

ISO 9001:2015 TECHNICAL GUIDE



LEAD



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ISO 9001:2015, the gold standard for **QUALITY** **MANAGEMENT**

Successful companies are driven to deliver **quality**, from the way they operate to the customer service standards they establish, and the products they manufacture and sell. A commitment to quality will improve **brand equity** and **image** and ensure you are better equipped to create new opportunities in an increasingly competitive global marketplace.

The **purpose** of ISO 9001:2015 is to help you develop a robust **Quality Management System** in order to be able to respond to evolving quality requirements in line with changing social, economic and environmental expectations. The ISO 9001:2015 standard offers flexibility, enabling you to design your own quality management system around your specific products, customer needs and risks.

With the ISO 9001:2015 standard, you will demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements.

“

ISO 9001:2015 provides a comprehensive model for managing your business processes and performance and improving customer satisfaction. By focusing the attention of everyone in the organization on risk, you influence your employees' behavior, increasing awareness and reducing failures

”

Why certify to ISO 9001:2015?

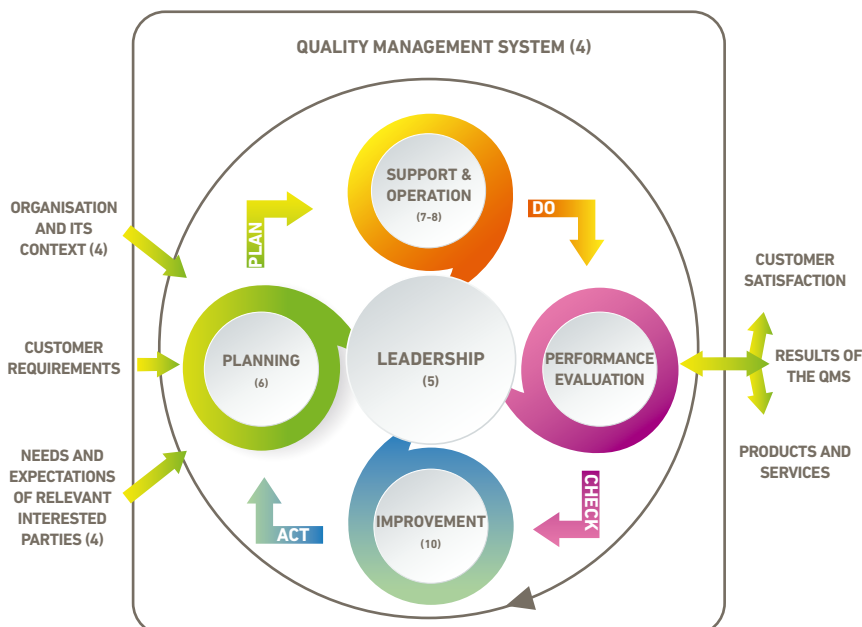
Certification to the **ISO 9001 Quality Management System** standard ensures that your business **meets consumer and legal requirements, and has a number of additional advantages:**

- Continuously improve performance
- Implement streamlined processes and optimize operational efficiency
- Ensure you are making the right decisions for your organization
- Exceed customer expectations



CLAUSE-BY-CLAUSE ANALYSIS

Use of a common High-Level Structure across a number of ISO standards make it easier for you to adopt an integrated approach to management of business risks including Quality, Health & Safety and Environmental Management.



The Quality Management System is based on the Plan-Do-Check-Act (PDCA) model, which was designed to help organizations achieve continual improvement.

CLAUSE 1 | SCOPE

ISO 9001:2015 is **applicable to any organization**, regardless of its size, type or the products or services it provides. All the requirements of the standard for a Quality Management System take into account factors like the context in which an organization operates and the needs and expectations of its stakeholders.

ISO 9001:2015 is applicable to any organization that needs to demonstrate its ability to consistently provide products and services that meet customer expectations and comply with legal requirements.

CLAUSE 2 | NORMATIVE REFERENCES

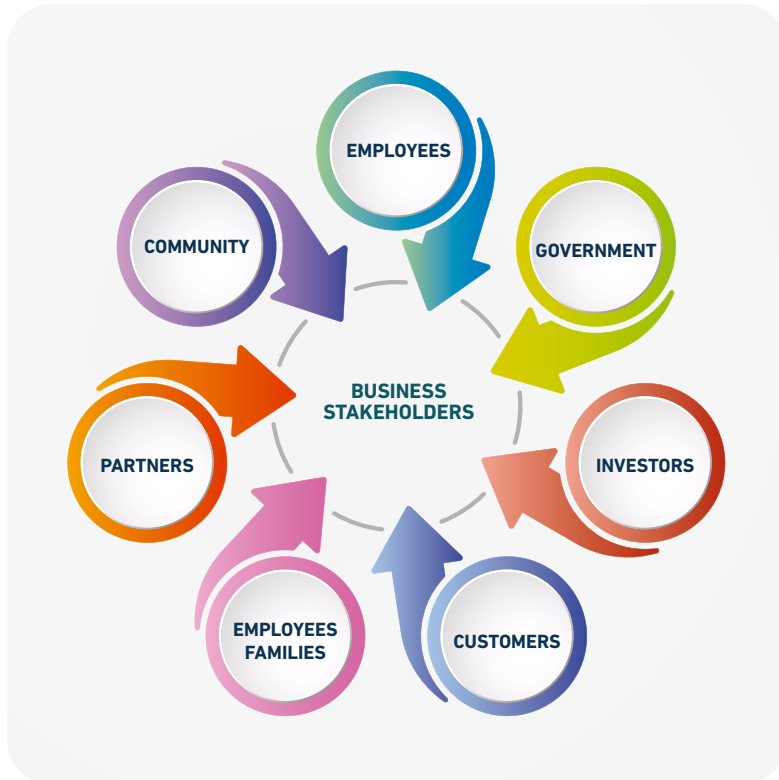
This clause designates ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary* as a normative reference. This means that ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary* is essential to the proper understanding and implementation of ISO 9001:2015.

Analyzing the context of the organization requires managers to consider the organization's strengths and weaknesses, and the opportunities and threats it faces. Outputs are used as one of the primary inputs to your quality management system

CLAUSE 3 | TERMS AND DEFINITIONS

Clause 3 states that ISO 9000:2015 provides definitions for all key terms found in ISO 9001:2015.

CLAUSE 4 | CONTEXT OF THE ORGANIZATION

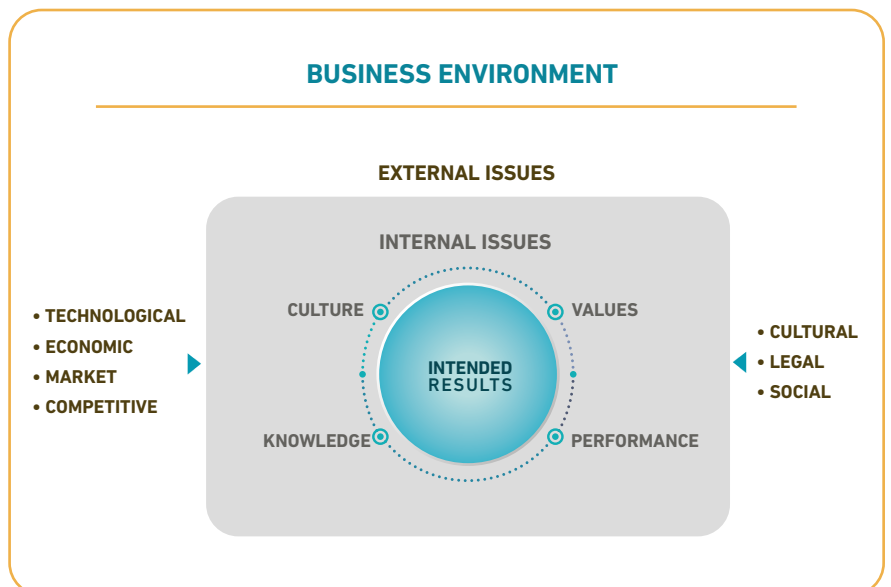


Chapter 4 Context explains the requirements for an organization to identify the issues and requirements that could impact the design of the Quality Management System, and can be used to develop the system. This exercise includes identifying relevant stakeholders and determining their requirements to ensure that goods and services meet external bodies' needs and expectations. The organization's senior management must be directly and actively involved in the shaping of its mission and vision and consider both the internal and external issues that may affect its ability to achieve its objectives. They must take into account **changes and trends, relationships, stakeholders' perceptions and values, strategic priorities and resource availability**, as well as any other issues that could have an impact on the organization's ability to reach its objectives.

The **"context"** of the organization is the **business environment** in which it operates. Understanding the external context requires considering **legal, technological, competitive, market, cultural, social and economic** factors, whether international, national, regional or local.

In order to understand the internal context, organizations must consider issues related to the **values, culture, knowledge and performance** of the company.

Clause 4 also explains how to determine **the scope** of the Quality Management System and what factors need to be considered, as well as the importance of establishing **processes** that maintain and improve a Quality Management System.



Top management play an integral role in ISO 9001:2015. Indeed, the success of the quality management system depends on their engagement and leadership

CLAUSE 5 | LEADERSHIP

The implementation of a Quality Management System requires **proactive leadership** and the **involvement of top management** in integrating Quality Management System requirements into its business processes and identifying risks that might affect the conformity of products and services or customer satisfaction. The quality policy must include a commitment to improving all relevant aspects of the Quality Management System—not just its **effectiveness**—and must provide a **framework** (i.e. **a process**) for setting quality objectives.

TOP MANAGEMENT MUST BE ACTIVELY ENGAGED IN THE:

- Shaping of **mission, vision** and **strategic priorities**
- Determination of the company's organizational **context**
- **Implementation** and **maintenance** of the Quality Management System
- **Communication** of the Quality Management System throughout the organization
- Evaluation of **changes** and **trends**
- Continuous **improvement** of the Quality Management System
- Assessment of **stakeholder** relationships, perceptions and priorities
- Securing of appropriate **resources**

CLAUSE 6 | PLANNING

This clause explains how to address **risks** and **opportunities**, set **quality objectives** and plan **actions**. Procedures for addressing risks and opportunities must be a fundamental element of the Quality Management System and should be proportionate to potential impact on the conformity of organization's products and services. The organization must also establish and document SMART objectives for all relevant processes and levels.

In order to remain competitive and compliant with regulations, companies must undertake changes in a systematic manner by considering a number of factors:

- Potential consequences of changes
- Integrity of the Quality Management System
- Availability of resources
- Allocation and reallocation of responsibilities and authority

CLAUSE 7 | SUPPORT

Resource management is covered in the Support clause. The organization must provide the necessary manpower for the effective execution of the Quality Management System and its processes. The company must also consider how its needs might evolve and what this might mean for human resource management (i.e. professional training, employee evaluation). It also explicitly states that all organizations must take work environment considerations into account in their Quality Management System.

CLAUSE 8 | OPERATION

Clause 8 discusses the importance of developing a process-oriented approach to delivering products and services that meet customer requirements. It explains how these standards need to be **determined, communicated, documented** and continuously **reviewed**. An emphasis is placed on the **design and development** of products and services as well as on the importance of controlling **external** processes, products and services.

The ISO 9001:2015 standard has a strong focus on risk management. As such, it can be used to increase employees' awareness of risk and help create a culture of prevention and risk management

CLAUSE 9 | PERFORMANCE EVALUATION

This clause covers all **monitoring, measurement, analysis** and **evaluation activities** required by the Quality Management System. It delves into the requirements in greater detail:

- What needs to be monitored
- Methods for monitoring, measurement and analysis
- Evaluation criteria for Quality Management System performance
- When performance should be monitored and measured
- When results should be evaluated

It is important to note that customers' perception of the degree to which requirements have been met as well as **their opinions** of the organization and its products and services must be monitored. Analysis and evaluation techniques are listed in detail.

The clause also explains the necessity of conducting internal audits and management reviews in order to ensure the compliance and sustainability of the Quality Management System.

CLAUSE 10 | IMPROVEMENT

Organizations should continuously identify opportunities for improvement of their products and services in order to minimize non-conformities and improve customer satisfaction. The clause explains how to deal with non-conformities and encourages continual improvement.

THE CERTIFICATION PROCESS



THE CERTIFICATION PROCESS TAKES FROM 6 TO 18 MONTHS

What benefits will **ISO 9001:2015?** bring to your organization



HOW BUREAU VERITAS CAN SUPPORT YOU IN YOUR CERTIFICATION

LEAD is an e-commerce platform developed by Bureau Veritas that supports your company in its transformation journey. LEAD combines Training, Tools and Digital Certification Services.

OUR TRAINING SYSTEM

Bureau Veritas is committed to helping your organization achieve its objectives. For this reason, we want to become your expert partner in **Management Systems** training. In order to better adapt to your unique needs, we have created a highly flexible **training system** accessible everywhere and on all platforms. Thanks to our 24/7 online system, you can manage your training experience on your own time.



With our “**ISO 9001:2015 In-Depth**” e-learning course, you will discover the clauses, sections, terms, definitions, requirements and High Level Structure of ISO 9001:2015. The High Level Structure (HLS), which always

consists of ten core clauses is a standardized way of presenting ISO management system standards. This course explains your company’s Quality Management obligations and responsibilities. The overview of the standard provided in this course will equip you with the necessary skills to start designing a Quality Management System in your organization.

WHY CHOOSE BUREAU VERITAS?



Deep knowledge of the regulation and the industries of our clients



World leader in inspection and certification



Technical expertise in over 140 countries



Effective international network



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