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# ISO 9004 - A stimulating quality management standard for the creative leaders of contemporary sustainable organizations

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### Abstract

International management standards can provide organizations with challenging opportunities only if they understand the intended aims and features of those standards and apply them creatively and integrated into their business management. For that to happen, the business leaders of the organizations play the key role. For this subject, this discursive article focuses on the ISO 9004 quality management (QM) standard, which is one of the international management standards, which can be applied to all kinds of organizations. In addition to the opportunities, this article discusses difficulties and pitfalls associated with the ISO 9004 standard, and their possible solutions in practical implementations.

The authors highlight aspects of how ISO 9004 can be considered as the most challenging standard in the ISO 9000 series of the QM standards. However, many organizations, which have not acknowledged the differences and relationship of the ISO 9004 and ISO 9001 standards, often apply the ISO 9000 standards in inadequate ways and hence have not the ability to exploit the potential opportunities of the standards. Especially, ISO 9004 considers QM from the entire business point of view and aims at the quality of the whole organization. ISO 9004 standard can provide QM guidance to achieve sustained success even in complex, demanding and ever-changing contemporary business environments, including the challenges of the 4th industrial revolution.

This article gives ideas and creative theoretical and practical views for the ISO 9004 implementations. The aim is to emphasize that, according to ISO 9004, the organization's identity and its differentiating competitive advantages are the bases for the quality of the organization and its sustained success. In this context, each organization has its own and always existing QM realization, which cannot be separated from business management and which can be continually improved according to the organization's business development strategies and practices. In this respect, the ISO 9004 can be seen as flexible and challenging. Based on the authors' experience, QM targets can be achieved and developed in the most natural way through the principles and practices of the learning organization. In addition to the ISO 9000 standards, organizations also use other well-known managerial references, including performance excellence models and many various management system standards of the specific disciplines. All these may be seen as sub-domains within the ISO 9004 framework. ISO 9004 also can be used for diverse TQM and sustainability implementations.

This article is based on the authors' long experience in the practical promotion and application of the ISO 9000 standard in different kinds of organizations. The first author of the article has involved in the international drafting process of the ISO 9004 standard-editions since the 1980s. He also was a co-writer of a similar ISO 9004 article about twenty years ago. That article has been publicly available on the Internet, and its over one thousand recent readers evidence a growing interest in this standard. Moreover, after 2000, ISO 9004 standard has been revised twice and rewritten completely recently. Hence, it is well-founded to re-examine this subject again in this article.

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## 1. Introduction

Business benefits of the generic international standards can only be realized if the organization understands the nature of the standards and is able to implement them creatively within the business management. In this case, the business leaders play a key role. This article considers the subject in all kinds of organizations and focuses on the ISO 9004 quality management (QM) standard (ISO, 2018a), which is one of many international management standards (ISO/IEC, 2019).

Organizational management requires, in addition to QM, many other specific managerial contents 'XXX', such as environmental protection (ISO 14000), information security (ISO/IEC 27000), and occupational health and safety (ISO 4500), which also are dealt with in their related international management standards. All these specific issues are abstract entities and cannot be managed directly. Hence, the 'XXX' management in an organization is defined as the management of an organization with regard to the 'XXX' (ISO/IEC, 2019). Likewise, also QM is defined as the management of an organization with regard to quality.

All general standards, including ISO 9004, are the result of a broad and often compromised consensus and cannot represent the exceptional excellence of a particular organization (Anttila and Jussila 2017a). This means that the creative application of the standards is a prerequisite for gaining the overwhelming advantage of them. General standards are voluntary, but they may become obligatory in certain contexts through reference to standards. However, in these cases, too, innovations are essential for competitiveness.

ISO 9000 is a standards series for QM, and its basic parts are ISO 9004 for QM in a broad sense and ISO 9001 (ISO, 2015b) for quality assurance (QA). Often, however, organizations applying the ISO 9000 standards have not recognized the differences and relationship of the ISO 9004 and ISO 9001. Hence, the use of ISO 9004 has been negligible and misunderstood, and its benefits have not been exploited. Overly emphasizing the usage of ISO 9001 (Anttila and Jussila, 2017a) implies inadequate solutions, which also is adverse to the creative implementation of QM.

The ISO 9004 deals with QM aspects from the holistic business and organization point of view and aims at the *quality of organization*. QA and ISO 9001 represent only a sub-area of QM and focus on general assurance requirements to create confidence and satisfaction in the organization's products among its customers. ISO 9001 may be useful in contractual contexts, and if so needed, it can also be used as a basis for auditing and certification but ISO 9001 does not define any organizational quality management system (QMS) as a whole.

ISO 9004 standard emphasizes that the organization's identity and its differentiating competitive advantages are bases for the organization's *sustained success*. In this context, sustained success means that the organization's business continues for an extended period or without interruption for the desired time. The standard provides guidance on how this can be realized by the means of effective and efficient QM practices. However, QM cannot be separated from business manage-

ment, and hence, a particular QMS is harmful. Business-integrated QM, or 'Quality Integration' as used by the authors (Anttila and Jussila, 2017b), is understood as the implementation of the general and specific quality concepts, principles, and methodology embedded within the normal business management activities. This not only requires operational quality effectiveness and efficiency but also proactive QM in the area of strategic management.

ISO 9004 is aimed at providing QM guidance also for complex, demanding and ever-changing environments. However, the specific issues of the contemporary business environment, for instance, in the emerging challenges of the 4<sup>th</sup> industrial revolution (Anttila and Jussila, 2018b), are not explicitly taken into account in the standard. This belongs to the responsibility of each organization.

The following main subject areas are covered by ISO 9004:

- Terms and definitions
- Quality of an organization and sustained success
- Context of an organization
- Identity of an organization
- Leadership
- Process management
- Resource management
- Analysis and evaluation of an organization's performance
- Improvement, learning and innovation

This article addresses various aspects of these topics and additionally opens up theoretical and practical points of view for supporting the use of the standard for sustained success.

Each organization has always its own existing realization and implementation of QM and way to use ISO 9004, which can be improved according to the organization's business development strategies and practices. In this respect, the use of ISO 9004 is flexible. In a natural way, an organization's targets can be achieved and the performance improved through the principles and practices of the learning organization (Anttila and Jussila, 2018c). All organizations and their interested parties have unique needs and business environments. Big established organizations, SMEs, and startups are different genres of business (Anttila and Jussila, 2019b). They need different QM approaches and ISO 9004 applications.

In addition to the ISO 9000 standards, organizations also use other well-known managerial references, including performance excellence models (or quality awards criteria) and many specific management system standards ('XXX'). All these different references may be included as the sub-elements of ISO 9004. ISO 9004 is also aligned with the TQM (Total Quality Management) and sustainability thinking and movements. However, TQM is not any longer a popular concept (Dahlgaard-Park, 2011), and in fact, the concept of QM in ISO 9000 standards equals the concept of TQM. Considering sustainability in the QM context is natural because the sustainability aspects are included in the scope of quality concept (Anttila and Jussila, 2019a). Sustainability can be viewed as a personal, organizational, and societal issue.

ISO 9000 standards are constantly being developed in the committee ISO/TC 176, and currently, drafting the future concepts of QM are underway for renewing the whole ISO 9000 standardization. These concepts should be of interest also for the organizations implementing the ISO 9004 standard.

This article aims at presenting ideas and promoting discussions for new opportunities for standards-based QM solutions. The authors want to broaden the horizon for critical discussion on theoretical and practical QM issues. This article includes collated and updated material, which the authors have presented in many different conferences, training courses, articles, etc. during recent decades. The first author was a co-writer of a similar ISO 9004 article about twenty years ago (Bird and Anttila, 2002). That article is also publicly available on the Internet, and over a thousand recent readers evidence a growing interest in the subject. Therefore, it is well-founded to re-examine the subject, since, after 2000, the ISO 9004 standard has been revised twice and completely rewritten recently. This article also builds also on the manuscripts of two accepted conference papers that the authors were going to present in Autumn 2020 in Bratislava, Slovakia, and Crikvenica, Croatia (Anttila and Jussila, 2020), but the both conferences were cancelled.

In addition to the opportunities, the article also discusses some of the practical difficulties and pitfalls and possible solutions associated with the ISO 9004 standard. The first author of the article has a long experience in the international drafting process of the ISO 9004 standard-editions since the 1980s, and both authors in the practical promotion and application of the standard in different kinds of organizations.

## 2. Ontological and epistemological foundation

The international standardization and standards are based on the consolidated results of science (ISO, 2004). This should also be the case when implementing standards. Science describes reality through theories. The ontology and epistemology provide a solid scientific basis for organizational management and thus for QM (Anttila and Jussila, 2017b), also. This helps us in understanding and conceptualizing the quality of an organization and the complex entirety of the related quality phenomena and details in today's organizational and societal environments. This approach also supports creating ideas and methodologies for dealing with the relevant problems of QM. On the other hand, through practical applications, the theories are being tested, which in turn leads to the improvement of the theories (Senge et al., 1995).

Business ontology means an extensive awareness of all aspects of business (von Rosing, 2015), and it consists of the concepts and categories of business phenomena, including their properties and the relations between them. QM aspects are a subdomain in the business ontology. Ontology has direct links to the organization's operational practices and organization-internal standards, where also international standards can be utilized.

ISO 9004 terms and concepts are consistently based on the terminology of the ISO 9000 standard (ISO, 2015a), which also is aligned with the general terminology principles and

practices. The most important terms and concepts that are necessary for standard-based QM implementations are:

- Quality: Degree to which an object fulfills the needs and expectations
- Quality management (QM): Management of an organization with regard to quality (in the sense of Quality Integration)
- Quality assurance (QA): Providing confidence that the needs and expectations will be fulfilled
- Quality improvement: Increasing the ability to fulfill the needs and expectations

With these concepts, one can ensure dealing with professional QM in all types of organizations.

ISO 9001 has a restricted scope focusing only on the organization's products and on assuring the customers' needs and expectations. However, for ensuring sustained success, the organization needs to fulfill the needs and expectations of all interested parties. Hence, ISO 9004 emphasizes that the organization should strategically determine its *relevant* interested parties and fulfill their specific needs and expectations. When the organization takes this into account, it is called in ISO 9004 as the *quality of organization*. An important difference between ISO 9001 and ISO 9004 is that ISO 9001 only focuses on operational effectiveness, but ISO 9004 also requires ensuring efficiency.

According to the QM definition, quality cannot be directly managed but only through organizational processes and their management, i.e. through the management of the entire organization. Hence, QM has an organization-internal purpose ('to ensure') for success and QA an external communicative purpose ('to assure') for creating and strengthening confidence among the customers and other interested parties. Organizational learning is a challenging way to achieve quality improvement (Anttila and Jussila, 2018c).

The general quality management principles (QMPs), as defined in the ISO 9000 standard, also have a key ontological and epistemological role in the implementation of ISO 9004. QMPs are a set of fundamental beliefs, norms, rules, and values that are accepted as true for QM and hence are used as bases for QM standardization. QMPs should be taken into account in all contexts of ISO 9000 standardization and applications. QMPs should be utilized together with the general management principles that have been proposed by many recognized business management teachers (Anttila and Jussila, 2011). ISO 9000 QMPs consist of the following at the title level (ISO, 2015a):

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

The committee ISO/TC 176 is currently exploring future concepts for the coming revisions of all ISO 9000 standards. These concepts are aimed at taking into account the emerging

organizational and societal changes and associated megatrends, including the 4<sup>th</sup> industrial revolution and the UN sustainable development goals. The futures concepts to be selected are currently in the draft phase and include the following topics:

- Customer experience
- People aspects
- Change management
- Integration
- Knowledge management
- Emerging technologies
- Ethics & integrity
- Organizational culture

Forward-looking organizations should consider these new concepts when developing their QM solutions.

Management implies coordinated activities to direct and control an organization (Ibid.). Management, as well as QM, are based on knowledge. Epistemology provides the scientific basis for understanding things and conditions, and sources of related knowledge, and introducing to the knowledge-related methodology. Management requires a systematic way of thinking, models for reality, and a sense of good reasoning. This leads to assessing the questions of the business environment objectively. Epistemology is a branch of philosophy concerned with the nature of knowledge. It asks questions such as 'How do we know?' and 'What is meaningful knowledge?' Epistemology is a way to critical thinking. Many business-related issues such as the nature of logical inference, why we should accept one line of reasoning over another, and how we understand the nature of evidence and its contribution to decision making, are all epistemic concerns (Perla and Parry, 2011; Ellerton, 2017).

Traditionally, knowledge is defined as a 'justified true belief' (Burton, 2018) or in other words 'conscious effort to establish belief upon a firm basis of reasons'. In managing an organization, knowledge can relate to all aspects of an organization's operations, and it has both operational and strategic purposes. Knowledge is either explicit or implicit (tacit) knowledge.

Fact-based operation is valued as a consistent approach to business management including QM. *Data* can be obtained from the existing *facts* by measuring the conditions and processes of an organization. The scientific basis for measurements is metrology, which is a well-established discipline, whose concepts, principles, and practices are also internationally standardized. Management-relevant *information* is achieved when data is analyzed and linked with the business questions. The ISO 9000 standards emphasize the importance of documented information for management and QM. When information is utilized collaboratively and effectively by the employees and managers, they learn and internalize the business *knowledge*, and hence, often in operational situations, knowledge is tacit knowledge by nature (Harsh, 2009).

Critical scientific realism and scientific methods have proved to be the best theoretical basis for rational action (Niniluoto 1999). Knowledge, justified true belief, requires a theoretical basis. Deming (Deming, 1993) emphasized that information is not knowledge. Knowledge originates from theory.

Without theory, there is no way to use the information, which comes to us in some particular instant.

Quality improvement as part of QM cannot be realized professionally without appropriate knowledge, which also results in the new enhanced knowledge. Organization-wide quality improvement is achieved through organizational learning (Anttila and Jussila, 2018c) in a natural way.

Any organization in striving for sustained success should have necessary and sufficient knowledge of various specialized disciplines as described, for instance, in the various management system standards (ISO/IEC, 2019). However, an organization is a living organism and a set of conversations among people. Language defines the environment, in which the organization lives. A common shared language helps the organization arrive at decisions more efficiently (Pangaro, 2013). By narrowing language, efficiency increases but also ignorance increases, which leads to the fact that the organization becomes unable to adapt and revitalize itself to challenging changes in its environment. An organization is able to learn and grow only if it creates conditions that help generate a new language, with which the organization can create new paths to productivity, and regenerate itself.

### 3. The organization and its internal and external context

The organization is a core concept in all managerial contexts including QM and ISO 9004. It is a group of people, which has its own functions with responsibilities, authorities, and relationships to achieve its objectives (ISO, 2015a). The concept includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity, or institution, or part or combination thereof, whether incorporated or not, public or private. The organization may be a big one or SME. In today's business environment, SMEs are the backbone of the economy of countries, providing potentials for jobs, renewal of organizations and economic growth. Startups also have become a significant business area (Ries, 2011). The most management practices and also ISO 9000 standards have been developed for well-established organizations in predictable business environments. However, the situation in the SMEs and startups is very different; they are different organizational genres and hence require different management methodologies (Anttila and Jussila, 2019b) and creative application of the general standards.

Organizations can be understood as systems, i.e. as collections of interrelated or interacting real-world items organized for given purposes. Many recognized management experts emphasize the system aspects of management. All systems have the internal and external context. Through its border, the system interacts with its environments. The system functions through interrelated or interacting activities of processes, which transform certain inputs into desired outputs (Anttila and Jussila, 2013).

Sustained success requires a differentiated approach that reflects the competitive identity of the organization. The organizational identity is understood as the character, profile, or personality of an organization (Anttila and Jussila, 2014).

The internal context of an organization consists of values, culture, knowledge, and operational performance (Ibid.). Especially the business processes have the main role in the internal context. Also, QM and QA have the same foundation. Management of an organization consists of operational and strategic responsibilities (Figure 1), which are very different managerial areas and based on different foundations.



**Fig. 1.** An organization’s internal context and its strategic and operational management elements, which are the foundation for QM and QA implementation (Anttila and Jussila 2018c).

The external context of an organization consists of the value network, which arises from the legal, technological, competitive, market, cultural, social and economic environments (ISO, 2018a). The organization’s relevant interested parties are those, which strongly affect or are affected by the decisions or activities of the organization (ISO, 2015a). Different parties should be considered separately for QM and QA because they have different needs and expectations with regard to the organization. This relates to the product and confidence requirements. In this context, the key QM and QA related questions with regard to each relevant interested party include the following (Anttila and Jussila, 2019b):

1. Who is the relevant interested party?
2. Why is the party relevant, what is its value to the organization?
3. Why is the party interested in the organization, what is its value to the party?
4. What is the organization's contribution (output or product) to the party?
5. How to contribute to the party (policy and processes)?

#### 4. Organization-wide process management

Organizations are business systems that consist of interrelated business *processes* and organizational *structures* (Anttila and Jussila, 2013). Performance of the business processes has the greatest strategic and operational importance to the organizations’ competitiveness and sustained success. All products (goods and services) and other organizational outcomes are the results of processes. Processes imply to all kinds of activities, which are performed by people, hardware or software mechanisms. In fact, originally the process concept just denotes any kind of productive doing.

According to the authors' experience in different kinds of organizations, the following four-level business infrastructure

model has proved useful for managing a comprehensive system of business processes (Anttila and Jussila, 2018c):

- Corporate level (the whole organization): Establishing and maintaining the fundamental and normative process concepts, principles, visions, and general process management methodology.
- Strategic business level: Establishing and managing the system of interlinked business processes towards strategic targets of the particular strategic business units within the corporation.
- Operational level: Managing individual business processes in real-time.
- Individual personal and team level: Emphasizing the human commitment and role in business processes.

A strategic business system may be described by four major domains of business processes:

- Market processes: Anticipating the current and future market requirements. Launching new competitive products/solutions to the market, establishing and maintaining product management, and practicing market communication.
- Customer processes: Fulfilling individual customers’ needs with products, and establishing and practicing high-quality customer relationships and servicing.
- Management processes: Controlling and enhancing business performance, managing the organization’s business processes as a whole.
- Support processes: Providing effective support to the business processes and management in the organization.

Process management implies how the strategic and operational business objectives are carried out through business processes. A well-known and simple model for all management, including process management, is the PDCA (Plan - Do - Check - Act) model (Anttila and Jussila, 2018c), which should be applied in three different management scopes (the authors call it as ‘Triple’ PDCA model) (Ibid.):

- Control: Managing daily operations in business processes in order to achieve the specified results. Normally rectifying nonconformities is carried out in connection with control.
- Operational improvements: Solving acute problems and implementing operational small-step improvements in business processes.
- Breakthrough improvements: Inventing and implementing strategically significant changes successfully in the business-wide process system and transforming organizations.

ISO 9004 devotes a whole chapter to the organization's resource management, how the resources support the operation of all processes in the organization and are critical for ensuring effective and efficient performance and sustained success. In particular, the following resources are highlighted (ISO, 2018a):

- Financial resources
- People
- Information and organizational knowledge

- Technology
- Infrastructure, such as equipment, facilities, energy and utilities
- The environment for the organization’s processes
- The materials needed for the provision of products (goods and services)
- Natural resources
- Resources provided externally, including subsidiaries, partnerships, alliances, and outsourced processes.

For these resources, a lot of various management systems have been presented in various sources. The most appropriate way is to implement and manage them within the QM and process management.

People are the most significant resources in the business processes and in the roles of business leaders, managers, and employees. In order to avoid problems in the personal work-actions and in interpersonal collaboration, the business process activities and personal somesthetic, mental, and spiritual processes should not be in conflict with each other (Anttila and Jussila, 2013). Human activities have a crucial role in the realization of quality through producing products (goods and services) that effectively and efficiently fulfill the needs and expectations of customers and the other relevant interested parties.

The information, digital and telecommunication technologies provide unlimited opportunities for new product development and business process solutions (Anttila and Jussila, 2018b).

## 5. Performance evaluation

Performance evaluation of an organization is a QM activity incorporated with the improvement of the business system. Self-assessment is a fact-based business performance improvement approach deployed in accordance with business requirements and preconditions.

Two different methodological approaches (Anttila and Jussila, 2017b) are available for the self-assessment: (a) Evaluations based on *maturity* models, and (b) evaluations based on performance *excellence* models. The first one is for assessing the performance against certain specified maturity level criteria based on the existing best practices. The latter one emphasizes the continual performance growth based on learning, refining, and integrating. In its annex, ISO 9004 standard provides a self-assessment tool, which is based on the approach (a). However, the authors’ preferred approach is the option (b) because it is more proactive to respond to future challenges.

Critical views can be presented for maturity-model based assessments. Performance excellence models have achieved a more recognized position in all kinds of organizations and in the general quality awards. These models have been used all over the world for a long time, and they are revised regularly. The most well-known models are the American Malcolm Baldrige model and the European EFQM model. The ISO 9004 assessment methodology cannot likely compete with

these practices. In the maturity models, the different evaluation areas are assessed separately, and the model does not provide clear links between them. Results are not evaluated at all in the maturity models. Hence in practice, it is difficult to get holistic business performance from the evaluation-item related results. Because the criteria are general and standardized, the relevance to the specific organizational situations and needs is not necessarily ensured. Best practices of the maturity models do not necessarily present brand new creative organization-specific solutions. Maturity is not necessarily a good business target for sustained success, which depends on the nature of the organization and its activities. Many organizations prefer agility more than maturity. For instance, SMEs and startups, do not want to strive for maturity, because it does not represent their competitiveness that is more based on dynamics and continual regeneration.

In performance excellence models, the evaluation criteria take into account performance enablers (processes) and also the results obtained with them, and they emphasize organizational learning and integration. In order to achieve excellent performance and sustained success, the organization cannot optimize a single area of activities and neglect the entirety, but one should recognize connections between the performance of the processes (enablers) and the overall business results. Processes and results are assessed separately but the criteria emphasize the causal relations between them. Numerical scoring is based on the open assessment criteria (table 1) (Anttila and Jussila, 2018c).

**Table 1.** An example of the scoring dimensions for the self-assessment according to the performance excellence model. Processes and results are assessed separately and scored from 0 to 100% according to the scoring criteria (Ibid.).

| Processes   | Results  |
|---|--|
| 1. Approach: The planned actions, including process plans, measures, and deployment of requirements                         | 1. Level: Levels of the achieved results   |
| 2. Deployment: Executing the planned approach in practice   | 2. Trends: Sustained rate of improvement of the performance results over time  |
| 3. Learning: Capturing new knowledge, including new innovations   | 3. Comparisons: Performance relative to appropriate comparisons or benchmarks  |
| 4. Integration: Embedding the approach in the organization's strategies and the management of the processes and activities. | 4. Integration: Achieving the results in a balanced and comprehensive manner according to the organization's strategic objectives and anticipating future development. |

Self-assessments and audits complement each other. Auditing has a long development history (Anttila and Jussila, 2018a). Today internal audits are well-established management tools for examining, monitoring and analyzing the organizational activities for sustained success. The ISO 19011 standard for auditing (ISO, 2018b) covers the needs of all different management system standards.

## 6. Performance improvement, and risk and innovation management

ISO 9004 emphasizes that the organization should continually recognize challenges for effectiveness and efficiency in its external and internal circumstances, and changes in the needs and expectations of its interested parties. Also organizational learning and innovation support the organization's QM and quality improvement by increasing the ability to respond to the situation in a manner that enables to fulfill the business targets for sustained success. The organization should focus on improving process performance by using two basic approaches: a) Strategic breakthrough projects, which lead to the revision of existing processes or the implementation of new processes, and which are usually carried out by the cross-functional groups separately from the routine process-operations and b) continual small-step improvements made by natural work-teams within the existing process operations. Well-established and popular practices of the business process improvement, including Kaizen, SixSigma, and Lean methodologies, can be used in the ISO 9004 implementations.

Sustained success as a major business target requires that the organization should recognize uncertainties and their effects on objectives, which means utilizing adequate risk management practices (ISO, 2018c). In this context, also business continuity (London First, 2003), resilience (Seville, 2016), and robustness methodologies may be useful.

Quality and innovation can be seen as partnering disciplines (Anttila and Jussila, 2019a). They can be useful to each other and together create business improvements and differentiation for competitive advantage. The European technical specification CEN/TS 16555-1 defines innovation as the 'implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations' (CEN, 2013). In this definition, the 'significantly' and 'implementation' are keywords. Hence, the innovations should be conceptually new and commercially viable solutions that are available to the markets and society. Thus, in fact, all innovations aim at quality improvement. Business innovations are directly related to improving product performance, increasing the effectiveness and efficiency of the business processes, and making possible organizations' structural and operational reforms. All these topics are basic intentions of the professional QM and ISO 9004. The exploitation of new technologies is central to innovation (Christensen, 1997). The authors have recognized serious needs for innovations in QM practices and methodologies also (Anttila and Jussila, 2019a). Professional QM may be beneficial in the innovation process, too.

The successful development of business integration is a holistic learning process that leads on to continual refining QM related concepts and principles, tools and methodologies in a compatible and balanced way (Anttila and Jussila, 2018c). This organizational learning constitutes the development not just of new capacities, but of fundamental shifts of mind, individually and collectively (Senge et al., 1995)

## 7. Conclusion

Professional QM is a promising approach in striving for organizations' business benefits. ISO 9004 is the most challenging general international QM standard. Its holistic organization-wide approach provides guidance for the sustained success of the organization. As a side effect, it also can lead to fulfilling the ISO 9001 requirements of QA.

ISO 9004 is built on a systemic process-based approach and aligned with the sound scientific ontological and epistemological thinking. It makes multidisciplinary QM solutions possible in a flexible way, which easily allow the integration of different specialized managerial requirements that are presented in many various management system standards.

Key aspects of ISO 9004 implementation can be summarized as follows:

1. Integration: Implementing effective and efficient and business-relevant quality principles and methodology embedded within the organization's normal activities of strategic and operational management and originating from the business needs and the challenges of competitiveness.
2. Responsiveness: Striving for agile adjusting to suddenly altering business conditions and resuming stable operation without undue delay, and aiming at successful business continuity and resilience.
3. Learning: Continual individual and organizational learning for quality improvement.
4. Innovation: Striving continuously for new organization-dedicated creative solutions and encouraging various choices for QM in different organizations.
5. Collaboration: Communicating and working together with colleagues and appropriate multidisciplinary knowledge communities appreciating connectivity, interactivity, and shared knowledge and resources.

## Reference

- Anttila, J., Jussila, K., 2020. ISO 9004 - A stimulating quality management standard for the creative leaders of contemporary organizations, The manuscript of the paper accepted for the cancelled 21st International Symposium on Quality, "Quality – Yesterday, Today, Tomorrow", Crikvenica, Croatia, The Conference Proceedings, ISSN 2670-8825.
- Anttila, J., Jussila, K., 2019a. Striving for benefits of sustainability from the interactivity of quality and innovation, *Journal of Cleaner Production* 212.
- Anttila, J., Jussila, K., 2019b. Implementing quality management in startups, QMOD Conference, Krakow Poland.
- Anttila, J., Jussila, K., 2018a. The role of internal auditing in the development of the organization towards the excellent performance, The 19th International Symposium on Quality, Plitvička jezera Croatia.
- Anttila, J., Jussila, K., 2018b. Universities and smart cities: the challenges to high quality, *Total Quality Management & Business Excellence*, DOI: 10.1080/14783363.2018.1486552.
- Anttila, J., Jussila, K., 2018c. Organizational learning in developing the integrated quality management, *Production engineering archives*, 18, DOI: 10.30657/pea.2018.18.01.
- Anttila, J., Jussila, K., 2017a. ISO 9001:2015 - A questionable reform. What should the implementing organizations understand and do? *Total Quality Management*, DOI: 10.1080/14783363.2017.1309119.
- Anttila, J., Jussila, K., 2017b. Understanding quality - conceptualization of the fundamental concepts of quality, (Updated and improved from the conference paper presented at QMOD 2016 Conference, Rome, Italy.), *Int. J. Qual. Serv. Sci.*, 9(3e4).

- Anttila, J., Jussila, K., 2014. The growth of an organization's identity and the management systems standardization, The 15th International Symposium on Quality, Zagreb, Croatia.
- Anttila, J., Jussila, K., 2013. An advanced insight into managing business processes in practice, Total Quality Management & Business Excellence, 24(7-8).
- Anttila, J., Jussila, K., 2011a. Standardization and integrated management systems - Business-practitioners' viewpoints, 55th EOQ Congress/World Quality Congress, 'Navigating Global Quality in a New Era', Budapest Hungary.
- Anttila, J., Jussila, K., 2011b. From quality management principles to good management principles - Business-integrated approach to quality management, The 8th China Shanghai international symposium on quality and the forum of International Academy for Quality, Shanghai China.
- Bird, M., Anttila, J., 2002. Using ISO 9004 to achieve excellence. In Cianfrani, C.A., Tsiakalis, J.J. and West, J.J. (eds.), The ASQ ISO 9000:2000 handbook, ASQ Quality Press, Milwaukee, USA.
- Burton, N., 2018. The Problem of Knowledge, available at: <https://www.psychologytoday.com/intl/blog/hidden-and-look-for/201806/the-problem-of-knowledge>.
- CEN, 2013. CEN/TS 16555-1 Innovation management - Part 1: Innovation management system, CEN Brussels, Belgium.
- Christensen, C., 1997. The innovator's dilemma. Harvard Business School Press, USA.
- Dahlgaard-Park, S.M., 2011. The quality movement: Where are you going? Total Quality Management & Business Excellence, 22(5).
- Deming, W.E., 1993. The New Economics, MIT Press, Cambridge, MA USA.
- Ellerton, P., 2017. How do you know that what you know is true? That's epistemology, available at: <https://theconversation.com/how-do-you-know-that-what-you-know-is-true-thats-epistemology-63884>.
- Harsh, O.K., 2009. Three dimensional knowledge management and explicit knowledge reuse, Journal of Knowledge Management Practice, 10(2), <http://www.tlinc.com/article1187.htm>.
- ISO/IEC, 2019. Annex L (normative) Proposals for management system standards, ISO/IEC Directives, Part 1 Consolidated ISO Supplement - Procedures specific to ISO, ISO, Geneva Switzerland.
- ISO/IEC, 2004. Guide 2 Standardization and related activities - general vocabulary, ISO, Geneva Switzerland.
- ISO Central Office, 1994. Press release. ISO, Geneva Switzerland.
- ISO, 2018a. ISO 9004 Quality management - Quality of an organization - Guidance to achieve sustained success, ISO, Geneva Switzerland.
- ISO, 2018b. ISO 19011 Guidelines for auditing management systems, ISO, Geneva Switzerland
- ISO, 2018c. ISO 31000 Risk management - principles and guidelines. Geneva Switzerland.
- ISO, 2015a. ISO 9000, Quality management systems - Fundamentals and vocabulary, ISO, Geneva Switzerland.
- ISO, 2015b. ISO 9001 Quality management systems - requirements, ISO, Geneva Switzerland.
- ISO, 2004. ISO Guide 2 - Standardization and related activities - General vocabulary, Geneva Switzerland.
- Kim, O., 2009. What are the four Ways of Knowing (WOKs)?, available at: <http://www.toktalk.net/2009/12/06/what-are-the-four-ways-of-knowing-woks/>.
- London First, 2003. Business continuity, London, UK. [www.thebci.org/London%20First.pdf](http://www.thebci.org/London%20First.pdf).
- Niiniluoto, I., 1999. Critical Scientific Realism, Oxford University Press, Oxford UK.
- Pangaro, P., 2013. Notes on the role of leadership and language in regenerating organizations, available at: <http://pangaro.com/leadership-language-regenerating-organizations.html>.
- Perla, R., Parry, G., 2011. The epistemology of quality improvement: It's all Greek [https://qualitysafety.bmj.com/content/20/Suppl\\_1/i24](https://qualitysafety.bmj.com/content/20/Suppl_1/i24).
- Ries, E., 2011. The lean startup: How today's entrepreneurs use continuous innovation to create radically successful businesses, Random House, New York USA.
- Senge, P., Roberts, C., Ross, B., Kleiner, A., 1995. The fifth discipline fieldbook, Nicholas Brealey Publishing Limited, London, UK.
- Seville, E., 2016. What makes a resilient organization? <https://www.koganpage.com/article/what-makes-a-resilient-organization>.
- von Rosing, M., 2015. Overview of the Business Ontology Research & Analysis, available at: [https://www.researchgate.net/publication/287958619\\_Overview\\_of\\_the\\_Business\\_Ontology\\_Research\\_Analy](https://www.researchgate.net/publication/287958619_Overview_of_the_Business_Ontology_Research_Analy)

## ISO 9004-激励性的质量管理标准，适用于当代可持续发展组织的创新领导者

### 關鍵詞

质量  
质量管理  
ISO 9004  
持续成功  
组织质量

### 摘要

国际管理标准只有在了解了这些标准的预期目的和特征并将其创造性地应用到企业管理中后，才能为组织提供具有挑战性的机会。为此，组织的业务领导者扮演着关键角色。对于这个主题，这篇讨论性文章着重于 ISO 9004 质量管理 (QM) 标准，这是国际管理标准之一，可以应用于各种组织。除了机会以外，本文还讨论与 ISO 9004 标准相关的困难和陷阱，以及在实际实施中的可能解决方案。作者重点介绍了如何将 ISO 9004 视为 QM 标准的 ISO 9000 系列中最具挑战性的标准。但是，许多没有意识到 ISO 9004 和 ISO 9001 标准之间的区别和关系的组织经常以不适当的方式应用 ISO 9000 标准，因此没有能力利用这些标准的潜在机会。尤其是，ISO 9004 从整个业务角度考虑质量管理，并以整个组织的质量为目标。ISO 9004 标准可以提供 QM 指导，即使在复杂，苛刻和瞬息万变的当代商业环境（包括第四次工业革命的挑战）中也能取得持续的成功。本文提供了有关 ISO 9004 实施的想法以及创新的理论和实践观点。目的是强调，根据 ISO 9004，组织的身份及其与众不同的竞争优势是组织质量及其持续成功的基础。在这种情况下，每个组织都有自己并且始终存在的质量管理实现，不能将其与业务管理分开，并且可以根据组织的业务发展策略和实践对其进行持续改进。在这方面，ISO 9004 可以被视为具有灵活性和挑战性。根据作者的经验，可以通过学习组织的原则和实践以最自然的方式实现和制定质量管理目标。除 ISO 9000 标准外，组织还使用其他知名的管理参考，包括卓越绩效模型和特定学科的许多各种管理系统标准。所有这些都可以看作是 ISO 9004 框架内的子域。ISO 9004 还可以用于各种 TQM 和可持续性实施。本文基于作者在各种组织中实际推广和应用 ISO 9000 标准的长期经验。自 1980 年代以来，本文的第一作者就参与了 ISO 9004 标准版本的国际起草过程。大约 20 年前，他还是类似 ISO 9004 文章的合著者。该文章已在 Internet 上公开发布，最近的一千多读者证明了对该标准的日益增长的兴趣。此外，自 2000 年以来，ISO 9004 标准已进行了两次修订，并且最近已完全重写。因此，在本文中重新审查该主题是有充分根据的。

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