

# WHITE PAPER

Ultimate transition guide

## ISO 9001:2015

Quality Management System

The impact in international standard  
for quality management system



*Success through management excellence*



Global Standards happy to guide about quality management system - ISO 9001:2015 in a way that can easily be understood. The change is obvious and the same has been applied this time for QMS standard with concrete impacts. This standard with new formation has value meanings for all the organizations on any kind of scope further to ensure the customer satisfaction.

In this white paper the core changes related to structure, auditable requirements, implications and risk based thinking has been incorporated for better guidance.

**All ISO management system standards are subject to a regular review under the rules by which all are written. Following a substantial ISO user survey the committee decided that a review was appropriate and created the following objectives to maintain its relevance to current market for long term bases. However, this change is not going to change upto ten years so that organizations can penetrate in QMS with more durability.**

The ISO 9001:2015 standard is one of the most widely known standards for quality management system to achieve customer satisfaction as outcome, is implemented by over 850,000 organizations in 163 countries.

The ISO 9001 standard has become an international reference for Quality Management requirements in Business-to-business relationships.

ISO 9001 helps organizations of any type and size with “Quality Management System” including:

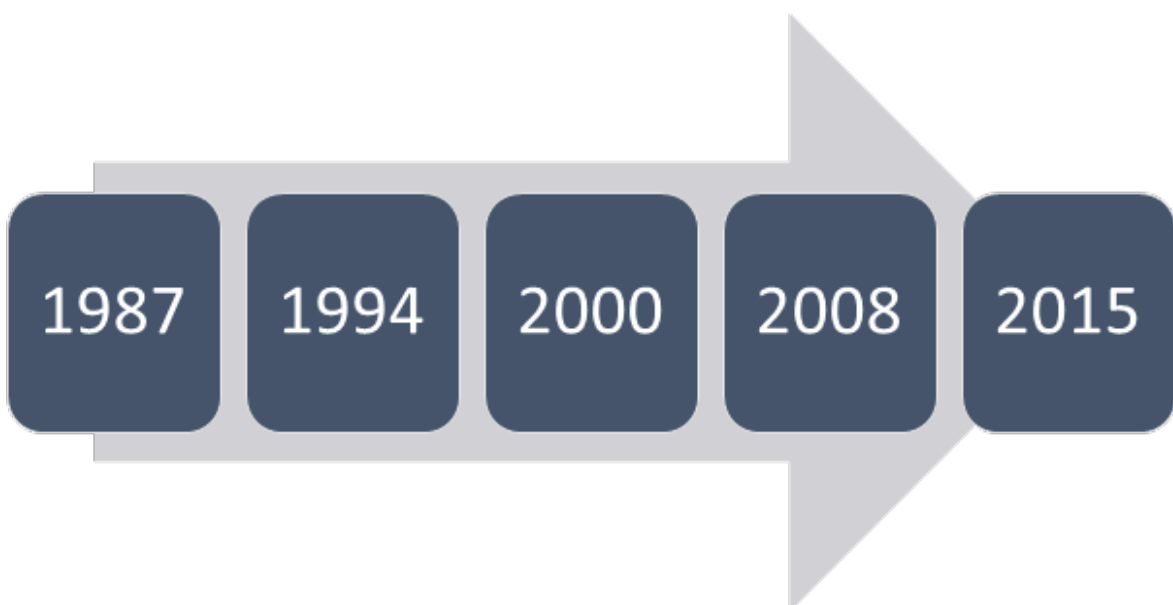
- Fulfilling interested parties’ quality requirements
- Following applicable regulatory requirements
- Enhancement of PDCA cycle
- Achieving improvement through risk based strategy
- Reduce the cost of nonconformities

The standard has earned a worldwide reputation known as the “Quality Management System Standard”, which can be applied to any organization, large or small, whatever its business, products or Services.

“Management system” refers to the organization’s structure for managing its processes or business Activities.

This structure transforms input of resources into a product or service that meets the organization’s business objectives, satisfies the customer’s quality Requirements and complies with regulations.

ISO 9001 provides a framework of requirements for management to address customer focus, process the management approach, and pursue continual Performance improvement



# BENEFITS OF ISO 9001 STANDARD

- Achieve consistency of product and service quality and compliance with legal and associated requirements of interested parties.
- Formalize good working practices through better planning.
- Assure satisfaction and added value to interested parties and feature of existing services.
- Introducing Risk based thinking approach as preventive action and to promote 'Proactive Approach'.
- Understanding and monitoring needs and expectations of interested parties.
- Be internationally recognized as a well-managed organization and business holder for quality management system.
- To increase the promotion of product and services through this standard's tools.
- Employee know what to do and how to execute.
- Better management controls through quality team.
- Monitoring of quality assured working environment.
- Increase credibility among business associates.
- Be confident through internal auditing, organizational knowledge and management reviews.
- Successful achievement of goals through encouraging the continual improvement.

The ISO 9001:2015 standard is based on the management Principles as shown below.

- Principle 1 – **Focus on customer and interested parties**
- Principle 2 – **Provide leadership for your organization**
- Principle 3 – **Engage and involve your people**
- Principle 4 – **Use a process approach**
- Principle 5 – **Encourage improvement**
- Principle 6 – **Use evidence to make decisions**
- Principle 7 – **Manage your corporate relationships**

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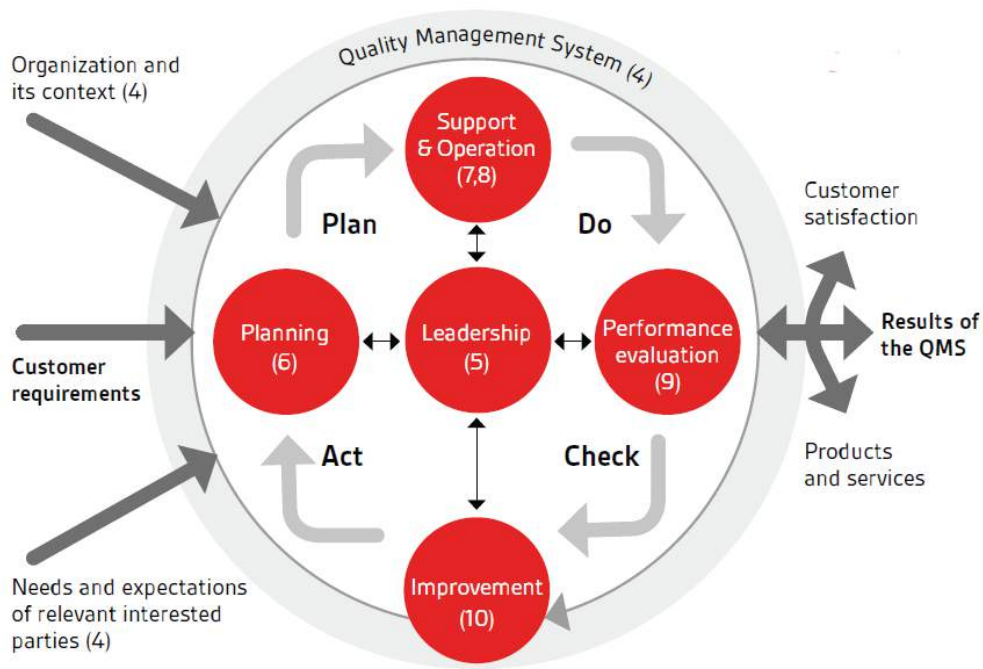
Global Standards ensures to provide the essence of all the core principles of ISO 9001:2015. Previously obsoleting the eight principles by introducing seven principles to adopt QMS standard for any kind of industries, working sector, volume and ergonomics.

# WHAT IS THE CHANGE

## STRUCTURE

ISO 9001:2015 will be based on Annex SL – the new high level structure (HLS) that brings a common framework to all ISO management systems. This helps to keep consistency, align different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards.

## PDCA MODULE



## AUDITABLE CLAUSES

- 4- Context of Organization
- 5- Leadership
- 6- Planning
- 7- Support
- 8- Operation
- 9- Performance Evaluation
- 10- Improvement

## DOCUMENTED INFORMATION

As part of the alignment with other management system standards a common clause on 'Documented Information' has been adopted. The terms "documented procedure" and "record" have both been replaced throughout the requirements text by "documented information". Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to maintain documented information.

# COMPARISION

ISO 9001:2008		ISO 9001:2015	
4	Quality management system	4	Quality management system
4.1	General requirements	4.4	Quality management system and its processes
4.2	Documentation requirements	7.5	Documented information
4.2.1	General	7.5.1	General
4.2.2	Quality manual	4.3	Determining the scope of the quality management system
		7.5.1	General
		4.4	Quality management system and its Processes
4.2.3	Control of documents	7.5.2	Creating and updating
		7.5.3	Control of documented Information
4.2.4	Control of records	7.5.2	Creating and updating
		7.5.3	Control of documented Information
5	Management responsibility	5	Leadership
5.1	Management commitment	5.1	Leadership and commitment
		5.1.1	Leadership and commitment for the quality management system
5.2	Customer focus	5.1.2	Customer focus
5.3	Quality policy	5.2	Quality policy
5.4	Planning	6	Planning for the quality management system
5.4.1	Quality objectives	6.2	Quality objectives and planning to achieve them
5.4.2	Quality management system planning	6	Planning for the quality management system
		6.1	Actions to address risks and opportunities
		6.3	Planning of changes
5.5	Responsibility, authority and communication	5	Leadership
5.5.1	Responsibility and authority	5.3	Organizational roles, responsibilities and authorities
5.5.2	Management representative		Title removed
		5.3	Organizational roles, responsibilities and authorities
5.5.3	Internal communication	7.4	Communication
5.6	Management review	9.3	Management review
5.6.1	General	9.3.1	General
5.6.2	Review input	9.3.1	Review Input

# COMPARISION

5.6.3 Review output	9.3.2 Review Output
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General 7.1.2 People
6.2 Human resources	Title removed 7.2 Competence
6.2.1 General	7.2 Competence
6.2.2 Competence, training and awareness	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Determination of requirements for products and services
7.2.1 Determination of requirements related to the product	8.2.2 Determination of requirements related to products and services
7.2.2 Review of requirements related to the product	8.2.3 Review of requirements related to the products and services
7.2.3 Customer communication	8.2.1 Customer communication
7.3 Design and development	8.5 Production and service provision
7.3.1 Design and development planning	8.3 Design and development of products and services 8.3.1 General 8.3.2 Design and development planning
7.3.2 Design and development inputs	8.3.3 Design and development Inputs
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.4 Design and development review	8.3.4 Design and development controls
7.3.5 Design and development verification	8.3.4 Design and development controls
7.3.6 Design and development validation	8.3.4 Design and development controls
7.3.7 Control of design and development changes	8.3.6 Design and development changes
7.4 Purchasing	8.4 Control of externally provided products and services
7.4.1 Purchasing process	8.4.1 General 8.4.2 Type and extent of control of external provision

# COMPARISON

7.4.2 Purchasing information	8.4.3 Information for external providers
7.4.3 Verification of purchased product	8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities
7.5.2 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8.0 Measurement, analysis and improvement	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes	9.1.1 General
8.2.4 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming process outputs, products and services
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 Continual improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	Clause removed 6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2)

**The correlation between ISO 9001 ver 2008 & 2015 better differentiate the difference the change to adopt the impact easily with less associated risks. It will help organizations to implement or transit their quality management system in better and right ways.**



# ANNEX-SL

## A new high level structure for all management standards

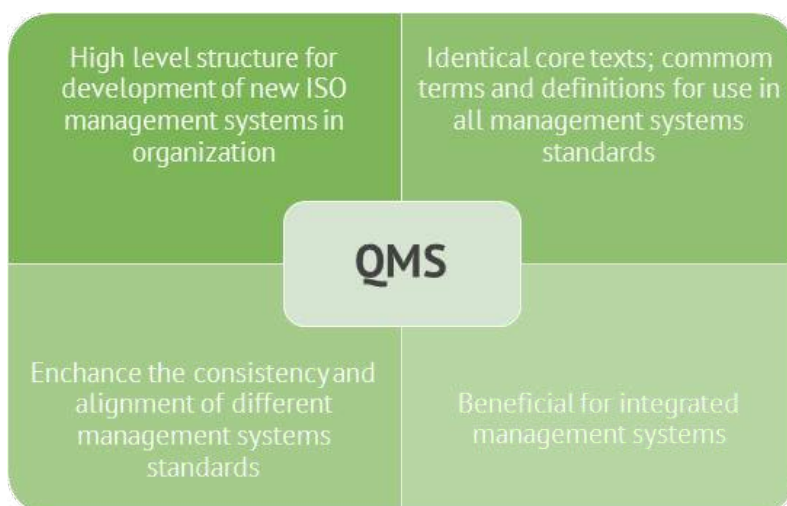
Annex-SL, is a type of structure that was introduced by ISO technical committee to eliminate the gap among all its management standards. This provides the framework of 'common structure' with similar use of terms, definitions, clause patterns and easy integration of standards for organization at the same time.

The common structure of standard requirements:

- Clause 1: **Scope**
- Clause 2: **Normative references**
- Clause 3: **Terms and definitions**
- Clause 4: **Context of the organization**
- Clause 5: **Leadership**
- Clause 6: **Planning**
- Clause 7: **Support**
- Clause 8: **Operation**
- Clause 9: **Performance evaluation**
- Clause 10: **Improvement**

## TRANSITION TIME LINE

September 2018, is the deadline for the transition. Transition should be executed timely to those who are already on ver 2008. After September 2018 no organization shall be eligible to continue ISO 9001:2008 version at all. The timely transition shall secure your continuation of certification and involvement of people to understand the new standard for the continuation of quality management system with spirit of confidence.



**The quick contact to Global Standards shall be in benefit to introduce your organization for true means of ver. 2015 with effective implementation. Global Standards is passionate to deliver for the change and integration with similar standards.**



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