THE QUALITY MANAGEMENT PRINCIPLES AND PRODUCT DESIGN REALIZATION REQUIREMENTS

Prof.dr. Nedžad Repčić, dipl.ing.
Mašinski fakultet Sarajevo, Vilsonovo 9, 033/ 65 31 92, e-mail: nrepcic @utic.net.ba

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SUMMARY
To effectively plan the design and development process, the organization must: clearly define the stages involved in the design and development process, quality, identify how the review and verification of the design will take place,describe clear responsibility and authority for the people doing this work, see that design information flows effectively among the various groups having a role in designing, selling, managing, manufacturing, and servicing the products, keep design and development plans up to date. Determine the product requirements, including: what it does and how well it must perform, legal and regulatory requirements, pertinent information from similar designs, other pertinent requirements. The output of design and development must include sufficient information to verify that design output meets design input requirements. In addition, it must: include the information need to purchase component materials, manufacture the product, and service the product,specify how to determine if the product has acceptable performance, highlight safety and usage considerations. Review the design and development work products to:determine if the design meets the design input requirements, identify and problems with the design, propose solutions to identified design problems. Include representatives from each function concerned with the design and development stage being reviewed. Validate the operation of the resulting product under actual operating conditions. If the product has multiple uses, validate operation for each intended use. The methods for validation defined in the design output should be followed. Whenever possible, the validation of a product or service should be performed prior to delivery to the customer.Identify, document, review, and approve all design changes before carrying them out. Evaluate the impact of the changes on the present design of the product and quality.

1. INTRODUCTION

Plan and carry out the inspection, test, measurement, analysis, and improvement activities needed to: assure product meets product requirements, assure the QMS works as planned, improve the operation and results from the QMS. Monitor the end customers' opinion of your product and service. Determine how to gather and use this information.Internal audits are verification activities performed by trained auditors within the organization. Their purpose is to determine how well the plans making up the QMS are being followed. The Standard requires internal audits be carried out regularly in each area covered by the QMS. Audits address conformity with the QMS, the requirements of ISO 9001:2000, and the effectiveness of the implementation.Audit plans address:Audit criteria, and extent, Frequency, and methods used, Responsibility for conducting the audit.
Auditors are trained, objective, and never audit their own work.Identified problems are quickly resolved by the manager responsible for area being audited.Audit results are reported

and recorded, follow up actions are verified.Monitor and measure the performance of the processes that make up the QMS. Compare these actual results to the planned results. Take corrective action to make sure the product or service meets requirements.During the production process, monitor and measure the product to assess if requirements are met. Keep records showing:The product meets acceptance criteria, The name of the person who authorized release of the product, The product has proceeded through all of the planned process steps, including all planned verifications. Nonconforming product is any product or service that does not meet requirements. Have documented procedures to identify nonconforming products and to make sure they are not used by accident. Define who is responsible for deciding what to do with a bad product. One of the following three actions must be taken:fix the product as if the problem never happened, ask the customer to accept it, perhaps on new terms, discard it or clearly mark it as unsuitable for its original use.
Re-inspect any corrected products according to the procedures for new products.Mitigate potential losses, perhaps by recall, from any product that has been found to be defective after its release to the customer.The standard requires the organization to collect information on the functioning of the QMS. This information is then analyzed to evaluate the effectiveness and efficiency of your system and to identify opportunities for continual improvement of the QMS. Information collected and analyzed relates to:customer satisfaction, meeting product requirements,process characteristics and trends, product characteristics and trends, supplier performance. Make use of the quality policy, quality objectives, audit results, data analysis, corrective and preventive actions and management review to improve the QMS.When problems occur, fix the underlying process responsible for the defect.

2. PRODUCT REALIZATION REQUIREMENTS

Product realization is the term used to describe the work that the organization goes through to develop, manufacture, and deliver the finished goods or services. An effective Quality Management System (QMS) includes a comprehensive approach to getting from the product concept to the finished product. This approach, sometimes called a *quality plan*, includes the following:

- product requirements and quality objectives,
- creation of the processes, documents, and resources needed for product realization,
- required verification, monitoring, inspection, and test activities,
- the records to be kept.

The Standard requires the organization to determine product requirements. These requirements can come from the customer, may be mandated by laws or regulations, and include generally accepted standards within your industry or market. Requirements are established by standard contracts or oral agreements that the sales department uses in discussions with customers, and other sources.After gathering preliminary product requirements, these requirements need to be reviewed to be sure that the customer understands them and that the organization is meeting these requirements. This review must ensure:

- The requirements are known and understood,
- Any changes from the original contract or discussions is understood,
- The organization has the ability to meet the requirements,
- Records are kept of this review.

Routine orders for items described in a catalog of products are considered reviewed when the relevant product information is reviewed.
Put in place effective customer communications channels, to allow dialogue regarding:

- product information,

- questions about contracts, order handling, changes, and
- receiving customer feedback, including complaints.

3. DESIGN AND DEVELOPMENT PLANNING

To effectively plan the design and development process, the organization must:
- Clearly define the stages involved in the design and development process,
- Identify how the review and verification of the design will take place,
- Describe clear responsibility and authority for the people doing this work,
- See that design information flows effectively among the various groups having a role in designing, selling, managing, manufacturing, and servicing the products,
- Keep design and development plans up to date.

Determine the product requirements, including:
- what it does and how well it must perform,
- legal and regulatory requirements,
- pertinent information from similar designs,
- other pertinent requirements.

The output of design and development must include sufficient information to verify that design output meets design input requirements. In addition, it must:
- include the information need to purchase component materials, manufacture the product, and service the product,
- specify how to determine if the product has acceptable performance,
- highlight safety and usage considerations.

Review the design and development work products to:
- determine if the design meets the design input requirements,
- identify and problems with the design,
- propose solutions to identified design problems.

Include representatives from each function concerned with the design and development stage being reviewed.Verify, according to your plan, that the design output meets design input requirements. Validate the operation of the resulting product under actual operating conditions. If the product has multiple uses, validate operation for each intended use. The methods for validation defined in the design output should be followed. Whenever possible, the validation of a product or service should be performed prior to delivery to the customer. Identify, document, review, and approve all design changes before carrying them out. Evaluate the impact of the changes on the present design of the product. The organization needs to ensure that purchased products and services meet purchasing requirements. The purchasing group must establish criteria for how they evaluate and choose suppliers. These criteria must be based on the suppliers' ability to provide products and services that meet order specifications, especially product and service quality requirements. The extent of the controls depend on the importance of the purchased goods in the finished product. Finally, records must be kept showing how purchased products and services were evaluated.Clearly describe on purchase orders the product or service being ordered. Consider including the following specifications:how products, procedures, processes, and equipment are approved for purchase, required competencies for contracted personnel, requirements for the supplier's quality management system. Review and approve purchasing requirements before sending them out.Carry out a plan for verifying that purchased services and materials are adequate, i.e. meet purchase specifications.

Plan production, installation, and service processes and provide an environment where work can proceed in an orderly fashion. These controlled conditions may include:
- information regarding product specifications,

- written instructions for carrying out the work,
- suitable equipment,
- adequate tools for monitoring and measuring process and product characteristics,
- activities for monitoring and measuring process and product characteristics,
- criteria for product release,
- delivery and post delivery servicing activities.

Process validation demonstrates that operation of the processes achieves the planned results. When it is not possible to verify the finished good or service through monitoring or measurement the QMS must require validation. Validation is particularly important where deficiencies are not identified until the product is in use, or the service is delivered. When validation is required, the QMS must define the criteria for the following:

- review and approval of the process,
- approval of the equipment used,
- competency of the people who operate the process,
- specific methods and procedures used,
- records to be kept,
- ongoing assessment of the process validation.

Where appropriate, establish procedures to identify a product and determine what specifications pertain to it as it moves through manufacturing, delivery, and installation. Record the inspection and measurement status of the product. Individual products or batches of products must have unique serial identification recorded if assuring product product quality requires this.Special care must be taken when a customer provides their property for use or incorporation into the product. Identify, verify, and protect customer property provided and maintain records of lost, damaged or unsuitable customer property. This may include intellectual property.The standard requires the organization to preserve the product, including identification, handling, storage, packaging, protection, and delivery of parts and products throughout all processes.Any measurement worth taking is worth taking correctly. The standard requires the organization to identify the inspection, test and measurements taken, their required accuracy, and the equipment used to make the measurements. Procedures must describe how measurements are carried out.Measuring equipment must be carefully cared for, including:

- timely calibration to national standards,
- identification with a calibration label,
- preventing adjustments that would invalidate the calibration,
- preserving the equipment accuracy during handling, storage and use.

Measurements taken with equipment later found to be inaccurate must be assessed and corrected.

4. MANAGEMENT RESPONSIBILITY

The Standard recognizes that an effective quality program requires the involvement and commitment of the organization's top management. Therefore, the Standard assigns top management the following responsibilities:

- Overseeing the creation of the Quality Management System (QMS),
- Communicating the importance of meeting requirements, including customer, legal, and regulatory requirements,
- Establishing the quality policy and the quality objectives,
- Communicating with parties responsible for product and service quality,
- Providing adequate resources for the operation of the QMS,
- Reviewing the operation of the QMS.

Top management must ensure that customer requirements are understood and met with the goal of improving customer satisfaction.
The quality policy identifies the main goals of the QMS. The quality policy must be:

- Appropriate to the organization's purpose,
- Include a commitment to meet customer, legal and regulatory requirements,
- Create a background for establishing quality objectives,
- Communicated throughout the organization,
- Reviewed for ongoing suitability to the needs of the organization and its customers.

Establish measurable quality objectives that support the quality policy and communicate them throughout the organization.Plan the QMS so that the quality objectives are met and so the system continues to work as it is changed to incorporate improvements.Effective work depends on a clear understanding of each persons responsibility and authority. Therefore responsibility and authority must be defined and communicated.Top management must appoint a manager to have ongoing operational responsibility for the QMS. This person is referred to as the Management Representative. The duties of the Management Representative include:

- Ensuring that processes needed for the QMS are established, implemented, and maintained,
- Reporting on the performance of the QMS and any improvements needed,
- Promoting awareness of customer requirements throughout the organization.

Top management needs to set up an effective system of communication to ensure effective operation of the QMS.Top management is required to regularly review certain aspects of the QMS to make sure that the goals are being achieved and to look for ways to improve the QMS. The review must cover suitability, adequacy, and effectiveness of the QMS. The review also includes assessing opportunities for improvement and needed changes to the QMS, quality policy, and quality objectives.These meetings must address the following areas:

- Internal audit results,
- Customer feedback,
- How well processes have been working,
- How well products have been meeting requirements,
- Status of previously identified problems,
- Items identified for follow-up in previous management reviews,
- Planned process or product changes that could affect quality,
- Recommendations for improvement generated through the operation of the QMS.

These reviews result in decisions and actions related to:

- improving the QMS,
- improving the product,
- the need for additional resources, including human resources.

Provide the people, equipment, tools, and materials need to:

- build and maintain the QMS,
- continually improve the effectiveness of the QMS, and to
- meet customer requirements.

People performing work affecting product and service quality must be competent to carry out that work. This competency is attained through a combination of education, training, skills, and experience.The organization must:

- Identify the talents, skills, knowledge, and capabilities each person needs to carry out their assigned responsibilities,
- train or otherwise assist people to meet these identified competencies,
- assess the competency of each person to carry out their responsibilities,

- make sure each person understand how their work contributes to the quality of products and services and to meeting quality objectives,
- keep records of each person's education, training, skills, and experience.

The infrastructure for a QMS includes the building, workspace, equipment, and the supporting services involved in creating the organization's products or services. The organization will needs to determine, provide and maintain the infrastructure needed to achieve the planned results.The work environment of the organization must not interfere with the ability of employees to perform effectively in order to meet quality requirements.

5. QUALITY MANAGEMENT SYSTEM

The Quality Management System (QMS) is the collection of processes, documents, resources, and monitoring systems that direct the work of an organization regarding product and service quality. The organization needs to establish, document, carry out, and maintain this system to meet the requirements of ISO 9001:2000.The organization needs to document – either electronically or on paper – the quality policy, quality objectives, and quality manual. Written procedure, plans, and operations need to describe how product and service quality is attained. Certain records, providing evidence of activities that were carried out (i.e. purchase orders, sales contracts, inspection records, design review notes, etc.), have to be retained.The quantity, detail, and form of the documentation can differ from one organization to another depending on size, type of activities, or complexity of processes.The quality manual describes the extent of the QMS and may exclude certain sections of the Standard that don't pertain to the organization. All of the quality procedures are either included in the quality manual or are referenced by it. The interaction between processes making up the QMS is also described. All of the documents in your QMS must be legible, identified, reviewed, authorized, up-to-date, issued, distributed, and periodically updated. Obsolete documents have to be identified and protected from unintended use. Documents that come from outside the organization also have to be identified and controlled.Certain records need to be kept to demonstrate how the QMS is operating. These records must be legible, and easy to identify and retrieve. A written procedure must describe how they are identified, stored, protected, retrievable, and define their retention and disposal times.Auditors, whether external or internal, need to demonstrate their competence not only on the structure, content and terminology of the revised standards, but also on the underlying quality management principles. The revised standards require that auditors be able to understand the organization's activities and processes and appropriately audit against the requirements of the standard in relation to the organization's objectives. According to the IAF/ISO-CASCO/ISO TC 176 Transition Policy, auditors must demonstrate competency in:

- The requirements of ISO 9001:2000,
- The concepts and terminology of ISO 9000:2000,
- The eight Quality Management Principles,
- A general understanding of the performance improvement guidelines of ISO 9004:2000,
- Familiarity with the latest draft of the auditing guidance standard (ISO 19011).

"Customer satisfaction" is recognized as one of the driving criteria for any organization. In order to evaluate if the product meets customer needs and expectations, it is necessary to monitor the extent of customer satisfaction. Improvements can be made by taking action to address any identified issues and concerns.

The quality management system described in the revised standard is based on quality management principles that include the process approach and customer focus.

The adoption of these principles should provide customers with a higher level of confidence that the product meets their needs and increases their satisfaction.Any activity or operation,

which receives inputs and converts them to outputs, can be considered as a process. Almost all activities and operations involved in making a product or providing a service are processes.For organizations to function, they have to define and manage numerous inter-linked processes. Often the output from one process will directly form the input into the next process. The systematic identification and management of the various processes employed within an organization, and particularly the interactions between such processes, may be referred to as the 'process approach' to management.

The revised quality management system standards are based on just such a process approach, in line with the guiding quality management principles.Continual improvement is the process focused on continually increasing the effectiveness and/or efficiency of the organization to fulfill its policies and objectives. Continual improvement (where "continual" highlights that an improvement process requires progressive consolidation steps) responds to the growing needs and expectations of the customers and ensures a dynamic evolution of the quality management system. ISO 9001:2000 aims at guaranteeing the effectiveness (but not necessarily the efficiency) of the organization. For improved organizational efficiency, however, the best results can be obtained by using the new ISO 9004:2000 in addition to ISO 9001:2000. The guiding quality management principles are intended to assist an organization in continual improvement, which should lead to efficiencies throughout the organization.

Existing ISO 9001, ISO 9002, and ISO 9003 standards will be replaced by the revised ISO 9001 standard. The scope of registration needs to reflect clearly the activities covered by the organization's Quality Management System, and any exclusions to non-applicable requirements of the standard (through clause 1.2 "Application") documented and justified in the quality manual.By demonstrating to organizations that the process of certification based on the new ISO 9000 standards adds value to their own business goals, a market-wide improvement in the perception of ISO 9001 certification should be developed. The rationale behind the revision process places great emphasis on making quality management systems closer to the processes of the organization and on continual improvement. As a result, the revised standards (ISO 9001:2000 and ISO 9004:2000) are directed to the achievement of business results, including satisfaction of customers and others.

There is confidence that management of the organization will be able to adopt the quality management system standards not only for certification purposes, but also as a profitable investment.The organization is not obliged to include within the scope of its certification all the products that it provides. (Note that the ISO 9000:2000 definition of "Product" includes services!). HOWEVER, for those products that ARE included in the certification scope, all applicable requirements of ISO 9001:2000 will need to be addressed. The standard allows for the exclusion of some requirements (via clause 1.2 "Application"), but only if it can be shown that these requirements are not applicable to the organization.

Exclusions are limited to Section 7 ("Product Realization"), and requirements may only be excluded if it can be shown that they do not affect the organization's ability to provide product which meets customer and applicable statutory/regulatory requirements. If design activities are required to demonstrate your organization's capability to meet customer or statutory/regulatory requirements for products covered by the quality management system certification, then these design activities must be included in the scope of your registration/certification to the ISO 9001:2000 standard.

If design activities are not required to demonstrate your organization's capability to meet customer and applicable statutory/regulatory requirements, or if your product is provided on the basis of established design, you will still be registered to ISO 9001:2000. In this case, you will need to justify the exclusion of the design and development requirements in your quality manual.Although organizations are encouraged to make the transition to ISO 9001:2000 certification as soon as possible, according to the IAF/ISO-CASCO/ISO-TC 176

Communiqué on transition policy, organizations may choose to continue or even seek new certification/registration to the 1994 versions of ISO 9001, ISO 9002, and ISO 9003. Any certificates issued or renewed will, however, only remain valid for a maximum of three years from the publication of ISO 9001:2000.

6. CONCLUSION

Now that ISO 9001:2000 is published, ISO 9002 and ISO 9003 have become obsolete. You need to evaluate which specific requirements of ISO 9001:2000 are applicable to the nature of your business and the extent to which your present QMS meets those requirements. Provisions have been made to exclude non-applicable requirements within Section 7 of the standard through clause 1.2 "Application".If, for example, the nature of your products does not require you to perform design activities or if your product is provided on the basis of established design, you will need to discuss and justify the exclusion of these requirements with your certification/registration body.
Since ISO 9004:2000 is a guidance document, it is not intended to be used for third party certification purposes. A key element in the new ISO 9004 is the ability to perform self-evaluation, but third party QMS certifications/registrations are to ISO 9001:2000, which consolidate the old ISO 9001, 9002, and 9003 standards.It has always been necessary to define clearly the scope of registration/certification. The merging of ISO 9001, 9002, and 9003 into a single requirements standard (ISO 9001:2000) requires more emphasis for the scope to define the products, services and processes covered by registration. The idea of a "consistent pair" of standards is the very core of the revised standards. The aligned structure of ISO 9001:2000 and ISO 9004:2000 encourages organizations not only to look at their activities from a process standpoint, but also to look beyond certification to a system which is truly beneficial in improving operational performance.The revised ISO 9001 was developed to have enhanced compatibility with ISO 14001, particularly with regard to terminology and content.
There is close collaboration between the technical experts of ISO/TC 176 and ISO/TC 207 (the Technical Committee responsible for the ISO 14000 series of standards).ISO 14001 and ISO 14004 are currently being revised by ISO/TC 207/SC 1. This will provide the opportunity for further enhancement of the compatibility between the ISO 9000 and ISO 14000 standards. The requirements of the revised ISO 9001 are applicable to small, medium, and large organizations alike. Provisions have been made to exclude non-applicable requirements through clause 1.2 "Application". It is, however, up to the individual organization to determine the complexity of the system needed to demonstrate its capability to meet customer and applicable statutory/regulatory requirements for its products.

7. LITERATURE

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