

## QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

### INTRODUCTION

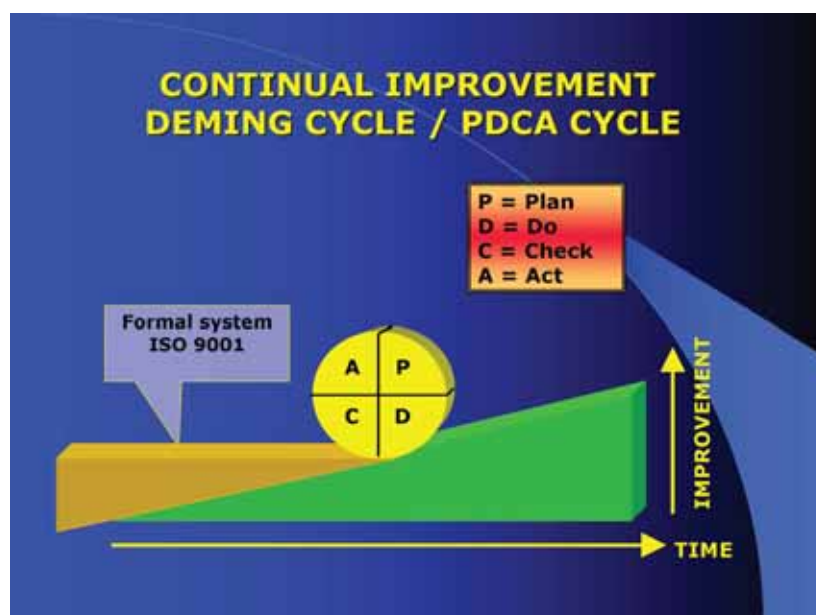
Quality of products and services is one of the crucial factors, that influence the business performance of any organization. The present day business-wide needs, especially these related to quality are more and more exacting. It is possible to meet these needs and improve the economical situation at the same time by continuous quality improvement.

Quality management system which meets the requirements of ISO 9001 ensures stable position on the market, continuous progress and development in quality. It can be achieved through planning, maintaining and continuous improvement of all processes, which leads to higher profit, effectiveness, customer satisfaction, etc. Moreover, the certificate assuring conformity of the quality management system with the requirements of the ISO 9001 standard can be very effective marketing tool.

### WHAT IS QUALITY MANAGEMENT SYSTEM (QMS)?

Quality management system (QMS) is a tool that enables every organization to achieve better and better quality of their products and/or services through continual improvement of methods and means of performance. According to the definition QMS is that part of the organization's management system that focuses on the achievement of results, in relation to the quality objectives, to satisfy the needs, expectations and requirements of interested parties, as appropriate. The quality objectives complement other objectives of the organization such as those related to growth, funding, profitability, the environment and occupational health and safety. The various parts of an organization's management system might be integrated, together with the quality management system into a single management system using common elements. *(source: ISO 9000:2000 Quality Management Systems – Fundamentals and vocabulary).*

The fundamental principle of every quality management system is concept of continual improvement. This concept is aimed at improving on a regular basis the overall quality management system and is depicted by "Plan-Do-Check-Act" model introduced by Deming.



## THE ISO 9000 FAMILY

The ISO 9000 family of standards have been internationally recognized as a basis for developing, maintaining and documenting quality management systems. The newest, revised ISO 9000:2000 series consist of the following, interrelated documents:

- ISO 9000:2000 - Quality Management Systems – Fundamentals and vocabulary
- ISO 9001:2000 - Quality Management Systems – Requirements
- ISO 9004:2000 - Quality Management Systems – Guidelines for performance improvements.

**Requirements for quality management systems are specified in the ISO 9001:2000 standard, which provides the baseline for the certification of the organization's QMS.**

The standard that supplements the ISO 9000 family is ISO 19011:2002, that provides guidance on auditing quality and/or environmental management systems.

## QUALITY PRINCIPLES

The following eight quality management principles form the basis for the quality management system standards within the ISO 9000 family. These can be used by top management in order to lead the organization towards improved performance.

Principle 1: **Customer focus** – Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Principle 2: **Leadership** – Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Principle 3: **Involvement of people** – People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Principle 4: **Process approach** – A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5: **System approach to management** – Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

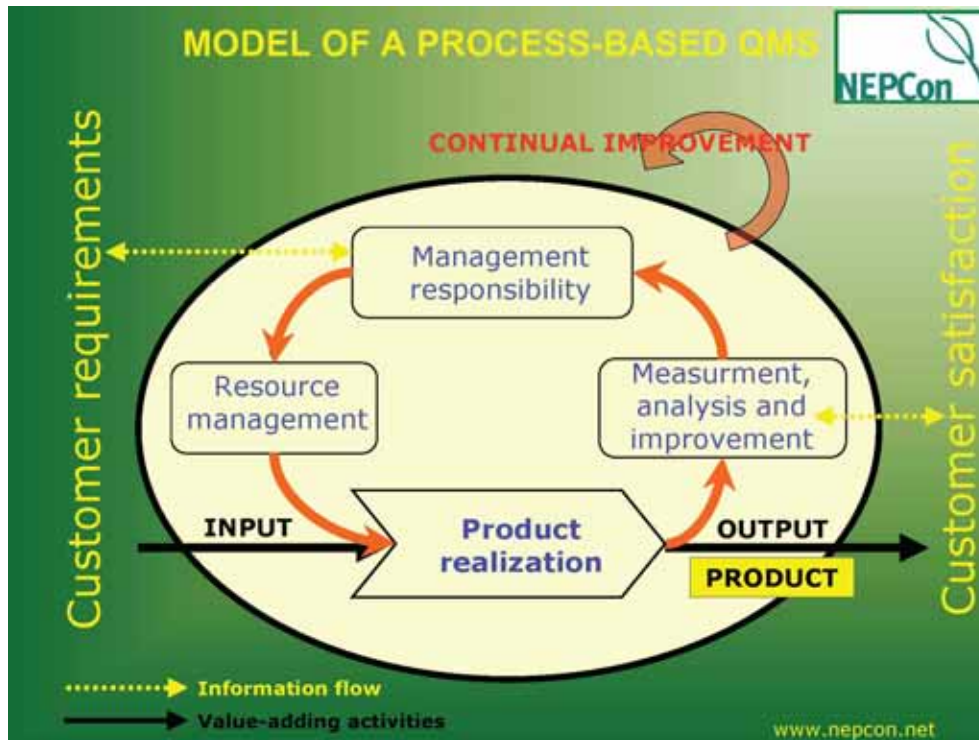
Principle 6: **Continual improvement** – Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Principle 7: **Factual approach to decision making** – Effective decisions are based on the analysis of data and information.

Principle 8: **Mutually beneficial supplier relationships** – An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

**MAIN ELEMENTS OF QMS ACCORDING TO THE ISO 9001 STANDARD**

Process approach provides the basis for developing, implementing and improving the quality management system specified in ISO 9001. Process approach requires from the management of organization to look at its activities as a system of numerous interrelated and interacting processes, where each process has its own purpose, assigned resources and methods of surveillance. According to the standard any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process. Processes can be also activities related to product realization and/or service providing. Extremely important are processes indirectly connected with product/service realization such as: management, monitoring, measurement, communication, internal audit, and management review. According to the process approach principle, management system of an organization should be taken as a whole, starting from determining of client’s requirements, through identification, implementation and management of the processes, ensuring adequate resources, monitoring, measurement and analysis of results, system enhancement, and meeting client’s needs and expectations as a final stage.



Implementation of the QMS is voluntary. Its adoption will only be successful, if it is a strategic decision of organization’s top management. Top management is responsible for ensuring the availability of resources for process realization, including qualified personnel, infrastructure and technology, financing, etc.

Top management is responsible for formulating the quality policy, that provides a framework for establishing and reviewing quality objectives. Crucial prerequisite of successful QMS is engagement of employees. They should be adequately trained and aware of the relevance and importance of their activities in achieving the quality objectives. Moreover, the effective management system requires proper information flow within the organization and outside (communication with customer and other parties).

In order to determine whether the QMS works properly, it should be periodically controlled. The ISO 9001:2000 standard requires to conduct internal audits. The aim of the internal audit is to determine, if the QMS conforms to the planned arrangements, to the requirements of the standard and requirements established by the organization. All encountered nonconformities should be the basis for corrective and preventive actions, that would eliminate the causes of nonconformities in the future. Other method of QMS control is management review. The aim of the management review is to ensure continuing suitability, adequacy and effectiveness of the QMS.

## **CERTIFICATION OF QUALITY MANAGEMENT SYSTEM**

Many organization seek independent verification of their management system. Certification attests that organization's QMS conforms the requirements of QM standard such as ISO 9001.

*Certified Quality Management System confirms organization's ability to continually deliver its products and/or services that satisfy clients' expectations and comply with legal requirements. QMS certificate shows that processes influencing quality of products/services are under control, tasks are realized to achieve quality objectives, and that quality improvement is a fundamental principle of the organization.*

NEPCon provides independent evaluation and certification of the quality management system against ISO 9001:2000. During the certification audit auditor checks, whether all system elements fulfill relevant requirements. Certificate confirming that QMS conforms the requirements of the ISO 9001 standard is valid for 3 years. In this period NEPCon conducts annual surveillance audits.

NEPCon's services comply with international standards set in ISO/IEC Guide 62:1996 (General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems), which constitutes basis for European standard EN-45012:1998 under the same name.

NEPCon plans and conducts certification processes, and selects auditors using methods and techniques required by the international standard ISO 19011:2002 "Guidelines for quality and/or environmental management systems auditing".

NEPCon cooperates and employs high qualified auditors and experts that have experience and qualifications, which enable them to comprehend the technological context in which the audit is being conducted.

### **CERTIFICATION STEP BY STEP**

- 1. Initial contact** is made between the organization and NEPCon.
- The organization fills in the **application form** and sends it to NEPCon by e-mail, fax, or traditional mail.
- NEPCon estimates the cost for personnel, travel, administration and other costs, and prepares a **proposal for certification** covering cost of certification and surveillance audits.
- If the organization accepts the proposal, NEPCon prepares **certification agreement** for certification and surveillance of the management system, which both parties sign.

## **5. Certification audit in the organization.**

Certification audit consists of two stages.

The objectives of the stage 1 are to provide a focus for planning the stage 2 by gaining an understanding of the QMS in the context of the organization's quality policy and objectives, and, in particular, of the organization's state of preparedness for certification audit. During the first stage auditor checks if:

- processes have been correctly identified;
- the QMS is designed to achieve the organization's quality policy and objectives;
- the internal audit conforms to the requirements of the QMS standard;
- management reviews are being conducted and cover the continuing suitability, adequacy and effectiveness of the QMS;

As a result of stage 1 of the certification audit the following information should be obtained:

- QMS documentation including procedures;
- a description of the organization and its on-site processes;
- the means by which the concept of continual improvement is realized;
- internal audit programs and reports.

The objectives of the first stage of the audit are usually achieved through the QMS documentation review, which is provided by the organization. Under justifiable conditions a preliminary on-site visit may be necessary to achieve the objectives of the first stage.

The main objectives of the on site audit (stage 2) are to confirm that the organization adheres to its own policies, objectives and procedures, and to confirm that the QMS conforms with all the requirements of the QMS standard and is achieving the organization's policy objectives.

The second stage of the audit addresses the implementation of all elements of the standard (except those fully and successfully audited in stage 1) and in particular focus on the organization's:

- documented processes;
- management responsibility for the environmental policy;
- responsibility of top management for quality policy;
- performance monitoring, measuring, reporting and reviewing against the objectives and targets;
- identification and evaluation of nonconformities and completion of corrective/preventive actions;
- internal auditing and management review;
- links between policy, quality objectives and targets, responsibilities, programs, procedures, performance data, internal audit and review.

During the audit, information relevant to the audit objectives, scope and criteria are gathered. Methods of collecting information include interviews, observation of activities, and/or review of documents. All collected information is verified. Only verified information may be audit evidence. Audit evidence is recorded and evaluated against audit criteria to generate the audit findings. Audit findings can indicate either conformity or nonconformity with audit criteria. They can identify an opportunity for improvement as well. Nonconformities are summarized and agreed by auditor team, then recorded in the Nonconformities Report.

NEPCon distinguishes the following grades of nonconformity:

- a. Observation – Audit evidence exists but relevant requirements (criteria) can not be found. The observation might refer to potential problems that were noticed, or suggested improvements that could be made even though an actual non-compliance was not found.
- b. Minor nonconformity – failure in some part of the QMS documentation, which is not required by the standard. It is not likely to result in the failure of the quality system.
- c. Major nonconformity – any noncompliance with the standard requirement. A number of minor nonconformities against one requirements, that can represent a total breakdown of the system.

*!!! Caution: Audit is based on sampling techniques. Fact, that nonconformities haven't been identified in a certain area, does not mean that they do not exist there.*

*!!! Caution: NEPCon strictly obeys its confidentiality policy. All information and other property rights of our clients are kept confidential. Subcontracted personnel and all employees are required and obliged to keep all such information confidential.*

6. NEPCon prepares **audit report** and sends the final version to the organization within one month after certification audit.
7. NEPCon takes the **certification decision** and issues the certificate (if the decision is positive).
8. **Surveillance** over certified management system.

After certificate is issued the organization must follow the criteria of certification, which is confirmed during annual surveillance audits within 3 year period of validity of the certificate. The purpose of surveillance is to verify that the approved quality management system continues to be implemented, to consider the implications of changes to that system initiated as a result of changes in the organization's operation and to confirm continued conformity with certification requirements.

*!!!Caution: The above-mentioned procedure might vary depending on size of organization and types of operation. For large and complicated operation we might suggest to conduct an initial audit to identify major weaknesses in their system before the certification audit.*

**BENEFITS OF AN ISO 9001 BASED QUALITY MANAGEMENT SYSTEM  
IMPLEMENTATION AND CERTIFICATION**

Among the most important benefits of quality management system implementation and certification the following are to be mentioned:

- Better position on the competitive national and global market, as well as access to new markets,
- Lower production costs because of fewer nonconforming products, less rework, lowered rejection rates, streamlined processes and fewer mistakes,
- Higher confidence and will of cooperation from clients, contractors, and other third parties,
- Higher internal operational efficiency,
- Continuous and effective process of improvement that saves time and money and improves quality,
- Higher engagement, self-control, and motivation of employees,
- Compliance with regulatory requirements.