THE HISTORY OF ISO 9001 SERIES PAST 2000

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Abstract: Nowadays ISO 9001 standards are highly widespread in the business world. Many international organization use it in its everyday business practice to standardize and manage their business processes. This paper concentrate on the history of ISO 9001 standard. There is an description of first two versions on the mentioned standards – ISO 9001:2008 and ISO:2015. The aim of the paper is to analyze this to standards especially the differences between them.

Keywords: ISO 9001, quality standards, standardization, quality management, quality management systems, ISO 9001 history.

1. Introduction

Quality management systems are very broadly widespread in today opalizations. World, European and polish firms implement quality management system according to ISO 9000 series requirement (Poksińska, et al. 2002; Gębczyńska, and Wolniak, 2018; Horodecka, and Wolniak, 2015, Juszczak-Wiśniewska, and Ligarski, 2015a; Juszczak-Wiśniewska, and Ligarski, 2015b; Juszczak-Wiśniewska, and Ligarski, 2016; Wolniak, and Skotnicka, 2006; Wolniak, and Skotnicka-Zasadzień, 2010; Wolniak, and Sułkowski, 2015; Wolniak, 2013; Wolniak, 2014; Wolniak, 2016; Wolniak, 2017).

One some years there is a new edition of the ISO 9001 standard and organization should to rearrange its management system according to its requirement. The newest version of the quality management standard which can be implemented in organizations come back from 2015 and has name ISO 9001:2015 Quality management systems – Requirements. The standard describes basic requirements that organization need to implement.

Quality management system us planned and established by documenting procedures for the processes of organization to fulfill the needs and expectations of internal and external customers (Wolniak, 2013; Ligarski, 2013; Ligarski, 2014; Łuczak, and Wolniak, 2016; Wolniak, 2017a; Wolniak 2017b; Sułkowski, and Wolniak, 2018). The international standard ISO 9001:2015 specifies the requirements of quality management system to consistently

provide products that meet customer and applicable statutory and regulatory requirements. The standard is applied by many organizations through the world (Ścierski 2011; Wolniak, 20111; Wolniak, and, Sułkowski, 2015; Wolniak, and Sułkowski, 2016; Wolniak, and Hąbek, 2015).

2. Chronology of the quality management systems

The brief chronology of Quality Management System Standards we can describe as follows (Hoyle, 2009):

- 1956 10CFR 50 Appendix B Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants (US NRC),
- 1959 Mil-Q-9858, Quality Program Requirements (US DoD),
- 1968 AQAP 1, NATO Quality Control Requirement for Industry (NATO),
- 1972 BS 4891, A guide to quality assurance (BSI),
- 1973 Def Stan 05-21, Quality Control Requirements for Industry (UK MoD),
- 1974 CSA CAN3 Z299 Quality Assurance Program,
- 1974 BS 5179, Guide to the Operation and Evaluation of Quality Assurance Systems (BSI),
- 1979 BS 5750, Quality Systems (BSI),
- 1987 ISO 9000, Quality Management Systems – First series (ISO),
- 1990 Investors in People Standard (Originally DfEE now IIP),
- 1992 BS 7750, Specification for environmental management systems (BSI),
- 1994 ISO 9000, Second series,
- 1995 BS 7799, Information Security management (BSI),
- 1996 ISO 14001, Environmental management systems – Requirements with guidance for use,
- 1996 BS 8800, Guide to occupational health and safety management systems (BSI),
- 1997 SA 8000 Social Accountability (Originally the Council on Economic Priorities Accreditation,
- Agency now Social Accountability International),
- 1999 OHSAS 18001, Occupational Health and Safety Management Systems Specifications (BSI),
- 2000 ISO 9000, Third series (ISO),
- 2005 ISO/IEC 27001 Information security management systems requirements (ISO),
- 2005 ISO 2200 Food Safety Management System – Requirements for any organization in the food chain (ISO),

- 2008 ISO 9001:2008, Fourth series (ISO),
- 2009 ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach. Fourth series (ISO),
- 2015 ISO 9000:2015 Quality management systems — Fundamentals and vocabulary,
- 2015 ISO 9001 :2015 Quality management systems – Requirements.

3. The ISO 9001 standards in the years 2005-2010

Version of the standards from years 2005-2010 contains following documents (International, 2018):

- ISO 9000:2005 Quality management systems – Fundamentals and vocabulary. ISO 9000:2005 describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.
- ISO 9001:2008. Quality management systems – Requirements. ISO 9001:2008 specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. All requirements of ISO 9001:2008 are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Where any requirement(s) of ISO 9001:2008 cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to ISO 9001:2008 are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

Now are three international quality management standards (figure 1) (ISO 9001:2015):

- ISO 9000:2015 Quality management systems – Fundamentals and vocabulary provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. ISO 9000 also defines the terms, definitions and concepts used in this International Standard.

- ISO 9001:2015 Quality management systems – Requirements specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby enhancing customer satisfaction. Its proper implementation can also be expected to bring other organizational benefits, such as improved internal communication, better understanding and control of the organization's processes (Cholewicka-Goździk, 2016; Łagowski, and Żuchowski, 2016; Żemigała, 2017; Chen, et al., 2016; Novakova, et al., 2016; Ząbek, 2016).

ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach provides guidance for organizations that choose to progress beyond the requirements of this International Standard, to address a broader range of topics that can lead to improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system. Provides guidance to organizations to support the achievement of sustained success by a quality management approach. It is applicable to any organization, regardless of size, type and activity.

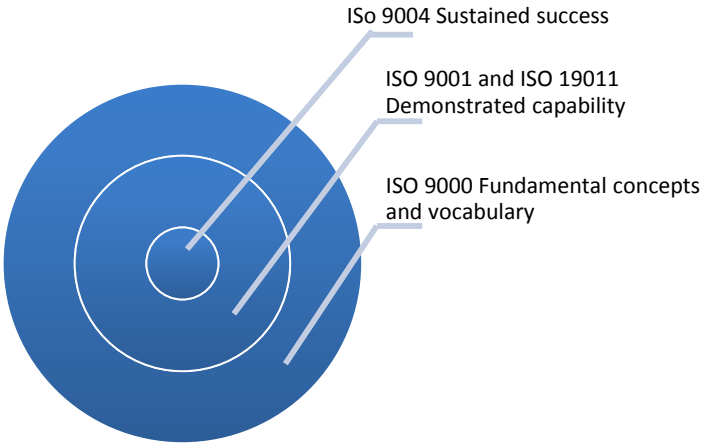

Figure 1. Contecxt of the organization. Source: Hoyle, D. (2009). *ISO 9000. Quality systems handbook*. Boston: Elsevier.

4. ISO 9001:2015

ISO 9000:2015 describes the fundamental concepts and principles of quality management which are universally applicable to the following (ISO 9000:2015, 2018):

- organizations seeking sustained success through the implementation of a quality management system,
- customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements,

- organizations seeking confidence in their supply chain that their product and service requirements will be met,
- organizations and interested parties seeking to improve communication through a common understanding of the vocabulary used in quality management,
- organizations performing conformity assessments against the requirements of ISO 9001,
- providers of training, assessment or advice in quality management,
- developers of related standards.

The structure of new ISO 9001:2015 standard there is presented in the table 2.

Table 2.
The structure of ISO 9001:2015

Lp.	Point
1.	**Scope**
2.	**Normative references**
3.	**Terms and definitions**
4.	**Context of the organization**
4.1.	Understanding the organization and its context
4.2.	Understanding the needs and expectations of interested parties
4.3.	Determining the scope of the quality management system.
4.4.	Quality management system and its processes
5.	**Leadership**
5.1.	Leadership and commitment
5.1.1.	General
5.1.2.	Customer focus
5.2.	Policy
5.2.1.	Developing the quality policy
5.2.2.	Communicating the quality policy
5.3.	Organizational roles, responsibilities and authorities
6.	**Planning**
6.1.	Actions to address risks and opportunities.
6.2.	Quality objectives and planning to achieve them
6.3.	Planning of changes
7.	**Support**
7.1.	Resources
7.1.1.	General
7.1.2.	People
7.1.3.	Infrastructure
7.1.4.	Environment for the operation of processes
7.1.5.	Monitoring and measuring resources
7.1.6.	Organizational knowledge
7.2.	Competence
7.3.	Awareness
7.4.	Communication
7.5.	Documented information
7.5.1.	General
7.5.2.	Creating and updating
7.5.3.	Control of documented information
8.	**Operation**
8.1.	Operational planning and control
8.2.	Requirements for products and services
8.2.1.	Customer communication

cont. table 2

8.2.2.	Determining the requirements related to products and services
8.2.3.	Review of requirements related to products and services
8.2.4.	Changes to requirements for products and services
8.3.	Design and development of products and services
8.3.1.	General
8.3.2.	Design and development planning
8.3.3.	Design and development inputs
8.3.4.	Design and development controls
8.3.5.	Design and development outputs
8.3.6.	Design and development changes
8.4.	Control of externally provided processes, products and services.
8.4.1.	General
8.4.2.	Type and extent of control
8.4.3.	Information for external providers
8.5.	Production and service provision
8.5.1.	Control of production and service provision
8.5.2.	Identification and traceability
8.5.3.	Property belonging to customers or external providers
8.5.4.	Perservation
8.5.5.	Post-delivery activities
8.5.6.	Control of changes
8.6.	Release of products and services
8.7.	Control of nonconforming outputs
9.	**Performance evaluation**
9.1.	Monitoring, measurement, analysis and evaluation
9.1.1.	General
9.1.2.	Customer satisfaction
9.2.3.	Analysis and evaluation
9.2.	Internal audit
9.3.	Management review
9.3.1.	General
9.3.2.	Management review inputs
9.3.3.	Management review outputs
10.	**Improvement**
10.1.	General
10.2.	Nonconformity and corrective action
10.3.	Continual improvement

Source: on basis: ISO 9001:2015. Quality management systems – Requirements.

All requirement of the ISO 9001:2015 standard are applicable to any kind of organization regardless of its type or size, also regardless to the type of product and services it provides. The main important facts about the ISO 9001:2015 series are (Abuhay. 2017; International, 2015; Edmund, 2008):

- The ISO 9001 Standard is an international standard for the establishment, design, and implementation of a quality management system (quality management systems) in an organization.
- Applying the ISO 9001 Standard requirements enables an organization to demonstrate its ability to consistently provide products or services that meet customer requirements.

- Applying the ISO 9001 Standard requirements enables an organization to demonstrate its ability to consistently provide products or services that meet applicable statutory or regulatory requirements.
- Applying the ISO 9001 Standard requirements enables an organization to enhance customer satisfaction through the use of quality management instruments that include methods for planning and improvements of processes and ensuring conformity to customer and applicable statutory and regulatory requirements.

The requirements of this standard are generic and apply to any sector and area of business and may be implemented.

5. Conclusion

This paper concentrated on the history of ISO 9001 systems. We described the overview about the genesis of this systems and systems on which the ISO 9001 standard was based. In this paper we analyze the two ISO 9001 standards – version from 2008 and 2015. In the table 3 there is an characteristic of main differences of two described versions of quality management systems according to ISO 9001 – from 2008 and 2015.

Table 3.
Differences between ISO 9001:2008 and ISO 9001:2015 standards

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used
Management representative	Not used
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider
Application	Determining the scope of quality Management system
Documentation requirement	Documented information
Control of documents	Control of documented information
Management responsibility	Leadership
Management commitment	Leadership and commitment
Quality management system planning	Planning of changes
Responsibility, authority, and communication	Organizational roles and responsibilities
Work environment	Process environment
Planning of product realization	Operational planning and control
Determination of requirements related to the product	Determination of market needs and interaction with customers
Review of requirements related to the product	Determination of requirements related to the goods and services
Control of production and service provision	Control of production of goods and provision of services
Customer property	Property belonging to customers or external providers

cont. table 3

Preservation of product	Preservation of goods and services
Control of monitoring and measuring devices	Monitoring and measuring devices
Measurement, analysis, and improvement	Performance evaluation
Control of nonconforming product	Nonconforming goods and services

Source: on basis: ISO 9001:2015. Quality management systems – Requirements; Purushothama, B. (2015). *Implementing ISO 9001:2015.* New Delhi: Woodhead Publishing India.

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