



THE VISION OF NEW ISO 9000:2015 STANDARDS

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Abstract

Quality management represent a set of activities aimed at achieving objectives through optimal use of resources, set that includes activities of planning, organizing, coordinating, leading, controlling the organization in the field of quality and another specific functions such as quality assurance and continuous quality improvement. International Organization for Standardization (ISO) has developed standards for organizations that want to implement a quality management system since 1987, as the series of standards ISO 9000, series which over time has modified by five time, if we consider even the 2015 edition. At this time, the current ISO 9001 standard has the largest worldwide applicability, with over 1.1 million organizations certified by this reference. ISO 9001 standard has a great impact on the organization's competitiveness being used identically in more than 100 countries. The new series of standards ISO 9000: 2015 brings major changes compared to the 2008 edition, in an attempt to achieve a better understanding of the quality philosophy and also for a better adaptation of economic activities to the continuous changes from international business environment. Therefore, we will try in this paper to outline several directions regarding the changes that have been made in this edition of ISO 9000 series of standards, changes that have to be implemented in the three years, after ISO specification, by all organizations certified or under certification.

Key words:

Quality, standards, quality management, quality management system, total quality management, ISO

JEL Codes:

M16, M21

1. Introduction

The first decades of this century have produced radical changes in all economic, political and social fields. The desire of economic agents to obtain an immediately and more substantially profit has been replaced gradually by the fierce fight for supremacy in quality field between competitors.

In the current period, the term "quality" has become a watchword in all countries. The only reason for this was the phenomenal expansion of the "Japanese miracle", because of the quality industrial revolution in this country, that can be comparable perhaps only with the industrial revolution from Britain in the middle of XIX century (Militaru, *et al.*, 2014).

The quality concept has a history equal to that of human existence and, over time were expressed many opinions regarding this subject. There are over a hundred definitions, resulting in all it is a complex and multidimensional phenomenon both on spiritual and material point of view (Ruxandra, 1997).

The "quality" concept can be analysed through philosophical, technical, economic and social meaning (Stanciu, 2005). Quality, in the most general sense is treated like a philosophical category and it expresses the essential characteristics of an object that makes it stand out from all other similar products, which have the same purpose, namely the utility.

The main concern of organizations to be competitive and to maintain to the market, or to gain new positions can be achieved only by offering products or services of superior quality with a lower price as compared to competitors. One way that this can be achieved is to implement a quality management system. This management system controls all the processes within an organization in order to provide services or products of better quality. In a market economy in a highly competitive world market the every organization credibility it become very important. The quality management system implementation and certification in totally accordance with the international standard ISO 9001 requirements aims to create a set of presumptions and evidences of the organization capability to produce quality products in accordance both with clients requirements and legal regulation.

In 1987, ISO (International Standard Organization) has developed the first edition of a standard for "quality".

This was the beginning of a new era in quality field, because the prerequisites standard are older and date back to 1971 when the British Standards Institute (BSI) developed the first standard for "quality assurance" BS 9000 that was intended primarily for the electronics industry. It was renamed in 1979 as BS 5750. The main purpose of BS 5750 standard was to provide a common contractual document, to demonstrate that industrial production was controlled.

ISO 9000 series of standards has gone through several revisions. Original version of ISO 9000 by 1987 has the same structure as the BS 5750 British Standard, with three „models” according to the organization activity. Schematically, we could synthesize the history of ISO 9001, as follows:

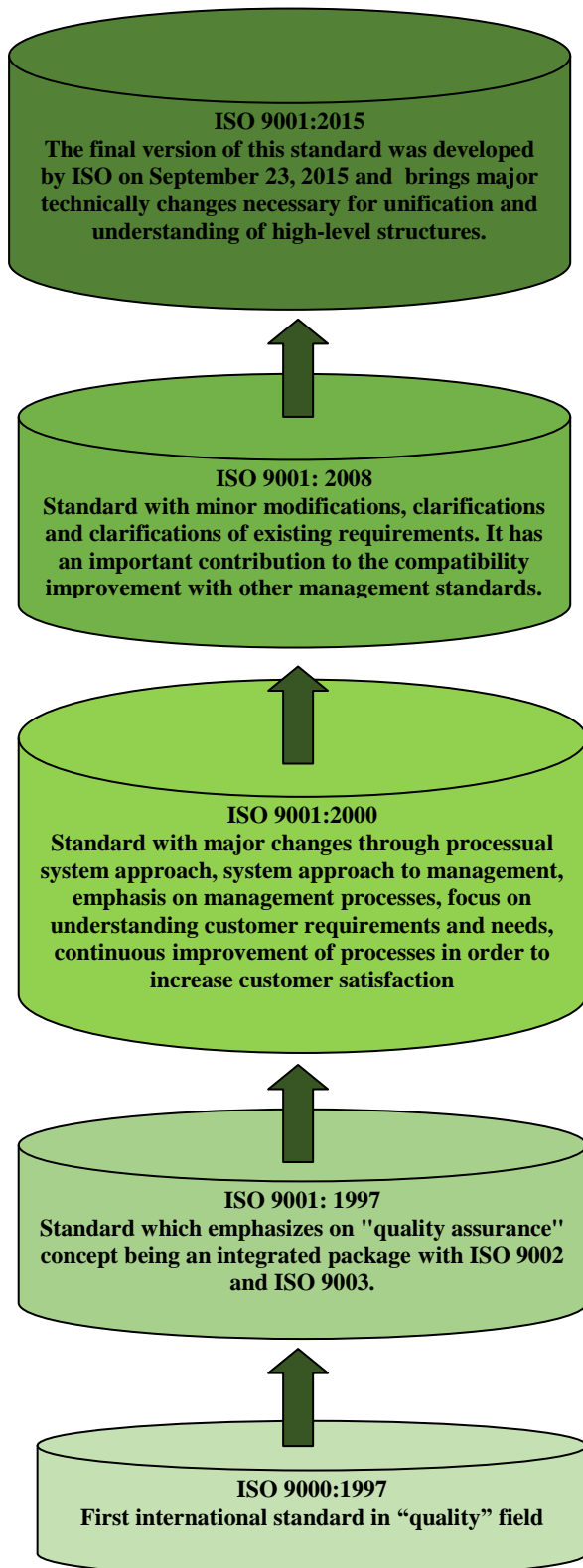


Figure 1. ISO 9001 revision history

According to *Quality Encyclopedia*, a "quality management system" represent "all interrelated management processes and its associated documents and also the all structural elements of organization, whose purpose is guiding and controlling the organization in terms of quality " (Hohan and Wiener, 2005).

Due to market dynamics and also from the necessity to increase business efficiency, the ISO 9000:2015 series of standards has introduced a new concept in quality management system, that of *sustainable development*, taking into account the risks associated with business.

The concept of "thinking based on risk" was introduced in the new series of standards to satisfy the growing demands of customers, but also to allow greater flexibility of an organization in the context of the competition sharp rise and of profound changes from international business environment.

In conclusion, ISO 9001:2015 constitutes a "major revision" of the quality management system, a new approach, similar to what should be this system: business management, how business is organized through quality, the whole activity of an organizations.

2. Methodology of research

The quality of products and services has developed new dimensions, and this requires a strong efficiency of all processes and specific activities within firms.

Literature highlights some aspects that should be taken into account to maintain a certain balance in the company and ensure a sustainable transition to the new requirements of ISO 9001:2015.

We suggest in this paper that these aspects must be highlighted through a rigorous synthesis of the literature and we try to point out some coordinated for an efficient implementation of change in organizations, according with the new recommendations of ISO 9000 standards. Having regard the contribution of previous standards series to the efficiency of companies activities, we believe that the new ISO vision should be discussed in terms of organizational practice.

As supporters of organizational change, we highlight the necessity to implement new recommendations from ISO in all organizations. In this paper, we will attempt a comparative approach to standards of quality, in terms of quality transformation into a powerful business strategy.

3. Literature review

The literature identifies a number of references of papers that analyses the quality management phenomenon, total quality management and quality management systems.

According to specialists, "quality management" and "total quality management" represents development of

the management science and it make a whole from all the theoretical and methodological elements which create the base for real work of managers (Hohan and Wiener, 2005).

Through quality management system we must understand a system of processes. To implement a quality management system means a good management of this system of processes "in accordance with the requirements of quality standard" (SR EN ISO 9000:2006).

In the speciality literature they were formulated in time many definitions of quality management:

- system of processes that includes three functions: planning, quality control and quality improvement (Juran, 2000);
- all activities undertaken for achieving quality, activities that are found in all stages of product realization (Rinne and Mittag, 1991);
- a set of activities aimed at achieving some objectives through optimal use of resources. This set includes activities of planning, coordination, organization, control and quality assurance (Kelada, 1990);
- coordinated activities to direct and control an organization in terms of quality (SR EN ISO 9000:2006).

Whatever the definition, experts in this field consider that a quality management system can be developed and implemented on different bases:

- descriptive or normative systems, based on a reference document which sets out certain requirements, with different criteria and that refers to each system element (e.g. ISO 9000);
- systems based on models of excellence, not very descriptive, that are set up as a whole set of criteria that constitute an indicative structure (e. g. excellence models based on the criteria of international quality awards);
- original systems, without a document or reference model, that are based on the own vision of the organization top management.

The first category is actually the largest model of quality management system and is used by over 1100000 organizations in over 180 countries.

At international level, the standard has spread rapidly, as a proof of undeniable efficiency in every field of activity where rigor in execution represent the essential element of quality.

In addition to the standard itself there is a rich literature in this area, including papers describing the model in detail. In this context the understanding the requirements of ISO 9001 version 2015 is essential.

4. Changes in the new ISO 9000 series of standards

The basic principle of quality management in accordance with ISO 9000 vision is based on organization's activities division in a branched manner to the level of relatively simple execution tasks which are unequivocally defined and based on clear identification of responsibilities, the way non-conformities are treated or another specific aspect. Execution instructions and procedures are developed for all organization's activities such that to be ensured a consistent quality of supplied products. The model requires establishing a real system in which any "defect" is found through customer feedback and corrected in time.

ISO 9001:2015 provides a set of essential requirements relevant to all dimensions and types of organizations from different sectors, keeping the focus on the effectiveness of management processes through increased compatibility and alignment with other management systems and using a simplified language and writing style. This standard aims to apply the requirements set out for a long period of time (10 years) thus ensuring continuity with the current edition.

ISO defines the advantages of implementing a quality management system in organizations after the new series of standards as follows (*"Reaping the benefits of ISO 9001"*, ISO, 2015):

- by evaluating the overall context in which operates the organization. This identifies elements that affect its work and also the requirements and expectations of stakeholders. Therefore, is very important to establish clearly its objectives and identify new business opportunities in accordance with this requirements;
- through a correct orientation to the customer, the organization ensures that can satisfy their needs and increase their satisfaction. This can lead to more personalized offers, can increase the number of new customers or loyal customers. The final result will be an increase of the business;
- increasing productivity and efficiency of the processes within the organization and reduce non quality costs by development activities in an organized way that is known by all stakeholders;
- expansion into new markets with new customers, because many businesses are conducted between partners with certified quality management systems;
- identifying business risks that allowing a business approach based on timely managing of their.

The new ISO 9000 series of standards introduces several changes summarized as follows (Ciobanu, 2015):

- an adaptability improvement of the requirements from standard to the nature of activities within services organizations;

- a more detailed description of the requirements formulated in the standard content;
 - the application limits of the system should be defined by the organization;
 - the flexibility to use documents was increased, the requirements regarding the terms "documented procedures", "quality plan" or "quality manual" were replaced with "documented information";
 - increased requirements relating to the organization management through more implication of the management at the highest level;
 - the changes in the organization must be planned;
 - there is no requirement for a *management representative*;
 - the organization's objectives must be formulated precisely with deadlines and resources;
 - knowledge management grows in importance;
 - there are no asked a *quality manual* in explicitly way even those *six system procedures* specified in ISO 9001:2008, being replaced by other mandatory documents like "field of application", "quality policy" or others;
 - no longer focus on *continuous improvement* of products or services, but the *results improvement* becoming essential;
 - it appeared the "*risk-based thinking*" concept by focusing on a very important aspect of a business namely business risk defined as the effect of an uncertainty;
 - requirement of "preventive action" is missing due to the decision to take into account concept of "risk-based thinking";
 - has increased the importance of product development processes and customer satisfaction;
 - the orientation on process is more clearly and strongly worded, increasing the importance of the process approach being a new condition for the evaluation indicators of processes
 - through risk assessment and customer satisfaction the term "continuous improvement" is replaced with the term "*improvement*", because a wrong assessment of risks or customers' needs can lead to the "over-quality" from the desire to increase customer satisfaction;
 - It was amplified requirement on strategy;
 - Staff competence should be ensured at all organization levels to ensure an adequate involvement of staff;
 - the term "product" refers to products and services.
- Also, the overall structure of the standard was changed, it being composed by 10 chapters of requirements, compared to 8 in the previous edition. That was made from the desire that all standards, for all management systems, to have the same structure and the same number of chapters of requirements (environment, information security), which will make easier the

integration of several standards into one integrated management system.

In the new edition of quality standard appear new requirements which did not exist in the 2008 edition (e.g. 4. Background to the organization, stakeholders involved, 6.1. Actions to address the risks and opportunities) and requirements of the previous edition which was no longer found in the new standard (e.g. 4.2.2. Quality Manual, 5.5.2. Management representative, 8.5.3. Preventive actions).

Not least, the new ISO 9001:2015 standard proposes a series of *seven principles*, instead of eight as were made in the previous edition.

They are: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making and relationship management.

5. The transition to the new ISO 9000 series of standards

The edition from 2015 has replaced the 2008 version of ISO 9001 standard, the main purpose of this review being to satisfy the needs of current business environment marked by profound modifications and changes caused by globalization impact in businesses field. In this context, ISO recommends updating of quality management system for all organizations that have such a system certified according to the requirements of ISO 9001:2008 to adapt to the new standard.

Starting September 2015 may be released certificates for the compliance management systems with ISO 9001:2015. The organizations that have planned to implement and certify their quality management system until this date were able to choose as referential any of the two editions of ISO 9001 at 2008 or at 2015. After September 2016 organizations will have to implement the requirements of the new standard, ISO 9001:2015 because after 23 September 2016 are no longer issued new certificates for compliance with the 2008 standard, this series being withdrawn.

Organizations that already have certified its quality management system have enough time until September 2018 to review and implementing their system, according to the requirements of the 2015 standard.

Every organization is different, so the necessary steps to adjust the quality management system may be different. So, ISO has elaborated a guide, giving in this way advices regarding the transition from the old to the new version of the standard (ISO - "*Moving from ISO 2008 to ISO 2015*", 2015).

✓ organizations should familiarize themselves with the new document, because there are some chapters or requirements that have changed, but others have remained the same. In this context a correlation matrix,

available from ISO / TC 176 / SC 2 helps identify changes and some parts of the standard were moved elsewhere.

- ✓ organizations should identify any organizational issues that must be addressed to implement the new requirements of the standard;
- ✓ organizations must develop an implementation plan of the new requirements and clauses;
- ✓ organizations should conduct training and awareness programs appropriate for all parties that have an impact on the efficiency of the organization;
- ✓ organizations must update their existing quality management system to satisfy the requirements of the new series of revised standard;
- ✓ during the implementation of new requirements, organizations need to collaborate carefully with the certification body for a correct transition to the new version and also for the management system recertification.

6. Conclusions and recommendations

Organizational practice proved us over time the importance of designing and implementing a quality management system according to ISO 9000 recommendations.

In organizations with long-term vision, quality is a strategy. Quality management implementation must be carefully conducted and reported directly to the company's specific objectives in quality field and also to the real and concrete situations for company, situations which may affect its activity.

Regarding the dynamism of the business environment, we see this transition to the new requires of ISO 9000 family of standards as an absolute necessity. If we refer to the fact that the new standard treats company's activities through the multiple risks, we can better understand their importance in this business environment.

Top management has the responsibility to correctly identify the current internal situation within the organization (diagnostic analysis) and must to determine what changes are needed to ensure long-term success. Also, if we talk about quality management another main responsibility is to make the transition to a quality management system based on the new vision of ISO 9000 series of standards.

The coordinates that we have highlighted in this work can have a contribution for the assurance of high performances in quality field even in less favourable situations for the organization.

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