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ТРЕБОВАНИЯ К СИСТЕМАМ МЕНЕДЖМЕНТА КАЧЕСТВА И ИХ ИНТЕГРАЦИЯ: ISO 9001:2015, ISO 17025:2019, ISO 17065:2012

Загидуллина Карина Рафаиловна
докторант Ташкентского государственного технического университета
Ибрахимова Феруза Гайратовна
магистр Совместный Белорусско-Узбекский межотраслевой института прикладных технических квалификаций

Аннотация: *В данной статье рассматривается роль требований к системам менеджмента качества (СМК), установленных стандартами ISO 9001:2015, ISO 17025:2019 и ISO 17065:2012, а также преимущества и вызовы интегрированной системы менеджмента (ИСМ). Подчёркивается, что ИСМ, объединяющая эти стандарты, значительно повышает эффективность, снижает затраты и улучшает согласованность операций, обеспечивая синергетический эффект, превосходящий сумму отдельных частей. Статья анализирует общие элементы и специфические различия стандартов, предлагая практические подходы к гармонизации требований и преодолению таких проблем, как сложность интеграции и сопротивление персонала, что ведёт к укреплению доверия и конкурентоспособности на мировом рынке.*

Ключевые слова: *система менеджмента качества, интегрированная система менеджмента, ISO 9001:2015, ISO 17025:2019, ISO 17065:2012, интеграция стандартов, преимущества ИСМ, вызовы внедрения, гармонизация требований, управление рисками*

REQUIREMENTS FOR QUALITY MANAGEMENT SYSTEMS AND THEIR INTEGRATION: ISO 9001:2015, ISO 17025:2019, ISO 17065:2012

Zagidullina Karina Rafailovna
PhD Student at Tashkent State Technical University
IbrakhimovaFeruza Gayratovna
Master's Student, Joint Belarusian-Uzbek Intersectoral Institute of Applied Technical Qualifications

Abstract: *This article examines the role of Quality Management System (QMS) requirements outlined in ISO 9001:2015, ISO 17025:2019, and ISO 17065:2012, along with the benefits and challenges of an Integrated Management System (IMS). It highlights that an IMS, by combining these standards, significantly boosts efficiency, reduces costs, and improves operational consistency, delivering a synergistic effect greater than the sum of its individual parts. The paper analyzes the common elements*

and specific differences among the standards, proposing practical approaches to harmonize requirements and overcome challenges like integration complexity and employee resistance, ultimately strengthening trust and competitiveness in the global market.

Keywords: *quality management system, integrated management system, ISO 9001:2015, ISO 17025:2019, ISO 17065:2012, standards integration, IMS benefits, implementation challenges, requirements harmonization, risk management*

SIFATNI BOSHQARISH TIZIMLARI TALABLARI VA ULARNING INTEGRATSIYASI: ISO 9001:2015, ISO 17025:2019, ISO 17065:2012

Zagidullina Karina Rafailovna
Toshkent davlat texnika universiteti doktoranti
Ibraximova Feruza Gayratovna
Qo'shma Belarus-O'zbek Tarmoqlararo Amaliy Texnik Malaka Instituti magistri

Annotatsiya: *Ushbu maqolada ko'rib chiqiladi sifatni boshqarish tizimlari (SBT) talablarining, xususan ISO 9001:2015, ISO 17025:2019 va ISO 17065:2012 standartlarida belgilangan roli, shuningdek, **integratsiyalashgan boshqaruv tizimi (IBT)**ning afzalliklari va qiyinchiliklari. Ta'kidlanishicha, ushbu standartlarni birlashtirgan IBT samaradorlikni sezilarli darajada oshiradi, xarajatlarni kamaytiradi va operatsiyalar mutanosibligini yaxshilaydi, alohida qismlarning yig'indisidan ustun bo'lgan sinergik effektni ta'minlaydi. Maqolada standartlarning umumiy elementlari va o'ziga xos farqlari tahlil qilinadi, talablarni muvofiqlashtirishning amaliy yondashuvlari va integratsiya murakkabligi hamda xodimlar qarshiligi kabi muammolarni bartaraf etish yo'llari taklif qilinadi, bu esa global bozorda ishonch va raqobatbardoshlikni mustahkamlashga olib keladi.*

Kalit so‘zlar: *sifatni boshqarish tizimi, integratsiyalashgan boshqaruv tizimi, ISO 9001:2015, ISO 17025:2019, ISO 17065:2012, standartlar integratsiyasi, IBT afzalliklari, joriy etish qiyinchiliklari, talablarni muvofiqlashtirish, xavfni boshqarish*

Introduction

In today's global economy, Quality Management Systems (QMS) are crucial for organizations to remain competitive and ensure sustainable development. Standards developed by the International Organization for Standardization (ISO) help organizations regulate their activities, improve product and service quality, manage risks, and build customer trust. Specific standards like ISO 9001:2015, ISO 17025:2019, and ISO 17065:2012 set distinct requirements for various types of organizations (e.g., manufacturers, testing laboratories, certification bodies). While each of these standards serves its unique purpose, their integration within an Integrated

Management System (IMS) offers significant synergistic advantages.

This paper will examine the core requirements of the aforementioned ISO standards, analyze the definition and essential components of an IMS, and explore both the benefits and challenges associated with IMS implementation. Furthermore, practical approaches and best practices for integrating ISO 9001, ISO 17025, and ISO 17065 into a single management system will be presented. The objective of this paper is to demonstrate the critical role of an integrated management system in ensuring operational excellence and international recognition for organizations.

Literature Review

A review of the literature on quality management systems and their integration reveals the central role of ISO standards in enhancing organizational efficiency and competitiveness in global markets.

- ISO 9001:2015 (Quality management systems – Requirements): This standard is broadly applicable to all types of organizations. It emphasizes customer satisfaction, a process approach, and risk-based thinking. Numerous studies confirm that implementing ISO 9001 contributes to increased organizational efficiency and strengthens customer confidence. Its "High-Level Structure" (HLS) facilitates integration with other ISO standards.
- ISO 17025:2019 (General requirements for the competence of testing and calibration laboratories): This standard focuses specifically on the technical competence of laboratories and the validity of their test and calibration results. It includes stringent requirements for method validation, metrological traceability to SI units, and detailed personnel qualifications. Literature indicates that adopting ISO 17025 in laboratories significantly enhances the reliability and reputation of their results.
- ISO 17065:2012 (Conformity assessment – Requirements for bodies certifying products, processes and services): This standard ensures the impartiality and competence of certification bodies. Its purpose is to provide confidence to all interested parties in the conformity of a product, process, or service to specified requirements. Research highlights the importance of this standard for certification bodies and its role in boosting market trust.

The concept of an Integrated Management System (IMS) has gained increasing prominence in recent years. The literature consistently suggests that an IMS achieves a synergistic effect, qualitatively surpassing the mere summation of benefits from implementing individual management systems. This leads to optimized resources, elimination of redundancies, reduced bureaucracy, and simplified decision-making. However, challenges in IMS implementation, such as integration complexity, employee resistance, and resource constraints, are also recognized. Many sources emphasize the crucial role of top management commitment, effective training, and clear communication in overcoming these obstacles.

This study aims to ascertain how the combined application and integration of these standards create additional value for organizations.

Research Methodology

This study is based on qualitative analysis and utilizes the following methodological approaches:

1. Document Analysis: The official texts of ISO 9001:2015, ISO 17025:2019, and ISO 17065:2012 standards were thoroughly examined. The main requirements, structure, and objectives of each standard were identified.

2. Comparative Analysis: Common elements and specific differences between the three standards were identified and systematized. This analysis helped to pinpoint areas that facilitate integration and those that require particular attention when building an IMS. Tables (Table 1 and Table 2) were constructed to clearly illustrate common and specific aspects.

3. Conceptual Framework Exploration: The concept of an Integrated Management System (IMS), its core components, benefits, and implementation challenges were analyzed based on existing scientific literature and publications.

4. Identification of Best Practices: Practical approaches and recommendations for implementing IMS and harmonizing ISO standards were synthesized. These approaches are designed to assist organizations in effectively managing the integration process.

This methodology allowed for a systematic understanding of the complex interrelationships between ISO standards and IMS, as well as the development of practical recommendations for their successful integration.

Analysis and Results

Definition of an Integrated Management System (IMS) and Its Core Components

An Integrated Management System (IMS) is defined as a combination of two or more management systems that function as a single entity. This holds true even if these systems do not encompass every aspect of an organization's activities (e.g., financial management). The most frequently encountered components within an IMS include quality management systems (ISO 9001), environmental management (ISO 14001), and occupational health and safety management (OHSAS 18001/ISO 45001). Other relevant systems, such as information security (ISO 27000) or food safety (ISO 22000), can also be integrated. At its foundation, an IMS is built upon widely accepted quality management principles. These principles include a process-oriented approach, a systemic approach, strong leadership, active involvement of personnel, and a commitment to continuous improvement.

Benefits of IMS Implementation

Implementing an IMS delivers significant advantages that extend far beyond

simply accumulating the benefits of individual management systems. It enables an organization to achieve a qualitatively superior overall outcome compared to the sum of its individual parts. Key benefits observed include:

- Increased Productivity and Efficiency: Achieved through aligned actions and optimized processes across different management disciplines.
- Elimination of Redundancy and Cost Reduction: Avoids the duplication of documents, processes, positions, and functions, leading to substantial savings in system development, operation, and certification efforts.
- Accountability and Consistency: Ensures consistent actions within process interactions, facilitating prompt problem-solving and a unified approach.
- Reduced Bureaucracy: Processes are better adapted to changes, streamlining operations and lessening administrative burdens.
- Facilitation of Decision-Making: An IMS simplifies the holistic perception of the management system by leadership, which enhances the effectiveness of planning and control.
- Attractiveness to Consumers and Investors: Significantly enhances the organization's reputation and fosters greater trust from clients, society, and governmental bodies.
- Simplified Audits: Enables integrated audits and inspections, thereby reducing the time and financial costs associated with external checks.
- Production Optimization and Traceability: Increases management's awareness of processes and helps in identifying weaknesses and areas for improvement.

These advantages, such as heightened productivity, eliminated redundancy, cost savings, improved consistency, and simplified audits, are consistently highlighted across various sources. They truly represent an effect that goes beyond the straightforward summation of benefits from implementing separate management systems. The concept of a "synergistic premium" accurately describes how the cumulative impact of an IMS qualitatively outperforms the sum of its constituent parts. By integrating these systems, organizations gain substantial efficiencies, drastically cut bureaucratic overhead, and achieve a more comprehensive and coherent perspective on their operations. This, in turn, leads to considerable improvements in overall performance, adaptability, and responsiveness to evolving circumstances. This synergistic benefit directly stems from the application of common management system requirements across diverse ISO standards.

Main Challenges in IMS Implementation and Ways to Overcome Them

Despite its numerous benefits, implementing an IMS presents several challenges that organizations must address:

- Complexity of Integration: Each standard possesses unique requirements, documentation, and processes. Harmonizing these diverse standards without compromising their individual effectiveness can be technically demanding.

- Employee Resistance and Cultural Changes: Employees may resist changes due to fears of increased responsibilities or a misunderstanding of the true value of an IMS.
- Resource Constraints: IMS implementation often demands significant investments in time, financial resources, and qualified personnel, which can be particularly challenging for small and medium-sized enterprises (SMEs).
- Balancing Multiple Objectives: Organizations face the necessity of balancing various objectives (e.g., quality, safety, environmental performance) without compromising any single one.
- Documentation Overload: The task of developing, maintaining, and synchronizing documentation across all integrated standards can become highly complex and burdensome.
- Auditor and Certification Issues: Finding auditors with comprehensive experience in evaluating integrated management systems can be difficult.

While technical complexities and resource constraints are well-recognized challenges in IMS implementation, the continuous emphasis on "employee resistance and cultural changes" and their corresponding solutions, such as "top management support" and "effective training and communication," underscore that the most significant obstacles are frequently human and cultural, rather than purely technical. This suggests that successful IMS implementation is less about simply merging documents and more about cultivating a unified organizational culture that actively embraces integrated thinking, cross-functional collaboration, and a commitment to continuous improvement. Without strong, visible leadership and broad employee support, even the most technically robust integration plan is likely to encounter significant resistance, exhibit low effectiveness, or ultimately fail. This indicates a deeper causal relationship where human factors and cultural alignment are paramount for the sustainable success of IMS implementation.

Ways to overcome these challenges include:

- Strategic Planning and Gap Analysis: Conducting a thorough analysis of the current state and developing a detailed plan with clear objectives and timelines.
- Top Management Commitment: Ensuring active support and a visible demonstration of commitment from leadership is crucial for driving the initiative.
- Stakeholder Involvement: Engaging employees and other stakeholders early through comprehensive training and open communication.
- Documentation Optimization: Developing a unified documentation structure and leveraging digital tools to manage and streamline documentation processes.
- Training and Capacity Building: Providing targeted training to personnel on IMS principles and their specific roles within the integrated system.
- Technological Integration: Implementing management system software (e.g.,

LIMS for laboratories) to automate data collection, compliance tracking, and reporting, thereby enhancing efficiency and accuracy.

- Phased Implementation: Adopting a phased approach, starting with the most compatible standards, to manage complexity and build momentum gradually.

Integrating ISO 9001, ISO 17025, and ISO 17065 into a Single Management System

Integrating various ISO standards into a single management system is a complex but highly beneficial undertaking. It necessitates a deep understanding of both the common principles and the specific requirements unique to each standard.

Common Elements and Synergies Between Standards

Despite their specific differences, ISO 9001, ISO 17025, and ISO 17065 share several common elements that significantly facilitate their integration within an IMS. These shared features are rooted in fundamental quality management principles and encompass:

- Document and Record Control: All standards mandate documented procedures and records. While ISO 9001 focuses on the completeness of documents and general record-keeping, ISO 17025 requires detailed records for laboratory methods, equipment, and personnel. ISO 17065 also necessitates structural documentation to ensure the stable and confidential operation of the certification body.
- Internal Audits: Required by all three standards for monitoring system conformity and effectiveness. However, ISO 17025 audits must delve into technical areas of laboratory operations, not just administrative ones. ISO 17065 audits are specifically designed to ensure competence and impartiality of the certification body.
- Corrective Actions: All standards emphasize the need to respond to nonconformities, identify their root causes, and implement measures to eliminate and prevent their recurrence.
- Management Review: Management is required to regularly review the management system to ensure its continuing suitability, adequacy, and effectiveness.
- Risk and Opportunity Management: While their specific focus may vary, all standards necessitate the identification and management of risks and opportunities relevant to their scope. For ISO 17025, this includes risks related to impartiality and the validity of results, and for ISO 17065, risks affecting impartiality are central.
- Continuous Improvement: The principle of continuous improvement is an intrinsic element embedded within all three standards. ISO 17025 specifically requires the implementation of improvements and corrective actions, while ISO 17065 aims to improve the quality of services provided.
- Personnel Competence: All standards include requirements for personnel competence. ISO 17025 has explicit demands for personnel competence (education, qualification, experience) directly tied to specific testing/calibration methods, and ISO

17065 also details requirements for personnel competencies and education.

- Impartiality/Confidentiality: While ISO 9001 has general, implicit requirements for impartiality, both ISO 17025 and ISO 17065 contain explicit and strict requirements for maintaining impartiality and confidentiality, which are crucial to their respective scopes.

For clarity, these common elements are presented in Table 1 below.

Table 1

Common Elements of ISO 9001, ISO 17025, and ISO 17065 Standards

Common Element	ISO 9001:2015	ISO 17025:2019	ISO 17065:2012
Document and Record Control	Requires documented procedures and records, focuses on completeness.	Requires documented procedures and detailed records (methods, equipment, personnel).	Requires structural documentation for stable operation and confidentiality.
Internal Audits	Required for monitoring conformity and effectiveness.	Required, must delve into technical areas.	Required to ensure competence and impartiality.
Corrective Actions	Requires response to nonconformities and their elimination.	Requires response to nonconformities, root cause analysis, and prevention of recurrence.	Requires procedures for eliminating nonconformities.
Management Review	Management must regularly review the QMS.	Management must regularly review the management system.	Management must ensure stable operation and impartiality.
Risk and Opportunity Management	Requires identification and management of risks and opportunities.	Requires assessment of risks and opportunities related to impartiality and results.	Requires impartiality and management of risks affecting it.
Continuous Improvement	Principle of continuous improvement.	Requires implementation of improvements and corrective actions.	Aims to improve the quality of services provided.

Personnel Competence	Requirements for personnel competence.	Requirements for personnel competence (education, qualification, experience), tied to specific methods.	Requirements for personnel competencies and education.
Impartiality/ Confidentiality	General requirements for impartiality (implicit).	Explicit and strict requirements for impartiality and confidentiality.	Explicit and strict requirements for impartiality and confidentiality.

Specific Differences and Features Requiring Attention During Integration

Despite their commonalities, each standard possesses unique and highly specific requirements that are crucial and cannot be overlooked during integration. These differences define the specific application of each standard and necessitate particular attention when constructing an integrated system.

- ISO 9001:2015: This standard focuses on overall customer satisfaction and the organization's business processes as a whole. It is considered "broader" and less prescriptive regarding "how" to meet requirements. Its primary objective is to demonstrate the organization's capability to consistently provide products and services that fulfill both customer and regulatory requirements.
- ISO 17025:2019: This standard is extremely specific to laboratories, emphasizing technical competence and the validity of test and calibration results. It mandates requirements for method validation, metrological traceability to SI units, specific conditions for equipment and environmental control, and detailed personnel records that are linked to specific testing/calibration methods.
- ISO 17065:2012: This standard is specific to product, process, and service certification bodies, with a strong emphasis on impartiality and competence in conducting third-party conformity assessments. Its purpose is to instil confidence in all interested parties regarding the conformity of a product, process, or service to specified requirements.

Key differences in focus and requirements are presented in Table 2 below.

Table 2

Specific Differences of ISO 9001, ISO 17025, and ISO 17065 Standards

Aspect	ISO 9001:2015	ISO 17025:2019	ISO 17065:2012
Primary Focus	General quality management, customer satisfaction, applicable to any	Competence of testing and calibration laboratories, validity of results.	Requirements for product, process, and service certification bodies, impartiality, and

	industry.		competence.
Method Validation	Does not require method validation.	Requires validation of non-standard/modified methods.	Not directly applicable to certification (focus on schemes).
Metrological Traceability	Does not mention traceability.	Requires traceability to SI units through calibrated standards.	Not directly applicable, but important for testing within schemes.
Equipment/Environment Requirements	Requires "suitable" resources.	Requires specific environmental conditions and calibrated equipment for result validity.	Requires availability of material resources to perform work.
Handling of Samples	May relate to general procedures.	Includes detailed requirements to prevent contamination, degradation, and misidentification of samples.	Not directly applicable, but important for testing within schemes.
Certification/ Accreditation	Certification (any organization).	Accreditation (laboratories).	Accreditation (certification bodies).
Surveillance/ Reassessment	Periodic surveillance (annually), reassessment (every 3 years).	Regular surveillance with in-depth technical audits, including observation of work.	Regular surveillance to ensure impartiality and competence.

Practical Approaches and Best Practices for Harmonizing Requirements

Effective integration requires a strategic approach that meticulously considers both the common and specific requirements of each standard:

- Unified Document and Record Control Procedure: Establishing a single, comprehensive set of documents and procedures for controlling documents and records across all three standards significantly reduces bureaucracy and duplication. This ensures consistency and traceability of information throughout the integrated system.
- Separate but Coordinated Risk Management Systems: It's recommended to

maintain separate risk management systems for each standard. This accounts for their differing focuses (e.g., business risks and customer satisfaction for ISO 9001; risks to laboratory result validity for ISO 17025; risks to certification impartiality for ISO 17065). This approach ensures adequate attention to specific threats without diluting the focus of any individual standard.

- Unified Improvement and Corrective Action Procedures: Procedures for improvement and corrective actions can be combined effectively, as the principles of nonconformity elimination and continuous improvement are universal across all management systems. This promotes a more effective and coordinated problem-solving process.
- Unified Internal Audit Procedure, but Separate Programs/Schedules: While the overarching internal audit procedure can be common, audit programs should be separate for each standard to ensure in-depth verification of their specific requirements. It's important to remember that external auditors will likely conduct separate audits for each standard, necessitating corresponding depth of review during internal audits.
- Unified Management Review Procedure, but Separate Agendas: It is feasible to conduct a combined management review, but with distinct agendas and focus points for each standard. This ensures that all necessary input and output data specific to each system are comprehensively considered. This allows management to maintain a holistic view of the system without overlooking details critical to each standard's compliance.
- Comprehensive Staff Training: Staff training should encompass the requirements of all integrated standards. This ensures personnel's awareness and competence within the IMS, promoting cross-functional understanding and collaboration. Such training is instrumental in overcoming resistance to change and fostering a unified corporate culture.
- Use of Technological Solutions: Implementing management system software (e.g., a Laboratory Information Management System - LIMS for laboratories) significantly facilitates integration. These tools automate data collection, compliance tracking, and reporting, thereby enhancing both efficiency and accuracy. Technology plays a pivotal role in reducing complexity and managing documentation overload effectively.

Conclusion and Recommendations

The analysis of regulatory requirements for quality management systems, particularly ISO 9001:2015, ISO 17025:2019, and ISO 17065:2012, alongside the concept of an Integrated Management System (IMS), reveals their critical role in ensuring organizational operational excellence and international recognition. ISO 9001 serves as a universal foundation for a general quality management system, applicable to any organization, promoting proactive risk management and strategic leadership.

ISO 17025 and ISO 17065, in turn, are specialized standards that ensure the technical competence of laboratories and the impartiality of certification bodies, respectively. These standards are not merely compliance tools; rather, they are strategic assets that enable organizations to gain market trust and act as "multipliers of trust" in the global economy.

The integration of these standards within an IMS offers significant advantages, including increased productivity, reduced redundancy and costs, improved consistency, and simplified audits. This synergistic effect allows for qualitatively superior results compared to separate system implementations. However, successful integration is not without challenges, such as the complexity of harmonizing diverse requirements, potential employee resistance, and resource constraints. Overcoming these obstacles necessitates strategic planning, active commitment from top management, comprehensive involvement of all stakeholders, optimized documentation practices, thorough training, and the judicious use of modern technological solutions.

Ultimately, a comprehensive approach to quality management through an IMS, by effectively combining the common and specific requirements of ISO 9001, ISO 17025, and ISO 17065, is more than just a matter of compliance. It is a strategic imperative for organizations striving for sustainable development, enhanced competitiveness, and strengthened trust in the global market.

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