those which only conduct the records of these costs. Companies conducting records and cost analysis are placed at solving the problem of losses, at the third level of awareness development. However, the optimisation of quality costs is os connected with the fourth (the highest) level of awareness

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LEGAL ASPECTS CONNECTED WITH QUALITY

New Approach Directives

These directives have been developed since 1985. A list of directives designed to date is included in Table 1.

Table 1. Selected Directives of the European Union

Number	Title
87/404/EEC	Simple pressure containers
88/378/EEC	Safety of toys
89/106/EEC	Construction products
89/339/EEC	Electromagnetic compatibility
89/382/EEC	Machines
89/686/EEC	Personal protection
90/384/EEC	Non-automatic weighing machines
90/385/EEC	Active implantable medical devices (implants)
90/396/EEC	Appliances burning gaseous fuels
91/263/EEC	Communications equipment
92/42/EEC	Efficiency of heating boilers
93/15/EEC	Explosives used for non-military purposes
93/42/EEC	Medical devices
93.68/EEC	Low voltage
94/9/EEC	Protective equipment and systems for use in potentially explosive atmospheres
94/25/EEC	Recreational boats

Currently, the Directives include about 65% of products which are marketed. Works are being conducted on the development of further directives concerning among others:

- measurement tools,

- marine equipment,
- upholstered furniture,
- equipment in playgrounds,
- packaging,
- incineration of hazardous products.

In the period from the adoption of a directive to the date of its validity there is the so-called transition period in which manufacturers have the right to use both the directive and the "old" regulation in accordance with the existing national law.

Content Elements of Directives:

- Scope (range of products covered with the Directive)
- General clause on the introduction to the market
  – safety of persons, domestic animals or goods cannot be put at risk by the product which is introduced to the market
- Basic safety requirements
  – the core of the "new approach" directive
  – protection of public interest
  – possibility to ensure compliance with the directive on the basis of the basic requirements
- Free movement clause

Proof of compliance

- – compliance with harmonised standards
- – lack of compliance
- – lack of standards
- Administering the list of standards (procedure applied in the case when the Commission or a Member State is not satisfies with the harmonised standard
- Safety clause
- Means of attestation of conformity
- The Standing Committee (manages the Directive)

A Standing Committee is nominated for each Directive to supervise the development of harmonised standards, collects comments on the Directive and proposes amendments. The technical requirements of products which are subject to the Directive are included in the harmonised standards.

During the development of a European standard or a harmonisation document it is prohibited for the standardisation bodies of particular member states to undertake work or publish a standard on the same subject.

Each member state of the European standardisation organisations must implement a European standard to its collection of standards and withdraw all the standards which are contrary to the adopted standard.

Compliance assessment

Each Directive includes the procedures whereby a manufacturer or and importer may demonstrate to relative authorities that the product introduced into the market meets the basic requirements included in the directives. The modular approach was proposed in the case of the proposed procedures. The Directives determine the modules which may be applied and the final choice is up to the manufacturer.

The modular approach divides the procedures of compliance confirmation into 8 basic modules which differ depending on: the stage of product development, assessment type and the unit which conducts assessment. These modules have been presented in Table 2. They may be characterised as follows:

Module A (declaration of conformity)

The manufacturer declares the conformity of their products with the requirements of the directive. They keep the technical documentation available to the government authorities. The producer prepares a written declaration of conformity and marks the product with the CE marking.

Module B (type testing)

The manufacturer presents the technical documentation and/or product prototype to the authorised unit. The authorised unit checks and carries out research, issuing a type testing certificate.

Module C (type compatibility) applied with module B

The manufacturer declares the conformity of the product with the type for which he received a certificate. The producer prepares declaration of conformity and marks the product with the CE marking.

Module D (ensuring production quality) applied with module B

The manufacturer having a certified quality system declares the conformity of the product with the certified type. The producer prepares declaration of conformity and marks the product with the CE marking.

Module E (ensuring product quality) applied with module B

A manufacturer having a certified quality system declares the conformity of the product with a certified type, prepares a declaration of conformity and marks the product with the CE marking.

Module F (product verification) applied with module B

An authorised body examines the conformity of the product with the certified type. The producer prepares a declaration of conformity and marks the product with the CE marking.

Module G (unit production verification)

An authorised body examines the documentation and the product, and issues a compliance certificate. The producer prepares declaration of conformity and marks the product with the CE marking.

Module H (full quality assurance)

A producer having a certified quality system in accordance with ISO 9001 prepares a declaration of conformity and marks the product with the CE marking.

Table 2. Conformity assessment procedures in the legislation of the European Union

DESIGN	**A. INTERNAL CONTROL OF PRODUCTION**	**B. TYPE TESTING**				**G. UNIT CONTROL OF EACH PRODUCT**	**H. TOTAL QUALITY ASSURANCE**
	Manufacturer: stores technical documentation for the control of the national authorities	**Manufacturer submits the following to the notified authority:** - technical documentation - typical product **Notified authority:** - performs tests (if necessary) - certifies compliance with the basic requirements - issues the type testing certificate				**Manufacturer:** submits technical documentation	**ISO 9001** **Manufacturer:** acts according to the approved quality system for design **Notified authority:** - controls the quality system system jakości - confirms the design compliance - issues a project certificate
PRODUCTION	**Producent:** - declares compliance with the requirements - places **CE** marking	**C. TYPE COMPATIBILITY** **Producent:** - declares compliance with the approved type - places **CE** marking	**D. ENSURING QUALITY OF PRODUCTION** **Producent:** - acts in accordance with the approved quality system for production and tests - declares compliance with the approved type- places **CE** marking	**E. ENSURING QUALITY OF PRODUCT** **Producent:** - acts in accordance with the approved quality system for control and testing - declares compliance with the approved type - places **CE** marking	**F. PRODUCT CONTROL** **Producent:** - declares compliance with the approved type - places **CE** marking	**Producent:** - submits the product for control - declares compliance- places **CE** marking	**Producent:** - acts in accordance with the approved quality system for production and control - declares compliance- places **CE** marking
	Notified authority: - conducts random product checks	**Notified authority:** - tests the product in terms of the essential parameters and functions - conducts random product checks	**Notified authority:** - approves the quality system - conducts an inspection of the quality system	**Notified authority:** - approves the quality system - conducts an inspection of the quality system	**Notified authority:** - checks compliance with the requirements - issues a certificate of compliance	**Notified authority:** - checks compliance with the requirements - issues a certificate of compliance	**Notified authority:** - conducts an inspection of the quality system

"Recognised" or "notified" authorities participate in the assessment of compliance. These are units selected by the national authorities and notified to the Commission of the European Union. They are reported by the member states of the European Union for each directive. These units should be competent and recognised laboratories, inspection or certification units. These units are usually accredited units. Units outside the EU can be approved for a given directive on condition of concluding an agreement on a mutual recognition of research results and certificates of conformity between the interested parties and the EU. In Poland such a recognition procedure has been initiated by 4 laboratories.

CE Marking

Labelling a product with a CE marking means that the manufacturer ensures that the product which is subject to the requirements of one or several directives, meets them. It may be accompanied by a code identifying the notified authority.

This marking does not inform about the assessment procedure (which mode of assessment was selected by the manufacturer). This gives the right to the free circulation within the European Union. Products which are subject to the directives, regardless of the manufacturer, which have not undergone the conformity assessment procedures and have not been granted the right to label the product with the CE marking, cannot be traded on EU markets.

It is necessary to emphasise that countries (through their authorised notified authorities) have a supervision over the proper application of CE markings, regardless of the mode of obtaining them.

Product liability

The European Union legislation, and especially Directive 85/374/EEC on the liability for defective products requires its members to implement common liability rules for defective products to their national law. The Directive determines the following:

- a product is considered defective if it does not ensure safety, which can be expected by a person;
- it is required from the injured party to prove the existence of damage, a defect and a causal connection between the damage and the defect;
- the manufacturer is responsible for damage caused by the defect of their product;
- the manufacturer is obliged to prove that the product at the time of marketing did not have the defect which caused damage or that the defect could not be recognised with the contemporary state of knowledge and technology

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