ISO 9001:2015 – A questionable reform. What should the implementing organizations understand and do?

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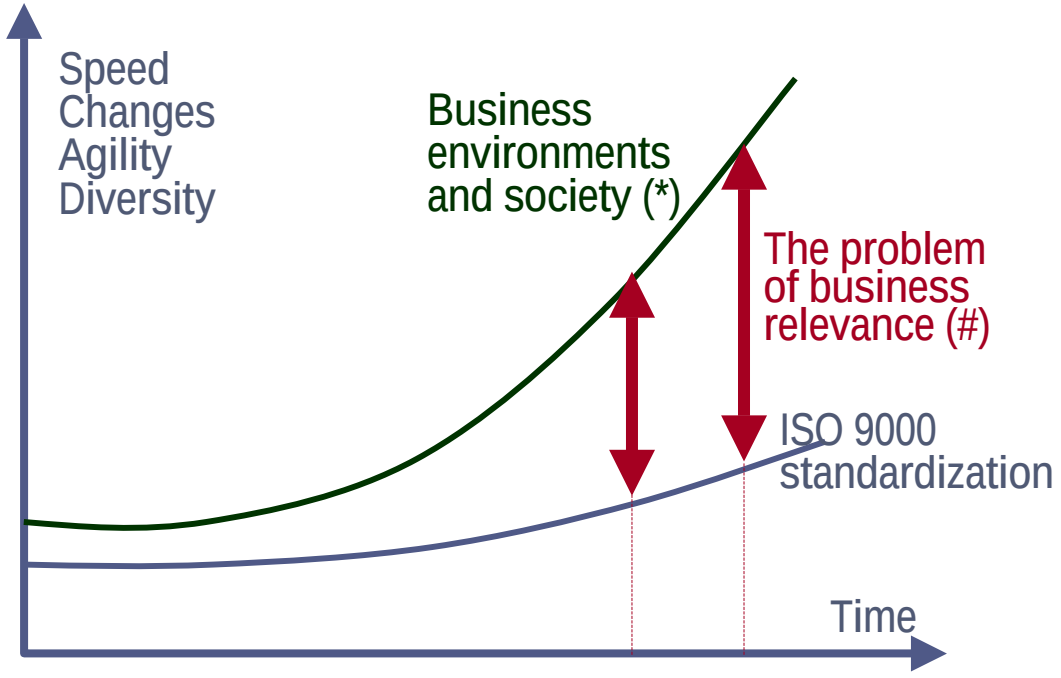
Business relevance and the future foresight of the ISO 9001:2015



(#) In ISO 9001 the gap is widening: Although textual changes, the ISO 9001:2015 brings nothing new in substance compared with ISO 9001:2008, but at the same time the business environments have continuously changed (*).

ISO 9001:2015:
"Plus ça change, plus c'est la même chose"
(The more things change, the more they stay the same)

(*) Especially new technologies have challenges for all managerial and operational factors in organizations and strong impact on product quality, quality management, quality assurance and on customer perception through environmental, social, health and safety, and security and privacy influence. In addition to these new technologies, all organizations operate today in networked business environments and in ecosystems.

Design specification for the ISO 9001:2015 for the business relevance and the future foresight

Design Specification for the revision of ISO 9001:2008 (28 June 2012):

"The revision will:

a) Take account of changes in quality management systems practices and technology since the last major revision to ISO 9001 (in the year 2000) and to provide a stable core set of requirements for the next 10 years or more.

b) Ensure that requirements in this standard reflect the changes in the increasingly complex, demanding, and dynamic environments in which organizations operate.

c) Ensure that requirements are stated to facilitate effective* implementation by organizations and effective conformity assessment by 1st, 2nd and 3rd parties.

d) Ensure that the standard is adequate to provide confidence in those organizations meeting the standard's requirements"

These requirements are not fulfilled in the published ISO 9001:2015, because the standard does not provide any new perspectives or requirements with regard to these aspects.

* Effectiveness is considered in the ISO 9001, efficiency is in the responsibility of the implementing organizations

Verification test of the ISO 9001:2015

The verification test of the ISO 9001:2015 draft, i.e. examination of the draft standard against the design specification, was never made, although is a normal activity in the standards drafting process.

- The standard was not prepared in accordance with its own requirements:
  - "The organization shall apply controls to the design and development process to ensure that verification activities are conducted to ensure that the design and development outputs meet the input requirements."
  - Nor did the risk-based thinking applied.

Process approach and risk-based thinking in the ISO 9001:2015

Process approach and risk-based thinking are not any new elements in the ISO 9001 standardization:

- ISO 9001:2015 promotes the adoption of a process approach, but requirements for it have been already also in the previous versions of the ISO 9001.
- The concept of risk-based thinking has been implicit in previous editions of the ISO 9001, e.g. through requirements for planning, review and improvement. In the ISO 9001:2015 it is more explicit and covers the whole standard, however without any specific requirements.

Process approach and risk-based thinking are important elements for quality management, but:

- They do not solve the problems of business relevance and future foresight.
- Their requirements in the ISO 9001:2015 are superficial and vague, and hence impossible to implement and audit unambiguously.

Validation test of the ISO 9001:2015

Validation test

- Indicated critical comments particularly on auditability, including:
  - (a) lack of clarity in the requirements
  - (b) absence of a requirement for objective evidence
  - (c) vagueness of the stated requirements.

  - These aspects are very essential aspects in the requirement standard. Especially from the auditability point of view, the requirements of opportunity, knowledge, awareness and innovation are challenging.
- The test was made very late and its results were presented too late in March 2015, when it was not any more possible to do improvements.

The new structure of the ISO 9001:2015

The new structure and the general text of the ISO 9001:2015 that follow the ISO Directives Annex SL:

- Are for the harmonizing purposes of the standardization and for promoting business integration of the different MSSs.
- Are not any new requirements, as the standard clearly says that "it is not the intent of this international standard to imply the need for uniformity in the structure of different quality management systems".

Revised quality management principles (QMPs)

QMPs are fundamental truths or propositions that serve as the foundation for a system of belief or behavior, or for a chain of reasoning for the ISO 9000 standardization.

Revised QMPs were used in the new ISO 9001:2015 but:

- The differences from the previous QMSs were very minimal.
- The standard presents that the standard is based on these principles that are described in ISO 9000:2015, and in ISO 9001:2015 the QMPs are only listed in the introduction. It is very unclear what the meaning of the "standard is based" from the requirements' implementation point of view is. How should the implementers and auditors consider the QMPs in this context?

Terminological and textual pitfalls

Clarity and unambiguousness of the terms and their definitions are the unconditional requirements in standards and especially in the requirement standards. ISO 9000:2015 as the normative reference includes many ambiguous concepts including:

- Organization
- Quality management system
- Products and services
- Design and development
- Risk
- Innovation
- Documented information
- Quality manual

However, the standard itself says that there is no requirement in the standard for the terms. Organizations can choose to use terms that suit to their operations. However, the risk is that the terms are not understood unambiguously.

The grouping of the terms in the standard ISO 9000:2015 is strange, confusing and difficult to use. Some clauses also contain too much anecdotal text that is not suitable in the requirement standard and compromises the effective implementation of the standard and auditing.

Why have we such unsatisfactory, incomplete and ambiguous standards that are difficult to implement?

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Q: What are the reasons for such a situation, and how it should be treated in organizations?

A: Such a situation is a natural consequence of the international standardization process. Organizations should understand it and be aware of the procedures of the standardization, and it is their duty to take the appropriate measures to remedy the deficiencies of standards in their own implementations.

Inherent weaknesses of the international standardization

Reasons for the weaknesses in the international standards:

- There are uneven and unbalanced groups of voluntary people participating the standardization work. Many of the involved members are certifiers and consultants that are not concerned about difficulties in the standard texts, because ambiguities only mean increasing business for them.
- Management of the standardization is weak.
- Only communally interesting issues are accepted to the final standard texts mainly due to the consensus principle.
- Influence of the strong and active individuals, and lobbying.
- No implementing means are allowed to be presented in the requirement standard.
- Handling of the issues in the standard text is superficial in the working group meetings.
- Slow and inefficient standardization process combined with the predetermined time schedule from the ISO committee and central office
- Participating in standardization is expensive.
- Simple majority voting impairs the quality of standards.

Implementers' duty to supplement and remedy standards on the basis of the best available knowledge

Standardization = An activity giving solutions for repetitive application, to problems essentially in the spheres of science, technology and economics, aimed at the achievement of the optimum degree of order in a given context. Generally, the activity consists of the processes of formulating, issuing and implementing standards. (*)

Standard = A technical specification or other document available to the public, drawn up with the cooperation and consensus or general approval of all interests affected by it, based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits and approved by a standardization body (*)

The implementation of standards in organizations is a part of the standardization.
It is the responsibility of organizations through taking advantage of science, technology and experience, and organizations' own business situations.

 (*) ISO Guide 2

How well the standard renewal has been successful?

What is good in the ISO 9001:2015 (although nothing substantially new in the ISO 9001)?

- The new harmonized structure
- More explicit emphasizing of the risk-based thinking and reference to the ISO 31000
- Reinforced business centered focus on business processes
- Development from distinct requirement items to more liberal discretion (although causing difficulties in auditing)

What is not good in the standard?

- A general ambiguity of the fundamental concepts and definitions (ISO 9000)
- The overall presentation of the issues and the quality of the text
- Too much guiding anecdotal text in the requirement standard
- Separate development of the basic standards of the ISO 9000 series
- Not fulfilling of the requirements of the design specification (lack of verification)
- Quality management principles weakly linked with the main contents of the standard
- Risk management has not dealt with in a systematic and logical way and according to the recognized business practices

Organizations should take advantage of the good points and avoid the bad ones

The wise implementing of the ISO 9001 standard

The ISO 9000 quality management standards series is an ensemble of:

- ISO 9000:2015 Fundamentals and vocabulary
- ISO 9001:2015 Requirements
- ISO 9004:2009 Managing for the sustained success of an organization - A quality management approach

These parts of the basic ISO 9000 series form a complementary whole although the relationship of the three standards are not clear.

Starting point for implementing ISO 9001 is the organization itself, its business needs, and its existing QMS:

- ISO 9001 presents requirements for the organization's QMS. Today ISO 9001 is overly emphasized.
- The QMS should be created in a creative way by organizations themselves based on their particular needs and integrated with their business system.
- The QMS has not been specified in any standards.

ISO 9001 should be simultaneously integrated with the other necessary management system standards into the organization's business system. A business system isolated separate QMS should be avoided.

Too strong emphasis on the third party certifications may have adverse effect on the effective and efficient of implementation of the management system standards.