

## QUALITY MANAGEMENT SYSTEMS - NEW APPROACH BY ISO 9000/2000

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The paper presents information on new standards for quality management systems, ISO 9000/2000. Differences between the set of ISO 9000/1994 standards, that are not valid now, and a new one are presented. Special interest is focused on new features of the system, e.g. process approach, flexibility of the standards regarding their use in all kinds of work organizations, documentation of the system, principles of continual improvement, self-assessment of the organization.

**Key words:** *ISO standards, quality, management systems*

**Sustav upravljanja kakvoćom - novi pristup prema ISO 9000/2000.** Članak priopćava o novim normama sustava za upravljanje kakvoćom, ISO 9000/2000. Razlike između niza normi ISO 9000/1994 koje sada nisu važeće te su prikazane nove norme. Posebno zanimanje posvećeno je novim svojstvima tog sustava, npr. postupku prilaza, fleksibilnosti normi u smislu njihove uporabe u svim vidovima radnih organizacija, dokumentacije sustava, načela kontinuiranog napretka, samoocjenjivanja radnih organizacija.

**Ključne riječi:** *ISO norme, kvaliteta, sustavi upravljanja*

### INTRODUCTION

In December 2000 European Committee for Standardization /CEN/ approved the new standards for quality management systems, generally named as family of standards ISO 9000/2000. The family replaces the family of ISO 9000/1994 standards for quality systems. The main aim of the standards is to assist organizations, regardless to their size and type of their activity, in implementation and operation of quality management systems.

The family consists of four basic documents.

1. ISO 9000 has descriptive functions. It describes the fundamentals of quality management systems and is focused mainly on the role of top management and quality policy, documentation of the system, evaluation of the system effectivity. The terminology used in quality management systems, is also included.
2. ISO 9001 states requirements that must be met in implementation and operation of quality management system. The standard has direction character, certification audit requirements are derived from its statements.
3. ISO 9004 is the guidance on how to attain and keep both the effectiveness and efficiency of the system. The

main idea of this standard is continual improvement of all items of the system.

4. ISO 19011 is the guidance on auditing of quality management systems. The auditing of environmental management systems is also included in this standard.

### WHY

#### NEW STANDARDS ISO 9000/2000 WERE NEEDED?

The ISO 9000/1994 standards became the base of market success for many enterprises producing goods or services. They were tailored for three distinctive groups of enterprises related to scope and content of their business. The use of standards for establishing quality systems in institutions of non-productive character, i.e. in schools, artistic institutions, research institutions, public and governing bodies etc, was not very simple with ISO 9000/1994 standards because of their mostly technical character and direction to keep and document all items of the standards. The application of the standards for quality systems was very expensive, moreover, it produced a huge amount of documents, that had no connections with institution's activity.

The quality of products was determined by customer's demands, but feedback, the measurement of customer's satisfaction, was not decided. The workers in the whole

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business cycle were not considered and treated on the same level as the customers were. No items, considering their status, working conditions, healths and safety regulations were included into the quality standards. The focus on quality systems influence on economic results of the institution was not included in 1994 standards. The costs of the goods non-conformity, the share of the market, are very important indicators of the whole system.

Awarding of the quality system certificate, control audits, reaudits, internal audits were the tools that help the organization to keep the system on certificated level. No systematic approach to continual improvement of all business activities was included in the standards.

The above mentioned deficiencies of the ISO 9000/1994 standards were corrected by adoption on the free will basis of some principles of Total Quality Management approach, International Quality Awards /European, Deming's prize, Malcolm Baldrige/, EFQM activities and some others to established quality systems in institutions. Continual press of non-productive institutions, seeking quality systems benefits, culminated in new family of ISO standards, EN ISO 9000/2000.

**WHAT ARE THE MOST DISTINCTIVE DIFFERENCES OF NEW STANDARDS?**

The Quality Management System, defined by EN ISO 9000/2000, is designed to address the needs of all interested parties, customers, suppliers, employees, and owners. It uses eight management principles:

1. Customer focus;
2. Leadership;
3. Involvement of people;
4. Process approach;
5. System approach to management;
6. Continual improvement;
7. Factual approach to decision making;
8. Mutually beneficial supplier relationship.

**Process approach**

The standards ISO 9000/2000 promote the new approach to the whole business activity. It is divided into the chain of processes. As a process is considered each activity that is able by using resources transform input into output. The whole business is understood as a chain of

interlinked processes when the output of one process is the input of the other, subsequent process.

The model of a process - based quality management system is in Figure 1.

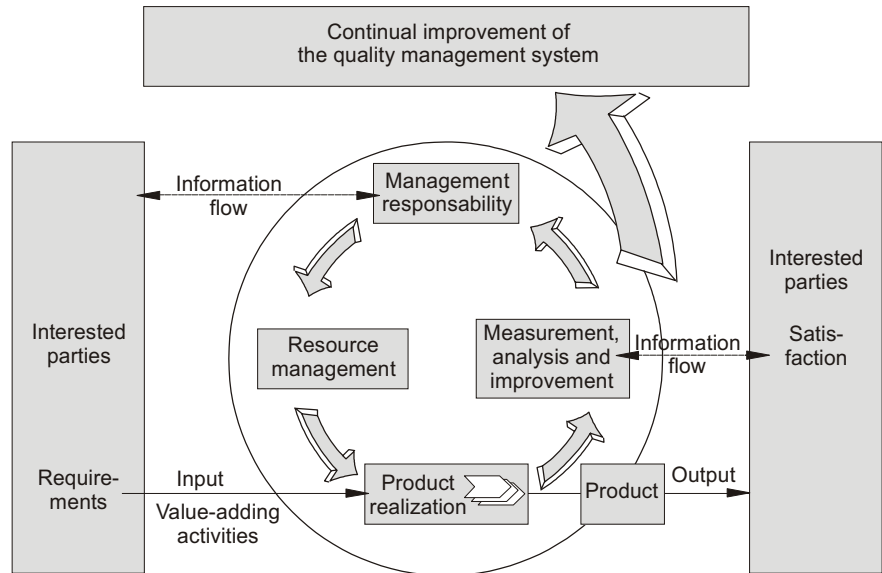


Figure 1. Model of a process-based quality management system  
Slika 1. Model sustava upravljanja kakvoćom koji se zasniva na obradi

As it can be seen from the Figure, not only internal activities, but also activities of customers and suppliers are linked into the chain. The processes are subdivided into three groups:

- managerial processes,
- main processes,
- supporting processes.

The example of productive business divided into the processes is in Figure 2. One of the main principles of the new standards is that quality of products is reached by controlling and improving of the all processes.

**Flexibility of the standards**

The standards are applicable to all work organizations, regardless of type of their business and their size. If some of the requirements, stated by the standards, do not match the organization activities, they can be omitted. These exclusions are limited only to the content of the clause 7: Product realization. Only exclusions that in no way affect the organization's ability to provide products that meet customer requirements, are allowed. All exclusions and reasons why they are applied should be documented in principal document - quality manual.

Some other differences, i.e. documentation of the system, continual improvement, cost analysis etc. will be mentioned in the next chapter.

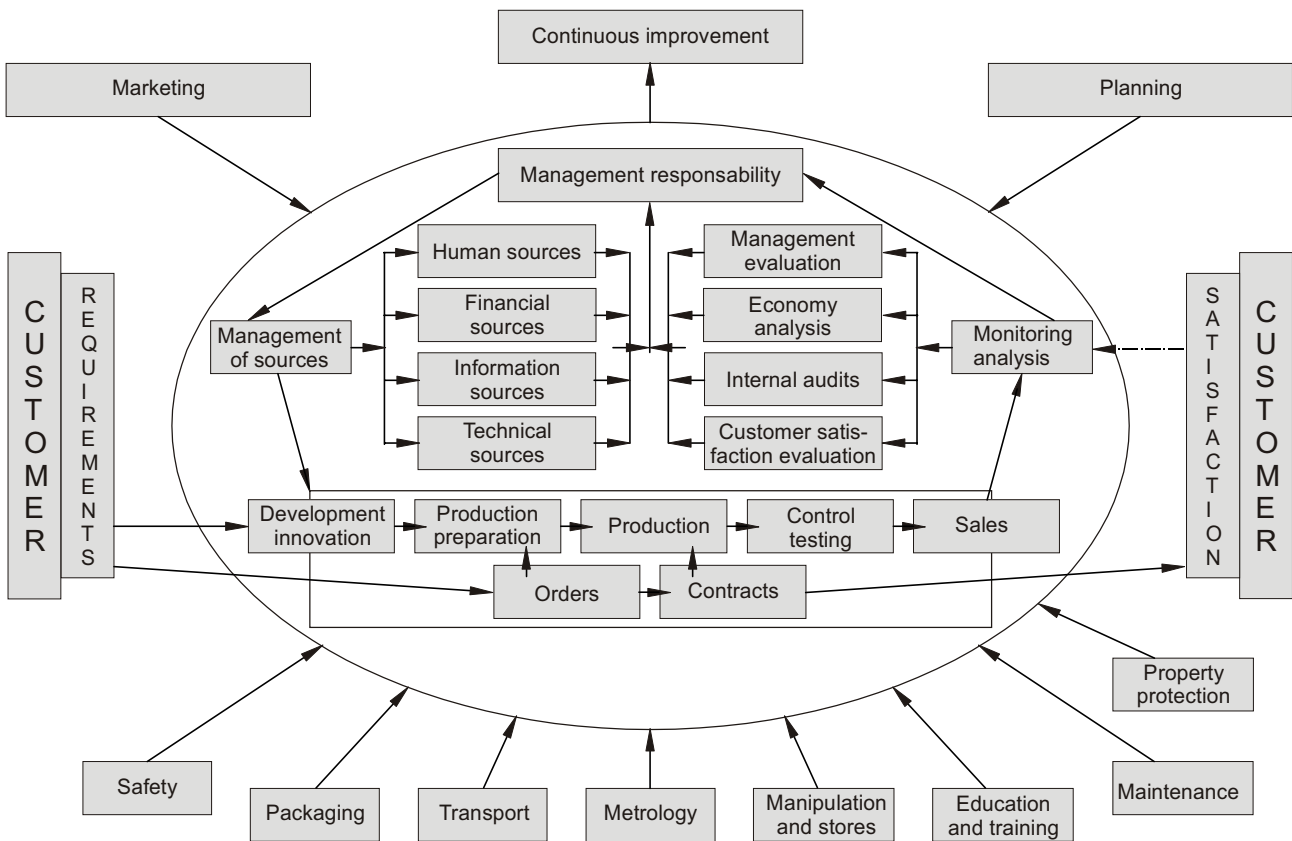


Figure 2. Productive business divided into processes  
 Slika 2. Proizvodno poslovanje podijeljeno u postupke

**STRUCTURE OF THE EN ISO 9001/2000 STANDARDS**

The requirements of the ISO 9001/2000 standards are subdivided into five clauses:

1. Quality management system;
2. Management responsibility;
3. Resource management;
4. Product realization;
5. Measurement, analysis and improvement.

The structure of the standard and its clauses is very different from the standard EN ISO 9001/1994. It configures in one clause the items that are similar regardless of their character. In description of the clauses we shall draw attention mainly to major differences and new items when compared with 1994 standards.

**Clause 4: Quality management system**

General requirement: The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness. The first part of the clause relates to identification of the processes and their sequence, criteria and methods for operation and

control of the processes, resources of the processes, measurement and analysis of the processes, continual improvement of the processes. These requirements are treated in detail in next clauses.

The second part relates to quality management system documentation. Five groups of documents are characterized.

1. Statements of a quality policy and quality objectives. The statements, prepared by top management, have general information role about commitments of organization in the field of quality.
2. Quality manual. It is fundamental document that presents the scope of the quality management system in the organization, exclusions from the clause 7 and justifications for them, list of documented procedures established for the system, description of the interactions between the processes of the system.
3. Documented procedures, required by the standard. They are:
  - operative control of documents,
  - operative control of quality records,
  - internal audit,
  - operative control of non - conforming product,
  - corrective action,
  - preventive action.

4. Documents needed by the organization to ensure the effective planning, operation and control of its processes. They are:
- quality plans; they describe how the quality management system is applied to a specific product,
  - specifications. These documents state requirements,
  - guidelines. These documents state recommendations or suggestions,
  - documented procedures, work instructions, drawings.
5. Records. They are documents that provide objective evidence of activities performed and results achieved. The organization determines the extent of documentation in groups 4 and 5. The clause also deals with control of documents. This part is similar to the one in 1994 standards.

#### **Clause 5: Management responsibility**

Customer focus is emphasized in all points characterizing management responsibility. Top management establishes the quality policy, official commitment of the organization to quality of its outputs in every aspect of their applications. The quality policy is transformed to quality objectives in the organization, that have to be measurable and controlled. The top management appoints management representative in quality, a member of top management, and the member with top responsibility and authority in quality management system.

One of the main management responsibilities is quality planning. Outputs of the quality planning define main actions and goals needed for keeping and improving all aspects of quality management system in the organization. Top management has to review the quality management system in planned intervals. The most important items of the review are:

- results of quality objectives,
- results of internal and external audits,
- satisfaction of interested parties,
- results of continual improvement of the processes,
- financial effects of quality related activities,
- competitors performance and others. Interested parties of organization include:
  - customers and end - users,
  - people in organization,
  - owners / investors,
  - suppliers,
  - community and public affected by the organization.

#### **Clause 6: Resource management**

Top management should ensure that resources essential for all processes are available. The resources include:

- people,
- infrastructure,

- work environment,
- information,
- suppliers and partners,
- natural resources,
- financial resources.

Compared to 1994 standards, resources are characterized in complex manner, not limited only to people, information and purchased materials. On the first place competence of human resources is stressed. Only competent people can handle and improve the processes and produce the outputs of necessary quality. Documented procedures for education and training of personnel are the part of the system. To strengthen the involvement of people in quality management system activities, education and training also include:

- the vision for the future of the organization,
- the organization's policies and objectives,
- the initiation and implementation of improvement processes,
- benefits from creativity and innovation,
- the organization's impact on society.

The very new in the standards are the aspects of infrastructure. The infrastructure resources include plant configuration and premises, workspace, tools and equipment, support services, information and communication technology, transport facilities. To enhance the motivation, satisfaction and performance of people in the organization, creation of suitable work environment is one of the items of the system. It includes:

- safety rules and guidance,
- ergonomics,
- work place location,
- social interaction,
- facilities for people in the organization,
- hygienic factors /heat, humidity, light, airflow, cleanliness, noise, vibration.

Role of resources controlling by new character of partnership with suppliers, including their involvement in design and development activities and continual improvement programmes has also important place in the system.

#### **Clause 7: Product realization**

Top management should ensure the effective and efficient operation of realization processes; support processes and the associated process network so that the organization has the capability of satisfying its interested parties. The clause deals with processes starting with review of requirements related to the product, design and development of products and processes, purchasing of sources, controlling of production processes up to preservation of the products. The analysis and measurement of product

properties and process characteristics are not included in the clause. Most of the activities described in the clause 7 are included also in ISO 9000/1994 standards.

The activities in clause 7 start with planning of product realization, i.e. planning and development of processes needed for product realization. The organization shall determine:

- quality objectives and requirements for the product,
- the need to establish processes, documents and provide resources,
- required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance,
- records needed to provide evidence concerning realization processes and the results.

Based on the activities of the organization it determines what parts of the clause are applicable for organization and what could be omitted.

Planning of the product realization also includes the validation of products so that they meet the needs and expectations of customers and other interested parties. The validation includes modelling, simulation and trials, as well as reviews. Consequently, organization should define mutually acceptable processes for effective and efficient communication with customers and other interested parties.

From the other processes defined in the clause 7 the part related to design of products and processes is in growing importance. It is recognized by quality managers, that most of the product non-conformities can be solved and eliminated in the design stage. Here the utmost importance is a design review conducted by group of appropriate specialists.

#### **Clause 8: Measurement, analysis and improvement**

The three major effects of the activities in the clause are:

- to demonstrate conformity of the product,
- to ensure conformity of the quality management system,
- to continually improve all processes in the quality management system.

Monitoring and measurement of the processes and measurement and monitoring of materials, semiproducts and products are complex activities described very thoroughly and similarly in both ISO 9000/1994 and ISO 9000/2000 standards, so they are not mentioned in detail in this text. The same can be applied to one of the most important activities: control of nonconforming product.

Measurement and monitoring of the system performance include methods of control related to current state of the quality management system. The well-known methods are:

- surveys of customers and other interested parties satisfaction,

- internal audits,
- financial measurements,
- self - assessment.

Management should establish effective and efficient processes to collect, analyze and use of information from customers. It includes:

- customer complaints,
- direct communication with customers,
- questionnaires and surveys,
- reports from customer organizations,
- reports in various media, etc.

Internal audits are audits in planned intervals, that are focused on all activities of the quality management system in all organization's processes. They are performed by specialized group of organization employees. The results and corrective actions, made on the basis of the results serve to keep the whole system in accredited state.

Financial measures provide comparable measures across the processes. They can help to find weak sides of the quality management system by evaluation of such measures, as:

- prevention and appraisal costs analysis,
- nonconformity costs analysis,
- internal and external failure costs analysis,
- life - cycle cost analysis.

Self - assessment is a method of evaluation of the effectiveness, efficiency and current state of the quality management system. It is based on judgement or opinion of specialists from the organization staff, that can work in multi - discipline teams, on selected issues of the system or on entire system. The self - assessment questions can be applied also on the other parts of the integrated management system or on other functions of the organization. The self - assessment as a powerful tool for recognizing of current state of organization's activities and needs for improvement, is supported and backed by top management. The specialists, conducting self - assessment, are appointed by the top management.

There are many models for the self - assessment methods, most of them use principles of quality award models, both national and international. Example of performance maturity level assessment, used for various activities of the organization, is in Table 1.

Requirements of audits performed by the third side / certification audits, audits by customers, etc/ are stated in EN ISO 19011 standard, they are not included in this paper.

Management of the organization should be aware that unceasing control of all processes and their continual improvement are the substantial steps to quality of the products and satisfaction of the customers. A lot of important information can be gained from the corrective actions, mainly from determination of nonconformities causes.



Table 1. **Assessment of maturity level**  
 Tablica 1. **Ocjena zrelosti razine proizvodnog poslovanja**

Maturity Level	Performance level	Guidance
1	No formal approach	No systematic approach evident, no results, poor results or unpredictable results.
2	Reactive approach	Problem- or corrective-based systematic approach; minimum data on improvement results available.
3	Stable formal system approach	Systematic process-based approach, early stage of systematic improvements; data available on conformance to objectives and existence of improvement trends.
4	Continual improvement emphasized	Improvement process in use; good results and sustained improvement trends.
5	Best-in-class performance	Strongly integrated improvement process; best-in-class benchmarked results demonstrated.

Continual improvement has preventive character. Improvement actions can range from small - step improvements of parts of the processes through organization's level quality improvements to strategic improvement projects. Small - step improvements are performed by workers and line managers directly in the shop, organization's level quality projects by teams of specialists, strategic improvements

by reengineering team. Subject of the continual improvement can be a product, processes, quality managements systems or even structure and character of organization.

## CONCLUSIONS

Starting from December 2003 only ISO standard that can be used for establishing and auditing of quality management system is EN ISO 9000/2000 and EN ISO 19011. The committee that prepared the new version of the standards, accepted many suggestions from organizations that have used or planned to use the ISO 9000 standards. It included into them some new ideas from TQM, quality awards and excellence models. The standards have character that enables them to be used by any kind of organization. This fact will help to spread the quality systems to nearly all-human activities, ultimately finishing in quality of life.

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