ISO 9001:2015 Draft International Standard

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Purpose

The main purpose of this presentation is to provide an update on the expected contents of the ISO 9001:2015 (based on the ISO 9001 Draft International Standard (DIS) published on May 2014), and to present the top level main differences introduced by the new version of the standard.

Transition Timeline

June 2013 – Committee Draft

April 2014 – Draft International Standard

July 2015 – Final Draft International Standard

September 2015 – Published International Standard

September 2015 to September 2018 – Transition Period

Overview of Main Changes

- High Level Structure (HLS) in accordance with Annex SL.

- Introduces Elements of Strategic Approach (Context of the Organization).

- Emphasis is given on risk based thinking.

- Provides flexibility on the use of documentation

- Corrective actions incorporate elements of preventive actions, while other elements of prevention are fed into the risk based thinking.

- Terminology used is more readily applicable to "Service" type organizations.

- Purchasing is now clearly incorporating the purchasing of services.

Annex SL
High Level Structure (HLS)

- ISO is in process to harmonize all management systems standards. For this, a harmonized structure (Annex SL) has been developed.

- New standards have been already issued in accordance with the HLS proposed by Annex SL. E.g. ISO 22301, ISO 27001:2013.

- The new issue of ISO 9001:2015 will be also issued with the same HLS proposed by Annex SL

ISO 9001 New Structure
(in accordance with Annex SL HLS)

1   Scope
2   Normative references
3   Terms and definitions
4   Context of the organization
5   Leadership
6   Planning for the quality management system
7   Support
8   Operation
9   Performance evaluation
10   Improvement

Context of the Organization

- The new draft version of ISO 9001 is taking a more strategic approach by incorporating tools of strategic management.

- On this respect, two new clauses have been added to the draft of the standard:
  - Understanding the organization and its context (cl. 4.1.).
  - Understanding the needs and expectations of interested parties (cl. 4.2.).

Risk Based Thinking

- The new draft version of ISO 9001 is also introducing risk based thinking by incorporating tools of risk management.

- On this respect, a new clauses has been added to the draft of the standard:

    - Actions to address the risks and opportunities (cl. 6.1.)

- The requirement so far is for an organization to determine and address risks – mainly as a proactive (preventive) measure. No requirement yet for a formal risk management process.

Flexibility on Use of Documentation

- A more flexible approach on the use of documentation is taken by the new draft version of ISO 9001.

- The draft version of the standard does not make any separation of the terms 'Document' and 'Record'. Both terms are combined under the term 'Documented Information'.

- In this sense, this approach is more flexible and it eliminates some of the confusion caused by the previous separation of the terms.

Corrective Actions

- The new draft version of ISO 9001 does not longer have a clause on Preventive Action.

- The corrective actions needed for potential nonconformities were incorporated in the clause:

  - Nonconformity and corrective actions (cl. 10.2.)

- Preventive measures are also indirectly incorporated the cl. 6.1. for risk based thinking (as per previous slide)

Goods and Services

- In the 2008 version of the standard the term 'Product' was used and included also the services.

- The draft version of the 2015 standard, the term 'Product' is replaced with the term 'Goods and Services'

- The new term used, makes it easier for organizations offering services to adopt to the terminology used by the standard.

Externally Provided Products and Services

- In the 2008 version of the standard the term 'Purchased Product' was used and included also the purchased services.

- The draft version of the 2015 standard, the term 'Purchased Product' is replaced with the term 'Externally Provided Products and Services'

- Similarly, the term 'Supplier' was replaced by the term 'External Provider'

- The new terms used, makes it easier for organizations to include service providers into their purchasing process.

Comparison between ISO 9001:2008 and ISO 9001:2015 Draft International Standard (DIS)

Comparison 1/5

ISO 9001:2008	ISO 9001:2015 (DIS)
0 Introduction	0 Introduction
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Quality management system	4 Context of the organization
	4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the quality management system
4.1 General requirements	4.4 Quality management system and its processes
4.2 Documentation requirements	7.5 Documented information

Comparison 2/5

ISO 9001:2008	ISO 9001:2015 (DIS)
5 Management responsibility	**5 Leadership**
5.1 Management commitment	**5.1 Leadership and commitment**
5.2 Customer focus	**5.1.2 Customer focus**
5.3 Quality policy	**5.2 Quality policy**
5.4 Planning	**6 Planning for the QMS** **6.1 Actions to address risks and opportunities** **6.2 Quality objectives and planning to achieve them** **6.3 Planning of changes**
5.5 Responsibility, authority and communication	**5.3 Organizational roles, responsibilities and authorities** **7.4 Communication**
5.6 Management review	**9.3 Management review**

Comparison 3/5

ISO 9001:2008	ISO 9001:2015 (DIS)
6 Resource management	**7 Support**
6.1 Provision of resources	**7.1 Resources**
6.2 Human resources	**7.2 Competence** **7.3 Awareness** **7.4 Communication**
6.3 Infrastructure	**7.1.3 Infrastructure**
6.4 Work environment	**7.1.4 Environment for the operation of processes**

Comparison 4/5

ISO 9001:2008	ISO 9001:2015 (DIS)
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**
7.3 Design and development	**8.3 Design and Development of products and services**
7.4 Purchasing	**8.4 Control of externally provided products and services**
7.5 Production and service provision	**8.5 Production and service provision**
7.6 Control of monitoring and measuring equipment	**7.1.5 Monitoring and measuring resources**
	8.6 Release of products and services

Comparison 5/5

ISO 9001:2008	ISO 9001:2015 (DIS)
8 Measurement, analysis and improvement	**9 Performance evaluation**
8.1 General	**9.1 Monitoring, measurement, analysis and evaluation**
8.2 Monitoring and measurement	**9.2 Internal audit** **9.3 Management review**
8.3 Control of nonconforming product	**8.7 Control of nonconforming process outputs, products and services** **9.1 Monitoring, measurement, analysis and evaluation**
8.4 Analysis of data	**9.1 Monitoring, measurement, analysis and evaluation**
8.5 Improvement	**10 Improvement** **10.1 General** **10.2 Nonconformity and corrective action** **10.3 Continual improvement**

Keep in Touch

A webinar on ISO 9001:2015 changes will be organized within next months.

In case you are interested, please complete the online form, in order to receive more information.

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Thank You!

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