



**Kenya Bureau of  
Standards**

Standards for quality life

# ISO 9001:2015



## What is ISO 9001

ISO 9001 is the international standard that specifies requirements for a quality management system (QMS). Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements.

### STATISTICS

#### 1. About ISO



ISO is a global network of national standards bodies with one member per country.



Established in 1947, in Geneva, Switzerland



In Kenya ISO is represented by KEBS



ISO develops and sells International Standards.

165 members

20 500  
International Standards

100  
new standards each month

More than  
100 000 experts

229  
technical committees

#### 2. ISO 9001

- ISO 9001 was first published in 1987
- 1.2 million organizations are certified to this standard worldwide
- The current version of *ISO 9001* was released on 23<sup>rd</sup> September 2015, the reason why we refer to it as ISO 9001:2015
- **The ISO 9001 Revision Process**  
The process took approximately three years

## The ISO 9001: 2015 Journey...



**Note:** Original revision timing subject to change.

### Who should use the ISO 9001:2015?

ISO 9001:2015 applies to any organization, regardless of size or industry. More than one million organizations from more than 160 countries have applied the ISO 9001 standard requirements to their quality management systems.

Organizations of all types and sizes find that using the ISO 9001 standard helps them:

- Organize processes
- Improve Process efficiency
- Reduce errors
- Reduce operating costs
- Improve organizational performance
- Increase consumer confidence
- Increase customer satisfaction
- Increase speed to market
- Improve quality of products and services
- Manage risks related to the organizational context

All organizations that use ISO 9001 are encouraged to transition to ISO 9001:2015 as soon as possible. This includes not only organizations that are certified to ISO 9001:2008, but also any organizations to achieve certification.

## Reasons for Revision:

### Key perspectives

#### ISO 9001 needs to:

- maintain relevance
- integrate with other management systems
- provide an integrated approach to organizational management
- provide a consistent foundation for the next 10 years
- reflect the increasingly complex environments in which organizations operate
- ensure the new standard reflects the needs of all potential user groups
- enhance an organization's ability to satisfy its customers

ISO/TC 176/SC 2/WG23 N063

Date: 7

## What are the main changes?

### Structure

ISO 9001: 2015 uses a High Level Structure (HLS) of clauses which is intended to provide a coherent presentation of requirements. This is intended to enhance alignment among ISO's management system standards, and to facilitate their implementation for organizations that need to meet the requirements of two or more such standards simultaneously.

### Context of the organization

ISO 9001: 2015 requires an organization to consider the combination of internal and external factors and conditions that can affect an organization's approach to its products, services and investments and interested parties Issues. These aligns ISO 9001 to the organizations strategy.

### Risk-based thinking

The concept of risk-based thinking has been implicit in previous editions of ISO 9001 Standard. ISO 9001: 2015 specifies requirements for the organization to understand its context and determine risks as a basis for planning. This represents the application of risk-based thinking to planning and implementing quality management system processes.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

### **Applicability**

ISO 9001:2015 does not refer to “exclusions” in relation to the applicability of its requirements to the organization’s quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization’s activities and the nature of the risks and opportunities it encounters.

The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

### **Documented information**

Where ISO 9001:2008 used specific terminology such as “document” or “documented procedures”, “quality manual” or “quality plan”, ISO 9001: 2015 defines requirements to “maintain documented information”.

Where ISO 9001:2008 used the term “records” to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to “retain documented information”.

### **Organizational Knowledge**

ISO 9001:2015 addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services.

### **Control of externally provided products and services**

All forms of externally provided products and services must be controlled whether through purchasing from a supplier; an arrangement with an associate company; outsourcing processes to an external provider.

The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided products and services.

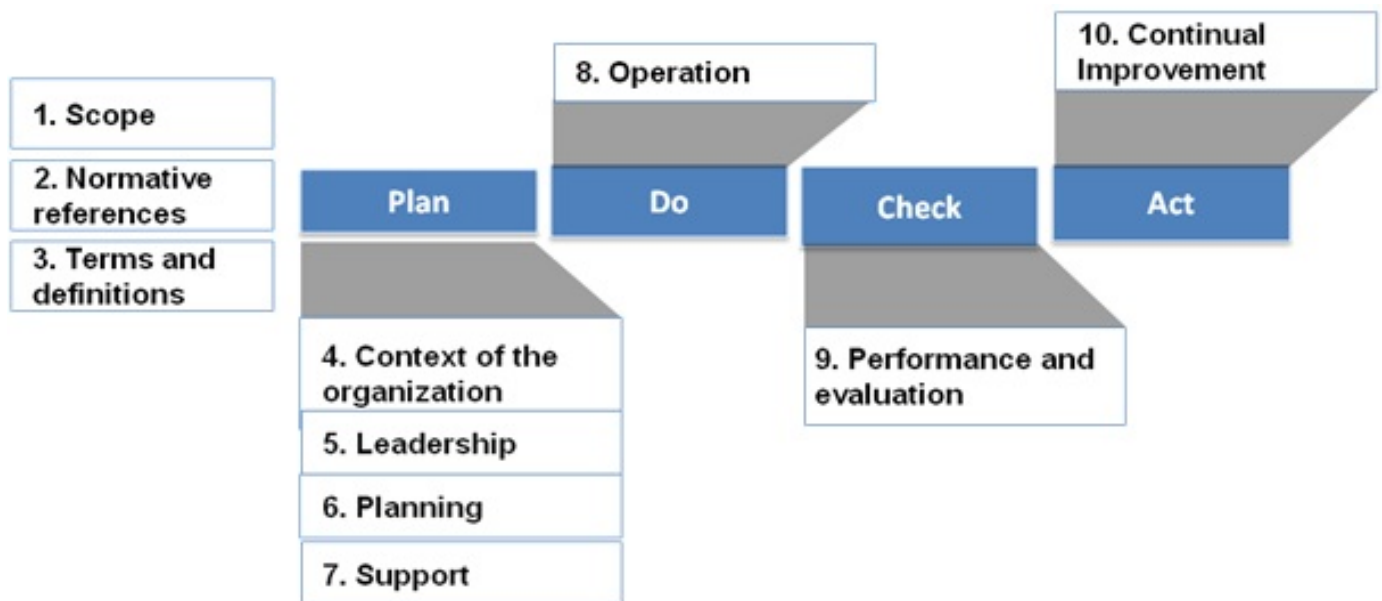
### **Communication**

There is an explicit and more detailed requirement for both internal and external communication.

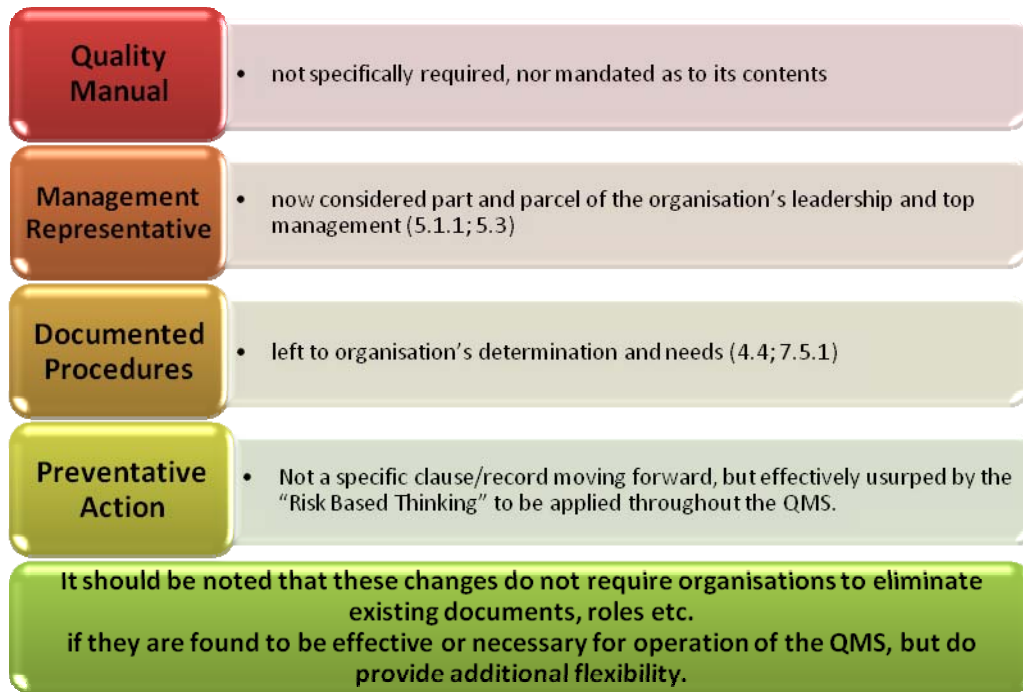
**Content comparison:**

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative Reference	2. Normative Reference
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management Systems	4. Context of the organisation
5. Management Responsibility	5. Leadership
6. Resource Management	6. Planning
7. Product Realisation	7. Support
8. Measurement, Analysis and Improvement	8. Operation
	9. Performance Evaluation
	10. Improvement

**The process model - Plan, Do, Check and Act cycle:**



## What has been dropped?



## I am certified to ISO 9001:2008. What does this mean for me?

Organizations are granted a **three-year transition period** after the revision has been published to migrate their quality management system to the new edition of the standard.



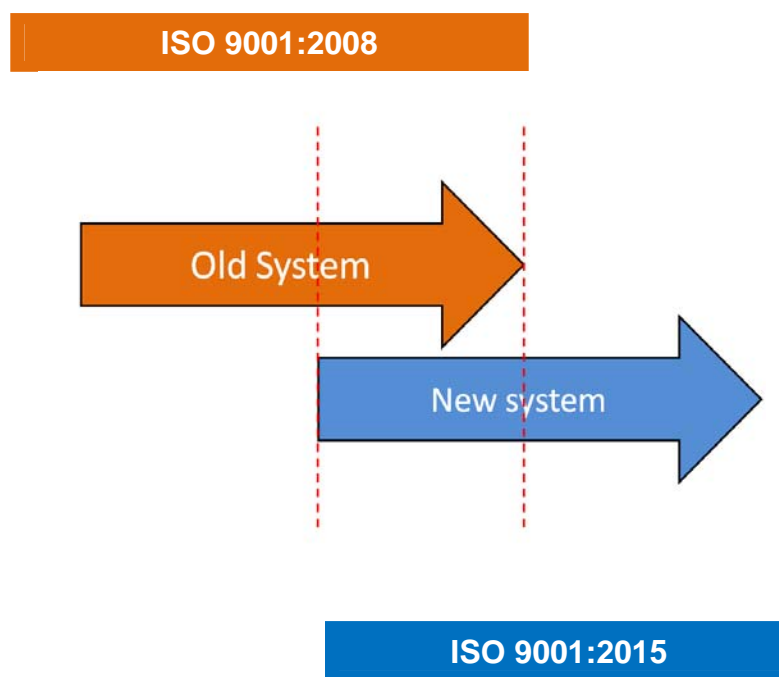
## Validity of certifications to ISO 9001:2008

ISO 9001:2008 certifications will not be valid after three years from publication of ISO 9001:2015. *That is up to 23<sup>rd</sup> Sep 2018*

The expiry date of certifications to ISO 9001:2008 issued during the transition period needs to correspond to the end of the three year transition period. KEBS advises that this transition should be done by July 2018.

Organisations should plan to remain compliant to the current standards while preparing for and implementing changes for the 2015 standards. Early disassociation from the existing requirements may leave organisations without certification should their 2015 transition not go as planned.

Organisations should consider themselves certified/compliant to the existing standard until such time as they have their 2015 certificate in hand; only then can they consider disassembling any previously required framework no longer mandated by the new standards.





## TRANSITION GUIDANCE:

Organizations using ISO 9001:2008 are recommended to take the following actions:

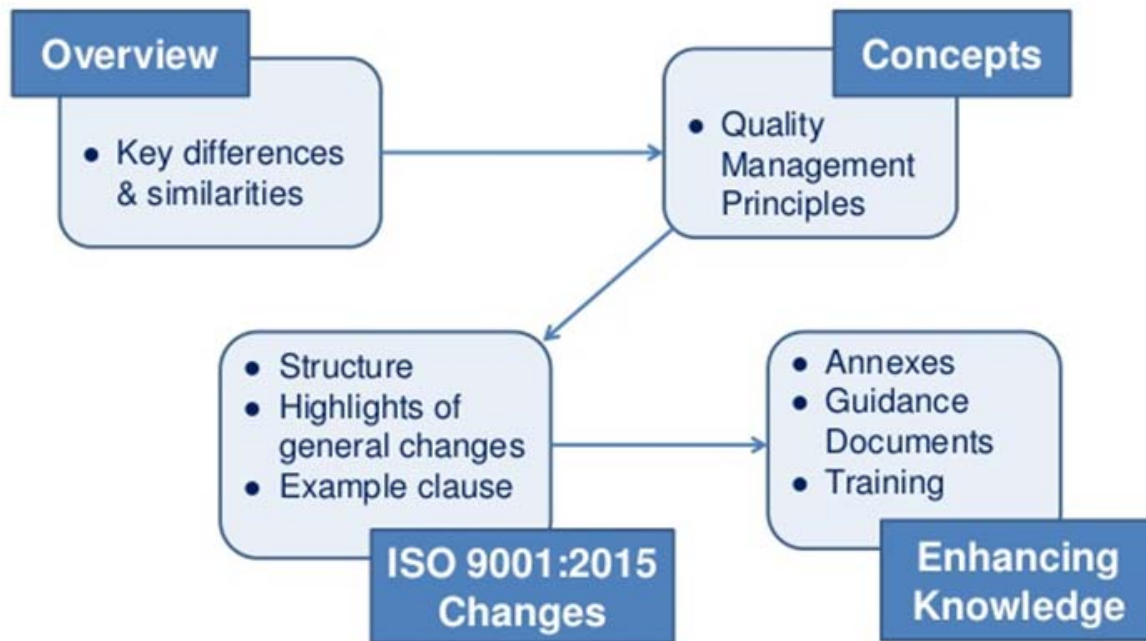
- 1** • Identify organisational gaps which need to be addressed to meet new requirements.
- 2** • Develop an implementation plan.
- 3** • Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation (Contact KEBS - NQI for training arrangements)
- 4** • Update the existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness.
- 5** • Where applicable, liaise with their Certification Body for transition arrangements.

## Training by the KEBS National Quality Institute (NQI)

KEBS - NQI is the leading trainer on quality related courses in the East African Region.

NQI offers customized in-house training as well as open courses where individuals from across the East African region attend and gain knowledge on understanding the requirements of ISO 9001:2015.

### The transition training will cover the following:



### For Organizations transiting from ISO 9001:2008 to ISO 9001:2015

NQI provides both in-house and open courses as follows:

TRAINING	TARGET	DURATION
Top Management Briefing	Top Management	Half day (4 hours)
Implementation Transition Training	Middle management & process owners	2 days
Auditors Transition Training	Internal Quality Auditors	2 days
Awareness Transition training	General staff	1 day

Clients/organizations that have not been trained on ISO 9001:

In-house customized training by NQI can be arranged as follows:

<b>TRAINING</b>	<b>TARGET</b>	<b>DURATION</b>
Top Management Briefing	Top Management	Half day (4 hours)
Implementation training	Middle management & process owners	3 days
Auditors training	Internal Quality Auditors	3 days
Awareness training	General staff	1 day

**For further information please contact:**

#### **1. TRAINING SERVICES**

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#### **2. CERTIFICATION SERVICES**

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HEAD OF CERTIFICATION

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