

Business has changed significantly since the last major revisions of ISO 9001 in 2000 & 2008. Technology has changed how we work, geographical boundaries are almost insignificant in today's global economy, supply chains are increasingly complex and the information available has multiplied exponentially.

To ensure that ISO 9001 continues to maintain its relevance in today's market-place, the standard has been revised to address the change in the business world. However, one thing remains constant, to be successful, organisations have to adapt to meet the growing needs of customers. ISO was originally written with the customer in mind and that remains the priority for ISO 9001: 2015.

The new standard brings a common framework to all management system standards. This helps to keep consistency, alignment of different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards.

The key changes in the standard are:

- The emphasis on leadership
- The focus on risk management
- Emphasis on objectives measurement and change
- Communication and awareness
- Fewer prescriptive requirements

With the new standard in place, organisations will find it easier to incorporate their quality management system into the core business processes and gain greater business benefit.

Benefits of the new standard

A. Bringing Quality and Continuous Improvement into the Heart of Business

The revised standard ensures that quality management is now completely integrated and aligned with the business strategies of the organisation

B. Leadership

Greater involvement in the management system by the leadership team will ensure the whole organisation is motivated towards the organisations goals and objectives.

C. Introduction of Risk and Opportunity Management

Reinforces the use of the management system as a governance tool and will help identify business opportunities that contribute to bottom line improvements.

D. An Integrated Approach

With the new structure applicable to all new ISO management systems standards it will be much easier to implement multiple, integrated management systems.

ISO9001:2015 is based on the quality management principles. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- evidence-based decision making;
- Supplier relationship management.

ISO9001:2015 promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

- a) understanding and consistency in meeting requirements;
- b) the consideration of processes in terms of added value;
- c) the achievement of effective process performance;
- d) improvement of processes based on evaluation of data and information.

Figure 1 - Schematic representation of the elements of a single process

The PDCA cycle can be applied to all processes and to the quality management system as a whole.

