



Kenya Bureau of
Standards

ISO 9001:2015 and ISO 14001:2015



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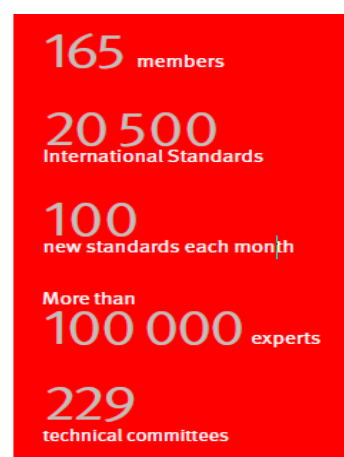
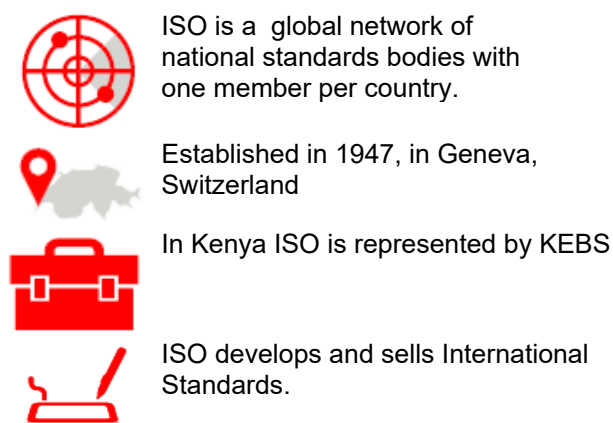
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1. What is ISO 9001?

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

About ISO



ISO 9001: 2015 Quality management system - Requirements

- The first edition of ISO 9001 was published in 1987, second edition in 1994, third and fourth edition in 2000 and 2008, respectively.
- The current version is the 5th edition which was *published on 15th September 2015*.
- Over 1.2 million organizations are certified to this standard worldwide

2. The Journey to ISO 9001:2015

The process took approximately three years

The ISO 9001: 2015 Journey...



Reasons for Revision:

ISO/TC 176/SC 2/WG23 N063

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

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Date:

3. 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. This 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.

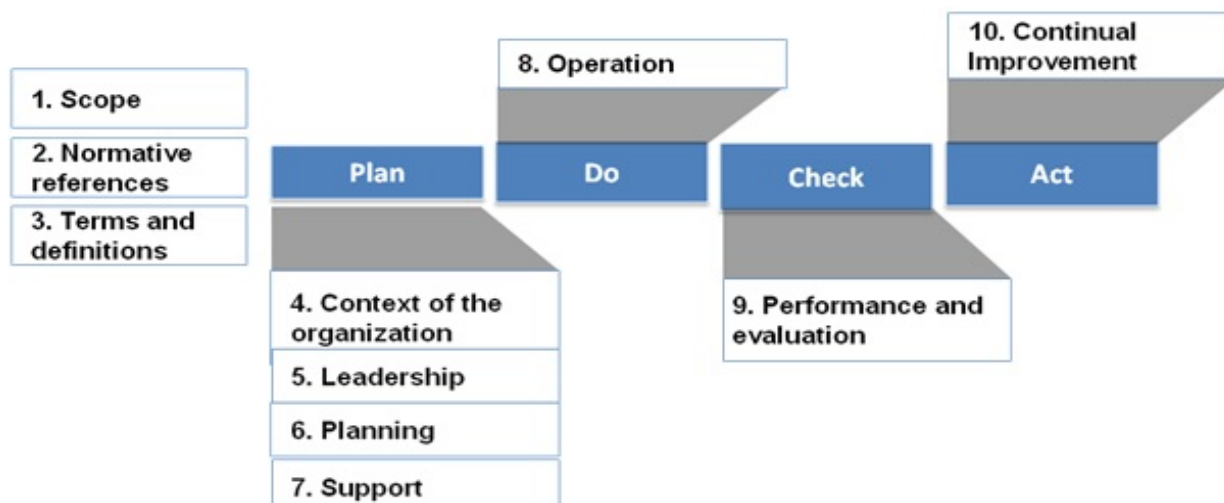
● Communication

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

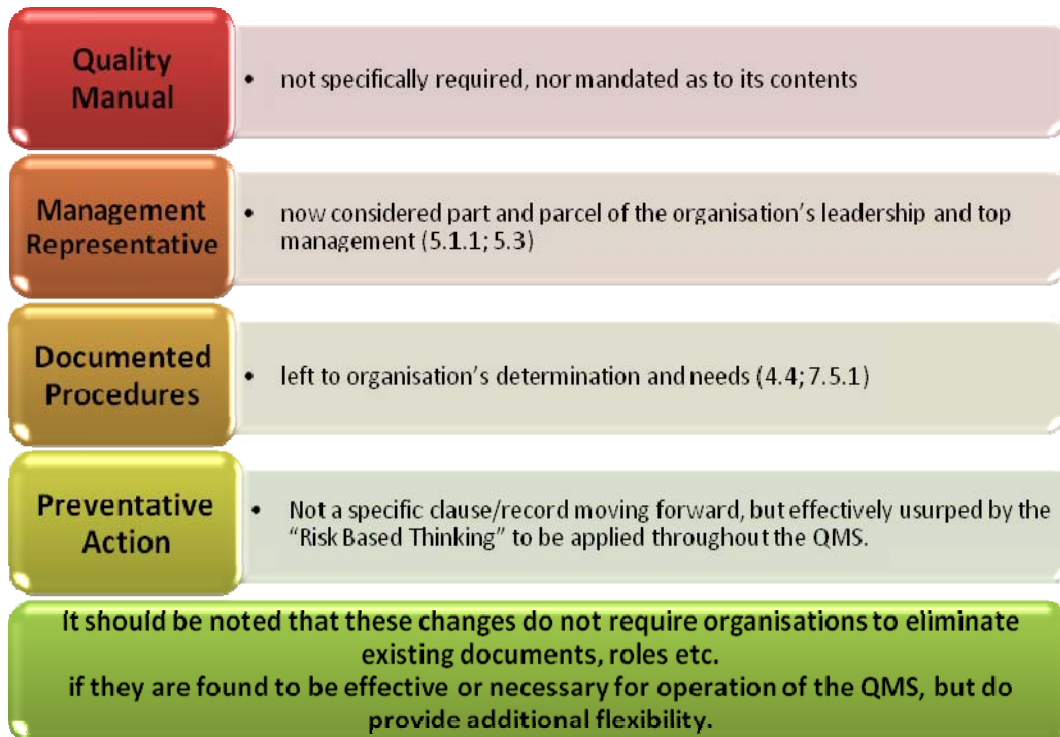
● Content comparison:

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. Planning
6. Resource Management	7. Support
7. Product Realisation	8. Operation
8. Measurement, Analysis and Improvement	9. Performance Evaluation
	10. Improvement

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



What else is new?



4. Benefits of Implementing ISO 9001:2015

ISO 9001:2015 applies to any organization, regardless of type, size or industry.

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

5. What is ISO 14001?

ISO 14001 – Environmental Management Systems, the world's first international environmental standard has been helping thousands of organizations to improve their environmental, sustainability and operational performance since it was first published as BS 7750 in 1992. The new version has been written to maintain its relevance in today's marketplace and to continue to offer organizations improved performance and business benefits.

6. Key changes between ISO 14001:2004 and ISO 14001:2015

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

● **Strategic Environmental Management**

There is an increased prominence of environmental management within the organization's strategic planning processes. A new requirement to understand the organization's context has been incorporated to identify and leverage opportunities for the benefit of both the organization and the environment. Particular focus is on issues or changing circumstances related to the needs and expectations of interested parties (including regulatory requirements) and local, regional or global environmental conditions that can affect, or be affected by, the organization. Once identified as a priority, actions to mitigate adverse risk or exploit beneficial opportunities are integrated in the operational planning of the environmental management system.

● **Leadership**

To ensure the success of the system, a new clause has been added that assigns specific responsibilities for those in leadership roles to promote environmental management within the organization.

● **Protecting the environment**

The expectation on organizations has been expanded to commit to proactive initiatives to protect the environment from harm and degradation, consistent with the context of the organization. The revised text does not define 'protect the environment' but it notes that it can include prevention of pollution, sustainable resource use, climate change mitigation and adaptation, protection of biodiversity and ecosystems, etc.

● **Environmental performance**

There is a shift in emphasis with regard to continual improvement, from improving the management system to improving environmental performance. Consistent with the organization's policy commitments the organization would, as applicable, reduce emissions, effluents and waste to levels set by the organization.

● **Lifecycle thinking**

In addition to the current requirement to manage environmental aspects associated with procured goods and service, organizations will need to extend their control and influence to the environmental impacts associated with product use and end-of-life treatment or disposal. This does not imply a requirement to do a life cycle assessment.

● **Communication**

The development of a communications strategy with equal emphasis on external and internal communications has been added. This includes a requirement on communicating consistent and reliable information, and establishing mechanisms for persons working under the organization's control to make suggestions on improving the environmental management system. The decision to communicate externally is retained by the organization but the decision needs to take into account information reporting required by regulatory agencies and the expectations of other interested parties.

● **Documentation**

Reflecting the evolution of computer and cloud based systems for running management systems, the revision incorporates the term 'documented information', instead of 'documents' and 'records'. To align with ISO 9001, the organization will retain the flexibility to determine when 'procedures' are needed to ensure effective process control.

7. Benefits of Implementing ISO 14001:2015

- Bringing the Environment and Continuous Improvement into the heart of your business
- Greater involvement in the management system by the leadership team will ensure the whole organization will be motivated towards the organizations goals and objectives.
- Improved Environmental Performance
- An Integrated Approach
- Improves environmental performance, saving money, reducing waste and preserving natural resources
- Improves risk and opportunity management ensuring continual improvement is systematic
- Improves lifecycle management helps identify specific product improvements
- Helps comply with legislation, reducing the risk of fines and adverse publicity
- Improves corporate responsibility to meet your supply chain requirements
- Helps you to become a more consistent competitor in your marketplace
- Motivates and engages staff with more efficient processes

8. Transition Guidance

Organizations are granted a **three-year transition period** after the revision after 15th September 2015 published to migrate their quality management system to the new edition of the standard. This means that certification to ISO 9001: 2008 and ISO 14001:2004 will be invalid beyond 15th September 2018.



Organizations 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.

Organizations using ISO 9001:2008/ISO 14001:2004 are recommended to take the following actions:

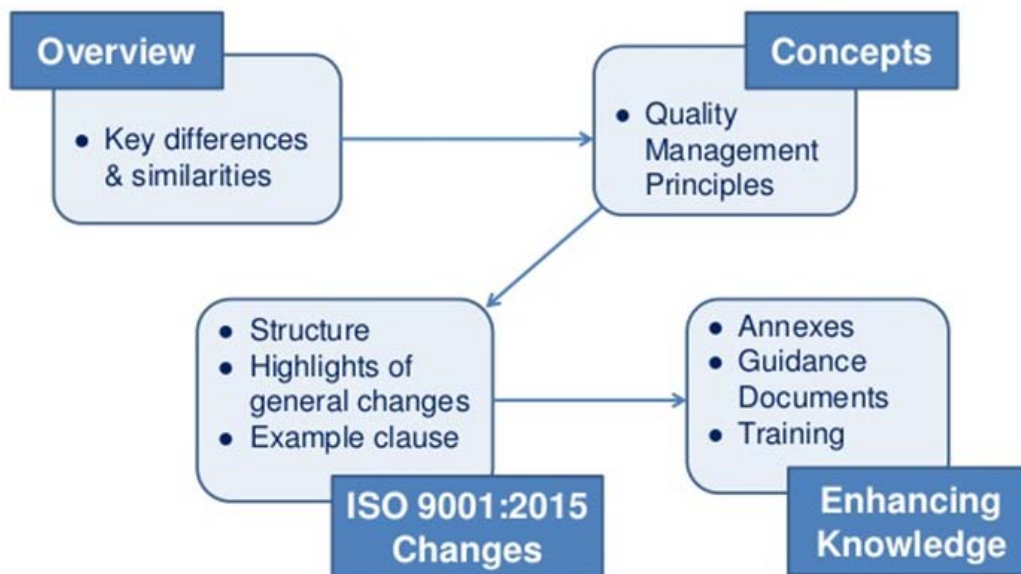


Training by the KEBS National Quality Institute (NQI)

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:



Training Options - ISO 9001:2008 TO ISO 9001:2015 & 14001:2004 to 14001:2015

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

TRAINING	TARGET	DURATION FOR TRANSITIONING CLIENTS	DURATION FOR DEVELOPING CLIENTS
Top Management Briefing	Top Management	Half day (4 hours)	Half day (4 hours)
Implementation Training	Middle management & process owners	2 days	3 days
Auditors Training	Internal Quality Auditors	2 days	3 days
Awareness Training	General staff	1 day	1 day

Certification services by the Kenya Bureau of Standards Certification Body – KEBS CB

The KEBS CB, an accredited conformity assessment body and a leading player in the region, has the necessary competence to carry out certification to ISO 9001:2015 and ISO 14001:2015. A sufficient number of auditors and technical experts have been trained on the requirements of the new standards.

For organizations at an advanced stage of Implementation of ISO 9001:2008 or ISO 14001:2004 but have not yet been certified, it is advised:

- Go ahead with the certification to ISO 9001:2008 or ISO 14001:2004. The ISO 9001:2008 and/or ISO 14001:2004 certificates for these clients shall be valid until 15th September 2018.
- Start transition arrangements immediately and ensure transition is carried out as soon as possible. The audits to be new standards shall be carried out as soon as the client is ready or together with surveillance audits

9. CONTACT INFORMATION



For Training services

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