GUIDELINES FOR THE IMPLEMENTATION OF A QUALITY MANAGEMENT SYSTEM IN INDUSTRIAL COMPANIES

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Abstract - This article presents an implementation guide of a quality management system based on the family of ISO 9000 standards, according to the 2015 revision of ISO 9001. In line with the literature review, the study is based on a case study on the mechatronics sector. The presented implementation guide allows managers, technicians, academics and students, a practical reflection on the implementation of a quality management system in order to obtain a competitive advantage in the increasingly globalized market, requiring to the industry a solid foundation in terms of sustainability.

Keywords: Quality Management Systems, ISO 9001, Management Standards, Mechatronics Industry, Continuous Improvement, Firm Competitiveness.

1. Introduction

In a market increasingly competitive, where organizations suffer from the pressure of competition, there is a need to find ways of management in order to adequately respond to new challenges. The optimization of resources and skills in order to achieve better performance is the main goal, thus resulting in the need to integrate management systems.

Increasingly firms implement ISO (International Organization for Standardization) management standards as a strategic initiative to remain competitive through continuous improvement of its processes [1]. Given the strategic nature of ISO standards implementation, the

question becomes how can ISO management systems be used to improve organisational practices and firm competitiveness?

Despite the increased number of ISO management systems certified organisations, such questions are being asked by an increasing number of managers. In the view of some, the adoption of ISO management standards is equivalent to ensuring the implementation of efficient, proven practices. For others, these systems have a debatable impact, representing a marketing tool that may lead to negative consequences within organisations [2], [3]. In fact, ISO 9000 quality system certification has been widely applied around the world, but with mixed success [4]. Some academic research concludes that ISO 9000 certification increases bureaucracy and reduces innovation, and that the most important benefit gained from ISO 9000 certification is improvement of internal processes. On the other hand, ISO 9000 certification may be more productive in stable environments where process innovation is more prevalent. However, managers are striving to reduce variation of their processes and hence improve quality and delivery of their products in full on time, in order in order to increase customer satisfaction [4].

Industrial firms often operate in turbulent environments characterized by intense competitiveness, constant technological progress, new market requirements, and scarce natural resources. This scenario imposes the constant need for change in the operation and firms' management. The implementation of certifiable management systems is an effective alternative in this sense [5].

The paper presents in section 2 a synthesis of the theoretical framework, in section 3 comes the methodology, followed by guidelines for implementation in section 4 and finally, the conclusions in Section 5.

2. Synthesis of the theoretical framework

The globalization of the world economy and the expansion of international trade has led companies to implement quality management processes, which have become a crucial part of manufacturing industries' competitiveness [6], [7]. With more than 1.1 million certificates issued worldwide, ISO 9001 is the standard used [8]. The ISO management standards are a set of requirements that organizations must meet in order to receive a certificate of compliance. In this process, independent auditors from third parties determine if the standards have been met, and issue a certificate of compliance if a facility met the requirements [3]. The standard was first published in 1987 and then revised in 1994, 2000, 2008 and 2015 [8], [9].

According to a number published studies, ISO quality management systems comprise rather specific recommendations. However, they are far from explicit in their method of application, affording managers a great deal of leeway, also giving them the possibility of increasing bureaucracy and loss of organizational flexibility [2], [3]. Tendentiously, most studies on the impact of ISO management systems ignore the drawbacks, focusing instead on restrictive performance criteria: increased sales, quality improvement of internal processes, internationalisation of firms, implementation of quality policies, etc. Moreover, the positive and negative impacts of ISO management systems were not a foregone conclusion, depending rather on generally overlooked factors [2].

Quality standards contain guidelines that seem to adapt to a wide variety of industrial cases [2]. ISO management standards share common features, making them structurally compatible (e.g. ISO 9001 - Quality Management Systems (QMS) and ISO 14001 - Environmental Management Systems). They share the same requirements for document control, management policy, operations control, training, auditing, monitoring and evaluation [3].

Nowadays, quality management is considered to be suitable as support for the integration of sustainability considerations in areas such as product development, transversally to different sectors of activity. The Brundtland Commission's report [8], entitled "Our common future" sustainable development expanded to include not only environmental concerns, but social and economic dimensions Also. In these areas, the requirements of ISO 9001 can provide a starting point for the implementation of good organizational practices [10].

Terziovski and Guerrero [4] demonstrates a positive impact of the quality system certification in industrial performance through internal restructuring procedures, development of the internal customer concept, or through the adoption of recycling and reuse practices, leading to increased eco-efficiency. Many manufacturers understand that improved quality systems are extremely important in gaining greater global competitiveness. Their customers are increasingly demanding. In addition, the quality management systems can contribute to the increment of improvement of internal processes and development of new industrial projects [11]–[14].

The revision of the ISO 9001 encourages firms to implement changes in their quality management systems, in order to better understand the environmental context, identifying stakeholders [15], [16], developing projects and networks of cooperation between academia, business, national and regional governments and non-governmental organizations, anticipating risks and finding opportunities to build sustainable performance strategy [8], [10], [17].

3. Method and research position

Overcoming the gap in the literature in terms of the presentation of implementation guides for quality management systems, in particular, based on the 2015 ISO 9001 revision, this article follows an approach based on an interpretative case study, applied to mechatronics industry.

The unique application of quantitative methods cannot capture the essence of phenomena in certain areas of greater complexity, such as in the areas of quality management applied to industry, critical in research to produce new insights [18].

Through the case study, this research strives to present an implementation guide for a quality management system applied to industrial reality in the mechatronics industry, in line with the literature review in this area and based on the review of ISO 9001 in 2015.

The unit of analysis of this case study is a SME located in the Centro region of Portugal, which operates in the mechatronics industry, producing forestry equipment, agricultural and other equipment for the industry generally. The company operates in the domestic market, exporting to other European countries, Brazil and Indonesia.

This case study involved the participation of an intern finalist degree in Industrial Engineering from the Technology School of the Polytechnic Institute of Castelo Branco (IPCB), at Portugal. For about two months, the trainee captured information on industrial site, establishing informal contacts with operators and managers, while observed the functioning of internal processes and procedures. The same information was systematically supervised by his supervisor at the IPCB and his tutor in the company.

4. Guidelines for quality management system implementation

The proposed guidelines have a greater degree of specialization and detail than the generic orientations of the ISO standards. However, these guidelines are not closed and fixed requirements and allow tailoring of the systems to the specific reality of the industrial firms (culture, organizational structure and availability of human, technological and financial resources, specific activity sector, etc.).

The guidelines can be applied to companies of any size or industrial or services specific sector, in the same manner as the standards that served as a reference for the present study. However, in small-scale firms, despite financial and personnel restrictions, there is greater flexibility in the organizational structure, fewer hierarchical levels, and decision-making can sometimes become faster [5].

While developing these guidelines for companies, the focus must be on eliminating bureaucracy from the processes and increased organizational flexibility so as

to not affect the processes of decision making and innovation dynamics.

Although new procedures and documents are being generated in many cases, it is important to simplify the language, structure and, if necessary, the method of filling out documents. In general, illustrations (figures, photos, graphics, large placards of information in the plant, summarized information sheets, and plans) can contribute to an improved comprehension of the message (see figure 1).
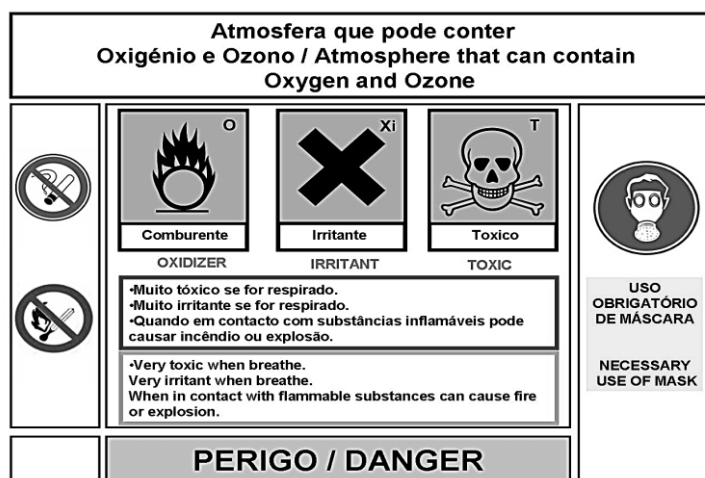

Figure 1 - Example signaling plate placed in the work area

To implement a Quality Management System according to ISO 9001: 2015 should be based on four pillars: quality management principles, process approach, risk-based thinking and Plan-Do-Check-Act (PDCA) cycle.

ISO 9001: 2015 is as fundamental pillars the seven principles of quality management [19]:
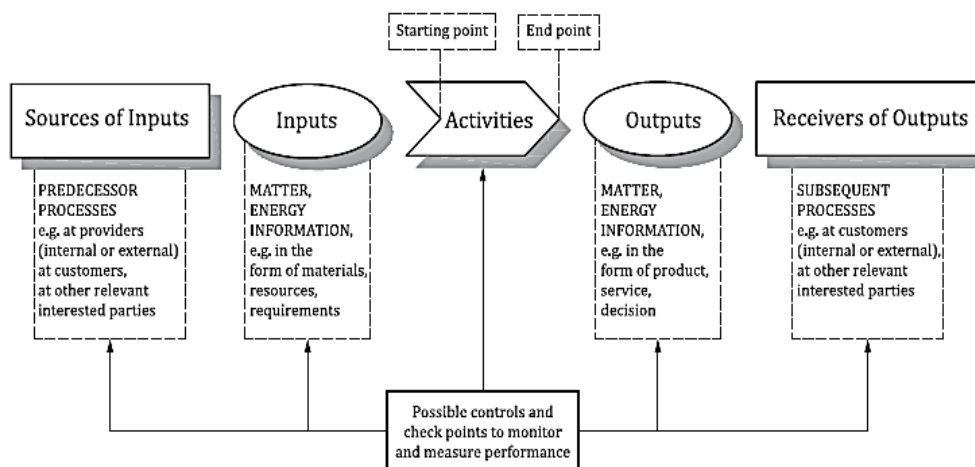

Figure 2 - Schematic representation of the elements of a single process
Source: ISO 9001:2015 [19]

- **Customer Focus** - The primary focus of quality management is the satisfaction of customer requirements and the effort to exceed your expectations;
- **Leadership** - Leaders establish, at all levels, unity in purpose and direction and create the conditions for people to commit themselves to achieving the organization's objectives;
- **Commitment of People -** It is essential for the organization that people are competent and equipped with the respective authority to make decisions independently and committed to add value to the company;

- **Process Approach -** Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that act as a coherent system;
- **Improvement -** Organizations that succeed are constantly focused on improvement;
- **Decision Making Evidence-Based -** It is more likely that decisions based on analysis and evaluation of data and information to produce the desired results;
- **Relations Management -** To have sustained success, organizations and companies generate its relations with stakeholders, such as suppliers.

The process approach is one of seven quality management principles on which ISO 9001 is based. According to ISO 9000:2015, a process is a set of interrelated or interacting activities that transform inputs the desired outputs (see figure 2).

The Organization or company defines the various inputs necessary for the effective implementation of the process (including raw materials, components, tools, knowledge, information, etc.) and the expected outputs (such as products and intermediate or final services, reports, information, etc.) . These inputs and outputs can be external or internal to the organization. Processes are usually interconnected with the output of a process typically serve as input in another

The focus on risk-based thinking is integrated throughout the ISO 9001:2015. According to this thinking, an organization needs to identify the risks and hence the opportunities associated with their activities and take steps to reduce the risks of producing non-compliant products and services.

The Organization should prioritize the QMS activities and processes according to their potential impact on desired outcomes, and seize the opportunities that will presenting. The risks and opportunities to be determined and treated are those who: may affect the ability to achieve the desired results of the QMS; potentialize desirable effects; they have the potential to cause unwanted effects, should be prevented or reduced; allow get improvements.

Are examples of risks: nonconforming Product delivered to the customer; failure to provide the customer: deadlines, quantities; customer dissatisfaction; failure to meet the Organization's requirements: the level of QMS processes, the quality policy, objectives, among others; complying with the legal requirements of products and services.

Examples of opportunities: new or improved products and services; increased customer satisfaction by anticipating needs and expectations; providing more robust processes or increased productivity by incorporating new technologies, new equipment, etc.; improvements in the QMS processes, faster, increasing efficiency by changing working methods, etc.

According to certain risks and opportunities, the organization must: to give confidence to the quality management system can achieve the desired results in view of the risks identified; increase the desirable effects by reducing and risk monitoring, as well as maximizing the opportunities identified through the implementation of actions; prevent or reduce the undesirable effects by analysing the effectiveness of the implemented actions associated risks and opportunities; and get improved by reducing and monitoring risks and maximize opportunities. In summary, Table 1 shows the main changes in the revision of ISO 2015 due to the 2008 edition:

Table 1 – Main terms differences between ISO 9001: 2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used
Management Representative	Not used
Documentation, quality manual, documented procedures, records	Documented information
Workplace	Environment for the operationalization of the processes
Monitoring and measuring equipment	Monitoring and measurement capabilities
Product Purchased	Products and services from external suppliers
Supplier	External supplier

Source: Elaborated from ISO 9001:2015 [19]

Based on the requirements of ISO 9001: 2015 to facilitate the reader's understanding, it is enumerated the set of standard requirements aligned with each of the principles of the QMS:

- **Principle 1: Customer Focus -** Standard requirements

4.2	Understanding the needs and expectations of stakeholders
5.1.2	Customer Focus

5.3	Roles, responsibilities and organizational authorities
8.2	Requirements for products and services
8.3	Design and development of products and services
8.5.3	Property customers or external suppliers
8.5.5	Subsequent delivery activities
9.1.2	Customer satisfaction

- **Principle 2: Leadership -** Standard requirements

5.1	Leadership and commitment
5.2	Policy
5.3	Roles, responsibilities and organizational authorities
7.3	Awareness
7.4	Communication
9.3	Management review

- **Principle 3: Commitment of People -** Standard requirements

5.1.1	Leadership and commitment
5.3	Roles, responsibilities and organizational authorities
7.2	Skills
7.3	Awareness
7.4	Communication

- **Principle 4: Process Approach -** Standard requirements

4.4	System of quality management and their processes
5.1.1	Leadership and commitment
5.3	Roles, responsibilities and organizational authorities
6.1	Actions to address risks and opportunities

- **Principle 5: Improvement -** Standard requirements

5.1	Leadership and commitment
5.2	Policy
6.1	Actions to address risks and opportunities
9.1	Monitoring, measurement, analysis and evaluation
10	Improvement

- **Principle 6: Decision Making Evidence-Based -** Standard requirements

4.1	Understanding the organization and its context
4.2	Understanding the needs and expectations of stakeholders
4.4	System of quality management and their processes
7.1.5	monitoring and measurement capabilities
9.1	Monitoring, measurement, analysis, evaluation

- **Principle 7: Relations Management -** Standard requirements

4.2	Understanding the needs and expectations of stakeholders
7.4	Communication
8.4	Control of processes, products and services from external suppliers

The implementation guide of quality management system that we describe is structured by sequential steps of implementation, based on the requirements of ISO 9001: 2015:

- **Step 1 - Recognition of the Initial Situation** - This step is intended to meet the Organization's current status in terms of quality. The first phase is to analyse what the organization does and how it does, identifying their critical processes and sub-processes any of these processes. A simple and effective way is to draw flow charts of the main activities in order to view the main processes. In the second phase the organization should conduct an audit of diagnosis regarding the quality aspects related to its processes, suppliers, products or services, identifying the regulatory requirements related and verifying the degree of compliance as well as others that the organization possibly want to subscribe .

- **Step 2 - Sensitization Management** - In this step we present the results of initial diagnosis. Top management and responsible for the implementation of QMS project present the results of the initial diagnosis trying to sensitize directions to the advantages of implementing a quality management system. The Organization should begin to give proper training to its directors and middle managers. The responsible for the effective implementation of the system, you may need to have training in management systems and the requirements of the standard. In addition to training is essential to promote awareness-raising for the largest possible number of employees in order to achieve the accession of all and the good cooperation of each to the project.

- **Step 3 - Quality Policy Definition** - At this stage the Organization defines its quality policy. The Organization defines its policy for the quality should take into account the reality of the organization (a result of the initial diagnosis), to be adapted to their needs, and shall ensure that top management commitment and participation of all employees. It is through the quality policy that the top management formalizes Organization's commitment to ensure that quality is a top priority, combined with the vision and strategy of the company. By that business goals are quality objectives, the organization's vision being the backbone of the system and the policy and quality objectives of its development. The Organization shall establish its view, based on the internal question in relation to its position in the future in a simple way: "Where we want to go?" The political and born objectives of this response and in

conjunction with the Organization's strategy (the "How do we get there?").

- **Step 4 - Definition of Project Team** - At this stage the organization analyses the work that has to be done and who can do it. After assessing the skills you have, the Organization decides on the need to hire outside help.
- **Step 5 - Definition of Implementation Plan** - At this stage the Organization defines the implementation plan. The Organization establishes the objectives of the project, defines its schedule, skills and individual responsibilities of each member of the project team, the form of monitoring of project progress and frequency of follow-up meetings with the representative of the top management.
- **Step 6 - Project Team Training in QMS -** At this stage, the Organization providence specialized training in order to provide the project team with the skills needed to develop the project (Quality management processes, document management, systems management, etc.).
- **Step 7 - Planning -** At this stage we proceed to the project planning. By analysing the requirements of the standard, usually, the Organization finds that a significant part of the requirements already a common practice. It is time to compile the existing internal documentation. However, it is necessary to make the framework in accordance with the requirements in the standard, improving some of the existing practices in order to show compliance with the requirements and writing the way they perform (or will hold), control and record the activities.
- **Step 8 - Implementation and Operation -** At this stage we proceed of project implementation. For the system to work, it is essential to involve all employees. The awareness-raising / training should disclose the policy and the objectives and goals to be achieved and clearly explain what is expected of contributions (disciplined) each to the success of the system, collecting ideas, suggestions, retaining situations and indicator occurrences the need for immediate corrective action or preventive action. It is important to stress that any employee can propose changes to the system, but that all changes have to be properly approved. The requirements that are not part of the Organization's daily practices have to be analysed and adapted to the organization. You must do it in a simple and practical way, without forgetting the need for clear and carefully explain to their users. It is important at this stage of confusion due to the amount of documents that may possibly be necessary to draw up, not create useless papers or invent unnecessarily complicated ways to show a control or a record. In order to encourage all employees and the top management it is advisable that the project team prepare monthly a newsletter giving news of the project advances.
- **Step 9 - Checking and corrective action -** At this stage makes up a critical analysis of the system as to achieve its objectives and create the mechanisms for

the systematic and continuous monitoring in order to act proactively on the system. Develop and implement to the control procedures of documents and records, non-conformities, corrective and preventive actions and audits. With internal audits seek to be objective evidence to confirm the effectiveness and compliance of what is being done or identify deviations so that in time we can act on them correcting them. This process culminates in the review of the top steering system, by considering data monitoring results and indicators on the performance of the Organization. It made the overall assessment of the effectiveness of the quality management system to achieve the goals set. This phase also provides the opportunity for the organization to take steps forward, drawing new and more ambitious goals.

- **Step 10 - Certification of QMS -** This step is required an external audit of the certification body in order to ensure that the system meets the requirements of ISO 9001 reference standard. Certification should not be the sole purpose of implementing the system, should be the final step, which is given when the system is already "rotated", i.e., when he completed a full Deming cycle (PDCA) and with satisfactory results. The advantages of certification are evidence, clear to the employees, customers, and other stakeholders the efforts of the Organization in terms of quality. To these, added advertising advantages as a certified company can use the brand of the company certified in documents and in advertising / marketing. For a company require a certification audit must make an application package to send to the certification body. This file, although slight variations depending on the certification body is essentially made up of the following documents: certification request to the certification entity (entities have their own draft for its formalization); documented information required by ISO 9001; Organization Chart of the Organization; simplified premises layout, in the case of industrial entities (if available); map or road layout with the location of the Organization; list of legislation identified as applicable for the organization and identification of specific commitments that the Organization has subscribed; list of measuring and monitoring equipment (by type of equipment and indication of the cases where it is used).

5. Conclusions and Managerial Implications

This article describes the fundamentals of QMS according to ISO 9000 family of standards, based on the ISO 9001 reviewed in 2015: Quality management systems - Requirements.

The results of the study, in line with the literature review reveals that the implementation of a quality management system can lead to a significant improvement in the performance of organizations, both in terms of process optimization, facilitation of

collaborative dynamics with stakeholders or yet in terms of improving customer satisfaction.

In practical terms, the article presents the significant differences between the revisions of ISO 9001 Standard occurred in 2015 compared to the 2008 version.

The implementation guide presented in this study follows the four pillars basis of standard ISO 9001: quality management principles, process approach, risk-based thinking and Plan-Do-Check-Act (PDCA) cycle; reorganizing the requirements of normative reference from the seven principles of quality management: Customer Focus, Leadership, Commitment of People, Process Approach, Improvement, Decision Making Evidence-Based, and Relations Management.

Designed from the literature review and the observation of good practices in industrial context, this guide presents ten steps to implement a QMS, since the recognition of the initial situation, where the organization seeks to identify their current status on robustness of its quality management system, to enable it to draw up a whole work plan; to the final stage, which results in a request for audit in order to obtain certification.

This study presents a contribution to the literature on quality management area, helping managers, technicians and academics to reflect on the implementation of QMS in organizations successfully and not only as an ad of paperwork and loss of competitiveness, or the level of barriers to new dynamics of innovation or in the areas of speed in decision making.

Future research work should investigate other case studies in industrial context, so you can make comparisons of results and thus be able to contribute to the strengthening of the literature in this area.

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