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.

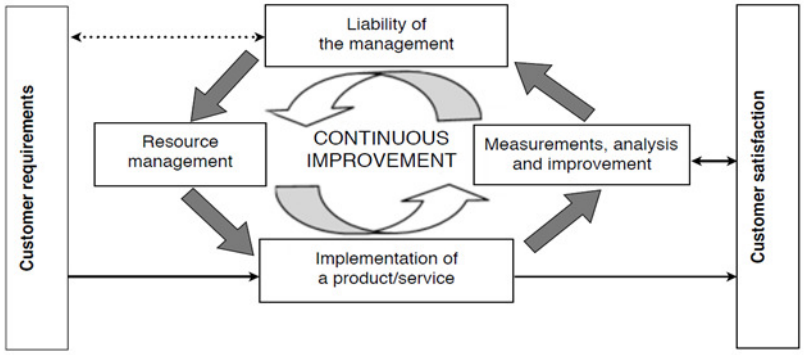

Fig. 1. Dynamic structure of the quality management systems according to ISO 9001:2008

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.

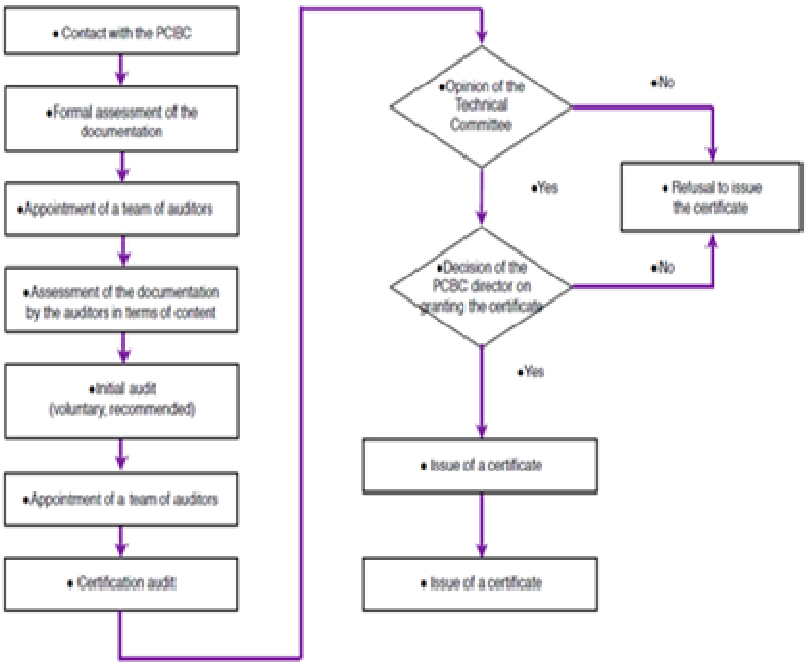

Fig. 2. The certification procedure of the management system applied by the PCBC

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).

Part-financed by the European Union (European Development Fund and European Neighborhood and Partnership Instrument) within the BSR QUICK Project