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

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Abstract: *The committee ISO/TC176 finished its work with the fifth revised version of the standard ISO 9001:2015. However, serious difficulties arose during the drafting project due to the fact that the time schedule was predetermined and too tight, and the normal standards drafting practices were not followed properly. This resulted problems in the standard itself. The standard does not ensure its future relevance, because there is nothing substantively new in the standard, but the changes are mainly editorial. The standard does not fulfill the essential requirements of its design specification, and the verification test was denied. Validation test indicated critical comments on auditability, but this was presented too late, when the improvements were no more possible. Many terminological difficulties in the standard particularly confuse implementing organizations. In this article, we consider the baselines of the drafting work, the working process and its results. The aim is to recognize how to take effectively the business advantage of the good sides of the standard and to avoid pitfalls, to identify the responsibility of the organizations that are implementing the standard, and to provoke them to creative solutions. The focus is in the business and quality practitioners' viewpoints for implementing the standard in organizations.*

Keywords ISO 9001:2015, ISO 9000 standardization, standard implementation

1 Introduction

After three working years, the international standardization committee ISO/TC176 has finished the fifth revised version of the standard ISO 9001 (ISO, 2015c) and published it in September 2015 (in 29 pages and CHF 138). ISO 9001 the world most-selling standard. In this article we consider critically the pros and cons of the new standard, the drafting process, and the interesting questions and necessary measures for the implementing organizations and quality practitioners. It is important to be aware of the international standardization process and the historical background of the ISO 9000 standards, which also provides better understanding to the produced standard its details and the reasons to the existing situation.

The viewpoints we present here are not much discussed among the quality people outside the drafting group, and they are very little recognized among the business people. We have detected this through our own discussion with many quality experts and also through following the related information and discussions at the national and international level, e.g. in many Internet pages and discussion groups of the social media. A lot of this kind of references are available, because ISO 9001 standard is a very interesting topic all over the world.

Our aim is to consider the standard from the business and quality practitioners' point of view who are involved with the implementation of the standard in organizations. Especially we want to ponder, how to take into account effectively the business advantage of the good sides of the standard and avoid pitfalls, how to identify the responsibility of the organizations that are implementing the standard, and how to provoke them to creative thinking and solutions.

The international standardization committee ISO/TC 176, ”Quality management and quality assurance”, is responsible for the standardization in the field of general quality management as well as quality management standardization in certain specific sectors. The ISO/TC 176 consists of three subcommittees. The subcommittee ISO/TC 176/SC 2 is responsible for the ISO 9000 standards family, and ISO 9001 is one of its products. The scope of the ISO/TC 176/SC 2, “Quality management systems”, covers the development of the quality management standards and guidelines. Practical drafting of the standards takes place in different working groups.

ISO/TC 176/SC2 now consists of the experts of 95 participating (P) countries from their own corresponding national “mirror committees”. Additionally there are 25 observing (O) countries and 44 liaison committees or organizations involved with this work. The national committees:

- Represent the country in the work of the ISO/TC 176 committee or its subcommittees.
- Nominate experts to the standardization working groups.
- Form the country’s views, comments, and votes to the draft standards and defend them.
- Are responsible for the national translations and issuing of the corresponding national standards.

The committee ISO/TC 176 was formed in 1979. The main output of the committee consists of three standards: ISO 9000 (ISO, 2015a), ISO 9001 and ISO 9004 (ISO, 2009b). During the 35 years working period of the ISO/TC 176, the committee has published five generations of these standards:

- ISO 8402:1986, and ISO 9000/9001/9002/9003/9004:1987 - The first edition
- ISO 9000/9001/9002/9003/9004:1994 – Combining ISO 8402 with ISO 9000 plus small changes
- ISO 9000/9001/9004:2000 - Structural and substantive changes
- ISO 9000:2005, ISO 9001:2008, and ISO 9004:2009 - Small changes
- ISO 9000:2015, ISO 9001:2015, and ISO 9004:20?? - Targeted for substantive changes

These three standards should be seen as a package of the associated standards, although unfortunately the general requirement standard ISO 9001 is overly emphasized in practice, which is harmful for the creative solutions of quality management in organizations and causes distortion in the general worldwide development of quality (Feary and Armstrong, 2015).

Through the generations of the ISO 9001 standard, its changes have been rather small and no innovations have been realized in the standard. However, simultaneously the organizational realities have changed very much in all business areas of the society. The ISO 9001:2015 was targeted for substantive changes due to the changes in the operational environments of all organizations and business areas. In this article we bring forward how and why this did not materialize in practice.

ISO/TC 176 has published a lot of other standards supporting the main ISO 9000 standards series, which may cause confusion among the basic standards implementations.

In addition to preparing the standards for quality management, the work in the committee ISO/TC 176 has an important role in the worldwide quality discipline and social collaboration of the professionals. The first author of this article has been involved in the international and national ISO 9000 work from the beginning of the committee ISO/TC 176 and the both authors together from different viewpoints in implementing and integrating the standards in the real organizational environments in a creative way (Anttila, 2007; Anttila, 2001).

2 Premise and objectives for the ISO 9001:2015 revision

Needs and expectations for the new revised ISO 9001:2015 standard were very challenging:

- Understanding the business context as the foundation for the standard clauses
- Emphasizing organization-specific implementations and integration with the business system of the organization
- Understanding the whole standards series (ISO 9000, 9001, and ISO 9004) holistically
- Promoting the adoption of the process approach for the implementations
- Taking the risk-based thinking explicitly as the central concept of the standardization
- Ensuring the compatibility with the other management system standards and easiness in simultaneous implementation

- Ensuring the future relevance

Actually, these are not any new aspects, because they have been featured also in the previous versions of the standard. However, in practical implementations, these viewpoints seem to have been forgotten.

Before starting the actual drafting work, the committee had strategic objectives and decisions, and basic preparations for the revision including:

a) Strategic objectives of the committee ISO/TC 176/SC2 (ISO/TC 176/SC 2, 2011c), and pressure from the ISO and Technical Committee especially speeding up the time schedule of the work
b) Systematic review of the ISO 9001:2008 by the participating countries for the needs of revision and the committee resolution to start the work
c) Worldwide user survey of the ISO 9001 and 9004 standards (ISO/TC 176/SC 2, 2011a)
d) Considering the time, speed and agility aspects for QMS standardization by an ad hoc working group (El-Meligy and Anttila, 2008)
e) Analysis of the quality management concepts for considering the future ISO 9000 work (ISO/TC 176/SC 2, 2011b)
f) Design specification: Challenging targets to meet the needs and expectations of modern organizations (ISO/TC 176/SC 2, 2012)
g) Renewed quality management principles (QMPs) (ISO/TC 176/SC 2, 2013)
h) ISO Directives Annex SL: High level harmonized structure, identical core text, common terms and core definitions in the management system standards (ISO/IEC, 2012)
i) Emphasized a harmonized risk management approach with the ISO 31000 (ISO, 2009a)

User survey, which consisted mainly responses from certified organizations, showed that the respondents were quite satisfied with the existing standard version and did not want major changes. However, the time, speed and agility working group and the future concepts working group presented that considerable modifications are needed because of the modern and changed business environments. These aspects were recognized and the following targets recorded into the design specification for the draft:

1) Take account of changes in quality management systems practices and technology since the last major revision to ISO 9001 (15 years ago in 2000) and to provide a stable core set of requirements *for the next 10 years or more*.
2) Ensure that requirements in this standard reflect the changes in the *increasingly complex, demanding, and dynamic environments* in which organizations operate.
3) Ensure that requirements are stated to facilitate effective implementation by organizations and effective *conformity assessment by 1st, 2nd and 3rd parties*.
4) Ensure that the standard is *adequate to provide confidence* in those organizations meeting the standard's requirements

Also the new QMPs, harmonized structure and ISO 31000 reference for the risk management were taken into account in the design specification.

The key issue to evaluate the work and its result is, how well these requirements have been realized in the standard ISO 9001:2015? This also is our basis when we are questioning the result.

3 Quality management principles

Standardized quality management principles (QMPs) have been defined as 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. Before the ISO 9001:2015 revision also the old QMPs were revised and the new ones consist of seven principles: (a) Customer focus, (b) Leadership, (c) Engagement of people, (d) Process approach, (e) Improvement, (f) Evidence-based decision making, and (g) Relationship management. Previous QMPs aimed at improved performance, and these new QMPs emphasize performance improvement and organizational excellence through quality management means.

How well have these QMPs taken into account in the standard ISO 9001:2015? 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 not clear 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?

4 The new structure of the standard text

The structure and the general text of the ISO 9001:2015 follows the ISO Directives Annex SL that is the general ISO harmonized requirement for all management system standards (MSSs) of the different specialized disciplines (Table 1).

Table 1. Structure and the standard chapters and clauses of the text in the ISO management system standards (MSSs) (In ISO 9001:2015, the discipline XXX = quality)

1. - 3. General introductory clauses	7.1Resources
4. Context of the organization	7.2 Competence
4.1 Understanding of the organization and its context	7.3 Awareness
4.2 Understanding the needs and expectations of interested parties	7.4 Communication
4.3 Determining the scope of the XXX management system	7.5 Documented information
4.4 XXX management system	7.5.1 General
5. Leadership	7.5.2 Creating and updating
5.1 Leadership and commitment	7.5.3 Control of documented Information
5.2 Policy	8. Operation
5.3 Organizational roles, responsibilities and authorities	8.1 Operational planning and control
6 Planning	9. Performance evaluation
6.1 Actions to address risks and opportunities	9.1 Monitoring, measurement, analysis and evaluation
6.2 XXX objectives and planning to achieve them	9.2 Internal Audit
7. Support	9.3 Management review
	10. Improvement
	10.1 Nonconformity and corrective action
	10.2 Continual improvement

In the previous standard the structure had emphasis on quality systems, but this new one follows very typical general managerial entities of any organization's business system. This same structure is used in many general discipline-specific MSSs, including asset management, environmental management, information security management, innovation management, occupational health and safety management, quality management, social responsibility (management), etc. It is also used in many sector-specific and discipline-dedicated MSSs, including automotive, aviation, education, electoral bodies, energy, food safety, health care, information systems and services, local government, medical devices, military, petroleum and gas, pharmaceutical companies, road safety, ship recycling, software, supply chain security, transportation, etc. The main purpose of this harmonized standard structure is to help organizations when they integrate the MSSs of many disciplines simultaneously into their businesses.

How well has this structure been realized in the standard text of the ISO 9001:2015? It seems that the new structure was applied rather mechanically without any creative thinking. The text of the old ISO 9001:2008 standard was only reallocated according to this new structure. However, this new structure would have been able to offer good opportunities for much more forward-looking solutions. This standard structure has already caused confusion and critics among some standard implementers in several countries. However, this structure was mainly created for drafting the standards, and it is not any requirement for implementing the standards in organizations. ISO 9001:2015 says clearly that "it is not the intent of this international standard to imply the need for uniformity in the structure of different quality management systems".

5 Risk management requirements and implementation

Risk management is an essential element of the effective quality management. The risk topic has been implicit in previous editions of the ISO 9001 standard and related to carrying out preventive action to eliminate potential nonconformities, analyzing nonconformities that do occur, and taking action to prevent recurrence. The new ISO 9001 standard presents the requirement of risk-based thinking in order

to make risk related activities more explicit than in the previous standards. Emphasizing the risk management originates from the new standard structure of ISO Directives Annex SL and the intention to apply the general risk management standard ISO 31000 in the connection of the ISO 9001. ISO 9001:2015 requirement is particularly the risk based thinking in the connection of all standard clauses, but the standard does not present any particular requirements for methodologies or practices.

The standard ISO 31000 provides principles and generic guidelines in risk management, but also a lot of literature and other references are available for different approaches and methodologies of risk management, e.g. the following three practical risk management approaches have been presented in the connection of the management system and risk management standards:

a) The organization identifying the risks through focusing on related assets, threats and vulnerabilities (ISO, 2008)
b) The organization identifying the risks associated with the loss of the performance without using assets, threats and vulnerabilities (Brever, 2011; Brewer and List, 2004)
c) The Bowtie method based on the events and the fault tree methodology (Lewis and Smith 2010)

The standard does not take a stand on how the risk management procedures are planted in the organization's normal business operations. The organization must decide how the necessary risk management actions are to be applied strategically to the entire organization and operationally at its different business areas and levels and at any time to specific functions, processes, projects and activities. For a consistent integration, the organization's risk management framework (ISO, 2009a) consists of managing processes at both strategic and operational level of the organizational management according to the needs and expectations of the organization and its business. The organization should have general all business related risks management ("corporate risk management") related to business continuity risks, financial risks, product risks, fire risks, crime risks, environmental risks, people risks, information risks, contractual risks, reputation risks, black swan risks, etc. and also specialized discipline related risk management related to quality risks, information security risks, occupational health and safety risks, environmental risks, asset risks, etc.

How well has the risk management requirement been articulated, realized and allocated in the ISO 9001:2015 standard text? Risk management is considered in the introductory part of the standard as risk-based thinking and in the main requirement clauses following the reference structure of the ISO Directives Annex SL in a sketchy and unsystematic way. Implementation of the risk management requirement of the ISO 9001:2015 bring up many difficulties that may lead to different solutions:

- Risk-based thinking as the requirement means that risk viewpoints should be considered everywhere in the standard and not only in some particular risk clauses, and requirement deals with the general approach, "thinking", but not any particular methodologies or practices.
- Allocation of the risk related clauses in the standard is ambiguous, and difficult to align with the normal business practices and needs such as those described above.
- Risk related terminology is exposed to interpretations.
- Preventive action, which was in the earlier standard versions used to eliminate potential problems, is not any more used in the standard.

6 The process approach

The process approach is not any new issue in this standard, but it has already been in the previous version of the standard, too.

ISO 9001:2015 promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system to enhance customer satisfaction by meeting customer requirements. The standard also gives general textbook-like bullet points as specific requirements to be considered essential for the adoption of the process approach. Here, the standard goes too much into general details that are not necessarily suitable for all different modern organizational situations. This kind of requirements may lead to superficial solutions. The practical process approach in an organization is much more complicated issue (Anttila and Jussila, 2012; Anttila and Jussila, 2013b).

7 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 provides as the normative reference and the essential background for the proper understanding and implementation of the standard ISO 9001:2015. According to our research (Anttila, 2015) we are convinced that the existing ISO 9000 standard definition of the very main concepts of *quality* and *quality management* are valid, conceptually correct from the scientific point of view and also challenging for creative practical implementations. However, ISO 9000:2015 includes many ambiguous concepts and definitions that at the very least complicates and distorts the implementation of the standard. This has been revealed especially when translating them into other language. Confusing terms represent very central concepts of the ISO 9000 standardization including the following examples:

- An *organization* cannot be a person. Organization can be defined as a group, but not as a person.
- The definition of *management system* is unclear and can be understood at least in two different ways. For the normal business purposes the term management system is, however, not needed at all; it is more practical to talk about managing processes.
- *Quality management system* (QMS) is one of the most central terms in the whole ISO 9000 standardization. This concept has been a big question mark already for years. There are no specific standards that address the QMS as such holistically, and hence the content of the QMS always depends only on the particular organization's or person's opinion. ISO 9001 does not define the QMS as a whole; it only presents requirements for it. On the other hand, the ISO 9004:2009 provides guidance to organizations to support the achievement of sustained success by a quality management approach, and the organization's QMS should be based on the quality management principles. ISO 9000:2015 very unclearly states that the QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results. It is impossible to know where is the border between the management of the business system and the QMS. The QMS according to its definition is seamlessly embedded within the management of the organization. Hence, the whole concept QMS is totally useless in practice. It may be replaced by the expression "management of the organization with regard to quality in a systematic way".
- *Product* and *service* concepts have been discussed already for many years, and now the definitions have been made very complicated and confusing.
- *Design and development* defined as a concept is strange and not aligned with the normal thinking
- Risk based thinking is an important requirement in the standard. However, the *risk* concept arises questions. ISO 9001:2015 is required to follow the general risk management standard ISO 31000. However, the risk concept has been defined in ISO 31000 as "effect of uncertainty on objectives" but in ISO 9001:2015 as "effect of uncertainty on an expected result". It is not clear to practitioners what the difference of these two definitions is. Additionally confusion is caused that the risk may be "positive and/or negative" when in another place the standard talks about "risks and opportunities". What is the difference between the positive risk and opportunity? Positive risks are not used at all in the normal business language, and opportunities should not be as a standard requirement, they purely are organizations' internal business issues.
- The concept *performance* as it is defined in the ISO 9000:2015 seems not to be the same concept which is used in the texts of ISO 9000:2015 and ISO 9001:2015.
- The definition of *innovation* as "new or changed object realizing or redistributing value" is completely strange in respect of the established practice.
- This new concept *documented information* is confusing, useless and wrong in many ways.
- The definition of *quality manual* is wrong, it is not document stating requirements, and it is neither required nor used at all in ISO 9001:2015.

The grouping of terms in the standard ISO 9000:2015 is very strange, confusing and difficult to use.

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

Text of the standard ISO 9001:2015 is in some places ambiguous and difficult to translate and hence also to understand. 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.

8 Business relevance and technological challenges

The ISO 9000 standards have not been not able to follow the general development of organizations' business development and trends of the society (Figure 1) and the ISO 9001:2015 does not improve any of this situation. The challenging objectives of the design specification for the future relevance of the standard (as mentioned above) were not realized, because nothing new was introduced for this standard to fulfill those objectives. The standards reflects the old French saying, "Plus ça change, plus c'est la même chose “ (The more things change, the more they stay the same) (Karr, 1849).

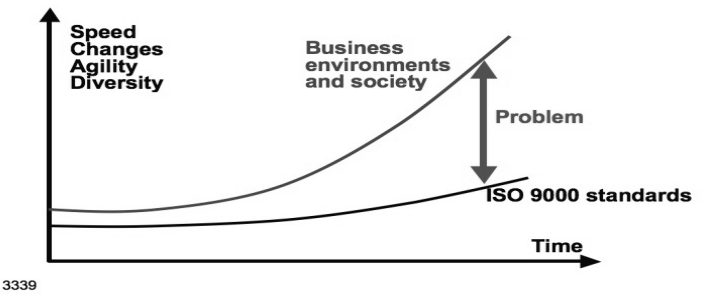

Figure 1. The problem of the ISO 9000 standardization

Especially the new technologies have essential impacts on product characteristics and the effectiveness and efficiency of the related processes. These technologies (Anttila and Jussila, 2013a) include information and communication technology ICT, biotechnology, nano- and microtechnology, optical technology, energy technology, social technology, wellbeing technology, etc. Examples of the ICT include:

- Ubiquitous information technology, near field communication (NFC), radio frequency identification (RFID), internet of things (IoT) or industrial internet, biohackering, etc.
- Robotics, 3D printing
- Mobile payment technology
- Mashup products, navigating technology
- Open source information and services, cloud computing
- “Big data” analyzing and crowd-sourcing activity

The new technologies have challenges for all managerial and operational factors in organizations of all areas and hence also strong impact on product quality, quality management and quality assurance, and also 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. That means that also the professional quality concepts, principles, and practical means must be reconsidered in a new way because of radical changes has happened inter alia in organization structures, business environments, interested parties (stakeholders), business targets and performance, management and leadership practices, products (goods and services), business processes, work and “employeeship”, custom, customers, and company culture.

In this context ISO 9001:2015 represents stagnation and the past.

9 The problems in the drafting process

Very big problems were in the working process of the drafting group deriving from the fact that the normal standards drafting practices were not respected and that the predetermined revision time schedule was considered more important than the quality of the standard text. Hence, we had not enough time for improvement. Especially at the very final DIS phase of the drafting project the work of the ISO 9001:2015 situation was catastrophic regarding both the standard ISO 9001 and ISO 9000. In the voting from the DIS stage to the FDIS stage the voting results were rather suspicious. The DIS documents achieved majority ”Approved” but many significant countries were against and several thousands comments were presented, and some of the comments were quite essential and critical. The working group had not enough time to consider all the comments properly. According to the rules, it is not possible (and actually not allowed) to make radical changes any more after the DIS voting. However, big changes were still introduced into text in this phase.

Validation test (ISO/TC 176/SC 2/WG 24/TG 5, 2015) 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 test indicated critical comments particularly on auditability, including (a) lack of clarity in the requirements, (b) absence of a requirement for objective evidence, and (c) vagueness of the stated requirements. These aspects are very essential in the requirement standard. Especially challenging from the auditability point of view are the requirements of opportunity, knowledge, awareness and innovation. It is questionable whether such topics should not at all exist in the requirement standard.

Verification test is also a normal activity in the standards drafting process. It means examination of the draft standard against the design specification. The verification test of the ISO 9001:2015 draft was never made. Hence, the non-fulfillment of certain key requirement – especially related to the objectives for the future relevance of the standard – was not brought forward resulting that the draft does not fulfill the essential requirements of the accepted design specification. Hence, the standard has not been 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.” (ISO, 2015b) Also, risk-based thinking should have been applied in the preparation of the standard.

Why have we ended up in such a situation that finally led to such unsatisfactory, incomplete and ambiguous standards that are ambiguous and difficult to implement? In fact, it is much a natural consequence of the international standardization process.

All standardization strives for positive and proactive aims, including (a) improved business performance and confidence, and quality of products, (b) decreased operational costs, and (c) improved communication between people and organizations. For these targets standardization has general pros:

- Broad acceptance and distribution of the texts
- Extensive expertise in preparing and commenting the standards
- Wide commitment and recognition
- No restrictions for innovative implementation

However, at the same time it also has general cons including serious inadequacies, inconsistencies and other problems mainly due to the normal standardization processes and particularly the consensus practices:

- There are uneven and unbalanced groups of voluntary people participating the standardization work. Many of the involved working group 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 in the working group and lobbying
- Only trivial means to implement the standard clauses may be considered in the standards.

- Handling of the issues in the standard text is superficial in the working group meetings.
- Standardization process is very slow.
- Participating in standardization is expensive.

Consensus process is the core feature of standardization practices. It is the strength of the international standardization, but at the same time it is the weakness and a major reason to the problems and deficiencies of the standards.

- Everyone involved has possibility to voice his or her opinion and all opinions should also be taken into account.
- The most important consensus practices in the standardization include the following possibilities:
  a) Someone's proposal is accepted although it is not the best possible solution or not even similarly understood by different experts.
  b) A text is edited together in a working group (or by the opposites) in order to get consensus although the compromises are not necessarily any improvements.
  c) "Competing" alternative texts are included in the standard although they may be contradictory and hence confusing.
  d) Disputed issues are not mentioned in the standard at all.
- Especially simple majority voting impairs the quality of standards.

It is important that also the standards implementers are aware of these facts so that they take them into account when implementing the standards in their organizations.

10 Implementing the standard and coping with the pitfalls

Many of those who involved with the drafting work of the ISO 9001:2015 standard have expressed the view that the revised standard does not provide much something new. That factually means that the organizations that properly fulfill the requirements of the previous standard version, ISO 9001:2008, can immediately notify that they also comply with the new standard version. No particular changing measures are needed in their quality management due to the new version of the standard. However, organizations normally have needs from their business reasons to improve their business effectiveness and efficiency continually, and in this context they of course can and should take into account also the new standard ISO 9001:2015. Consultants, training organizations and certifiers may however in the same time emphasize the changes in the new standard, but this can be understood from their needs to increase business. Actually all the changes in ISO 9001:2015 are very much of editorial nature in the standard text:

- Standard text chapter by chapter:
  - Chapters 1 – 5: Nothing essentially new from the previous version
  - Chapter 6: Risk management mentioned in the more explicit way, earlier it was only implicitly. Nothing else essentially new from the previous version
  - Chapter 7 – 10: Nothing else essentially new from the previous version
- Structure and textual changes:
  - The new chapter structure according to the "High level structure" of the ISO Directives Annex SL
  - Some new phraseology (terms and general sentences), e.g. according to the harmonizing requirements of the Annex SL
  - Organizations may, however, use their own business structure and language when implementing the standard.
- Substance changes:
  - The process approach is emphasized, but its is not any new requirement.
  - Risk-based thinking is more explicit than in the previous standard version and covers the whole standard.
  - No new innovations in the approaches, principles, or methodologies, and no essentially new contents from the previous version

- Applied approaches in the standard comply with established and traditional ways that are practiced in organizations.
- Organizations may use their own business practices when implementing the standard.

In order to respond wisely and efficiently to the strengths and weaknesses of the general international standardization the implementers should also be aware of the general principles of the standardization. When the standardization can be seen as a linking factor between science (theoretical foundations) and practice (organizational implementations, legislation, etc.), the implementers should make use of theoretical knowledge and the best practices when applying the ISO 9000 standards. In fact, the ISO defines (ISO/IEC, 2004) the concept *standard* as "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". Also ISO definition of the concept *standardization* is interesting as "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". This means that the implementation of standards in organizations is a part of the standardization. Hence, it is organizations' responsibility to take advantage of science, technology and experience in applying the standards and highlight their own responsibility through business leaders and experts and clarify, correct, and complete general standards and find creative solutions in their implementations in order to achieve business benefits. Thus, creating and implementing the standards are two different worlds (Figure 2) with their own particular processes, which may and should interact effectively.

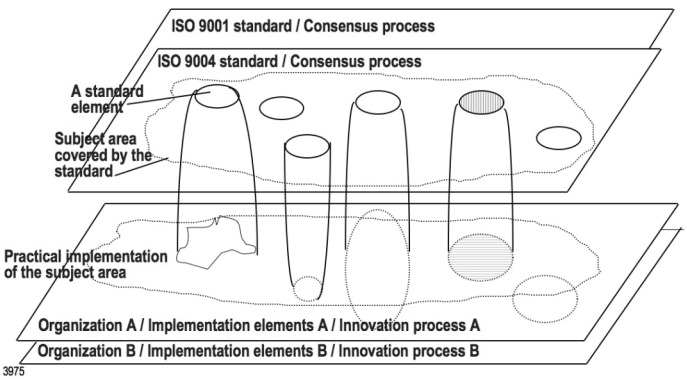

Figure 2. Creating and implementing the standards as two different worlds

However, organizations should be vigilant, because very often emotional aspects (Schein, 1987) impact in the understanding and applying the standards that causes at least inefficiency in the standards implementation (Figure 3).

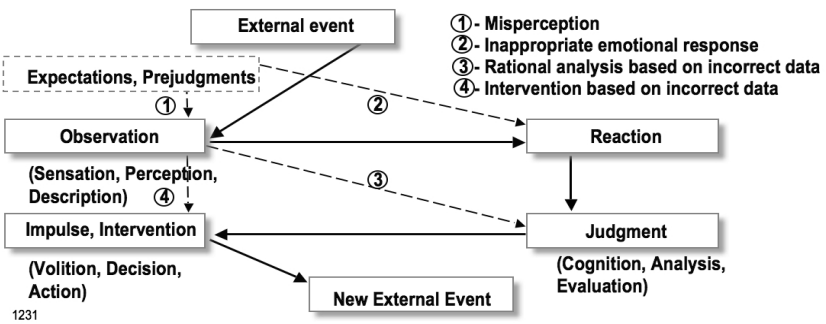

Figure 3. Recognizing intrapsychic processes in taking standard based measures (Schein, 1987)

11 Conclusions

We have questioned, how successful the standard ISO 9001:2015 renewal has been. We have recognized the following good aspects in the standard, which can be beneficial for the implementing organizations, although they are not any new or creative piece of the drafting work:

- The new harmonized structure
- 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

However, the standard clearly seems to be very incomplete and imperfect including:

- A general ambiguity of the fundamental concepts and definitions (ISO 9000:2015)
- 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)
- Not presenting anything new for the modern changed business environments
- Quality management principles weakly linked with the main contents of the standard
- Risk management has dealt with a unsystematic and illogical way in the standard chapters

Starting point in implementing the ISO 9001:2015 should be the organization itself and its business related quality management needs. The ISO 9001:2015 only presents the standard requirements for the organization's QMS, which as a whole cannot be standardized but only created by the organization itself.

ISO 9001:2015 should be simultaneously integrated with the other necessary management system standards into organizations' business systems. From the business systems isolated separate systems should be avoided. Overly emphasizing the third party certifications may have adverse effect on the effective and efficient of implementation of the management system standards. Even the ISO Central Office was already years ago concerned (ISO Central Office, 1994) about "The worldwide rush by businesses to obtain an ISO 9000 certificate as an external sign of quality is to detriment of the primary use of standards. --- The almost exclusive use of ISO 9001 as mere checklist to gain a certificate is a corruption of the core concept of ISO 9000 standards." Avoiding this organizations can stand gain full value from the ISO 9000 standards only when they use them in an integrated manner. The starting place for building quality effectiveness are the quality management standards, ISO 9000 and ISO 9004. These provide a foundation to set up an effective quality management through continual improvement and also to provide for a consistent use of the ISO 9001 for quality assurance and enhancing customer satisfaction.

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