INTEGRATED MANAGEMENT SYSTEM IMPLEMENTATION BASED ON ISO STANDARDS REQUIREMENTS

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Abstract: *The article explores the correlation of the requirements of standards related to management systems, such as: ISO 13485, ISO 9001, ISO 14001 and ISO 45001, with the aim of highlighting both the similarities and differences between them and proposing an integrated model applicable in companies. The article is based on the identification of a gap in specialized literature - few studies that analyze the implementation of an integrated management system that simultaneously combines ISO standards. The standards are described comparatively, analyzing their specific requirements for quality and environmental management, occupational health and safety. The study identifies common processes, such as leadership, risk management, monitoring and continuous development, and standard-specific processes, such as traceability of medical products or environmental impact management. Comparing implementation in different industries allows demonstrating the flexibility and adaptability of the IMS model, integrating common elements of ISO standards, with specificities applicable to certain areas, such as the requirements for medical devices according to ISO13485. A discussion on dedicated integrated management systems, such as EFQM model and an integrated management systems built to comply ISO standards related to management systems is conducted.*

Keywords: *Integrated management system, Standard requirements, Quality, Environment Impact*

1. Introduction

Implementing an Integrated Management System (IMS) based on the requirements of the International Organization for Standardization (ISO) standards involves analyzing and correlating the provisions of several standards so that they function as a single, cohesive entity [1]. In this context, this article examins ISO 13485:2016 [2], ISO 9001:2015 [3], ISO 14001:2015 [4] and ISO 45001:2018 [5], highlighting both the similarities and differences between them, to demonstrate how their integration into an IMS can support organizations. The aim is to propose an IMS framework that emphasizes common processes across standards while addressing their specific requirements. Throughout the paper, the following objectives (O) will be pursued: O1: The common processes identified between ISO standards (leadership, risk management, monitoring and continuous development) contribute more to the efficiency of the IMS than the processes specific to each standard; O2: The ISO 13485 sectoral standard can be integrated into a general IMS without affecting compliance with its specific requirements regarding the safety and traceability of medical products.

A single, integrated set of processes and resources, as an IMS is defined [6], brings development to organizations through a series of benefits and competitive advantages, such as increased product quality, reduced environmental pollution, improved working conditions to ensure employee safety and health, and access to new markets [7, 8]. In addition, an IMS contributes to increasing

customer satisfaction, identifying new clients, reducing operational costs and promoting sustainable development [8 - 10].

According to N. M. S. Algheriani et all [11], among the factors that direct organizations towards implementing various management systems are customer satisfaction, business pressure, competitiveness, health and safety of employees [11]. Moreover, in recent decades, many organizations have been implementing management systems (quality - ISO 9001, environment - ISO 14001, occupational health and safety - ISO 45001, medical devices - ISO 13485) both under customer pressure and due to the need for efficiency [12] with 80% of the activities are common between them.

An essential aspect is represented by the simplification of procedures - a necessity that arose due to employees' resistance to change. In addition, procedures and manuals based on the high-level structure are essential for reducing accidents, errors and waste, contributing to increasing organizational performance [13, 14].

The latest official data published by the ISO on the number of certifications and sites per standard highlights that ISO 9001 (837,978 certificates; 1,250,243 sites), ISO 14001 (300,410 certificates; 526,046 sites) and ISO 45001 (185,166 certificates; 309,056 sites) hold the top three positions in the countries reporting ISO certifications in terms of management system certification. Meanwhile, ISO 13485 (32,963 certificates; 52,950 sites) ranks fifth, after ISO/IEC 27001:2013. This data were collected in 2024 and refer to the situation in 2023, according to the Survey of Certifications to Management System Standards conducted by ISO [15].

This article starts from a gap identified in the specialized literature: the lack of analysis of sector-specific standards, such as ISO 13485 for medical devices, within the general IMS framework [16], as well as the absence of studies examining the implementation of an IMS that brings together ISO 13485, ISO 9001, ISO 14001 and ISO 14001.

The main stages of IMS implementation include IMS planning, project team formation, staff training, identification of risks and customer requirements, development of the implementation plan, development of policies and performance indicators, performance monitoring and evaluation, internal audits and management review [17].

The structure of the rest of the article is as follows: Section 2 presents the research methodology, Section 3 describes the case study, Section 4 covers results and discussion, Section 5 outlines the limitations and future directions, while Section 6 presents the main conclusions. To ensure relevance, recent literature published between 2018 and 2025 was reviewed with respect to various IMSs.

2. Methodology

The research was conducted through a literature review on various IMS. In parallel, a case study was developed on two companies implementing different IMS, noting that not all standards are common, but only some of them coincide between the two organizations. The study was conducted using public data available online. Based on the information collected, the research proposes an IMS model that highlights both the similarities and the differences resulting from the four management standards analyzed (ISO 9001, ISO 14001, ISO 45001 and ISO 13485).

3. Case study

3.1 Company Data

3.1.1. Groupe Renault

Renault’s corporate purpose is principally the design, manufacture, sale, repair, maintenance and leasing of motor vehicles. Renault, as a global automaker, has integrated ISO standards into its management systems to improve quality, efficiency and sustainability:

ISO 9001: Groupe Renault implemented this standard to standardize production processes, reducing waste and increasing efficiency. In its production facilities, Renault implemented quality control procedures,

internal audits and ongoing employee training, helping to reduce errors and optimize workflows.

ISO 14001 and ISO 45001: Groupe Renault integrates these standards for environmental management and occupational health and safety, contributing to a holistic approach to risks and corporate social responsibility. Renault has adopted green production technologies and invested in electric vehicles as part of its sustainability strategy. Renault Mégane E-Tech Electric – electric hatchback launched in 2022. Dacia Spring (part of Groupe Renault) – simple, affordable electric model for urban/suburban travel. Renault uses an IMS, combining ISO 9001 with ISO 14001 and ISO 45001, which allows for efficient process management and compliance with international requirements. Sandouville was the first Renault plant to obtain ISO 14001 certification, back in December 1998. Whenever Groupe Renault establishes a plant in a new country, it pays the utmost attention to economic, environmental and social development. A good example is the Pitești plant in Romania, which was consolidated under the Renault group in 2002 and obtained its initial ISO 14001 certification in 2005. A new physico-chemical treatment plant for industrial effluents was put into operation at Somaca in 2008. Another significant example is the global waste management system, according to European standards, established in 2007. And the action plans regarding the manufacturing system brought energy savings per machine of 15% in 2006 and 22% in 2007. Efforts were mainly focused on educating staff on environmental issues. Groupe Renault has decided to adopt the SASB standard starting with the 2020 financial year. SASB identifies a minimum set of sustainability topics and associated indicators that a company specific to an industry segment should disclose due to their materiality. In 2007, Renault launched the Renault eco² signature to identify and promote its line-up of economic and ecological vehicles. To earn the Renault eco² badge, a car must meet three criteria. First, it must emit under 140 grams of CO2 per km (or run on biofuel). Second, it must be made at an ISO 14001 certified plant. Third, at least 5% of its plastics content must be sourced from recycled materials, and the end-of-life utilization rate must be at least 95%. Renault eco² vehicles are ecological in terms of measurable results throughout the vehicle lifecycle. ISO 45001 is an ISO standard for occupational health and safety management systems, published in March 2018. The purpose of ISO 45001 is to reduce occupational accidents and diseases, including promoting and protecting physical and mental health. As part of its global commitment to social responsibility and sustainability, Groupe Renault has implemented a vigilance plan in accordance with the French law on the Duty of Vigilance. This plan specifically covers the health and safety of people affected by its activities, both in France and internationally. In September 2016, Renault created a dedicated department: DHSEE – Health, Safety, Ergonomy and the Environment [18, 19].

3.1.2. Siemens Healthineers

Siemens Healthineers is a medical technology company dedicated to supporting healthcare professionals in making the best clinical decisions, from early and rapid diagnosis to determining the most effective treatments and post-therapeutic monitoring. By continuously introducing revolutionary innovations to the market, the company contributes to improving the quality of healthcare and achieving optimal patient outcomes. Siemens Healthineers' broad portfolio of technology solutions is at the heart of clinical decision-making and the therapeutic pathway, reflecting a strong commitment to patient-centered innovation. The company is currently present in over 70 countries worldwide, ensuring we are close to the customers. The company's mission is to generate better outcomes and experiences for patients, regardless of geography or the medical challenges they face. This approach highlights Siemens Healthineers' strategic orientation towards equity in health, superior quality of healthcare services and continuous

technological progress. ISO 9001:2015 certification is an international standard that reflects a company's commitment to implementing and maintaining a consistent quality management system that meets the expectations and needs of all stakeholders, including customers, suppliers and patients. During the audit, Siemens Healthineers France's governance, managerial involvement, management of processes dedicated to the distribution and provision of services for medical devices and, more generally, the relevance of the national quality management system has allowed it to maintain ISO 9001:2015 certification for decades. Each Siemens Healthineers business area and product line is ISO 13485 certified, and it also satisfies the approach to the patient experience by responding to the most present requirements throughout the life cycle of the medical device. To ensure safety and effectiveness, ecoline systems must undergo a 5-step quality process for reconditioning. This process was the basis for the COCIR "Good Refurbishment Practices"1. The 5-step quality process meets the NEMA/MITA2,3 standard for refurbishing, as well as the ISO 13485 "Quality Management System for Medical Devices" standard. The Siemens Healthcare quality management system is certified by TUEV4 with respect to the requirements of ISO 13485. In addition, the requirements of ISO 14001 are met according to SGS (Société Générale de Surveillance) certification. At Siemens Healthineers, we value our stakeholders and are aware of the impact that our care operations may have on them and on the environment. We attach great importance to the well-being of our employees and those affected by our activities, as well as maintaining high standards of health and safety. Internal operations are certified to ISO 45001 for Occupational Health and Safety Management System, and the Health and Safety Management System has been independently recognized as a benchmark implementation in this field. Responsibilities towards the fulfillment of the area are fulfilled by implementing a rigorous system of product approval and field safety monitoring. Assurances compliance with European directives on medical devices and all applicable This product safety work. Dedicated specialist team in the clinic is available for product installation and all applications of the product life cycle to ensure that doctors and technicians receive care training to operate the equipment in a safe and efficient manner [20, 21].

3.2 A Proposed IMS Model

The proposed IMS integrates the requirements of four ISO standards: ISO 9001, which addresses quality management; ISO 14001, which focuses on environmental management; ISO 45001, which covers occupational health and safety; and ISO 13485, which is dedicated to quality in medical devices. The model is built on four specific areas that correspond to the unique requirements of each standard.

The processes listed are representative and have been extracted from the main requirements of each standard. These are summarized in Table 1.

Table 1: Correlation of ISO standards with specific organizational processes [14, 23].

Standard	Specific processes
ISO 9001	Customer satisfaction, quality planning, process performance, supplier control.
ISO 14001	Environmental impact assessment, resource control, waste management, and sustainability objectives.
ISO 45001	Pericol identification, risk control, staff training, safety culture.
ISO 13485	Traceability, medical process validation, design control, strict regulatory requirements, and reliability.

In the context of increasing compliance requirements and the increasing interest in sustainability, quality and safety, companies are faced with the need to adopt and integrate more ISO standards. This paper proposes a comparative analysis between four reference standards – ISO 9001, ISO 14001, ISO 45001 and ISO 13485 – through a model of alignment of the requirements of these

standards with organizational processes. The study was applied within two companies, aiming to identify the current level of compliance and illustrates to what extent the processes and activities analyzed are covered by the standards ISO 9001, ISO 14001, ISO 45001 (occupational health and safety) and ISO 13485. A guideline model for identifying compatibility between internal processes and the requirements of the main ISO standards that can be adapted according to the specifics of each organization is presented in Table 2.

Table 2: Proposed model for assessing the alignment of organizational processes with the requirements of ISO standards

Process / Activity [2-4, 22, 23]	ISO 9001	ISO 14001	ISO 45001	ISO 13485
Product quality control	☑	☐	☐	☑
Continuous improvement	☑	☑	☑	☑
Risk assessment	☑	☑	☑	☑
Documentation management	☑	☑	☑	☑
Employee safety	☐	☑	☑	☑
Accident prevention	☐	☑	☑	☑
Environmental impact	☐	☑	☐	☐
Legal regulations & compliance	☑	☑	☑	☑
Non-conformity management	☑	☑	☑	☑
Traceability	☑	☐	☑	☑
Leadership	☑	☑	☑	☑

Legend:
☑ – Process required / highlighted in the standard.

This section presents the application of the proposed IMS model in two companies from different industries. Although Groupe Renault does not operate in the medical devices industry, its inclusion demonstrates the applicability of the IMS framework in a different sector, while Siemens Healthineers exemplifies integration of a sector-specific standard. This comparison highlights both commonalities and differences in implementing IMS principles across industries, without implying the use of ISO 13485 outside its intended field.

Groupe Renault and Siemens Healthineers address some processes exemplified with concrete examples, above, using criteria derived from good practices and ISO requirements. Tables 3, 4 and 5 present a comparative analysis between the described companies regarding the application of key processes correlated with the requirements of ISO standards.

Table 3: Process: Employee safety

Criterion	Groupe Renault	Siemens Healthineers
Workplace Conditions & Flexibility	In plants, the principle is two alternating eight-hour shifts with, in the event of spiking demand, the possibility to add a fixed night shift team. Groupe Renault is also introducing an alternative, flexible work time organization, allowing a better personal work/life balance for its employees with, for example, telework in countries where this is possible.	Adaptation measures Flexible schedule adjustments based on role (R&D, manufacturing, sales, clinical services). Modern flexibility Programs such as "Mobile Working Policy" and supporting work-life balance through wellness programs, extended leave, etc.

Table 4: Process Leadership & Strategic Management

Criterion	Groupe Renault	Siemens Healthineers
Management structure	Executive Committee that includes an HSSE (Health, Safety, Ergonomics & Environment) department, reporting directly to the strategic level.	Integrated management, with direct involvement of management in quality, sustainability and medical safety policies.

Involvement in IMS	Leadership involved in defining health and safety policies. Groupe Renault's Vision “Everyone impacted by our activities goes home safe and well”.	Management approves and monitors the implementation of ISO standards and global initiatives (e.g., Transforming care delivery).

Table 5: Process Product quality control

Criterion	Groupe Renault	Siemens Healthineers
Quality Certification	Each vehicle undergoes a final inspection (visual, functional and electronic check) before delivery./IATF	Application of quality certificate and seal from Siemens Healthcare Conformity seals are applied ISO 13485

4. Results and discussion

The analysis of the correlation between the requirements of the four standards and the organizational processes highlights the fact that each standard emphasizes distinct areas beneficial for an IMS useful to each company.

Table 2 proposes a guiding model for assessing the alignment between an organization's internal processes and the requirements of four standards. This model is based on identifying common or specific processes to these standards, providing a clear framework for assessing their integration into an IMS. Activities such as leadership and risk assessment are addressed in all four standards, even if there are different according to the requirements. These processes can be considered fundamental components of an IMS and represent a starting point in building a coherent system. The model highlights processes that are specific to one or just a few of the standards, such as: Environmental Impact, Employee Safety and Accident Prevention. These differences show the importance of customizing the IMS depending on: the organization's field of activity, applicable regulations. The model is flexible and can be adapted depending on the complexity of the organization and its strategic objectives. Each organization can customize it by adding other relevant processes, updating symbols, or developing specific performance indicators for each activity.

The practical application of the processes analyzed within Groupe Renault and Siemens Healthineers highlights significant differences in approach, influenced by: the sector of activity (automotive vs. medical devices), organizational culture, and the level of management systems. Table 6 summarizes key ways the IMS model can be applied to manage common and specific processes.

Table 6: Practical Applications of the Proposed IMS Model

Practical use of the model	Description
Extending an IMS	Used as a starting point in developing or completing an IMS.
Internal communication	Clarifying the role of each process for employees and stakeholders; increasing engagement.
Adaptation and flexibility in the labor market	Adapting the model to the specifics of the industry (e.g. medical, automotive)

5. Limitations and future directions

The main limitations of this study are related to the scope of the analysis and the availability of data. Only two companies, Renault and Siemens Healthineers, were studied, which highly restricts the generalizability of the results. In addition, all the information collected was obtained exclusively from online sources, without the possibility of direct collaboration with these organizations. This limited access prevented a deeper understanding of their internal IMS processes and reduced the ability to validate the proposed model in practice. Another limitation is the absence of detailed information in the literature on an IMS that simultaneously combines the standards considered in this study (ISO 9001, ISO 14001, ISO 45001 and ISO 13485). Therefore, the benefits of implementing such a system over a longer period could not be assessed.

Future studies could focus on evaluating the effects of adopting the proposed model within

a real company, in order to concretely assess its usefulness for IMS implementation. Such an approach would allow for the investigation of the ease of understanding and application of the requirements, the simplification of the adoption process, and the potential benefits of integrating the four standards into a single system. Further research could explore other IMS configurations, in addition to those already studied, most of which currently integrate only ISO 9001, ISO 14001, and ISO 45001. For example, future models could include combinations such as ISO 9001, ISO 14001, ISO 45001 together with ISO 50001 (Energy Management) or ISO 27001 (Information Security). Another promising research direction would be to analyze the effectiveness of IMS approaches built on three core standards (ISO 9001, ISO 14001, ISO 45001) complemented by a sector-specific standard (such as ISO 13485 for medical devices), and to compare this perspective with business excellence models (e.g., EFQM), in order to identify differences in applicability and impact across industries.

6. Conclusions

The practical contributions of this case study consist in the development of a proposed model that can support managers in quickly identifying both overlaps and potential conflicts between standards. The study presents a framework that highlights common processes applicable to all four ISO standards, as well as specific requirements that need to be customized according to the industry. This model proposes a vision that can be used by researchers, managers and certification bodies as a tool for more effective integration of an IMS. By clarifying the common and unique processes of the standards, the model provides a practical guide to improving communication, facilitating implementation and ensuring compliance, while increasing the flexibility of organizations in highly regulated industries.

The practical application of the model demonstrates its adaptability to diverse organizational cultures, regulatory requirements, and operational complexities.

Furthermore, the case study addresses the objectives formulated in the first part of the article. Regarding O1, the findings confirm that the common processes identified within ISO standards - such as leadership, risk management, monitoring and continuous improvement - bring significant added value to the effectiveness of an IMS, proving to be more impactful than standard-specific processes. Regarding O2, the analysis demonstrates that the sector standard ISO 13485 can indeed be integrated into a general IMS, while maintaining compliance with its specific requirements related to the safety and traceability of medical products.

Theoretical contributions include the comparative analysis of four standards rarely studied together, the identification of integration gaps in the literature, and the proposal of a flexible conceptual model that highlights both common and specific processes within an IMS.

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