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Supporting the Functioning of the ISO 9001:2015 Quality Management System With Lean Management Principles

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Abstract:

Purpose: *The article compares the chapters (areas) of the ISO 9001: 2015 quality management standard with the principles of Lean Management in order to identify opportunities for enhancing quality management systems based on this standard, both in the context of quality management and in the context of business process management.*
Design/Methodology/Approach: *The aim of the study was to identify common areas of coexistence between Lean Management principles and the individual chapters (areas) of the ISO 9001: 2015 standard. The theoretical and cognitive objective was to conduct a substantive review of the literature and scholarly studies in the field of holistic quality management. The analysis of the presented problem revealed previously unidentified potential for applying Lean Management principles to improve the functioning of specific areas of management structured within the ISO 9001: 2015 standard.*
Findings: *The conclusions drawn will enable enterprises operating based on the ISO 9001: 2015 quality management system to increase the likelihood of achieving both quality and economic effectiveness in individual areas, as their functioning will be enhanced by the incorporation of Lean Management principles.*
Practical implications: *The principles of Lean Management have been presented in a form that enables their practical application in enterprises operating based on the ISO 9001: 2015 quality management system. The outcome of the conceptual work is a set of recommendations for enterprises using the ISO 9001: 2015 quality management system regarding the potential to enhance specific areas through principles derived from Lean Management.*
Originality/Value: *The author presents opportunities for applying principles derived from the Lean Management concept in enterprises operating based on the ISO 9001: 2015 quality management system. The implementation of Lean Management principles requires actions that lead to certain changes in the functioning of specific areas within an enterprise. These changes can contribute to the widespread elimination of waste. An organizational culture based on Lean Management principles also has the potential to support or foster the development of effective and modern solutions in enterprises with an implemented and structured quality management system.*

Keywords: *Defining value, value stream mapping, supply chain optimization, pull, pursuing perfection, Lean Management, quality, quality management, ISO 9001.*
JEL: *L15, M11, M54.*
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1. Introduction

The proposed support of the ISO 9001:2015 quality management system with Lean Management principles may contribute to the discovery of previously unidentified solutions that respond to the contemporary direction of changes observed in quality management standards and norms. It seems that the evolution of quality management systems is moving toward making them more realistic to market realities.

Better alignment of quality management system requirements with aspects related to economic profitability may lead to the development of practical guidelines for enterprises that address not only quality improvement but also the enhancement of business process profitability. Both the Lean Management concept and the ISO 9001:2015 system have evolved into universal approaches, and therefore, their practical implications could be applied in enterprises across various business profiles.

The purpose of the article is to analyze the requirements of the ISO 9001:2015 standard (with reference to its individual chapters) and to attempt to support the fulfillment of these requirements using five Lean Management principles. The article is conceptual in nature, and the research scheme is to correlate the chapters of ISO 9001:2015 with the five principles of Lean Management. The outcome of the conceptual work is a set of efficiency-oriented recommendations for enterprises operating based on the ISO 9001:2015 quality management system regarding the possibility of supporting this system with Lean Management principles.

The proposed research framework enabled a clear presentation of the role of the five Lean Management principles in increasing the likelihood of effective holistic management in enterprises with an implemented ISO 9001:2015 quality management system. This article is based on an extensive literature review covering the functioning of quality management systems as well as Lean Management (including Lean Manufacturing).

By identifying common ground between the ISO 9001:2015 standard and Lean Management principles, it became possible to propose actions that not only help meet the requirements outlined in the individual chapters of the standard but also assist enterprises in achieving efficiency-oriented benefits in an economic context.

2. Characteristics of Lean Management Principles

Lean Management should be understood as a low-cost management approach focused on eliminating waste and adding value to processes. Adding value can be realized by simplifying internal structures and procedures across all departments of a company (Janiszewski and Siemieniuk, 2012; Sivaram and Devadasan, 2012). The essence of this concept lies in achieving high labor productivity, efficient

management organization, high quality, and satisfactory economic performance. Its goal is to adapt the enterprise to current market conditions through fundamental transformations in organization, management, and operations (Asiński *et al.,* 1999).

The term Lean Management first appeared in 1996 through Womack and Jones (Womack and Jones, 1996). The authors defined this term as focusing on adding value that enhances customer satisfaction and loyalty, which in turn allows the company to maintain or increase its market share and strengthen its position in shaping the pricing of its products. In the original version of the definition, the authors also highlighted the significant benefits that can result from strengthening cooperation with partners, as customer value can be created both at the interface of the organization and beyond its boundaries.

The Lean Management concept demonstrates how to produce more with less consumption of resources, less labor, time, equipment, and space, while simultaneously maintaining an upward trend in customer satisfaction (Wójcik and Kocoń, 2015). In addition, Lean Management makes it possible to improve communication, increase health and safety, and reduce the negative environmental impacts of the company and its products (Womack and Jones, 1996). Lean Management aims to create an organizational culture focused on lean production using Lean Management principles. Table 1 shows the five principles of the Lean Management concept.

Table 1. *Principles of Lean Management*

No.	Lean Management Principles
1.	**Defining value** occurs with the participation of consumers who validate the market with their choices. Consumers are the final entities in logistics chains, and therefore, the value created is aimed at meeting their expectations (Loane and Webster, 2014). The decision on which tools to use during the implementation of a product or service has a significant impact on risk, efficiency, and cost (Gonzalez-Zugasti and Otto, 1999).
2.	**Value stream mapping** enables more effective identification of process inefficiencies and sources of waste. This principle makes it possible to identify areas that require improvement, for example, by eliminating unnecessary activities. The most common technique used in process mapping is Value Stream Mapping (Manjunath and Shiva Prasad, 2014).
3.	**Creating flow** increases the efficiency, or the speed at which a company can produce a product or service within a given unit of time (Little and Graves, 2008), of the entire process, which is the main goal of Lean Management (Chatzopoulos, 2014). Performance optimization has its roots in the Theory of Constraints (TOC), which holds that a chain is only as strong as its weakest link. TOC views every organization as a chain of interdependent processes, where the performance of each event (or process) depends on the preceding one. Effective elimination of constraints and bottlenecks is crucial for a company to perform well (Bahall, 2018).
4.	**Establishing pull**, assumes producing exactly what the customer needs. Essentially, a *pull* or *push* system refers to the flow of materials between production lines. An

	effective pull system will produce only what is consumed at the right time. Inventory is maintained solely to meet minimum customer demand, which means this system can help minimize overproduction (Jamaliah, Mohamad and Azianti, 2016).
5.	**Pursuing perfection** is a routine process of systematically seeking and implementing new and improved work methods. The strategic objective behind launching industrial production improvement initiatives is to build the capability to introduce improvements quickly and effectively as part of the organization's routine operations (Butler and Szwejczewski, 2018).

Source: *Own elaboration.*

The concept of Lean Management involves improving the operation of the production system by eliminating any kind of waste that may occur in enterprises (Burnasheva, 2016; Pajak, 2007). By applying the five principles of Lean Management, raw materials are delivered at the right time and in the right quantities, while finished goods are delivered to customers just in time, creating added value throughout the entire order fulfillment process (Al-Musawi *et al.,* 2019). In addition, the application of the five principles of the Lean Management concept makes it possible to reduce the consumption of everything needed in the production process, resulting in a product that is more in line with customer expectations (Sikorski, 1995).

Lean Management is a revolutionary concept that fundamentally transforms the way organizations and their internal processes function. Enterprises that choose to implement the five principles derived from Lean Management must be prepared for changes affecting, among others, the internal and external supply chain, decision-making processes, and human capital management (Borys and Rogala, 2012).

Today, the core assumptions of Lean Management (uninterrupted flow, customer value, pull systems, waste minimization, etc.) have become a paradigm in many organizations. The Lean Management concept should encompass the entire organization, as only then is a comprehensive analysis of processes and identification of both actual and potential losses possible (Šurinová, Daňo and Saniuk, 2014).

3. Applying Lean Management Principles to Support the Implementation of ISO 9001:2015

Both ISO 9001:2015 and Lean Management are aimed at improving the production processes taking place in a company (Micklewright, 2010). Integrating Lean Management with ISO 9001:2015 would enable the creation of a compatible quality management system, the comprehensive implementation of which could help avoid the duplication of certain activities (Gajendran and Sampath Kumar, 2011).

The ISO 9001 standard and Lean Management are among the most widely used quality management approaches worldwide. Standardized quality management

systems focus primarily on meeting the requirements defined in the standards on which they are based, whereas the Lean Management concept emphasizes the continuous improvement of value-adding activities and the elimination of waste across all areas of an organization's operations (Pepper and Spedding, 2010).

The main goal of integrating the ISO 9001:2015 quality management system with the Lean Management concept is to achieve synergy resulting from the simultaneous implementation and operation of both approaches. Lean Management principles should be regarded as those that, when implemented, can transform non-value-adding operations into value-adding ones.

It therefore appears that the potential for improving ISO 9001:2015 quality management systems in enterprises depends on their ability to integrate with individual Lean Management principles (Wirkus and Chmielarz, 2018). Regardless of the integration capabilities of specific enterprises, it should be noted that Lean Management principles have the potential to support companies operating based on the ISO 9001:2015 quality management system (Khalili *et al.,* 2017)

It should be noted that the structure of ISO 9001:2015 may lead to some difficulties during the process of implementing Lean Management principles (Chiarini, 2011). For the purposes of this study, the first three chapters of the ISO 9001:2015 standard were not included in the analysis due to their general nature.

These chapters provide a general introduction to the standard. Their main task is to clarify the scope and terminology used in the following sections of the document.

- *Chapter 1: Scope* - defines the scope of the standard, that is, the area in which the requirements of ISO 9001:2015 can be applied. ISO 9001: 2015 is applicable to companies, regardless of their type, size, or products and services offered.
- *Chapter 2: Normative* references - includes references to other standards and legislation that are relevant to understanding and applying ISO 9001:2015.
- *Chapter 3: Terms and definitions* - contains key terms and definitions used in the standard. Standardization of terms is necessary to avoid confusion and ensure a uniform understanding of the nomenclature used in the context of the quality management system.

The subsequent chapters of ISO 9001:2015 (from chapter four to chapter ten) cover specific requirements for a quality management system. Table 2 presents a comparison of the chapters of the ISO 9001: 2015 standard with the principles of Lean Management.

In Table 1, the chapters of the ISO 9001:2015 were juxtaposed with the principles of the Lean Management concept. In my assessment, the individual principles of Lean

Management have the potential to enrich and enhance all areas of operation in enterprises that function based on the ISO 9001:2015.

Table 2. *Comparison of ISO 9001: 2015 Chapters with the Five Lean Management Principles*

ISO 9001:2015 CHAPTER	LEAN MANAGEMENT PRINCIPLE
4. Context of the organization	First principle - Defining value
5. Leadership	Fifth principle - Pursuing perfection
6. Planning	Third principle - Creating flow
7. Support	Fourth principle - Establishing pull
8. Operation	Third principle - Creating flow
9. Performance evaluation	Rule Two - Value stream mapping
10. Improvement	Fifth principle - Pursuing perfection

Source: *Own compilation based on ISO 9001:2015, Quality Management - Guidelines.*

3.1 Defining Value as a Principle Supporting the Requirements of Chapter Four: "Context of the Organization"

Defining value for a specific customer is not possible without a very good understanding of your own organization and its processes. Conversely, without strong engagement in the enterprise's internal processes, the likelihood of failure in the customer service process increases.

Every major enterprise is capable of defining its mission and vision; it is aware of its competitive advantage and of what generates economic value (Collins, 2007).

Table 3. *Subsections of Chapter Four, "Context of the Organization," in ISO 9001: 2015*

4.1	Understanding the organization and its context
4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of the quality management system
4.4	Quality management system and its processes

Source: *Own compilation based on ISO 9001:2015, Quality Management - Guidelines.*

The Lean Management culture is strongly customer-oriented; its goal is to meet customer expectations by continuously delivering the highest possible value to them (Beitelspacher *et al.,* 2011).

By applying the first principle of Lean Management to the implementation and maintenance of the requirements outlined in Chapter Four of the ISO 9001: 2015 standard, enterprises have the opportunity to increase their economic profits.

This is because value definition is highly significant to stakeholders and is closely linked to the quality experienced by customers.

3.2 Pursuing Perfection as a Principle Supporting the Requirements of Chapter Five: "Leadership"

Pursuing perfection as defined by Lean Management can be defined as a never-ending organization-wide process aimed at generating sustainable and effective innovations (Bessant and Caffyn, 1997).

Leadership involves shaping the goals of a group or organization and motivating behavior aimed at achieving those goals. Leaders are those who are accepted in this role by their colleagues (Ciekanowski, 2011).

Table 4. *Subsections of Chapter Five, "Leadership," in ISO 9001:2015*

5.1	Leadership and commitment
5.2	Policy
5.3	Organizational roles, responsibilities, and authorities

Source: *Own compilation based on: ISO 9001:2015, Quality Management - Guidelines.*

To achieve a high level of collaboration among employees, a key responsibility of management is to create conditions that foster interaction between employees at different levels, which enables the development of an appropriate level of trust (Carter *et al.,* 2013). Lower-level employees tend to have greater trust in their leader when they experience more autonomy in performing their duties. Assigning specific areas of responsibility to individual employees increases their engagement in the work, giving them a sense of importance, which ultimately leads to better outcomes in the context of pursuing perfection (Brajer-Marczak, 2014).

Modern leadership, of which pursuing perfection (the fifth principle of Lean Management) is an essential component, is effective leadership. This is because full involvement of top management in shaping quality policy fosters a culture of excellence. Moreover, such an approach enables the effective implementation of quality strategies, increases employee engagement at all levels, and improves the likelihood of achieving the enterprise's defined objectives.

3.2 Creating Flow as a Principle Supporting the Requirements of Chapter Six: "Planning"

Planning is a systematic analysis involving the continuous making of a series of decisions. Decisions made during the planning process should take into account the risks to which the organization is exposed (Kulińska, 2012).

One of the fundamental assumptions of the Lean Management concept is the optimal execution of activities (previously planned) aimed at improving the processes functioning within the enterprise (Dias and Tenera, 2020).

Table 5. *Subsections of Chapter Six, "Planning," of ISO 9001:2015*

6.1	Actions to address risks and opportunities
6.2	Quality objectives and planning to achieve them

Source: *Own compilation based on: ISO 9001:2015, Quality Management - Guidelines.*

The use of the third principle of Lean Management (creating flow) to improve the planning process makes the process in companies operating under the ISO 9001: 2015 becomes more efficient, because optimization of the planning process reduces the risk of various types of waste, improves the flow of information, and harmonizes the activities of various departments in the organization. An important effect of creating flow optimization in the planning phase is improved risk analysis, which contributes to greater organizational efficiency.

3.3 Establishing Pull - A Principle to Support the Requirements of Chapter Seven "Support"

The fourth principle of the Lean Management concept (establishing pull) is to produce/manufacture finished goods only when a contractor places an order for that product. In other words, the production process depends on customer demand, and the volume of component production is determined by previously established minimum inventory levels (Spearman and Zazanis, 1992).

The economic viability of the pull system for enterprises results, among other things, from producing finished goods in small batches and from the speed of response to changes, that is, from flexibility in meeting customer orders. Moreover, organizing a pull-based product flow is a principle designed, among other functions, to help control workload distribution across different production sectors (Powell *et al.,* 2013). It therefore appears that this principle has relatively strong potential in supporting the implementation and maintenance of the requirements outlined in Chapter Seven of the ISO 9001:2015 standard.

Table 6. *Subsections of Chapter Seven, "Support," in ISO 9001:2015*

7.1	Resources
7.2	Competence
7.3	Awareness
7.4	Communication
7.5	Documented information

Source: *Own compilation based on: ISO 9001:2015, Quality Management - Guidelines.*

Organizing a pull-based product flow has the potential to support the requirements of all subsections comprising Chapter Seven of the ISO 9001: 2015 standard, as production that begins only after a customer order is placed promotes resource optimization and inventory minimization. It should also be noted that the implementation of the fourth Lean Management principle in enterprises operating under the ISO 9001:2015 standard may contribute to the improvement of

communication processes (including those related to document flow) between different departments of the organization, as well as to the broadening of employee awareness in the context of production and warehousing processes. As a result of increased awareness and improved communication processes, employee competencies may also increase organically.

3.4 Creating Flow as a Principle to Support the Requirements of Chapter Eight "Operation"

Operation concerns, either directly or indirectly, all actions related to the functioning of an enterprise - from sourcing suppliers, ordering raw materials, and production, to marketing, distribution of finished products, and after-sales service (Waters, 2001).

The Lean Management concept can be applied to a wide range of operational activities taking place within a company. Examples of such activities include (Hame, Kowang and Fei, 2017):

- organizational activities, such as planning research, managing ideas, intellectual property management, human resource management, etc.
- Support-related activities, for example, project planning and monitoring, risk management, managing cooperation with contractors, employee evaluation, etc.
- decision-making activities, including modeling organizational concepts, business analysis, product specification, product design, and development, etc.

Table 7. *Subsections of Chapter Eight, "Operation" in ISO 9001:2015*

8.1	Operational planning and control

Source: *Own compilation based on: ISO 9001:2015, Quality Management - Guidelines.*

Creating flow has the potential to support the operational activities of enterprises operating under the ISO 9001:2015 standard, as it emphasizes a holistic approach to process improvement, which aligns with the spirit of ISO 9001:2015. Through more effective analysis and planning, organizations can make their operational activities more coherent and efficient, which in turn may contribute to better fulfillment of customer expectations and market requirements. Moreover, creating flow can enhance risk management effectiveness, which may improve responsiveness, which is an increasingly critical capability in today's rapidly changing environment.

3.5 Value Stream Mapping as a Principle to Support the Requirements of Chapter Nine, "Performance Evaluation"

As early as the early 1990s, one of the greatest modern authorities on quality management, Peter Drucker, was of the opinion that one cannot manage something that cannot be measured (Drucker, 1993).

Value Stream Mapping (VSM) enables the graphical representation of the current state of processes within an organization. Moreover, through its application, it becomes possible to visualize the desired future state that the organization aims to achieve.

Graphically representing both the present and future states of processes requires personnel to measure the time of all activities performed at individual workstations (Saboo *et al.,* 2014). Value Stream Mapping can be applied continuously, as every process within an organization can be subject to ongoing improvement.

Table 8. *Subsections of Chapter Nine, "Performance Evaluation," in ISO 9001: 2015*

9.1	Monitoring, measurement, analysis, and evaluation
9.2	Internal audit
9.3	Management review

Source: *Own compilation based on: ISO 9001:2015, Quality Management - Guidelines.*

Value Stream Mapping highlights the importance of regular monitoring and analysis of results in the context of continuous improvement of the quality management system. The second principle of Lean Management can also be successfully applied during periodic internal assessments conducted within an organization (such as internal audits and management reviews), as it facilitates a detailed analysis of value flow and more effective identification of waste.

3.6 Pursuing Perfection as a Principle Supporting the Requirements of Chapter Ten, "Improvement"

The title of Chapter 10 of ISO 9001:2015 is identical to the fifth principle of the Lean Management concept. When comparing these two approaches (ISO 9001:2015 and Lean Management), it becomes clear that implementing a culture of pursuing perfection, or continuous improvement, has a universal character and supports the development of more efficient, flexible, and resilient structures capable of responding more rapidly to market changes and customer needs. Both approaches also emphasize the importance of engaging all employees in matters related to pursuing perfection.

An effectively implemented continuous improvement program should be characterized by employee involvement in enhancing the quality and efficiency of production and/or service processes (Lee, 2004). Continuous improvement is a process that can only be successfully implemented with the participation of all employees within the organization (Gatchalian, 1997).

Both approaches also emphasize the importance of detecting nonconformities as early as possible and implementing improvement actions without delay (Poksinska, 2010; Habelman, 2015). The effective implementation of corrective actions plays a

key role in eliminating waste and improving process efficiency – the systematic analysis of processes leads to operational improvement and the ongoing enhancement of organizational performance.

Table 9. *Subsections of Chapter Ten, "Improvement," in ISO 9001:2015*

10.1	General
10.2	Nonconformity and corrective action
10.3	Continual improvement

Source: *Own compilation based on: ISO 9001:2015, Quality Management - Guidelines.*

Chapter 10 of ISO 9001:2015 and the fifth principle of the Lean Management concept are complementary, together forming a comprehensive framework that supports the development and maintenance of a culture of continuous improvement. Organizations that apply both approaches simultaneously may benefit from the resulting synergy, which in turn can lead to increased competitiveness and greater customer satisfaction.

4. Conclusion

The implementation of both the ISO 9001: 2015 quality management system and the Lean Management concept requires a broad range of actions and significant changes to the way an organization operates. However, these efforts bring undeniable benefits in both organizational and economic terms. All employees should be involved in the implementation and maintenance of the quality management system and Lean Management principles, as they are expected to perform their duties in a specific manner once these approaches are adopted.

This conceptual study demonstrates that the principles of Lean Management do not present obstacles to the implementation and maintenance of the requirements outlined in ISO 9001:2015.

There are no provisions in the standard that prohibit organizations from:

- understanding what "value" means to their target customers;
- distinguishing between value-adding and non-value-adding activities within processes;
- eliminating non-value-adding activities (e.g., bottlenecks) as quickly as possible;
- producing finished goods in small batches, only after customer orders are confirmed;
- continuously improving their processes and fostering a supportive organizational culture.

The principles derived from the Lean Management concept appear to have considerable potential in supporting organizations in the implementation and

maintenance of the requirements found in the various chapters of ISO 9001:2015, especially considering that some elements of Lean principles can be indirectly identified within the standard (e.g., identifying customer value, continuous improvement). Integrating the two approaches discussed in this paper may help create a compatible quality management system that, through a synergy effect, could enhance operational efficiency within enterprises.

It should be noted that research in this area ought to be reviewed periodically, as updates to ISO 9001 occur irregularly. A new version of the ISO 9001 standard is expected to be released in the near future (Kowalski, 2024).

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