

KING FAHD UNIVERSITY OF PETROLEUM AND MINERALS
COLLEGE OF ENVIRONMENTAL DESIGN
CONSTRUCTION ENGINEERING AND MANAGEMENT

ISO 9001

FROM A QUALITY MANAGEMENT SYSTEM TO A
BUSINESS MODEL

DONE BY:

ABDULRAHMAN A. AL-HUSSAIN

DONE FOR:

PROF. ABDULAZIZ BUBSHAIT

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What is ISO 9001?

ISO 9001 is an international standard related to quality management, applicable to any organization from all types of business sectors and activities. It is based on eight quality management principles (all fundamental to good business practices): ¹

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Fact based decision-making
8. Mutually beneficial supplier relationships

What are the key benefits? ¹

- I. Proves your commitment to quality and customer satisfaction.
- II. Ensures your products and services effectively meet customer and applicable statutory and regulatory requirements.
- III. Allows you to measure your progress towards continual improvement of business performance creating a benchmark.
- IV. Helps improve your organizational performance.

What is the different between ISO 9001:1994, 2000 and 2008? ²

Under this paragraph I will discuss the major differences between the three ISO's (namely ISO 9001:1994, ISO 9001:2000 and ISO 9001:2008). We will start with the major differences between the oldest two ISO's, ISO 9001:1994 and ISO 9001:2000.

I. ISO 9001:1994 and ISO 9001:2000

In the past, ISO had three standards: ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. Now there's only one standard: ISO 9001:2000. ISO 9002 and ISO 9003 have been dropped. So, if any company is still ISO 9002:1994 or ISO 9003:1994 certified, they will now need to become

ISO 9001:2000 certified. And if they are now ISO 9001 certified, they have to update their quality system in order to meet the new ISO 9001:2000 requirements.

In comparing ISO 9001:1994 and ISO 9001:2000 it will be noticed that ISO has abandoned the 20-clause structure of the old standard. Instead of 20 sections, the new standard now has 5 sections. ISO reorganized the ISO 9001 standard in order to create a more logical structure, and in order to make it more compatible with the ISO 14001 environmental management standard.

In general, the new standard (ISO 9001:200) is more customer-oriented than the old standard. While the old standard was also oriented towards meeting customer requirements and achieving customer satisfaction, the new standard addresses this in much greater detail. In addition, it expects the user to communicate with customers and to measure and monitor customer satisfaction.

Other differences between the two ISO's listed below:

A. New Emphasis

The new standard also emphasizes the need to make improvements. While the old standard did implicitly expect organizations to make improvements, the new standard makes this explicit. Specifically, ISO 9001 now wants you to evaluate the effectiveness and suitability of your quality management system, and to identify and implement systemic improvements.

B. New Definition

In the past, organizations that wished to be certified were referred to as suppliers because they supplied products and services to customers. Since many people were confused by this usage, ISO has decided to use the word organization instead. Now the ISO standards focus on the organization, not the supplier. The term supplier now refers to the organization's supplier. The new redefined term supplier replaces the old term subcontractor (which has now been dropped). While this may sound a bit confusing, this new usage simply reflects the way these words are normally used. While you're probably familiar with the previous concepts, you may not have heard of the next one. ISO now uses the phrase product realization. While this is a rather

abstract concept, it is now central to ISO's approach. In fact, ISO devotes an entire section to this new concept (Section 7). So what does it mean (i.e. product realization)?

In order to grasp what product realization means, you need to recognize that a product starts out as an idea. The idea is realized or actualized by following a set of product realization processes. Product realization refers to the interconnected processes that are used to bring products into being. In brief, when you start out with an idea and end up with a product, you've gone through the process of product realization.

C. New Requirements

The new ISO 9001:2000 standard introduces some new requirements and modifies some old ones. These requirements are summarized below. For more detail, please see the associated ISO 9001:2000 clauses (in brackets).

- Communicate with customers (7.2.3).
- Identify customer requirements (5.2, 7.2.1).
- Meet customer requirements (5.2).
- Monitor and measure customer satisfaction (8.2.1).
- Meet regulatory requirements (5.1).
- Meet statutory requirements (5.1).
- Support internal communication (5.5.3).
- Provide quality infrastructure (6.3).
- Provide a quality work environment (6.4).
- Evaluate the effectiveness of training (6.2.2).
- Monitor and measure processes (8.2.3).
- Evaluate the suitability of quality management system (8.4).
- Evaluate the effectiveness of quality management system (8.4).
- Identify quality management system improvements (5.1, 8.4).
- Improve quality management system (5.1, 8.5).

II. ISO 9001:1994 and ISO 9001:2000 ²

ISO 9001 2008 and ISO 9001 2000 use the same numbering system to organize the standard. As a result, the new standard looks much like the old standard. However, some important clarifications and modifications were made. These changes are summarized below as follow:

A. Outsourced Processes

The process approach continues to be of central importance to ISO 9001. And since outsourcing has become increasingly common during the last few years, the new ISO 9001 standard has expanded its discussion of outsourced processes (see ISO 9001 Part 4.1). The new standard makes it clear that an outsourced process is still part of the QMS even though it is performed by a party that is external to the organization. The new standard emphasizes the need to ensure that outsourced processes comply with all customer and legal requirements. While the responsibility for a process may have been outsourced, your organization is, nevertheless, still responsible for ensuring that it meets all customer, regulatory, and statutory requirements. While the old standard said that outsourced processes must be controlled, the new standard goes further by expecting you also to specify the type, nature, and extent of control. ISO 9001 2008 also wants you to think carefully about how you're going to control outsourced processes. How a company chooses to control an outsourced process should be influenced by potential impact it could have on its products, whether or not process control will be shared with the process supplier, and whether or not adequate controls can be contractually established using the company's purchasing process.

B. Documentation

ISO 9001 2008, Part 4.2.1, makes it clear that QMS documentation includes not only the records required by the standard but also the records that your organization needs to have in order to be able to plan, operate, and control its QMS processes. So the new standard has expanded the definition of documentation to include all QMS process records.

Part 4.2.1 makes it clear that a single document may contain several procedures or several documents may be used to describe a single procedure. While this has always been an option, the new standard makes this possibility explicit.

ISO 9001 2000 Part 4.2.3 gave the impression that all external documents needed to be identified and controlled. This has now been clarified. The new standard says that you need to identify and control the distribution of only those external documents that you

need in order to be able to plan and operate your QMS. In other words, only relevant external QMS documents need to be controlled, not all of them

C. Management Representative

ISO 9001:2000, Part 5.5.2, allowed you to appoint any member of management to oversee the organization's QMS. Since the old standard did not explicitly say that the management representative must be a member of the organization's own management, outsiders were sometimes appointed, instead. This loophole has now been closed.

ISO 9001:2008 now makes it clear that the management representative must be a member of the organization's own management. Outsiders may no longer perform this important function.

D. Competence

While both old and new standards stress the importance of competence, the old standard wasn't very clear about who they were talking about. Now it's pretty clear that all QMS personnel must be competent. ISO 9001 2008, Part 6.2.1, makes it clear that any task within the QMS may directly or indirectly affect the organization's ability or willingness to meet product requirements. Since any QMS task could directly or indirectly influence product quality, the competence of anyone and everyone who carries out any QMS task must be assured.

E. Infrastructure

For ISO 9001 2000 (Part 6.3) the term infrastructure includes buildings, workspaces, equipment, software, utilities, and support services like transportation and communications. ISO 9001 2008 has now added information systems to the previous list of support services. Both old and new standards expect you to provide the infrastructure (including information systems) that your organization needs in order to ensure that product requirements are being met.

F. Work Environment

According to ISO 9001 2000, Part 6.4, you are expected to manage the work environment that your organization needs in order to be able to ensure that all product requirements are being met. However, it failed to indicate exactly what they were talking about. This problem has now been solved. ISO 9001 2008 says that the term work environment refers to working conditions. These working conditions include physical and environmental conditions, as well as things like noise, temperature, humidity, lighting, and weather. According to the new standard, all of these conditions need to be managed in order to help ensure that product requirements are being met.

G. Customer Requirements

According to ISO 9001 2000, Part 7.2.1, you are expected to identify your customers' specific delivery and post delivery requirements. Since some people weren't sure about what post delivery meant, the new standard has tried to clarify this.

According to ISO 9001 2008, post delivery requirements include things like warranty provisions, contractual obligations (such as maintenance), and supplementary services (such as recycling and final disposal).

H. Customer Satisfaction

Both old and new standards want you to monitor and measure customer satisfaction (perceptions). A new note to ISO 9001 2008, Part 8.2.1, explains that there are many ways to monitor and measure customer satisfaction. You could use customer satisfaction and opinion surveys. And you could collect product quality data (post delivery), track warranty claims, examine dealer reports, study customer compliments and criticisms, and analyze lost business opportunities.

I. Internal Audit Records

Both old and new standards refer to the need to establish a procedure to define how internal audits should be planned, performed, reported, and recorded (Part 8.2.2). However, the old standard did not explicitly state that audit records must actually be

maintained. This oversight has now been corrected. ISO 9001 2008 now explicitly says that you must maintain a record of your internal audit activities and results.

J. Process Monitoring and Measurement

Both old and new standards expect you to monitor and measure your QMS processes. A new note to ISO 9001 2008, Part 8.2.3, wants you to consider the impact each process has on the overall effectiveness of your QMS and the impact it has on your ability to meet product requirements (when you're making decisions about what kinds of process monitoring and measurement methods should be used).

Transitioning from ISO 9001:2000 to ISO 9001:2008 ³

The newest version of the ISO 9001 standard was released in November, 2008. As was the case the last time the standard was revised (2000), all currently certified companies must upgrade their quality management systems to meet the new requirements. The deadline for transitioning your certification to the ISO 9001:2008 is 24 months following the release of the new standard.

Those who went through the previous transition from the 1994 version to ISO 9001:2000 know first-hand the disruption that was caused by the significant changes introduced by the last revision. It was very costly for all certified companies to change over to the new version.

The good news is that the 2008 release does not have the same impact. In fact, the ISO technical committee (TC176) who develops the ISO 9000 series of standards purposely planned the new release as an amendment rather than a formal revision. The difference is that an "amendment" is focused on making changes for clarification purposes only and for better alignment with ISO 14001, the standard for environmental management. With the 2008 release, the ISO committee purposely intended not to introduce substantive changes that will affect the QMS processes and documentation of currently certified organizations. Thus, the new ISO 9001:2008 standard has less impact on companies already certified.

What types of changes were made? ³

Many of the edits to the new standard were to improve the clarity and consistency of the requirements but have no impact on the meaning of the text. There are, however, a few modifications that may require changes to the comp[any's quality management system. Here is a list of some of the more substantive changes in the ISO 9001:2008 standard:

Clause No.	Title	Description/Change
4.1	General Requirements	Ensure that the type and extent of control of your outsourced processes are clearly defined.
4.2.4	Control of Documents	Review the external documents you currently control to include those that pertain directly to the quality management system.
5.5.2	Management Representative	Confirm that your management representative is a member of your company's management, rather than someone who does not have management level responsibility or is not employed by your company.
6.2.1	Human Resources	Include in your training process all employees whose work directly or indirectly impacts conformity to product requirements or has responsibility for tasks within the quality management system.
6.2.2	Training	Confirm the necessary employee competence has been achieved following training.
6.3	Infrastructure	Include information systems in your infrastructure requirements.
6.4	Work Environment	Ensure that all applicable conditions listed in the new standard are being managed effectively.

7.2.1	Customer-related Processes	Include all applicable post-delivery activities described in the new standard in your planning processes.
7.3.3	Design and Development	Consider preservation of product (e.g. packaging/labeling requirements) during the design process.
7.5.5	Preservation of Product	Review controls in place to address applicable product preservation requirements as shown in the new standard.
7.6	Control of Monitoring and Measuring Equipment	Note the change from control of "devices" to "equipment"; also confirm computer software used for monitoring and measuring is verified and maintained rather than "calibrated."
8.2.1	Customer Satisfaction	Consider expanding your customer satisfaction to include more than a traditional customer survey.
8.2.2	Internal Audit	Distinguish between "corrections" and "corrective actions" in your audit process and records.
8.2.3	Monitoring and Measurement of Processes	Expand your use of correction and corrective action beyond problems affecting conformity of the product to include any process results that do not meet requirements.
8.2.4	Monitoring and Measurement of Product	Ensure that final authorization records include release of your product for delivery to the customer, not just internal release.

Is ISO 9001 Really a Documentation Nightmare? ⁴

There is a real misconception about ISO 9001; the documentation requirements. The common belief seems to be that implementing ISO 9001 can create a bureaucratic documentation nightmare with volumes of complicated procedures that require heavy oversight and manpower

to create and maintain. That is not really the case. In fact, implementing ISO 9001 can actually streamline and simplify your documentation/record creation and management.

ISO 9001 can help you simplify and improve your documentation and records. First; the ISO 9001 does not have complex or complicated documentation requirements. In fact, they are quite simple; there are only six required procedures for the ISO 9001 QMS. They are:

1. Document Control (*per ISO 9001 clause 4.2.3*)
2. Record Control (*per ISO 9001 clause 4.2.4*)
3. Internal Audit (*per ISO 9001 clause 8.2.2*)
4. Control of Non-Conformities (*per ISO 9001 clause 8.3*)
5. Corrective Action (*per ISO 9001 clause 8.5.2*)
6. Preventive Action (*per ISO 9001 clause 8.5.3*)

An important concept to understand is that procedures are only one way to document processes, and the ISO standard recognizes that. Processes can be documented by Work Instructions, Visuals Aids, or training materials. The real requirement by ISO is that key processes are understood and consistently carried out. ³

The Importance of Records

What receives more attention in the ISO 9001 standard are records. While there are only six required procedures, there are 21 required records. It is very likely that most organization is already keeping many of these records; but what should be done with them? The ultimate goal of ISO 9001 is improvement, and one key to improvement is record keeping that captures important data related to performance metrics.

Frequently, whether it relates to the production floor or finance operations, the key factor for auditors and regulators are concerns with process control or internal controls. Does the existence of procedures really prove control? Control is truly demonstrated by defined goals and objectives along with clear and complete records that demonstrate how well processes are meeting these objectives. Records should also demonstrate what analysis and actions are taken to improve the process when objectives are not being reached.

Using the ISO 9001 Standard can help organizations gain some perspective and reflection on how records are used, how they are controlled, and their role in gaining insight to your organization. In the proper perspective, ISO 9001 can help gain control of and assist with properly utilizing documents and records - not add additional record bureaucracy.²

Benefits of ISO 9000

Organizations that implement an ISO 9000 compliant QMS usually realize important benefits, including a more organized operating environment, a greater number of customers and a higher level of satisfaction among those customers. Whether you are planning a QMS in response to direct market requirements or want to increase the productivity of your organization, you will experience the following benefits:

1. Process Improvements

As you implement your QMS, you have the opportunity to improve your processes. You will outline the current process, add the requirements of the standard and then optimize the process with input from the process users. After achieving certification, you will likely see continual process improvements. A recent survey of 100 registered firms reported the average improvement in operating margin at 5% of sales. These firms also reported faster turnaround times, and a reduction in scrap and overtime.

2. Increased Quality Awareness

During implementation, quality awareness will increase, since all staff must be trained on ISO 9000. Staff will be required to take "ownership" of processes that they are involved in developing and improving. The QMS will also have built-in systems to report on key quality indicators, which will significantly reduce the reoccurrence of problems. This helps develop a strong quality culture, where the staff recognizes problems such as systems or process issues and works on fixing them, rather than placing blame with an individual. The result is increased confidence in workmanship and a more confident staff.

3. Consistency in Operations

With ISO 9000 certification, your operation will run more smoothly, as the QMS promotes consistency in how work is performed and recorded. This helps new employees learn processes more quickly and reduces misunderstandings with customers. If a problem does occur, it is traced to its root cause and fixed, saving the organization from "re-correcting" it every time it happens.

4. Market Advantages

ISO 9000 certification is becoming a requirement to do business in many markets. A recent survey of ISO 9000 certified companies shows that 41% were asked to achieve certification by a client. Considering that it can take 6 months or longer for some organizations to achieve certification, already having a compliant QMS in place can be a distinct advantage.

Implementation of the ISO 9001

The statement that ISO quality standards are an adequate system for quality assurance can be confirmed by the fact that only 0.8 percent of companies in the world have stopped maintaining the quality standard. The success of the ISO 9000 family of standards is still growing, and the number of countries where ISO 9000 is being implemented has increased 5. Up to the end of December 2003, at least 500.125 certificates to the ISO 9001:2000 quality management system standard had been issued in 149 countries and economies. The 2003 total represents an increase of 332.915 (200 percent) over 2002, when the total was 167.210 in 134 countries and economies. The 2003 total represents an increase of 455.737 (more than ten times higher) over 2001, the first year for which the survey recorded ISO 9001:2000 certifications, when the total was 44.388 in 98 countries and economies (www.ISO.org). The reasons that push companies to acquire the ISO 9000 certificate may be divided into two categories: external or market related, and internal. Within the first group, reasons such as customer pressures, better reputation or the possibility to access specific markets may be included. However, the real market benefit stemming from the introduction of the standard depends on each individual organization. The external reason for the acquisition of the standard must be supported by top management and consequently by all employees. Once the system is established, a company must inform its customers (e.g. through letters, newspapers, e-mails, television ...etc), and clearly indicate all the benefits for customers. On the other hand, motives such as the necessity to simplify and standardize a set of processes, the rationalization of company growth or profits improvement, productivity improvement, are related to internal aspects. Organizations expect to be rewarded

by their customer as a consequence of the certification 6. The globalization of markets and the elimination of trade barriers and borders between countries have both played a role in this process.

ISO 9000 implementation requires an important effort on planning this process (development of strategic analysis activities, prior to ISO 9000 implementation, has an impact on the resulting quality approach), and also the investment of considerable material and human resources. Owing to the potential benefits, the required effort and the heterogeneity of obtained results, quality management specialized literature has analyzed the process of implementation and certification of ISO 9000-based quality systems, key success factors, obstacles to overcome (organizational barriers such as a lack of implication of management team, the company culture, difficulties of communication among organizational units and groups), and expected and really achieved results. ⁷

Common way of examining the results is by conducting surveys ⁷. Prabhu et al. (2000) researched the influence of ISO 9000 standard and total quality management (TQM) on the competitive capacity of British undertakings. About 294 British companies from both manufacturing and services participated in the research. The study of individual elements (components) of ISO 9000 standard and TQM on the competitiveness of enterprises showed that there are significant correlations between the elements of TQM and the improvement in competitiveness in 74 percent of companies, as well as in 28 percent of companies that were ISO 9001 certified. The research also confirmed significantly higher values for indicators of competitive capacity in companies that initiated the implementation of the ISO 9001 quality standard and upgraded it into TQM and which used it as a managerial tool in companies. Conti (1999b) also researched quality systems as management tools in companies. They derive from TQM and are named organizational models for improvement. ⁷

Research on the effects of the ISO 9001 quality standard implementation, which included 288 Spanish companies showed that in 65 percent of companies positive internal and external effects of the ISO 9001 standard implementation were recorded. Among the internal effects the following were mentioned: increased order and transparency of processes and clearer competences and responsibilities. Among the external effects the following should be mentioned: improved responsiveness to customer demands, increased satisfaction and access to new markets. In the next research (Corbett et al., 2002) the effects of ISO 9000 certification on public traded manufacturing firms in the USA were examined. It was found that certification

does appear to lead to improved financial performance, measured by return on assets (ROA). More precisely, they found that firms that failed to seek certification experienced substantial deteriorations in ROA, productivity, and sales, while firms that did seek certification generally managed to avoid such declines. In other words, firms that received certification did not, on average, see their absolute performance improve, but they did see their relative performance improve substantially.

Research on the effect of the ISO 9000 on quality management practices in Thai industry showed that the requirements of the ISO 9000 standardization made a particular impact on five of the quality management practices:

1. Management responsibility affects leadership.
 2. Document and data control impinge on information and analysis;
 3. Quality goals and quality plans influence strategic quality planning;
 4. Human resource development is affected by the identification of training needs and the provision of training for all personnel who perform activities that affect quality; and
 5. New product design review, specification and process control, preventive maintenance, and quality control have an effect on quality assurance.
- The research (Heras et al., 2002) analyzed the comparative financial performance of ISO 9000 certified firms compared to those without certification. The research was undertaken in the Basque Autonomous Community; in Spain. Results showed significant differences in the profitability of the ISO 9000 certified companies and the non-certified companies. They stated that the implementation of any type of tool, system or program related to quality trends pay off in the long, rather than the short time. Tan et al. (2003) in their paper stated that under quality information system, organizations will be better able to manage their quality related knowledge.

Furthermore, ISO 9000 encourages information sharing as a key to internal auditing, overcomes the communication barriers existing in organizations (Ruiz et al., 2005).

Magd et al. (2003) studied the costs, benefits and the satisfaction level with ISO 9000 implementation in Saudi Arabian firms. A survey of 140 ISO 9000 certified manufacturing companies was carried out. The results suggest that manufacturing companies were satisfied with ISO 9000 as far as the benefits gained from certification and its costs were concerned. They considered the benefits of ISO 9000 certification to exceed the costs of attaining the standards, and believed that ISO 9000 contributed to organizational survival and success.

Reports on the results of an ISO 9000 mail survey, administered in four far eastern countries including Japan, South Korea, Hong Kong and Taiwan showed following benefits of ISO 9000

certification: improved corporate image, quality improvement, increased customer satisfaction, and improved internal procedures (Pan, 2003).

The research made by Prybutok and Cutshall (2004) proved a correlation between executive leadership and the Malcolm Baldrige National Quality Award factors. ⁸

Raisinghani et al. (2005) advice the introduction of Six Sigma tools for assessment and ensuring the quality of company's business activities. Leonard and McAdam (2002), Ho et al. (2005), Marti'nez-Lorente and Marti'nez-Costa (2004) and Carpinetti et al. (2003) researched the same area and equally confirmed positive effects of quality systems on company's business activities.

Juran (1989, 1991) wrote that in order to attain quality improvement of a certain product or service a quality leap is needed in order to decrease weaknesses and reach a new level of quality control. Unfortunately, the management does not always feel responsible for improvements. If the management does its job well (long-term company policy, education, interdepartmental communication and cooperation, etc.), the system is likely to improve, people are willing to cooperate and exploit their abilities, knowledge and creativity.

Owing to many external and internal positive effects of the quality system on the organization and company's business activities, which have been confirmed in the researches made all over the world, companies could use the quality system as a business model under the following conditions: the quality system must be implemented in all parts of a company and so-called TQM must be established.

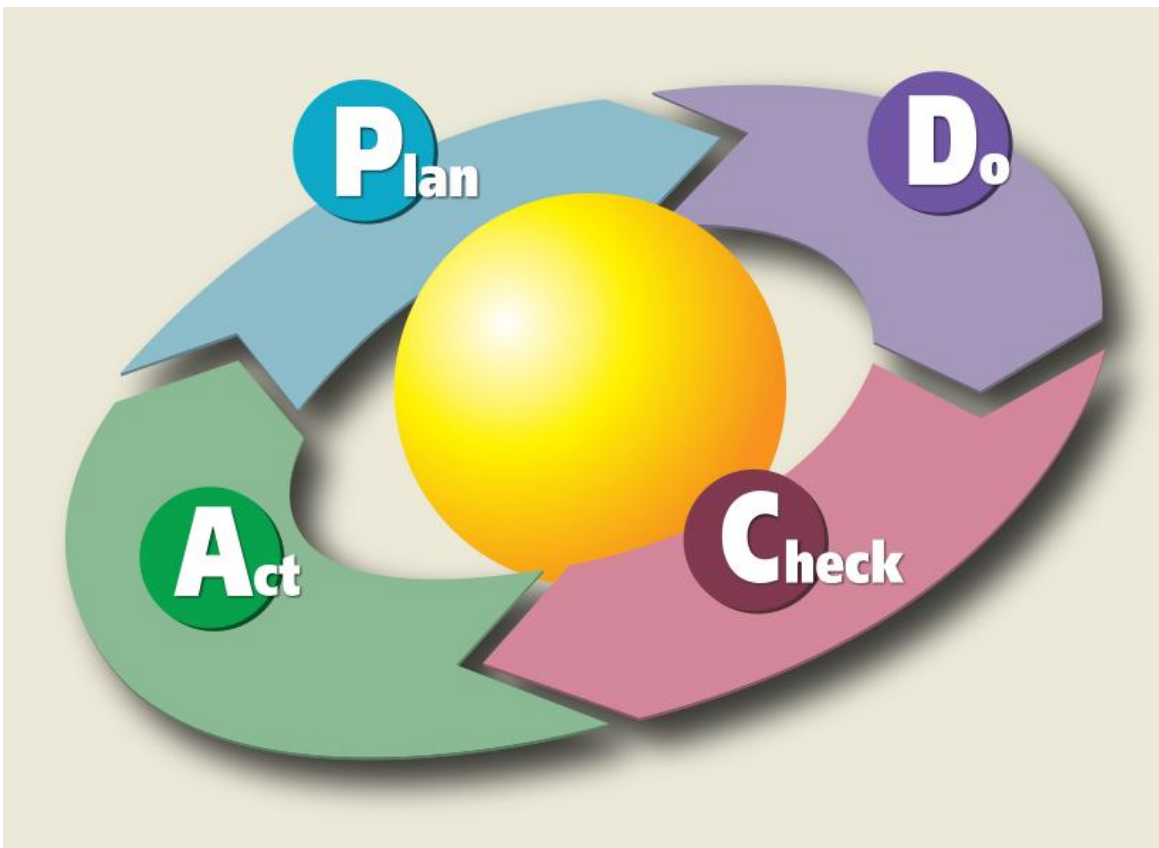
That means that all business decisions regarding vision, values, mission, company strategy, investments, business indicators, derive from the quality system and must be supported by data and their analysis (using four phases of the PDCA circle). This is the process of learning in which evaluations and knowledge gained are included in the new

Deming circle (Logothetis, 1992). It is also the basic philosophy of ISO 9001 standard and is thus also connected with continuous improvement of the quality system or processes within the company.

However, there are no empirical analyses to prove to what extent ISO quality standards can contribute to business success.

Conclusion

The results of research indicate a positive attitude towards the standard and to wide application of the standard as a management tool in companies. In addition to certain financial indicators, the standard promotes indicators which measure effectiveness and efficiency of business processes. It has been proved that the standard affects business decisions of top managers regarding continuous improvements, mostly improvements in processes (more than one fourth of companies), improvements achieved by the Deming circle (P-D-C-A) and internal audits. Their main non-financial goals will be directed towards employees (improving competences, encouraging working environment) and towards the development of information capabilities. They are also planning improvements in business processes (improvements in quality of business operations, company reputation in the eyes of customers, development of solutions with added value, e.g. finding new markets, new customers, etc.). These activities are consecutively connected with the Deming circle (P-D-C-A), which represents the basis for the implementation of continuous improvements. It can be concluded from the above that ISO 9001 standard is used, to some extent, in Slovenian companies as well as in some other countries as a managerial model.



But to achieve that the quality system becomes a business model, managers must consider certain strategical guidelines for the introduction, maintenance and improvement of the quality system. The success of the introduction of the quality system and further activities in this area depend on the initial phase of the project. It is important that the manager analyses the existing situation in the company, finds out what to expect from the standard, and when the standard must be acquired. As many employees as possible should be included from the very beginning. Their activities must be planned also for the period after the introduction of the standard because only this ensures the added value of the standard.

The standard should be introduced in the entire company and not only in one part of the company. An external consulting company with the references for their kind of activity should participate in the introduction of the standard.

Managers must reward employees who make considerable efforts to achieve better quality, and managers at all company levels must initiate the introduction of the standard. They have to participate actively in the beginning of the project, during the project, and when the upgrading of the quality system comes into question. Both practice and research results showed this is not always the case, so managers must seriously consider this factor. At the beginning, the organization must clearly define areas where the standard requirements allow freedom (continuous improvements) and where activities must be carried out in a certain sequence. This ensures the control over the situation and provides information for all employees. Management review must be carried out together with the annual report and plan, and not separately. The best solution is that it is all kept in one document. Also business decisions must be supported by data analysis deriving from, e.g. control points, performance indicators, effectiveness indicators. Both, external and internal customers must be continuously informed about the changes in standard ISO 9001:2000; internal and external marketing must be used in order to provide information about standard ISO 9001.

Last but not least, managers must serve as role models, because only in this case employees will follow and trust them. However, we must be aware of the fact that the guidelines stated above will not be entirely – according to their content and scope – followed in each and every organization. We can say that there is no “best model” fit for each and every organization, but the model should be adapted to the specific organization, its culture, its market, its technology (a concept that goes in the opposite direction with respect to standardization).

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