



QUALITY STRATEGY OR STRATEGY QUALITY? AN EVALUATION OF THE ADOPTION OF THE STRATEGIC MANAGEMENT IN THE NORM ABNT NBR ISO 9001: 2015

Adelson Pereira do Nascimento¹, Lucilaine Maria Pascuci², Luiz Carlos Nascimento³,
Marcos Paulo Valadares de Oliveira²

1 Federal University of Espírito Santo; Federal Institute of Espírito Santo

2 Federal University of Espírito Santo

3 Faculty of Economics and Administration, São Paulo University

ABSTRACT

Although the literature points out that quality management is closely linked to the strategic management of an organization, it is surprising that the pre-2015 versions of ISO 9001 - reference standard for the implementation of Quality Management Systems (QMS) - did not have mandatory requirements for linking quality management to organizational strategy. This study examines the new revision of the standard, published in September 2015, which incorporates new strategic management requirements aimed at reorienting organizations and their QMS into their business operations. In a first phase, a detailed verification of the changes of the standard proposed by the International Organization for Standardization (ISO), which expects a closer approximation of quality management to strategic management, was carried out. The work also sought to evaluate the implications of this review through the analysis of reviewers of the standard, consultants and auditors of certified companies. The analysis shows that the insertion of strategic management into ISO 9001 can leverage the degree of participation of top management in the effectiveness of QMS of certified companies, systematize strategic management as a routine in these companies and contribute with managers, auditors and consultants, in order to minimize potential impacts on the adequacy of its QMS.

Keywords: Strategy; Quality Management; ISO 9001:2008; ISO 9001:2015.

1. INTRODUCTION

Quality Management (QM) represents one of the most relevant research themes in Administration and Production Engineering. It is often associated with improved performance and customer satisfaction (Saraph *et al.*, 1989; Purushothama, 2010; Rosnah *et al.*, 2010). Some articles highlight the interest in terms of the implementation of Quality Management Systems (QMS) in several sectors of the economy, such as services, manufacturing, health, education and government (Dean *et Bowen*, 1994; Ahire *et al.*, 1996; Douglas *et Judge*, 2001; Singh *et Smith*, 2006; Rosnah *et al.*, 2010). This is proven by the ISO Survey report (ISO, 2014), which indicates that 1,541,983 companies in more than 160 countries have certified their QMS by December 2013 based on the requirements of ISO 9001 (ABNT, 2008).

The massification of the ISO 9001 standard indicates that standardizing the application of continuous quality improvement criteria constitutes a fundamental milestone for the maturity of organizational management (Nascimento, Oliveira, Zanqueto Filho, 2013). However, considering the norm finished and static over time reduces the insertion of emerging and consecrated themes. This happens in such a way that its constant updating and adaptation to the context becomes necessary to maintain the effectiveness of organizations.

The literature points out that the implementation of QMS positively affects organizational performance (Chapman *et Murray*, 1997; Stahl *et Grigsby*, 1997; Sam-



son *et Terziovski*, 1999; *Rusjan et Alic*, 2010) for promoting better product quality, increase customer satisfaction, improve competitive position, and maintain and increase market share of certified companies. Although quality management is conceptualized as a set of internal elements of the organizations, it is verified that the approach has a much broader meaning that incorporates the commercial relationship between the organization and its external environment and, going further, creates mechanisms that tend to involve all the resources of organizations in a systemic and interconnected way to the strategic management of the supply chain (*Paladini*, 2002).

Juran (1992) points out that the objectives of quality management would be the development of strategic quality planning and the involvement of top management in this effort. Such objectives would also include strategic management in the company at a global level (with the participation of departments and their respective specificities) and the inclusion of all company processes in addition to production.

The discussion around the themes of quality management and strategic management is fundamental and appropriate for any type of organization regardless of the product or service offered, since both aim at obtaining operational excellence and competitive advantage, in order to ensure the continuity of the organization (*Shank*, 1997).

In this way, quality management assists strategy management and vice versa, since quality favors the synchronization of manufacturing and competition strategies, particularly in terms of strategic performance objectives of operational environments (*Garvin*, 1992). This is because organizations look for extensions of strategy that leverage the existing system of activities in order to create services or specifications that rivals consider to be impossible to combat on individual performance bases (*Porter*, 1996).

Although the sources of consultation suggest that the topic of quality management is clearly associated with strategic management, it is noted, however, that none of the revisions to ISO 9001 - reference in terms of the request of QMS requirements - released until 2015 were focused on the integration of the QMS with strategic management. This fact had already been raised by *Rusjan et Alic* (2010) in an extensive research, which concluded that even though ISO 9001:2008 was seen as an important instrument of mediation between customer and supplier, it did not establish guidelines for strategic management.

The correction of this fragility of ISO 9001 apparently was corrected in September 2015, and the new version formally links quality management with strategic management in a generalist context. Thus, the standard adopts elements of strategic management as indispensable requirements for the continuous improvement of organizations and customer satisfaction, which refers to the research problem to be answered by this study: Does the new version of ISO 9001, released in September 2015, cover, in alignment with the literature, sufficient elements related to strategic management that contribute to the full integration between quality management and strategic management in certified companies?

2. OBJECTIVES

In view of the exposed problem, this study aims to identify which of the new elements of strategic management are included in ISO 9001: 2015. Consequently, the research intends to assess the implications of introducing these strategic management requirements into QMS. In a more profound sense, it is also intended to verify, through the evaluation of a group of experts, what are the challenges that organizations will have to adopt these requirements and continue to be certified in ISO 9001: 2015.

3. METHODOLOGY

Based on the classification of *Vergara* (2009), this is a research of descriptive nature, which uses a qualitative approach, as it is a documentary analysis. It was carried out from the final version of the ISO 9001:2015 standard, supported by bibliographic research on the subject and structured interviews with specialists who participated in the revision of the mentioned norm. For this, the Delphi technique was used, since it is usually related to the search for a response to a problem that is presented in conditions of uncertainty, with insufficient data or an incomplete theory.

The structured interviews comprised only three questions, and were applied to participants from the states of São Paulo, Rio de Janeiro and Espírito Santo during the period from May to September 2015. The questions defined were:

- 1) Are you aware of the changes to ISO 9001 regarding the inclusion of strategic management items?
- 2) What are the implications of this inclusion from your point of view?



- 3) Have you participated in the review of this standard, through regional and national committees?

Each of the 16 selected auditors and consultants met the following criteria: be certified as a leading auditor in ISO 9001, have more than 10 years of experience in QMS and have knowledge of strategic management. The professionals interviewed are associated to the *Federação da Indústria do Espírito Santo* (FINDES - Federation of Industry of Espírito Santo) and to the Brazilian Quality Committee of the *Associação Brasileira de Normas Técnicas* (ABNT/CB-25 - Brazilian Association of Technical Standards).

The literature points out that, for this methodology, the expert panel is often composed of 10 to 50 members in a homogeneous group. Richardson (1989) believes that the number of participants can be from 10 to 15 if the group is homogeneous. For the composition of the team, the basic criteria used were the experience (minimum of 10 years) and individual training in the area of study (senior level with leading auditor training), plus individual willingness to participate.

4. BIBLIOGRAPHIC REVIEW

4.1. Strategy

Since the 1960s, the conceptualization of the strategy has continued uninterrupted and the terminology has been conceptualized by several authors, such as Ansoff et McDonnell (1993), Andrews (1971), and Porter (1980). It has been defined as the process by which managers, using a long-term projection, evaluate external environmental opportunities, as well as internal capacity and resources, in order to decide on goals and set of action plans to accomplish them.

Whittington (2002), in turn, states that the concept of strategy can arise from four contexts:

- a) Classical approach: older and more influential, it is based on the rational and deliberate process, which believes in the planning for adaptation or anticipation of market changes;
- b) Evolutionary approach: based on biological evolution and anchored in the unpredictability of the environment, it advises strategists to remain low cost and open options, since evolutionists expect markets to ensure profit maximization;

- c) Proceduralist approach: based on organizational learning, where the strategic ones emerge from the intimate involvement with the operations and forces of the organization;
- d) Systemic approach: it reflects the social systems in which it participates, where the strategy path is to act by local rules.

Mintzberg (2006, 2010) brought together some of the approaches found in the literature and classified them into five strategies: plan, standard, maneuver, position and perspective. Strategy as a course of action intended to deal with a situation has the purpose of achieving the basic objectives of the organization. The strategy as a pretext is a tactic used by the company to communicate a false or true message to the market and to overcome a competitor. Now, strategy as a position is a means of locating an organization within the relations of environment, be it internal or external. Strategy as a standard is the consistency in terms of behavior, which arises from the actions of everyday life and may be intended or not. Finally, strategy as a perspective focuses more on the internal environment of the company and diffuses through the thoughts, values and cultures of the organization.

Mintzberg, Ahlstrand and Lampel (2000) outlined the strategy trajectory applied to business practice and proposed the division into three groups according to their characteristics:

- The first group is that of schools of a prescriptive nature, since it is more concerned with the way in which the strategies should be formulated and not in terms of how they were created. The group of schools of prescriptive nature is formed by the schools of design, planning and positioning.
- The second group is composed of six schools of descriptive nature. They consider specific aspects of the strategy formulation process and are less concerned with the prescription of ideal strategic behavior and more with the description of how strategies are, in fact, and how they unfold. This group includes the entrepreneurial, cognitive, learning, power, cultural and environmental schools.
- The third and last group consists of a single school: the configuration school, which seeks to integrate aspects of the different schools according to the various stages of the life of the organization. This school brings together two fundamental facets of the organizational phenomenon: the first (called configuration) describes states of the organiza-



tion and the contexts surrounding it; the second (transformation) describes the process for generating strategies.

For Wit *et Meyer* (2003), the strategy can be seen as a process, content and context. While process, it is concerned with the form, that is, how, who and when the strategy should be done. As content, it wants to know what it is, what the strategy should be for the company and for each of its constituent units. Finally, as a context, the strategy is concerned with where, that is, in which company and in what environment the strategy process should be incorporated.

The definitions of strategy, as well as their classification and trajectory, are varied, but they are not exclusive - on the contrary, they complement each other, since it is perceived that in the literature (Dess, Lumpkin, Eisner, 2007) the term "Strategy" has evolved into a discipline of management knowledge (strategic management), with content, concepts and practical reasons, conquering space in both the academic and corporate spheres.

Lobato *et al.* (2003) argue that the historical evolution of strategic thinking from the 1950s to the 1990s has come about through the development of some strategic paradigms, the diffusion of models for environmental analysis, the use of tools to manage change, and the recycling of previous ideas. The authors emphasize that each school not only encompasses the previous one, but also complements it, correcting limiting aspects or that can distort the whole. The main aspects of each school are described in Table 1.

Mintzberg (1994) observes criticisms of normative and functional strategic management, arguing that any organization has a strategy, even if it is not defined in terms of strategic planning: this is only one way organizations can formulate their strategies, whose fundamental presupposition is the predictability of the environment.

Along the same lines, authors, such as Whittington (2002), point out that strategy must be seen not only as something ready, but rather to be constructed in an incremental vision, since the strategy is treated as everyday practices that aggregate the conceptions and social constructions of the manager.

Although the prescriptive strategy is criticized, some authors, such as Andrews (1991), argue that strategy is the company's decision model, which defines goals and objectives to be achieved and outlines the plan to reach them within an organization. In this context, Prahalad *et Hamel* (1998) affirm that management aims to choose or create opportunities to use the resources of the company in order to create a competitive advantage.

Another methodology that seeks the same competitive advantage is quality management, which has been identified as a very important strategic component for competitiveness, especially when it comes to ISO 9001, a quality management model already consolidated and widespread throughout the world (Priede, 2012).

4.2. Standards for quality management systems and the origin of ISO 9001

The International Organization for Standardization was originated in 1946, when delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization "to facilitate international coordination and the unification of industrial standards" (ISO, 2015a). It is a non-governmental organization based in Geneva/Switzerland that develops voluntary international standards aimed to introduce good practices in organizations so as to make them more efficient and effective. The organization adopted the acronym ISO, since it refers to the Greek term ISOS (meaning "equal") and demonstrates the unifying character of the entity.

Soon after the creation of ISO, the US Department of Defense developed a standardization system called Quality Assurance, in which the organizations involved established procedures to manage all the functions that affected the quality of the manufactured products. These standards gave rise to the 1970 Allied Quality Assurance Publication (AQAP) standards, which were used by the North Atlantic Treaty Organization (NATO). Based on the benefits of the AQAP Standards, the Defense Ministry of England developed the Defense Standards, norms of the Armed Forces that established Quality Systems. Later, the ministry assessed that the application of standards to the Quality Management System was not restricted to the war industry, but should cover other suppliers of materials. In 1979, the International Organization for Standardization - Technical Committee for Quality (ISO TC 176) that was created to standardize concepts and models for quality assurance and provide guidelines for the implementation of quality management in organizations. As quality has become a major business focus around the world, several organizations have begun to establish standards and guidelines for QMS, entailing a diversity of standards that exporting companies should address, even if the product exported to different countries was the same. Thus, it was not long before ISO TC 176 elaborated the ISO 9000 series of quality standards in 1987.

In order to maintain the effectiveness of standards, ISO adopts a system that periodically updates standards. The revisions of the ISO 9000 series occur mainly be-



Quadro 1: Evolução do pensamento estratégico

Conceptualization	Financial Planning	Long Term Planning	Strategic planning	Strategic administration	Strategic management
Description	First phase of the evolution of strategic thinking. Founded in financial control, where top management approved a budget to control business performance over the annual budget. It used the top-down focus, in which there was only one strategist (executive).	It was based on the premise that the future would be estimated from the projection of past to current indicators that could be improved in the long term by interventions in the present. It worked with simple scenario-making methods that were often not adequate to explain more complex facts. The techniques of filling in gaps and the experience curve can be highlighted.	It uses the classic SWOT technique (Strengths, Weaknesses, Opportunities, and Threats). It was developed at Harvard, and is related to the assessment of internal and external environments of the company. There was the formulation-implementation dichotomy, where it was only after full formulation that the strategies were put into practice.	It brought the novelty of showing that the implementation of the strategy was as important as its formulation; it has created and perfected a set of analytical tools to adjust the generic strategy to the conditions of the business environment.	It has provided a more systemic focus to the planning process. In addition to strategically planning, it was also necessary to strategically organize, direct, coordinate and control. It argues that the process will have more chance of success if the organization is in tune with its business environment.
Key Features	Annual budget	Trend forecasting	Strategic Thinking	Analysis of the structure of industry	Systemic Thinking
	Financial control	Gap Analysis	Analysis of changes in the environment	Economic and Competitive Context	Integration between planning and control
	Administração por objetivos (APO - Management by objectives)	Experience curve	Analysis of internal resources and skills	Generic Strategies	Coordination of all resources for the objective
System of values	Fulfill Budget	Scenario study	Resource allocation	Value chain	Strategic organization
	Promote myopia	Designing the future	Focus on formulation	Focus on analysis and implementation	Strategic direction
Problems		Not to predict discontinuities	Define strategy	Determine industry attractiveness	Look for tuning with the internal and external environments
Predominance	1950s	1960s	Lack of focus on implementation	Not to develop systemic approach	Lack of alignment with organizational philosophy

Source: elaborated based on Lobato et al. (2003)



cause this is a non-technical standard that covers management issues and applies to any type of organization, regardless of its size. For this reason, since the initial edition of 1987, the reference standard of the series, ISO 9001, has been revised five times, and its new version - ISO 9001: 2015 is the first major revision since 2000. The 2015 version was launched in 2012 through the participation of hundreds of stakeholders including industry and trade standards experts (consultants, users, testing laboratories, certification bodies, among others), certification bodies, researchers, universities, government, and NGOs, totaling 81 ISO member bodies around the world, as well as thousands of participants in national committees that reviewed and commented on the draft standard during its development (ISO, 2015b). Currently the ISO 9000 series consists of the following standards:

ISO 9000:2015 — Quality Management Systems - Fundamentals and Vocabulary (ABNT, 2015): it describes the fundamentals of QMS and establishes the terminology for these systems;

- **ISO 9001:2015** — Quality Management Systems - Requirements (ABNT, 2015): it specifies requirements for a Quality Management System, in which an organization must demonstrate its ability to deliver products that meet customer requirements and applicable regulatory requirements, with a view to increasing customer satisfaction;
- **ISO 9004:2010** — Quality Management Systems Guidelines for Performance Improvement (ABNT, 2010): it provides guidelines that consider both the effectiveness and efficiency of the quality management system. The purpose of this standard is to improve the organization's performance, customer other stakeholders satisfaction.
- ISO 9001 is the only standard in the series that presents the requirements for certification. This standard focuses on five key areas of quality system management: management responsibility, resource management, product or service delivery, measurement, analysis and improvement.

Regarding the focus of this research, it is observed that the only reference that the previous version of ISO 9001 (ABNT, 2008) related to strategies was in the introductory part, which mentioned:

“...The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system are influenced by: a) its organizational environ-

ment, changes in the environment and the risks associated with it, b) its changing needs, c) its particular objectives, D) the products supplied, e) the processes used, and f) their size and organizational structure... “ (ABNT, 2008 - p. Vi)

It is noted, however, that this introductory part was not part of the certifiable requirements, which were defined from item 4 of the standard - Quality Management System Requirements. Fernandes *et. Al.* (2014) had already warned in a study that aimed to bring ISO 9001 closer to organizational reality that the standard should focus on greater involvement of the top management and respective strategic purposes of organizations. Therefore, the quality policy and objectives must be compatible with the strategic management of the organization, that is, the strategic management was mentioned, but not required in the implementation and maintenance of the QMS certification. Thus, this fact constituted an important motivator for the revision of ISO 9001: 2015.

4.3 The process of changing ISO standards and the new ISO 9001: 2015 standard

The existing rules in ISO aim that the normative reference (norms) is the object of a continuous process of revision, in order to maintain its permanent updating and adequacy in face of the current market.

The process of developing and revising a standard is the responsibility of ISO Technical Committees (ISO/TC) and Subcommittees (SC), and goes through six distinct phases (Paiva, 2011, p. 2):

1st – Proposal Phase: At this stage, the need for the publication of a new standard is verified. The Technical Committees / Subcommittees (TC / SC) will submit a new point of work, which will be expressed on whether or not the development of the new framework is accepted.

2nd – Preparatory phase: There is the appointment by TC/SC of a group of experts and a coordinator who will work on the preparation of a document called “Working Draft (WD)”.

3rd – Committee/commission stage: The “Working Draft” on CD is registered with the ISO Central Secretariat, and then distributed for obtaining comments and, if necessary, for voting by the TC/SC P-members. After reaching consensus on the content, the CD is finalized and submitted as Draft International Standard (DIS).

4th – Auscultation phase: The ISO Central Secretariat distributes the DIS document by ISO members and they have



five months to vote and comment. The document is approved for submission as final draft International Standard (FDIS) if it collects a favorable majority vote of two-thirds of the TC/SC P-members, and if more than one quarter of the total number of votes is not against their approval. Otherwise, the document is returned to the TC/SC for further analysis, and is again put to the vote as a DIS document.

5th – Approval phase: The ISO Secretariat Central sends the FDIS document to all members for a final and decisive vote, they have two months to make a decision whether to accept it or not. Technical comments are no longer accepted at this stage. However, if they exist, they will be registered for future revisions..

6th – Publication Phase: Only minor editorial changes can be made to the final text. The document is sent to the ISO Central Secretariat, which publishes its production as International Standard.

The revised standards are intended to reflect changes in the environment in which they are used and to ensure that they remain adequate for their purpose. ISO 9001: 2015 contains the main items, as shown¹ in Table 2.

4.4. Elements of strategic management incorporated into the new revision of ISO 9001

In evaluating the content of the document in question, it can be seen in Table 3 that the requirements of ISO 9001:2015 now incorporate some items related to strategic management.

It is noted that the standard begins to address issues in terms of how to contextualize the company in relation to the market and its competitors, so that the customer-centered concern is now extended to all stakeholders.

To adopt the new version of the standard, companies usually undergo a transition audit, which must be carried out within the validity period, since no certificate in the 2008 version will be valid as of September 2018.

According to Nigel Croft, chairman of the subcommittee that reviewed the ISO standard, and Nascimento (2016), Technical Coordinator of the Brazilian Committee reviewing the standard, the QMS will be strongly integrated with the organization's business and aligned with its strategic orientation, so that Analyzing the effectiveness of QMS will amount to reviewing the effectiveness of the business (ISO, 2015b).

In summary, Nascimento (2016) emphasizes that the most significant modifications of ISO 9001 in its 2015 version show the insertion of strategic management requirements in the following aspects: Risk-based thinking and change control as the basis for the management system. The standard challenges the organization to pre-analyze its risks in an internal and external context in order to plan an appropriate quality management system. In this context, it is possible to notice a great approximation between Quality Management and Strategic Management.

Another highlight is the monitoring of your business context, focusing on the needs and expectations of stakeholders. This provides opportunities for greater focus on goals such as encouraging improvements to the company's management system and its ability to achieve the intended results. Thus, based on the strategy contexts adopted by Whittington (2002), it can be said that the new version of the standard adopts elements of the classical approach, since it is not only part of a rational and deliberate process, which believes in the planning for adaptation or anticipation of market changes, but also adopts the evolutionary approach: anchored to the unpredictability of the environment, and counseling strategists to keep costs low and options open. It is noted that the proceduralist approach was already part of the requirements of ISO 9001, because it is based on organizational learning.

It is observed that the modifications are related specifically to the planning school described by Mintzberg *et al.* (2000), a functionalist school that has in Ansoff (1993), its main representative. In the planning school, strategic management is focused on programming and is based on the arbitrary formalization. As the requirements of ISO 9001 must be fully implemented to obtain certification, this arbitrariness is assumed in its adoption by the organizations.

The arbitrariness of systems is also highlighted as a negative point by Wit et Meyer (2003), who argue that an adjustment is needed between internal resources and environmental conditions resulting in a wide variety of perspectives among strategists. In this way, organizations develop different traits in the strategy formation process because they differ, as well as the context in which they are inserted.

These changes allow us to conclude that the norm adopts elements of the classical, evolutionary and proceduralist approach, but it is still a failure in terms of the systemic approach: The only missing point in the new revision of the norm is the systemic approach: it does not yet reflect the social systems of which it participates, where the path of the strategy is to act by local rules. Perhaps this point is not perceived precisely because the norm adopts more general characteristics that make pos-

1 The translation into Portuguese was free and preliminary and it was the authors' responsibility.



Table 2 - Summary of requirements of ISO 9001: 2015

Topic of ISO 9001: 2015	Basic description
0 - Introduction 1- Scope 2 - Normative Reference 3 - Terms and Definitions	Introductory part of the standard, with the presentation of the concepts and fundamentals. It presents the process approach, the Quality Management System Model and the PDCA cycle (Plan, Do, Check, Act). It clarifies that it is a requirement standard and therefore it is subject to certification.
Quality Management System Requirements 4 - CONTEXT OF THE ORGANIZATION	It comprises a new set of mandatory requirements, strongly related to strategic management. Defines that the company must before establishing, documenting, implementing and maintaining its QMS, know your organization: 4.1 understanding the organization and its context; 4.2 understanding the needs and expectations of stakeholders; 4.3 determining the scope of the quality management system; 4.4 Quality management system and its processes. It is based on the analysis of the internal and external environment and the needs and expectations of stakeholders as a prerequisite for the elaboration of the Quality Management System. It is equivalent to the Plan stage of the PDCA cycle.
5- LEADERSHIP	It details the requirements related to the leadership role in the elaboration and maintenance of the QMS, in particular the commitment of the Management and the focus on the client. It establishes that the company must define a quality policy and objectives, ensuring that organizational rules, responsibilities and authorities are defined and communicated throughout the organization and that senior management must critically review the QMS to ensure its continued suitability, sufficiency and effectiveness. Requirements: 5.1 leadership and commitment; 5.1.1 leadership and commitment to the quality management system; 5.1.2 focus on customers; 5.2 policy; 5.3 roles, responsibilities and organizational authorities. It is equivalent to the Plan stage of the PDCA cycle. Compared with the 2008 review, this version highlights the role of management in conducting the QMS.
6- PLANNING	It comprises a new set of mandatory requirements, strongly related to strategic management. It establishes that the organization should define: 6.1 actions to address risks and opportunities; 6.2 quality objectives and planning to achieve it; 6.3 planning changes. The only equivalent item in the previous version relates to the establishment of Quality Objectives, which is also strongly aligned with strategic management. It is equivalent to the Plan stage of the PDCA cycle.
7- SUPPORT	It comprises a new set of mandatory requirements, strongly related to strategic management. Mainly in relation to the requirements: 7.1.4 - Environment for the operation of processes and 7.1.6- Organizational knowledge. The set of requirements establishes that resources must be managed so that the processes have their goals achieved. The need for human resources, infrastructure work environment must be determined. It emphasizes the need to assess competence, training and awareness to ensure compliance: 7.1 Resources; 7.1.1 Generalities; 7.1.2 People; 7.1.3 Infrastructure; 7.1.4 Environment for the operation of the processes; 7.1.5 Monitoring and measurement resources; 7.1.6 Organizational knowledge; 7.2 Competence 7.3 Awareness; 7.4 Communication; 7.5 Documented information. It is equivalent to the Plan stage of the PDCA cycle.
8- OPERATION	This set of 24 requirements is directly related to the product realization (part of the PDCA cycle) and establishes mechanisms for the conformity of products and services, from its development project, to the delivery to the customer. It involves the following items: 8.1 planning and operational control; 8.2 determination of the requirements of products and services; 8.2.1 communication with the customer; 8.2.2 determination of requirements related to products and services; 8.2.3 critical analysis of requirements related to products and services; 8.3 design and development of products and services; 8.3.1 general; 8.3.2 development design and planning; 8.3.3 design and development inputs; 8.3.4 design and development controls; 8.3.5 design and development outputs; 8.3.6 changes in design and development; 8.4 control of externally supplied products and services; 8.4.3 information for external suppliers; 8.4.2 type and extent of external supply control; 8.5 production and service provision; 8.5.1 production control and service provision; 8.5.2 identification and traceability; 8.5.3 property belonging to customers or external suppliers; 8.5.4 preservation; 8.5.5 post-delivery activities; 8.5.6 change control; 8.6 delivery of products and services; 8.7 control of products and services and non-conforming process outputs.
9- PERFORMANCE EVALUATION	It contains the requirements for control (monitoring and measurement) of the QMS and it involves: 9.1 monitoring, measurement, analysis and evaluation; 9.1.1 general; 9.1.2 customer satisfaction; 9.1.3 analysis and evaluation; 9.2 internal audit and 9.3 critical analysis. Equivalent to C (Check) of PDCA.
10 - IMPROVEMENT	It contains the requirements for improvement and correction of deviations in the QMS and it involves: 10.1 generalities; 10.2 non-compliance and corrective action and 10.3 continuous improvement. The only change in this set of requirements concerns the withdrawal of the item preventive actions, existing in the previous version. It is equivalent to PDCA element A (Act).

Source: prepared based on ISO 9001: 2015 (ABNT, 2015)



Table 3 - Relationship between the requirements of ISO 9001:2015 and Management

ISO 9001: 2015 requirement	Requirement Summary	Relationship with strategic management
4.1 Understanding the organization and its context 4.2 Understanding stakeholder needs and expectations 4.4 Quality management system and its processes	The organization shall determine internal and external issues that are relevant to its purpose and strategic orientation and which affect its ability to achieve the desired result (s) of its quality management system. The organization shall monitor and analyze information on these external and internal issues. It should also determine the following: stakeholders who are relevant to the quality management system; the requirements of these stakeholders that are relevant to the quality management system; and risks and opportunities, in accordance with the requirements of 6.1, and to plan and implement the actions required for its resolution;	Associated with internal and external analysis (SWOT); Business analysis and stakeholder needs assessment;
6 Planning 6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them 6.3 Change Planning	“When designing the quality management system, the organization shall consider the problems referred to in point 4.1 and the requirements referred to in point 4.2 and determine the risks and opportunities that need to be addressed: (a) to ensure that the quality management system can achieve its intended result (s); (B) avoid or reduce undesirable effects and; C) achieve continuous improvement. The organization shall establish quality objectives in relevant functions, levels and processes. When the organization determines the need for change in the quality management system (see 4.4), the change must be planned and systematic.	Associated with the analysis of external factors (Political, Economic, Social and Technological) to the 5 forces (PORTER, 1996), the Critical Success Factors and the BSC - Balance Score card;
7 Support 7.1 Resources 7.1.6 Organizational knowledge	The organization must determine the knowledge necessary for the operation of its processes and achieve the conformity of products and services. This knowledge must be maintained and made available as necessary. When addressing needs and trends, the organization should consider its current knowledge and determine how to acquire or access the additional knowledge needed.	Associated with organizational skills

Source: prepared on the basis of ISO 9001: 2015 (ABNT, 2015)

sible the standardization of organizations in a global context. It is precisely this vulnerability that distances the norm from the four contexts of the strategy pointed out by Whittington (2002).

5. EXPERT OPINION ON NEW REQUIREMENTS

Aiming at a greater practical focus on the changes observed, structured interviews were conducted with the group of experts: Lead auditors and consultants (linked to the Federation of Industry of Espírito Santo - FINDES) and reviewing members of CB-25 (Brazilian Committee for the revision of ISO 9001 - linked to INMETRO)² to verify the implications for the companies certified in the standard. In general, the analysis of the experts shows that although the ISO 9001 standard is a robust manage-

ment model, in addressing other consolidated practices such as strategic management, the standard leverages the degree of responsibility of certified companies and systematizes strategic management as a routine in certified companies.

The greatest advantage, according to experts, lies in the opportunity to create a quality culture with a strong link with the organization's strategy, because in many organizations the strategy is restricted to senior management (managers or executives) and Quality management “democratizes” the planning and actions of the company, making everyone understand that they work for the market and that without it, any action does not make the least sense, including the company itself. The perception they have is that strategy is restricted to top management and quality is better disseminated. Once the quality standard establishes requirements, the strategy becomes better known.

The auditors also point out that ISO 9001: 2015 will be easier to use, particularly in conjunction with other management system standards, as it has become more users friendly with simplified language. Auditors point

² ABNT/CB-25 - Brazilian Quality Committee of the Brazilian Association of Technical Standards - aims to produce and disseminate the standards of Quality Management and Quality Assurance and Conformity Assessment systems and their related techniques. It is available at <http://abntcb25.com.br/sobre-abnt-cb-25/institucional/>



out that the new version of the standard will demonstrate more consistently whether the certified organization is achieving its planned results, and whether the system is actually delivering on its promise and is aligned with the organization's strategic objectives. This was also highlighted by Nigel Croft, chair of the subcommittee that revised ISO (ISO, 2015a).

Other benefits pointed out by experts and interviewees concern the possibility that certified companies will have to see outside the institution. The 2008 version focuses heavily on the customer and internal processes and now it is back in the same intensity for the market, competitors and stakeholders. This broader view brings more stability to the system and preparedness for any environmental changes. According to the interviewees, the new version combines the success of the "process approach" with a new concept of "risk-based thinking" to prioritize processes, employing the Plan-Do-Check-Act (PDCA) cycle at all levels of the organization in a strategic manner to manage the processes and the system as a whole and lead to improvement.

As limitations, experts state that certified companies that do not have Strategic Management should invest more time in the preparation of their QMS, and that the speed of scenario changes may lead to successive revisions in the Quality Management System documentation. The procedures will reflect a strategy that can change frequently and with some complexity, increasing the cycle of revisions of documents required by the QMS and increasing the risk of obsolete documents in use.

Another challenge will be the determination and negotiation of risk control under a macro view, not just the processes, as in the previous review. With this, change management will be strengthened in the new ISO 9001: 2015, and the risk analysis will have to be performed, when changes occur.

Another challenge will be organizational culture. We may find it difficult for companies to understand what the standard means by this new strategic approach. Some auditors fear that some companies may present a SWOT matrix and a generic risk matrix suggested by an exter-

nal consultant with a shallow knowledge in terms of the entire organization, which may lead to a misalignment of the strategy with operational practices. The interviewed experts point out, however, that this is not a vulnerability of the norm, since it becomes less prescriptive. According to the interviewees, the adoption of "ready models" of QMS will be a practice that will be abandoned, since the standard requires the clear understanding of the organization and its internal and external context.

Nascimento (2016), who represented Brazil in the international discussions and coordinated the Brazilian group in the revision of ISO 9001, summarizes that the new version of the standard brings significant impacts on the organization, certifiers and auditors, as described in table 4.

Finally, according to the experts interviewed, this review will initiate a new cycle of business decision-making. The standard prescribes strategic management items as mandatory and broadens the decision making level, since it establishes relationships with all groups of strategic objectives: guarantee of customer satisfaction, effective implementation of the process, focus on risk, need for organizational learning and positive financial effects. Previously, in the 2008 version, QMS was viewed narrowly as a way to help organizations increase customer satisfaction. This new review may start the process of forming a strategic culture, in which the Direction sees the long term and thinks about the positioning of the company in front of the environment, making everyone contribute to the strategy.

6. FINAL CONSIDERATIONS

The objective of this article was to identify the implications for organizations currently certified in the certification process, with the insertion of new strategic management requirements in ISO 9001: 2015. In this sense, it was identified that this standard prescribes eight new requirements that involve the establishment of strategic management for companies that wish to have their QMS (QMS) certified.

Table 4 - Impact of ISO 9001: 2015 revision for different audiences

Organizations	Certifiers	Auditors
Greater emphasis on effective senior management involvement in the QMS; Integration with business objectives; Risk management at all levels and stages.	Update criteria for certification Adopt more restricted criteria to provide auditors with the ability to audit strategic management.	Enable auditors to audit senior management as a key process; Audit requirements of products and services and link this audit to the results of the organization; Audit without documents (less paper)

Source: Elaborated on the basis of Nascimento (2016)



According to the experts interviewed, there was a great expectation in terms of the new revision, in the sense that the standard being used as a base in the strategic decision in order to support the leadership as a strategic management tool.

The new version of the standard appears to have been designed to address the disparity between planning and implementation: A strategy can be effective at the time it is being planned, but it can generate unexpected results as complexity increases when it is put into practice. There is a so-called disparity between the planned change and the emerging evolution: the goals achieved successfully and the break-up of marginal opportunities, neglected for the simple reason that they are not calculated in advance, and thus do not constitute in the elaborated plans; The disparity between means and ends: instead of reflecting the intertwining and mutually constituting means and ends, what must be done is to separate them and thereby simplify their complex interrelations; The disparity between a planner mind (the management) and a planned body (the organization) and finally the disparity between order and disorder: Strategic planning is necessary, otherwise the organization drowns in chaos and thus the strategic agenda requires discipline and continuity; its enemies are deviations and lack of commitment, however, chaos, constant change and noise make it more refined rather than destroyed. In this sense, experts point out that change management has also been inserted in the new ISO 9001, as a guide between planned and changing reality.

Some of these implications have been mentioned by the experts interviewed and concern the time that will be invested by the organizations in the preparation of their QMS, and that the speed of scenario changes may lead to successive revisions in the Quality Management System documentation. As the standard becomes less prescriptive, this consequence has been minimized. Another challenge will be the determination and negotiation of risk control under a macro view, not just the processes, as in the previous review. Another challenge addresses the issue of organizational culture. Some auditors fear that some of the companies will use external consultants to develop the strategic management pillars and because of the superficial knowledge of these consultants about the organization, management does not start in a comprehensive way.

In general, the experts' analysis points out that the new version of the ISO 9001 standard leverages the degree of responsibility of certified companies and systematizes strategic management as a routine in certified companies, with the opportunity to create a culture of quality with a strong bond with the organization's strategy.

These observations allow us to point out that the norm adopts elements of the classic, evolutionary and proceduralist approach, but it is still a failure in terms of the systemic approach: it still does not reflect the social systems in which it participates, where the strategy path is to act by local rules. Perhaps it is precisely the globalized nature of the norm that prevents it from being readily adaptable to the local context. Nevertheless, it is observed that the new version of the standard has sufficient elements of strategic management that can contribute to the full integration between Quality Management and Strategic Management in certified companies and in certification process.

It is concluded that Quality Management is closely linked to strategic management and that the insertion of strategy requirements in ISO 9001: 2015 will certainly bring challenges to certified companies, but will consolidate these two disciplines more comprehensively and routinely in organizations. It is suggested to carry out studies that can demonstrate empirically this relationship, after a considerable number of companies are certified in the new review.

Finally, the contributions of this article refer to the expectations of consultants and auditors regarding the maintenance of company certificates in the face of the new strategic management requirements included in the ISO 9001 standard and the need for new empirical investigations about the relationship between quality certification and the achievement of organizational strategies.

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