

# Lean, Six Sigma and ISO Management Systems Standards: An Integration Framework

Marques, Pedro A.A.<sup>1)</sup>, Reis, João C.G.<sup>1)</sup>, Sá, José C.V.<sup>2)</sup>, Mateus, Ricardo J.G.<sup>1)</sup> and Silva, Francisco P.<sup>1)</sup>

<sup>1)</sup> Lusófona University, Faculty of Engineering, Campo Grande 376, Lisbon, Portugal

<sup>2)</sup> Polytechnic Institute of Porto, School of Engineering, R. Dr. António Bernardino de Almeida, Porto, Portugal

## STRUCTURED ABSTRACT

**Purpose-** This paper proposes a conceptual framework to integrate three relevant business models: Lean Management, Six Sigma and international ISO Management Systems Standards (MSS). It explores the multiples synergies among them from an organizational excellence viewpoint.

**Design/methodology/approach-** From the literature review, Lean Management, Six Sigma, and international Management Systems Standards based on the Annex SL common structure provided by ISO are thoroughly discussed and compared. From this, logical synergies and complementarities between these three approaches are identified, explored and discussed. Altogether, those linkages will drive the development of a conceptual framework to guide their integration.

**Findings-** The integration model relies on many organizational excellence principles and its guidelines help managers and team leaders to properly utilize a set of Lean and Six Sigma methods and tools according to their purpose. In addition, the model provides a clear relationship between those tools and the clauses of requirements included in the ISO Management Systems Standards.

**Research limitations/implications-** The framework does not cover other normative references for management systems that are not published by ISO, such as SA 8000 on social accountability systems. In addition, it does not discuss management standards for specific sectors of activity, such as IATF 16949 for the automotive industry, ISO 13485 for medical devices, among others.

**Practical implications-** The model and its guidelines are useful for all those organizations that developed or intend to develop management systems based on ISO standards.



**Originality/value-** As far as the authors of the paper are aware, this is the first paper that proposes a conceptual model generalizing the integration of Lean and Six Sigma with certifiable ISO management systems standards that applies to all type of organizations, regardless of their size and sector.

**Keywords:** Lean, Management Systems Standards, Organizational Excellence, Six Sigma.

**Paper type:** Conceptual paper.

## INTRODUCTION

The past decades have witnessed the widespread diffusion of internationally recognized management systems standards (MSS) and their respective certification schemes (Lo and Young, 2018). Before the early 2000s, they tended to focus primarily on quality management systems, but since then their scopes has diversified substantially, currently covering many of the aspects of a modern management system, including: quality, environment, energy efficiency, information security, occupational health and safety, social accountability, among others (Kohl, 2020). This evolution was induced by the globalization process, which has led many organizations to seek to implement standards that helped them to improve their management practices and thus remain competitive in the market (Cabecinhas et al., 2021). In this regard, certifiable international standards published by the International Standards Organization (ISO) are particularly relevant. Although they can be helpful for companies to improve their overall performance, they are limited in terms of providing the tools for them to perform sustainability-improvement activities (Souza and Alves, 2018). Lean and Six Sigma are two well-known approaches that provide the means to conduct business process improvement initiatives (Ahmadi and Rahmani, 2023; Marques et al., 2016), as they also contribute to promoting a culture of continuous improvement, hence sustaining organizational management systems (Kelly, 2016).

The proliferation of ISO standards for management systems in most countries, especially over the last twenty years, led to the development of MSS integration models (Barbosa et al., 2022; Bernardo et al., 2018). The history of integrated management systems began when the ISO 14001 standard for environmental management systems was launched in 1996 (Gianni and Gotzamani, 2015), due to the need to articulate it with the already existing ISO 9001 for quality management systems. From the early 2000s onwards the number of new MSS issued by ISO has increased tremendously (Ferradaz et al., 2022; Asif et al., 2010). Nevertheless, ISO 9001 and ISO 14001 remain the most certified management systems standards worldwide (Hernandez-Vivanco and Bernardo, 2023; Cabecinhas et al., 2021). Other relevant international generic MSS include ISO 45011 for occupational health and safety systems, ISO 50001 for energy management systems, ISO 55001 for asset management systems, ISO 21001 for educational management systems, ISO 22301 for business continuity management systems, ISO/IEC 27001 for information security information systems, ISO 44001 for collaborative business relationship management systems, and ISO 22316 for security and resilience management systems (Kohl, 2020).

Many organizations expect to increase the economic benefits from their ISO certification, but to that purpose they need to pursue changes in their governance (Cândido et al., 2021) and business models

(Azevedo and Almeida, 2021). To foster productivity, many of them are seeking the adoption of more advanced management approaches, including Lean Management and Six Sigma, (Sá et al., 2022). More mature companies are even looking for an even broader perspective by pursuing the development of company-wide management systems based on the guiding principles and best practices provided by the organizational excellence models (Santos and De Waal, 2019). Despite the inherent advantages, this reality raises major practical challenges in terms of integrating this set of models. There is a high risk of creating redundancies and duplications of procedures. Symptoms of this fact include the creation of an excessive number of documents, unclear or overlapping responsibilities and authorities among functional areas of the organization, incrementation of bureaucracy in business processes, just to mention a few (Souza and Alves, 2018). The challenge is therefore to develop a framework that allows management systems based on the requirements of international ISO standards to be effectively integrated – given the reality of their spread in companies operating in Portugal – with Lean Management and Six Sigma programs – which will help to improve and sustain productivity and efficiency gains in various types of organizational processes.

The development of integration frameworks to link Lean Management and/or Six Sigma with quality management systems based on ISO 9001 and with few other relevant ISO MSS has been explored by various authors, but so far, no integrative model has been proposed that can be generalized to several management standards at the same time. This paper explores a conceptual integration framework capable of taking advantage of multiples synergies between Lean and Six Sigma with the common high-level structure for all generic ISO management systems standards provided by Annex SL. The framework that supports the proposed integration model consists of four interlinked blocks that together comprise all the main activities for managing an organization, hence relying on many of the core organizational excellence principles.

## **LITERATURE REVIEW**

The overview of the literature has been conducted through extensive research in books, scientific papers, and conferences proceedings using keywords such as ‘lean iso’, ‘six sigma iso’, ‘lean six sigma iso’, ‘lean management systems standards’, ‘six sigma management systems standards’, ‘lean six sigma management systems standards’, ‘lean iso management systems’, ‘six sigma iso management systems’, ‘lean six sigma iso management systems’, etc. Moreover, the search tools of ‘google scholar’ and ‘books.google.com/ngrams’ have been used for the quantification of the researched terms appearance over the past 30 years.

Born from many of the Total Quality Management (TQM) principles, both Lean and Six Sigma philosophies have captured increasing interest over the years (Sreedharan and Sunder, 2018; Andersson et al., 2006) by both the scientific and business communities. Lean and Six Sigma have different focus, but they are complementary, so they are often used in conjunction with an approach usually known as Lean Six Sigma (Yadav and Desai, 2016). Lean principles and tools focus on improving process flow/speed and eliminating waste (Onofrey et al., 2021), while Six Sigma aims to minimize the occurrence of defects by reducing process variability (Marques et al., 2016). Both Lean and Six Sigma tools can be used throughout improvement projects following the well-known five-step DMAIC roadmap (Define-Measure-Analyze-Improve-Control) roadmap (Trubetskaya et al., 2023; Snee, 2010).

The normative references for quality systems are the foundations of today's management systems standards (MSS). The first quality management standards derived from the architecture of military quality standards, as they were elaborated in the US and UK between 1940 and 1980 (Gibbon, P. and Henriksen, 2011). In 1979, The British Standards Institution eventually developed the military standards into BS 5750 series (parts 1, 2 and 3), being the source for the publication of the first versions of the ISO 9000 family of standards in 1987 (Ho, 1994). The ISO 9000 standards have resulted in a significant worldwide phenomenon, considering the impressive growth and diffusion of certification according to the ISO 9001 standard in several countries and different kinds of organizations (Ikram et al., 2021; Sampaio et al., 2009). Since the publication of the ISO 14001 for environmental management systems in 1996 and the 2000 version of ISO 9001, the world witnessed a proliferation of many other generic MSS (Barbosa et al., 2022; Gianni and Gotzamani, 2015). Because many organizations have been increasingly adopting different general and sectorial MSS, the International Organization for Standardization promoted the integration of MSS with the publication of the High-Level Structure, known as Annex SL, in 2012 (Silva et al., 2020). According to the results available in the 2022 ISO Survey of Certifications (ISO, 2023), ISO 9001 remain by far the standard with the highest number of certificates issued, followed by ISO 14001. After these, the list of generic MSS with the highest number of certifications worldwide comprises the following ranking: ISO 45001, ISO/IEC 27001, ISO 22000 (food safety management systems), ISO 50001, ISO/IEC 20000-1 (information technology service management systems), ISO 37001 (anti-bribery management systems), ISO 22301 (business continuity management systems), ISO 39001 (road traffic management systems), and ISO 50001.

The results of the literature review regarding the integration of Lean and/or Six Sigma with a set of generic MSS published by ISO are summarized in Table 1. The following conclusions can be derived:

- Attending to the search criteria described in the first paragraph of the “literature review section, a total of 55 references were identified matching the criteria, the first of which was in 2003.
- 37 of the references (i.e. 67%) focus on the integration with ISO 9001: 16 of them refer to synergies with Six Sigma, 7 with Lean, and 14 with both Lean and Six Sigma.
- The integration of Lean and/or Six Sigma with ISO 14001 is dealt with by 4 references, with ISO 45001 and ISO 55001 by 1 reference each, with ISO/IEC 27001 or ISO/IEC 27002 by 3 references, and with ISO 55001 by 2 references.
- Only 7 of the 55 references concern the integration of Lean and/or Six Sigma with two or more generic management systems standards.
- The first publications focused mainly on integrating Six Sigma with the ISO 9001 standard, but since 2010, the trend has been to extend the integration frameworks to an ever wider set of MSS and to include the Lean Management aspect as well.

The literature review and the conclusions drawn from it allowed to identify the following research gaps:

- There is still no framework that integrates Lean and/or Six Sigma with ISO management systems’ standards from an organizational excellence, company-wide, perspective.
- There is still a lack of integration models that generalize the synergies between continuous improvement approaches and all the international ISO MSS based on the high-level structure provided by Annex SL.
- To the best of our knowledge, no publication has yet described a clause-by-clause applicability of Lean and Six Sigma tools to assist organizations in meeting the requirements of ISO standards for management systems.

These gaps are addressed by the conceptual model proposed in the next section of this paper, thus contributing to the evolution of the state of the art in this field of science. The model also has practical implications for already certified companies, regardless of their size or business sector, namely by providing guidelines to help them develop initiatives for continuous improvement and organizational excellence, based on their existing management systems.

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS.

Reference	Integration scope	Description
Trubetskaya et al. (2023)	Lean and Six Sigma with ISO 55001	Present a Lean Six Sigma project conducted in an Irish dairy plant operation that resulted in an optimization of the energy consumption, hence demonstrating how Lean Six Sigma can be used in the context of an energy management system (ISO 55001).
Farahbod et al. (2022)	Six Sigma with ISO/IEC 27001	It is explored the role that Six Sigma can have in the enhancement of the information security management system (ISO/IEC 27001) effectiveness, in particular improving the cybersecurity methods and practices.
Farrukh et al. (2022)	Lean and Six Sigma with ISO 55001	Two case studies are conducted in Pakistani companies to assess if Green Lean Six Sigma practices, including the integration of Lean Six Sigma with ISO 14001, have a significant impact on environmental performance as well as on personnel safety.
Nedra et al. (2022)	Lean and Six Sigma with ISO 9001	From data collected through quantitative surveys and interviews conducted in 85 small and medium enterprises (SMEs) in the textile industry, it was concluded the ISO 9001 standard has a significant influence in the successful implementation of Lean Six Sigma (LSS), and this conclusion was validated through four case studies.
Vanichchinchai (2022)	Lean with ISO 9001	Based on data that was collected from 516 manufacturers in Thailand, it is examined if ISO 9001 certification impacts their Lean programs and the supply chain relationship.
Sá et al. (2022)	Lean and Six Sigma with ISO 9001	Propose an ISO 9001:2015 interface model with the integration of Lean Six Sigma tools and methodologies for all the standard's sections containing clauses of requirements
Velmurugan and Dhingra (2021)	Six Sigma with ISO 55001	Present the sequence of stages to develop an asset maintenance strategic plan to achieve maintenance excellence, which include some synergies between asset management related international standards, in particular ISO 55001, and the Six Sigma DMAIC roadmap that is adopted to promote continuous improvement.
Souza (2021)	Lean with ISO 9001, ISO 14001, ISO 45001, and ISO 26001	Describe the steps to implement the Lean-Integrated Management System for Sustainability Improvement (LIMSSI) model, hence developing a combined quality (ISO 9001), environmental (ISO 14001), occupational health and safety (ISO 45001), and social responsibility (ISO 26000) management systems standards with Lean tools.
Minovski et al. (2021)	Lean with ISO 9001	Investigate the global impact that the implementation of the Lean tools has on ISO 9001 certified companies in North Macedonia as well as such Lean tools are applicable throughout the ISO 9001 requirements.
Betegon et al. (2021)	Lean with ISO 9001	Illustrate the implementation of a quality management system based on ISO 9001:2015 at an Advanced Simulation Center (ASC), a training facility of a health and social care organization, also making use of Lean principles and tools.
Nevels et al. (2020)	Lean and Six Sigma with ISO 45001	It is explored how a wide set of Lean and Six Sigma tools can be utilized by occupational health and safety professionals in the context of a management system, including for the ISO 45001 standard.
Kaganov (2020)	Lean with ISO 9001, ISO 13485, ISO 14001, and ISO 45001	Propose the use of Lean tools, including visual management, to simplify the documentation system inherent to different types of ISO MSS and to prevent over-detailed standard operating procedures.
Veena and Prabhushanka (2020a)	Six Sigma with ISO 9001	The critical success factors for the implementation of Six Sigma are identified and then allocated to the different sections of clauses comprising the ISO 9001:2015 standard.
Veena and Prabhushanka (2020b)	Lean and Six Sigma with ISO 9001	Suggest a roadmap towards the implementation of Lean Six Sigma through the structure and requirements of a quality management system based on the ISO 9001:2015 standard.
Djapic et al. (2019)	Lean with ISO 9001	Propose a conceptual model that provides logical interconnections between: organization planning activities, PDCA cycles methodology, clauses of requirements from the ISO 9001:2015 standard, and a set of applicable Lean tools.
Marques et al. (2019)	Lean and Six Sigma with ISO 9001	A conceptual model is proposed to integrate Lean and/or Six Sigma methods, and tools with the clauses of the ISO 9001 standard using the high-level structure of Annex SL.
Veena and Prabhushankar (2019)	Lean and Six Sigma with ISO 9001	A comparative study among Lean, Six Sigma, and the 2015 version of ISO 9001, from which a conceptual framework to integrate them is proposed to fill the identified challenges and limitations.

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS.  
(continued)

Reference	Integration scope	Description
Bacoup et al. (2018)	Lean with ISO 9001 and ISO 14001	Propose a Lean quality management system (LQMS) model that enables the combination of the 2015 versions of the ISO 9001 and ISO 14001 standards with Lean Management.
Souza and Alves (2018)	Lean with ISO 9001, ISO 14001, ISO 45001, and ISO 26001	Propose a Lean-Integrated Management System for Sustainability Improvement (LIMSSI) model that incorporates correlations of quality (ISO 9001), environmental (ISO 14001), occupational health and safety (ISO 45001), and social responsibility (ISO 26000) requirements with the principles and tools of Lean manufacturing.
Ismyrlis and Moschidis (2018)	Six Sigma with ISO 9001	Based on a research survey study involving a sample of Greek companies, it is investigated whether Six Sigma, from a managerial point of view, have the potential to benefit the implementation of an ISO 9001 quality management system, and it was concluded that in general the answer is positive.
Fonseca and Domingues (2018)	Lean and Six Sigma with ISO 9001	Study the level of adoption of Lean, Six Sigma, and other continuous improvement (CI) methodologies by Portuguese ISO 9001 certified organizations, having concluded that there is a moderate degree of use of these (CI) approaches.
Bakator et al. (2018)	Lean and Six Sigma with ISO 9001	The concepts of Total Quality Management (TQM), ISO 9001, Lean, and Six Sigma are presented, and their differences, similarities, and success factors are identified so that synergies can be exploited between them.
Zenchanka, and Malchenka (2017)	Lean with ISO 9001, ISO 14001, ISO 50001 and ISO 45001	Analyze the relationship between Lean and the requirements of various generic MSS, including ISO 9001 (quality systems), ISO 14001 (environmental systems), ISO 50001 (energy systems), and ISO/DIS 45001 (occupational health and safety systems).
Olaru et al. (2017)	Six Sigma with ISO/IEC 27001	Explore multiple application possibilities of making use of Six Sigma tools to strengthen the effectiveness of information security management systems based on ISO/IEC 27001.
Mkhaimer (2017)	Lean and Six Sigma with ISO 50001	Develops the Lean Six Sigma energy management model (LSS_EnMS) that articulates the requirements contained in the ISO 50001 standard for energy management systems with the DMAIC roadmap used in Lean Six Sigma projects.
Marques et al. (2016)	Lean and Six Sigma with ISO 9001	Propose an integration framework where the life cycle stages inherent to a Lean and/or Six Sigma project can be systematically related with the applicable clauses of requirements contained in ISO 9001:2015.
More and Pawar (2015)	Six Sigma with ISO 9001	Discuss the implementation of Six Sigma along with ISO 9001 quality management systems in the textile industry of India.
Karthi et al. (2014)	Lean and Six Sigma with ISO 9001	Compare the results obtained by two ISO 9001:2008 certified enterprises that employed the L6QMS-2008 model in effectively adopting Lean Six Sigma practices within their quality management system.
Adina-Petruța and Roxana (2014)	Six Sigma with ISO 9001	Describe synergies between Six Sigma and quality management systems based on the model provided by ISO 9001 to promote the development of continuous improvement efforts in higher education institutions.
Kurdve et al. (2014)	Lean with ISO 9001, ISO 14001, and OHSAS 18001	Propose integration guidelines to articulate relevant production systems models, including Lean, with environmental management based on the ISO 14001 standard and related issues such as quality (ISO 9001) and safety (OHSAS 18001).
Vanzant-Stern (2014)	Lean and Six Sigma with ISO 9001	Presents how Lean and Six Sigma tools can play a key role in ISO 9001 certification or recertification efforts.
Chiarini and Vagnoni (2014)	Lean and Six Sigma with ISO 9001	Based on the investigation of how a group of 23 manufacturing organizations committed with Lean Six Sigma programs conduct efficient and effective shop-floor audits, a set of good practices patterns are identified and then compared with the more formal audit pattern used for evaluating compliance with the ISO 9001 standard.
Karthi et al. (2013)	Lean and Six Sigma and ISO 9001	Description of a case study of implementing the L6QMS-2008 model to integrate Lean Six Sigma with ISO 9001:2008 in a textile mill.
Marques et al. (2013)	Six Sigma with ISO 9001	Provide a set of guidelines to combine and integrate the activities of a Six Sigma program with the clauses of the ISO 9001:2008 standard.

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS.  
(continued)

Reference	Integration scope	Description
Swink and Jacobs (2012)	Six Sigma with ISO 9001	The impact that a previous ISO 9001 certification has on the adoption of a Six Sigma program by organizations is studied, with the conclusion that such certification is not a determining maturity factor in this adoption.
Sivaram et al. (2012)	Lean with ISO 9001	By establishing a set of connections between the elements, models, tools, and techniques inherent to the total productive maintenance (TPM) and the clauses of requirements contained in the ISO 9001:2008 standard, an integration roadmap is proposed.
Karthi et al. (2012)	Six Sigma with ISO 9001	Literature review regarding the integration between Six Sigma and ISO 9001-based quality systems.
Habidin and Yusof (2011)	Lean Six Sigma with ISO 14001	The effect that ISO 14001 certification has in the relationship between Lean Six Sigma and Operational Performance is analyzed based on a case study conducted in the Malaysian automotive industry.
Marques et al. (2011)	Six Sigma with ISO 9001	Propose ways to integrate Six Sigma with a quality management system based on ISO 9001 by making use of the structure and common elements of the ISO Guide 72.
Karthi et al. (2011a)	Lean and Six Sigma with ISO 9001	Propose the L6QMS-2008 framework for integrating the DMAIC methodology and the typical belt-based training infrastructure of a Lean Six Sigma program with the eight clauses of requirements the ISO 9001:2008 standard.
Karthi et al. (2011b)	Lean and Six Sigma with ISO 9001	An alternative version of the ISO 9001:2008 standard is proposed by adding specific Lean and Six Sigma requirements to the existing underlying structure.
Chiarini (2011)	Lean with ISO 9001	Explores the specific role that Lean tools and principles can have under each clause of the ISO 9001:2008 standard, formulating integration guidelines for all of them.
Johannsen (2011)	Six Sigma with ISO 9001	Review of the literature concerning the integration of techniques and methods in quality management, including the combination between Six Sigma and ISO 9001 for quality management systems.
Salah et al. (2010)	Lean and Six Sigma with ISO 9001	A high-level integration perspective called Total Company-Wide Management System (TCWMS) is presented, being regarded as an expansion for Total Quality Management (TQM) by incorporating synergies between continuous improvement methodologies like Lean Six Sigma and ISO 9001 quality management systems.
Marsh and Perera (2010)	Lean and Six Sigma with ISO 14001	Based on a research survey, it is concluded that by integrating business improvement tools and techniques such as Lean Six Sigma with ISO 14001 will contribute to increase the effectiveness of problem-solving efforts within the environmental management system.
Bewoor and Pawar (2010)	Six Sigma with ISO 9001	Propose two frameworks to integrate ISO 9001 and Six Sigma, one at a managerial/macro level (links Six Sigma with ISO 9001 attending to the quality management principles) and the other at an operational/micro level (relates the clauses of requirements of the ISO 9001:2008 standard with the five stages comprising the six Sigma DMAIC roadmap).
Micklewright (2010)	Lean with ISO 9001	Establish relationships between Lean principles and the quality principles grounding the business practices promoted by ISO 9001 and propose guidelines regarding the adoption of Lean tools and practices in the scope of the ISO 9001 standard.
Marques and Requeijo (2009)	Six Sigma with ISO 9001	Discuss how a SIPOC diagrams often used in Six Sigma projects can play an important role in mapping and interrelating key processes that are managed in the scope of an ISO 9001 quality management system.
Laddychuk (2008)	Lean and Six Sigma with ISO 14001 and OHSAS 18001	Present a case study at Alcan that illustrates how the company adopts Lean Manufacturing and Six Sigma to foster continuous improvement, one of the building blocks of the existing integrated management system based on the ISO 14001 and OHSAS 18001 standards.
Yeung (2007)	Six Sigma with ISO 9001	Based on the experience obtained from two ISO 9001 certified secondary schools in Hong Kong, it is concluded that incorporating the standard's clauses of requirements into a Six Sigma program can benefit the organizational cultural environment.
Saleh et al. (2006)	Six Sigma with ISO 17799	Present an approach to apply the ISO 17799:2005 standard (current ISO/IEC 27002) to manage information security systems attending to the phases of the DMAIC roadmap, by considering the basic domains of 'strategy, technology, organization, people, and environment' (STOPE).

Table 1 – Literature focusing on the integration of Lean and/or Six Sigma with generic ISO MSS.  
(continued)

Reference	Integration scope	Description
Tice et al. (2005)	Lean with ISO 14001	Identify a set of similarities between Lean Production principles and tools and the requirements of an environmental management system based on the ISO 14001 standard.
Lupan et al. (2005)	Six Sigma with ISO 9001	Propose an integration strategy between Six Sigma and ISO 9001:2000 by linking the DMAIC method used in Six Sigma with the PDCA cycle.
Pfeifer et al. (2004)	Six Sigma with ISO 9001	Suggest a systematic integration model that explores multiple synergies between a set of ISO 9001 requirements and the activities developed under a Six Sigma program.
Warnack (2003)	Six Sigma with ISO 9001	Proposes a Six Sigma and ISO 9001 integrated Quality Management System 7-step roadmap to achieve the integration.

## PROPOSED CONCEPTUAL INTEGRATION FRAMEWORK

The proposed framework aims to integrate the three management approaches depicted in Figure 1: Six Sigma, Lean Management, and non-sectorial management systems standards (MSS) published by ISO whose high-level structure is provided by Annex SL. Each one of them is herein described:

- **Six Sigma:** is a project-by-project approach (Kane, 2020), hence being driven by the typical life cycle stages of a project (Padhy, 2017): i) project identification; ii) project selection; iii) project planning, execution, and planning; iv) post-project. Potential Six Sigma projects are identified based on the analysis of existing or proactively gathered data, which can be collected both internally and externally (Marques et al., 2014). From the pool of candidates, the most impactful projects are prioritized, in what is one of the most critical activities of a Six Sigma or Lean Six Sigma program (Singh and Rathi, 2018). Two kinds of Six Sigma projects can be conducted: quality or process improvement efforts by following the DMAIC roadmap, or Design for Six Sigma (DFSS) for product and/or process design (Yang et al., 2022). There are plenty of DFSS roadmaps, but usually two are adopted: DMADV (Define, Measure, Analyze, Design, Verify) and IDOV (Identify, Design, Optimize, Verify) are used (Tefay, 2021). The post-project review process is of great importance to assess the project success measured by the results achieved (Furterer, 2009), along with the compilation of the lessons learned from the project (Sunder M., 2016), which gives this phase an important role in the knowledge transfer process regarding future improvement initiatives (Tukel et al., 2008).
- **Lean Management:** it is mainly focused on value-creation by identifying and removing all types of waste that can exist in a process. The “Lean House”, or “Toyota Production System (TPS) House”, is a recognizable symbol and a visual model of this management approach (Höök and Stehn, 2008). Its roof is customer-centric and contains the company’s true north (i.e. the ultimate goal) of achieving significant business growth by providing high-quality

products or services, at the lowest possible cost, in the shortest possible period of time (Dennis, 2016). There are two pillars holding up the house: Just-In-Time (JIT) and *Jidoka* (Autonomation). The former emphasizes the elimination of inconsistencies and waste factors in the processes to promote a pulled and continuous flow, while the objective of the latter is doing it right the first time (Pessôa and Trabasso, 2016). The combination of JIT and *Jidoka* means that problems, when they inevitably occur, can never be hidden (Liker and Convis, 2012). Leveled up production (*Heijunka*) and standardized procedures are two foundational elements of the house that support each one of the corresponding pillars. The whole system is built on a logic that is necessary to perform both monitoring and control activities to promote stability in the organizational processes and improvement (*Kaizen*) activities to enhance their performance, hence combining SDCA (Standardize, Do Check, Act) and PDCA (Plan, Do, Check, Act) cycles (Gitlow, 1995). Cultural enablers, including the quality of the leadership, peoples' knowledge, skills, and ability to solve problems, are the bedrock of the Lean house. Lean principles and tools are often combined with Six Sigma, since they are complementary approaches, despite their inherent differences (Rodgers et al., 2019; Marques et al., 2017), so it is important to look at them in a unified way.

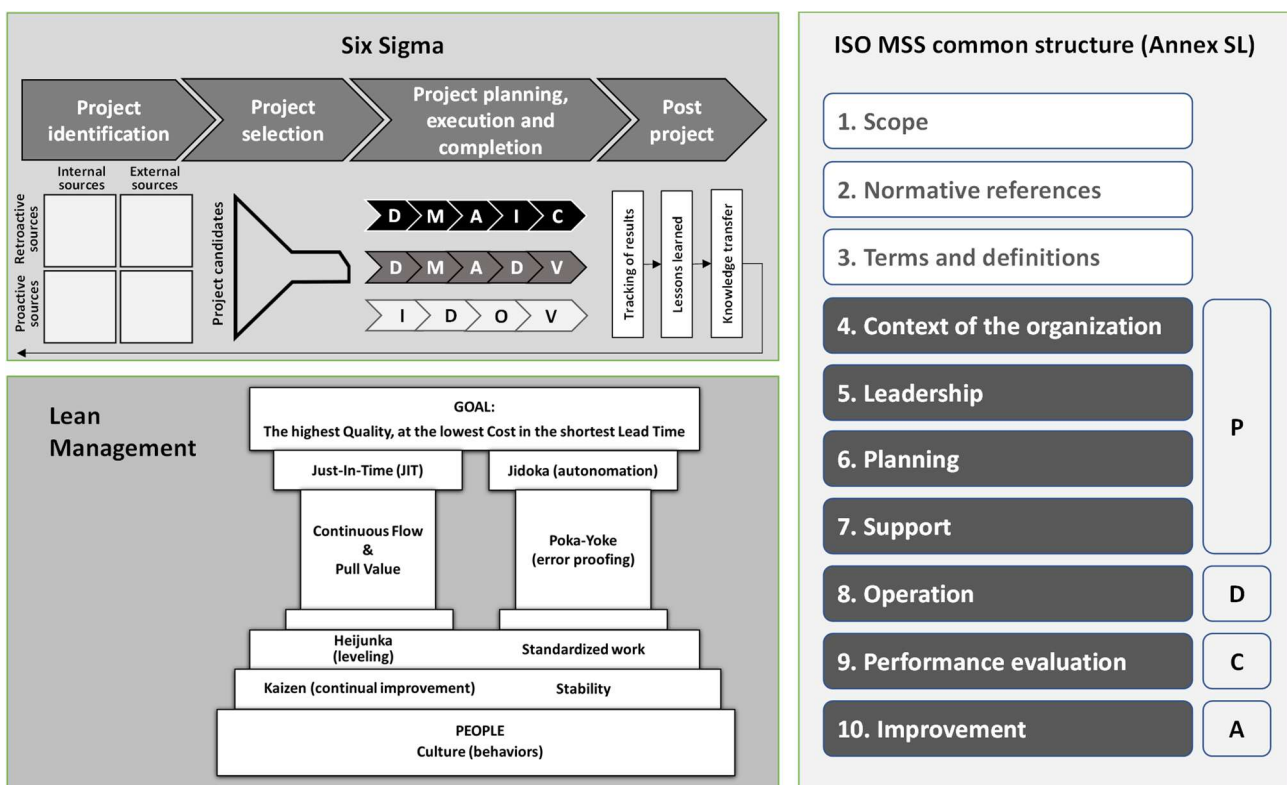


Figure 1 – Characteristics of the three management approaches to be integrated.

- **ISO MSS common structure:** currently all generic standards for management systems issued by ISO rely on the High-Level Structure, known as Annex SL, that provide the same title and core text for the clauses of requirements, standard terms, and definitions (Roncea, 2016). Every MSS is organized around ten sections, with the requirements for the management system starting with section 4 being arranged according to the reasoning behind the PDCA cycle (Silva et al., 2020).

The structured model depicted in Figure 2, which consists of four interlinked blocks, was developed under the scope of this research and serves as support to the conceptual integration framework herein proposed. Altogether, the blocks comprise the main activities that are required for managing an organization in a sustainable way, also encompassing all organizational levels – strategic, tactical, and operational level – that are needed to develop an effective TQM system (Dahlgaard et al., 2019) or Business Excellence Model (BEM) (Leonard and McAdam, 2002). Each block herein proposed consists in the following:

- The **Leadership and Strategy** block is at a strategic management level, involving long-range business planning, monitoring, analysis, and evaluation of all relevant areas for an organization to meet its aim and core objectives. Setting the strategic plan and deploying the strategic objectives in the entire organization are responsibilities of senior management (Watson, 2020). A set of opportunities derives from organizational strategy, feeding a portfolio of potential initiatives and project-based improvement projects (Vilarinho et al., 2018), which, according to the ISO 21502 (2020) standard, should be continuously managed to prioritize the most promising ones (Snee, 2002). Moreover, when executive team members act as role models and create constancy of purpose, they are enabling a culture of Excellence within the organization (Butterworth, 2019). Top management is also accountable for making good decisions towards the definition of proper organizational governance and structure of business processes (Plenert, 2021).
- The **Initiative Management** block, also referred to as project management or cross-functional management (Salah et al., 2011), corresponds to the tactical level where strategy is translated into deliverable or achievable initiatives (Leonard and McAdam, 2002). The prioritized strategic-oriented improvement initiatives can be more or less disruptive, (Marques et al., 2014), from kaizen events to breakthrough Six Sigma projects (Miller et al. 2014). The tracking or periodic review of the impact these initiatives are having in processes' performance and the extent to which the strategic goals are being met at departmental level (Leonard and

McAdam, 2002) are important outcomes taking place in this management block. Post-project activities, including the compilation of lessons learned and the transfer of the project/initiative deliverables to daily work and operations (Czarnecki, 2018), are also relevant.

- The **Daily Management** block involves the formalization of organizational processes and the management of the standards that drive the teams' daily efforts, tracking and reporting of performance metrics, and solving everyday problems (Vinardi, 2023). It helps to sustain and widen improvement efforts, linking it to daily performance (Cornider et al., 2023). Routine process planning and control activities are herein conducted by empowered and well-trained personnel who, by ensuring that standardized work is carried out, promote the stability of the processes they work in (Buttherworth, 2019).
- The **Support** block consists of a set of processes ensuring that activities encompassing the three management levels are running properly. Support processes provide relevant resources such as competence of personnel, technology, and knowledge (Abuhav, 2017) to the management system. It also involves the management of documented information and communication channels (Kohl, 2020) as well as the development of training, coaching, and mentoring activities (Miller et al., 2014),



Figure 2 – Conceptual model that supports the integration framework.

The main activities conducted in each of the mentioned blocks have been related to the clauses of requirements contained in the high-level structure, provided by Annex SL, commonly adopted by the MSS issued by ISO. Furthermore, the applicability of various Lean and/or Six Sigma methods and tools for each of that relationships have been proposed. These integration synergies are exhibited and described from Tables 2 to 5, one table per management block. The integration framework also considers the existing individually specific clauses of requirements (Rajabzadeh et al., 2023), not covered by Annex SL, of certain ISO MSS, with emphasis to the ISO 9001:2015 standard, that are relevant regarding the integration with Lean and/or Six Sigma.

Table 2 – Integration framework for the “Leadership and strategy” block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Vision, Mission, Values, and Policies	5.2. Policy	Hoshin Kanri	Lean	Enables policy setting, where organizational values and beliefs, vision and mission are stated. It helps to align the Policy describing the intentions and direction of the management system with the purpose of the organization
Strategy formulation, planning and deployment	4.1. Understanding the organization and its context	PESTLE (Political, Economic, Sociological, Technological, Legal, Environmental) analysis.	Six Sigma	Relevant to define the organization’s purpose and strategic direction
		SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis	Six Sigma	Assists in evaluating the internal and external business environment of the organization.
		Hoshin Kanri	Lean	Setting the long-term strategy plan to promote the strategic objectives
	4.2. Understanding the needs and expectations of interested parties	CVCA (Customer Value Chain Analysis)	Six Sigma	Allows the organization to identify relevant stakeholders and understand the way they relate to each other
		VOC (Voice Of the Customer) tools	Six Sigma	These are tools used in Design for Six Sigma, including: interviews, focus groups, surveys, Kano Model, among others. They are helpful in determining the stakeholders’ requirements for the management system
6.1. Actions to address risks and opportunities	SWIFT (Structured What If Technique)	Affinity Diagram	Six Sigma	Organize qualitative information regarding the needs and expectations of stakeholders
			Six Sigma	It can be used to identify and assess different types of organizational risks and opportunities, including strategic risks

Table 2 – Integration framework for the “Leadership and strategy” block. (continued)

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Organizational objectives, initiatives, and targets	6.2. XXX objectives and planning to achieve them	X-Matrix from Hoshin Kanri	Lean	The X-Matrix helps maintain coherence between the long-term strategy and the targeted annual objectives, and among the latter and the initiatives to be developed to achieve them. Similarly, it makes it possible to relate the Policy to the objectives for the management system and the latter to the actions to be planned to achieve them
	9.3. Management review	Obeya Room	Lean	It visually displays the data and information that are essential for strategy decision-making or for reviewing the management system
		Prioritization matrix	Six Sigma	The portfolio of potential initiatives and improved-based projects can be evaluated during management review sessions to prioritize the most impactful and strategic-oriented ones. To this purpose, this quality planning and management tool can be utilized
	9.1. Monitoring, measurement, analysis, and evaluation		Obeya Room	Lean.
Benchmarking			Six Sigma	Compare organizational performance with best-in-class companies
Leadership and corporate culture	5.1. Leadership and commitment	Gemba Walk	Lean	Reinforce trust between them and the different hierarchical levels of the organizations, contribute to foster a culture of continuous improvement, and enhance the perceived commitment of senior leadership with the management system.
		Leader Standard Work (LSW)	Lean	Provides a structured set of routines and tasks that contribute to demonstrate leadership and commitment
Organizational structure and governance	4.3. Determining the scope of the XXX management system	Is / Is Not	Six Sigma	Distill what elements are within the scope of the management system and those that are not
		5W2H (What? Where? When? Who? Why? How? How much?)	Six Sigma	Encourages asking basic questions that are useful to determine the context of the management system within the organization and its governance model
	4.4. XXX management system	SIPOC (Suppliers., Inputs, Process, Outputs, Customers)	Six Sigma	Facilitates the determination of the organization’s core, support, and management processes and how they relate to each other, hence enabling the definition of a network or structure of processes
		VSM (Value Stream Mapping)	Lean	Provides an holistic perspective to establish, maintain and continually improve the organizational processes
	5.3. Organization roles, responsibilities, and authorities	Standardization	Lean	Standardization is a core principle from Lean management and can be adopted to define and deploy job descriptions for all relevant organizational functions
		Help Chain	Lean	Define responsibilities and authorities for backup systems and escalation of problem-solving situations.

Table 3 – Integration framework for the “Initiative Management” block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Departmental objectives and targets	6.2. XXX objectives and planning to achieve them	Hoshin Kanri	Lean	Coherently deploy the strategic objectives down to the different departmental levels of the organization, hence the management system objectives can be strategically aligned when they are breakdown to lower levels
Planning of projects or initiatives	10. Improvement	Action Priority Matrix	Six Sigma	Prioritize departmental or cross-functional actions/initiatives attending to their potential impact and effort needed.
	6.1. Actions to address risks and opportunities	Project management planning tools: e.g. Project Charter, Gantt Chart, WBS (Work Breakdown Structure) PDPC (Process Decision Program Chart)	Six Sigma	Company-wide and departmental initiatives can be planned by making use of project management tools One of the quality planning and management tools, which can be adopted to perform project risk analysis
Execution of projects or initiatives	10.2. Continual improvement	Gemba Kaizen Events	Six Sigma	Promote focused, short-term, and cross-functional improvement efforts to improving process efficiency and effectiveness
		Value Stream Management	Lean	Map and analyze a specific key process to identify activities not adding value from the customer’s point of view and introduce a set of process flow improvements attending to the designed vision of its future state
		DMAIC roadmap	Six Sigma	Conduct projects related to breakthrough problem-solving initiatives
		SMED (Single minute Exchange of Die)	Lean	Reduce changeover or setup time of a machine or equipment
Periodic performance review	8.3. Design and development of products and services (ISO 9001:2015)	DFSS (Design for Six Sigma) roadmaps, such as DMADV and IDOV.	Six Sigma	Design methodologies to conduct new product/service development projects
		Lean Design.	Lean	Optimize the efficiency of the design and development process to minimize time to market
Periodic performance review	9.1. Monitoring, measurement, analysis, and evaluation	Obeya Room	Lean	Visually display relevant data from the prioritized initiatives and improved-based projects to monitor, measure, analyze, and evaluate their status, performance, and results
		Visual Management Boards	Lean	Monitor, measure, analyze, and evaluate the levels of performance being achieved by a certain department or unit area
		Gate Reviews.	Six Sigma	Conduct steering and review of improvement projects or initiatives
		A3 Project Report	Lean	Present the status of an initiative or project in a visual and objective way during a gate review
Project completion and post-project	7.1.6. Organizational knowledge (ISO 9001:2015)	A3 Project Report	Lean	When an initiative or project is completed, lessons learned are documented and reported
	10.2. Continual improvement	Value Stream Costing	Lean	Quantify the financial benefits of increased process efficiency
	10.3. Continual improvement (ISO 45001:2018)	Lean Safety	Lean	Lean Safety initiatives can contribute to improve health and safety performance

Table 4 – Integration framework for the “Daily Management” block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Standardized work	8.1. Operational planning and control	SOP (Standard Operational Procedures) and OPL (One Point Lesson).	Lean	Provide a visual and objective way of describing a procedure for carrying out a job or task, hence promoting standardized work
Process planning and scheduling	8.1. Operational planning and control	Job Sequencing	Lean	Effective short-term scheduling approach to allocate and prioritize demand orders available facilities, equipment, or other type of resource
		P-FMEA (Process Failure Mode and Effect Analysis)	Six Sigma	Identify and assess risk factors that may be present in a process, so preventive and mitigation actions can be defined, planned and implement to reduce the level of risk
		QFD (Quality Function Deployment).	Six Sigma	Provide process planning and production planning matrices to properly design or plan the operations of a process
		VOC (Voice Of the Customer) tools	Six Sigma	Gather and analyze statements made by customers and other stakeholders regarding the product or service, helpful to determine their needs and wants
		Affinity diagram	Six Sigma	Organize a wide set of qualitative customer statements, particularly their needs and wants gathered from VOC tools
		Kano Model	Six Sigma	Typify and prioritize customers’ requirements
		CTQ Tree	Six Sigma	Translate a broad set of customer needs into a more focused and measurable set of technical requirements for the product or service
Product and process control	8.1. Operational planning and control	QFD (Quality Function Deployment)	Six Sigma	Convert customer needs and expectation into functional requirements for the product or service and corresponding specifications
		SPC (Statistical Process Control)	Six Sigma	Make use of control charts which provide an effective way to analyze whether a repetitive process is stable/predictable or not
		Lot Acceptance Sampling Plans	Six Sigma	Control and evaluate the quality and compliance of externally provided materials
		Kanban	Lean	Regulate operational workflows as well as to control inventory levels throughout the production processes
Performance tracking and report	9.1. Monitoring, measurement, analysis and evaluation	Andon	Lean	Visually highlighting the status of operations in an area at a single glance, such as production status or an abnormality
		MSA (Measurement System Analysis)	Six Sigma	Ensure the reliability of data collected during process measurement and monitoring
		Process capability studies	Six Sigma	Assess how consistently an in-control process is capable to produce parts within specifications
		5S audits	Lean	Conduct audits in the workplace to evaluate compliance with the established housekeeping procedures and can be combined with internal safety and quality audits
Problem-solving and improvement	9.2. Internal audit	Kamishibai (also known as K-Cards)	Lean	Visually signaling whether a standard is being complied or not
		A3 Problem-Solving Report	Lean	Provide a structured, visual, and standardized method for management and operational teams to summarize their problem-solving exercises
Problem-solving and improvement	10.1. Nonconformity and corrective action	Quality Circles	Lean	Autonomous group of workers to collectively identify problems in their workplace, analyze them, and provide effective solutions

Table 5 – Integration framework for the “Support” block.

Main activities	ISO MSS high-level structure (Annex SL)	Applicable methods/tools	Usually adopted in	Applicability
Management of people and resources	7.1. Resources	TPM (Total Productive Maintenance)	Lean	Optimize operational infrastructure in terms of preventing breakdowns, small stops, defects, or workplace accidents
		Kobetsu Kaizen	Lean	Encourage autonomous maintenance of automation equipment
		Team Work Plan	Lean	Display on visual team boards the daily and /or weekly plan regarding the allocation of people that perform certain job functions to specific tasks
Training, mentoring, and coaching	7.2. Competence	Skills Matrix	Lean	Provide a grid that shows the levels of proficiency or competency of an employee regarding a specific task or job.
		Training Plan	Lean	A training plan stems from the existing gaps between the levels of competence required to perform a job or task and the actual levels of competence. These gaps can be identified by analyzing the teams’ skills matrices
		TWI (Training Within Industry)	Lean	To accelerate the acquisition of knowledge and skills of an employee to execute a job in a proper, productive, and safe manner
	7.3. Awareness	Coaching Kata	Lean	Promote the sense that every leader should be a mentor and that one of his/her main responsibilities is to promote awareness of individuals about the importance of adopting scientific thinking when conducting problem-solving efforts
Documentation	7.5. Documented information	OPL (One Point Lesson)	Lean	Provide a short (usually a single page length), objective, and visual format to display a work instruction or procedure
		Visual SOP (Standard Operating Procedure)	Lean	Visual and objective way to describe the step-by-step activities necessary to successfully complete an operational task
		Swimlane Diagram	Six Sigma	Visually and effectively depicts a process mapping, so it can be used as the main tool to develop the required process sheets that are used in the scope of management systems
Communication	7.4 Communication	5S and visual management	Lean	Promote an environment where communication become simpler, more intuitive and effective, hence contributing to improve quality, process flows, and safety
		Daily team meetings	Lean	provide the opportunity to discuss the team performance, their improvement or problem-solving actions. Holding these meeting contribute to engage all team members
		Communication Plan	Six Sigma	Clarify how communication will occur with the stakeholders of a project or initiative
Knowledge management	7.1.6. Organizational knowledge (ISO 9001:2015)	Benchmarking	Six Sigma	The introduction of internal and/or competitive benchmarking practices encourages team leaders and managers to introduce proven best practices in the organization

## CONCLUSIONS

The objective of this paper is to develop a conceptual framework to integrate the generic management systems standards published by ISO, whose high-level structure of requirements follow Annex SL, with Lean Management and Six Sigma. The framework that supports the proposed integration model consists of four interrelated blocks encompassing all organizational levels – strategical, tactical, and operational level – hence providing a company-wide perspective for managing an organization.

The following relevant topics were addressed in this paper:

- A thorough and extensive literature review was carried out to identify existing publications proposing guidelines, models, and frameworks on how to integrate the clauses of requirements from different types of ISO management system standards with Lean Management and/or Six Sigma.
- The literature review led us to conclude that existing integration frameworks still lacking to provide clause-by-clause relationships with the available toolbox from Lean Six Sigma.
- The main characteristics and features of the three management approaches being integrated were described, providing an initial insight into the natural synergies between them.
- A structured model consisting of four blocks covering all the main management activities of an organization were developed, providing the means to develop the integration framework where the joint use ISO management systems standards, Lean Management, and Six Sigma fit the vision of an organization-wide perspective of management.

The main contributions of this paper are the following:

- The proposed conceptual framework is not limited to integrating the requirements of ISO 9001 or to a single standard but has the capacity to be used to integrate Lean and Six Sigma with any set of ISO management systems standards.
- The integration guidelines are organized per clause of requirements contained in Annex SL, which contains the common high-level structure of requirements of ISO standards for management systems.
- A unique aspect of the proposed framework is that it is based on an interconnected set of good practices conducive to a company-wide perspective for managing an organization, as emanated from the principles of business excellence.
- From a practical viewpoint, it provides organizations with a set of good practices and guidelines to incorporate recognized business management models, such as Lean and Six



Sigma, into their management systems often designed based on the ISO standards. This is a worth contribution so they can avoid duplications, namely unnecessary documents and overlapping of authorities and responsibilities, and unnecessary efforts to sustain the management system as a whole.

- Attending the literature review conclusions, this is the first conceptual framework that integrates Lean and/or Six Sigma with ISO management systems standards from an organizational excellence, company-wide, perspective.

Nevertheless, the research conducted has some limitations. Attending to them, future research is also proposed:

- The proposed framework does not cover generic management systems standards that are not issued by ISO, including relevant ones such as SA 8000 on social accountability systems, and OHSAS 18001 for health and safety systems. In the future the conceptual framework can evolve to include other non-ISO relevant MSS.
- The framework is also not directly applicable to the majority of the MSS that are applicable to specific sectors of activity, such as IATF 16949 for the automotive industry, and ISO 13485 for medical devices. This provides another opportunity for the conceptual framework to evolve in the future.
- Finally, the developed framework does not fit the integration of Lean Six Sigma with the ISO 17000 series of standards related to “conformity assessment” (certification and accreditation), including the well-known ISO/IEC 17025 for the accreditation of testing and calibration laboratories. The conceptual framework can also be expanded to include this scope.

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