

**DEVELOPMENT AND IMPLEMENTATION OF A QUALITY MANAGEMENT
SYSTEM IN ENTERPRISES AND ORGANIZATIONS**

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Annotation: this article focuses on the organization of standards, processes and Product Quality Management in order to obtain a certificate of the enterprise quality management system, among others.

Keywords: quality management, standard, product quality, technical, economic employee, only Examiner, quality industry, business process.

In today's era of globalization, every enterprise and organization must implement a Quality Management System (QMS) in order to maintain its competitiveness and secure a leading position in the market. A quality management system is not merely the control of product or service quality but a strategic management framework aimed at the continuous improvement of all production, management, and service processes. The ISO 9000 series of standards is considered the most important international regulatory framework for quality management. These standards enable enterprises to standardize internal processes, increase customer trust, and produce competitive products suitable for market demands.

There are two main approaches to implementing ISO 9000 standards. In the first approach, the standards are used as an instrument for improving the organization's efficiency. This approach requires internal motivation for implementation, created and supported by senior management; without such commitment, long-term development is unlikely. The focus here is on enhancing the system's effectiveness, conducting impartial internal audits, allocating resources for self-assessment, and developing an optimal structure of documentation. Organizing the quality management system and ensuring high-quality processes and products become the main priorities. In the second approach, the standards are introduced specifically to obtain a certificate. This may arise from a desire not to fall behind competitors or from contractual obligations and tender requirements imposed by customers or partners. In such cases, the enterprise's efforts are directed primarily toward formally meeting the requirements of the certification body and preparing the required documentation, while technical and economic decision-making may receive less attention. Employees focus mainly on fulfilling tasks needed for inspections rather than genuine quality improvements, even though the true goal of implementing standards should be the enhancement of quality.

The development of a quality management system involves work in functional and organizational directions. The functional direction includes the formulation of the enterprise's quality policy, preparation of the quality manual, development of documented procedures for the core business processes, creation of internal standards, and introduction of analytical and statistical control methods when necessary. The organizational direction involves establishing a quality department, identifying individuals and divisions responsible for maintaining QMS documentation, appointing an authorized quality representative, and ensuring cooperation between the quality department and other divisions during QMS development and implementation.

For effective implementation of a QMS, it is necessary to clearly define the enterprise's quality strategy, create a working group to develop and introduce the system, conduct an analysis of business processes, and carefully review all quality-related activities carried out within the enterprise. Developing a QMS and its documented procedures is a complex and highly responsible stage and is therefore considered a separate phase of the project. The aim of ISO 9000 certification is to verify whether the various components of an enterprise's quality system satisfy the formal requirements of the standard. Assessing the conformity of the QMS to these requirements can be difficult and time-consuming. Before deciding whether the enterprise is ready for ISO 9000 certification, management must thoroughly assess internal agreement and potential objections, and clearly determine the reasons why the enterprise needs the certificate.

Some authors argue that enterprises certified under the ISO 9001:1994 standard did not achieve the expected outcomes. In our opinion, the issue lies not in the volume of work required by the standard but in the degree to which employees understand and correctly implement the requirements. Initial failures in QMS development and implementation are possible; however, major non-conformities, excessive formality, or criticisms by unqualified auditors tend to diminish over time. Even abroad, ISO 9000 certification is obligatory mainly in industries where product quality is directly linked to human health and safety, such as the defense, aerospace, and automotive sectors. In some cases, having a certificate becomes a requirement imposed by the customer. In other cases, the ISO 9000 certificate is not mandatory but offers advantages during supplier selection.

The widespread global use of the standard is explained by its universality, allowing it to be applied in any type of organization, from educational institutions to military industries. The ISO 9000 series thus serves as an organizational and methodological foundation for enterprise quality management. International certification has become widely used around the world as an instrument for improving the quality of products and services. A diagnostic audit of the existing management system is usually conducted to form the basis for QMS development. The purpose of this audit is an initial assessment of the structure and functioning of the current management system and its compliance with ISO 9001 international requirements.

Total Quality Management (TQM) represents a comprehensive approach to quality management based on the active participation of employees at all levels. It rests on principles such as customer orientation, the leadership role of management, a process-based approach, decision-making based on facts, continuous improvement, and collective responsibility within the organization. The TQM concept aligns closely with ISO 9001 standards and provides both theoretical and practical foundations for creating an effective management system within enterprises.

In today's rapidly advancing digital environment, quality management systems are undergoing transformation. The concept of smart quality management involves the automation of production processes, real-time quality monitoring through artificial intelligence, and data-driven analysis. Technologies such as the Internet of Things make it possible to automatically identify defects on production lines, while Big Data analytics enables the forecasting of quality indicators. These technological advancements significantly reinforce an enterprise's competitiveness.

Implementing a quality management system ensures not only international recognition but also improved efficiency, stronger customer trust, and greater stability in the market. A QMS aligned with the ISO 9000 standards is a crucial factor in ensuring the sustainable development of an organization. In the future, deeper integration of digital technologies will lead to the emergence of a new model of quality management that will transform traditional approaches and enhance enterprise performance.

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