ISO 9001:2008 vs. ISO 9001:2015

1. General Changes at Committee Draft Stage

The new standard:

- Adopts high-level structure and terminology of Annex SL, a unified guideline used for the development of all new ISO standards
- Has been redrafted to increase clarity and accessibility, reducing room for interpretation
- Introduces two new clauses relating to the context of the organization, which require the organization to determine the issues and requirements that can impact on the planning of the quality management system and can be used as an input into the development of the quality management system. These clauses can be found in sections 4.1 and 4.2.
- Makes the adoption of a process approach in the implementation of a quality management system more explicit, by including clause 4.4.2, which specifies the requirements for the adoption of a process approach
- Replaces the term 'products' by 'goods and services', in order to remove the existing bias towards organizations dealing with physical products. As a result, the new standard will be applicable for organizations of any kind.
- Does not contain a clause with specific requirements for preventive action. ISO motivates this decision by arguing that prevention is the task of the quality management system in its entirety, as opposed to a specific subsection of it.

2. Structural changes

Red text: text taken from Annex SL

Black text: text taken from existing ISO 9001:2008 and developed by WG 24

2008			2015	
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.	General requirements		4.1.	Understanding the organization and its context
4.2.	Documentation requirements	→	See section 7.5	
			4.2.	Understanding the needs and expectations of interested parties
			4.3.	Determining the scope of the quality management system
			4.4.	Quality Management System

Note: The new clauses in Section 4 require the organization to determine the issues and requirements that can impact on the planning of the quality management system and can be used as an input into the development of the quality system.

5.	**Management responsibility**	→	**5.**	**Leadership**
5.1.	Management commitment		5.1.	Leadership and commitment
5.2.	Customer focus		5.2.	Quality Policy
5.3.	Quality policy		5.3.	Organizational roles, responsibilities and authorities
5.4.	Planning		**6.**	**Planning**
			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	→	See section 5.3. for staff responsibility, and 7.4. for communication	
5.6.	Management review	→	See section 9.3. for management review	

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	→	See section 7.1 for infrastructure	
6.4.	Working Environment	→	See section 7.1. for workplace criteria	

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 market needs and interactions with customers
7.3.	Design and development		8.3.	Operational planning process
7.4.	Purchasing		8.4.	Control of external provision of goods and services
7.5.	Production and service provision		8.5.	Development of goods and services
7.6.	Control of monitoring and measuring equipment		8.6.	Production of goods and provision of services
			8.7.	Release of goods and services
			8.8.	Nonconforming goods and services

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	→	See 8.8	
8.4.	Analysis of data	→	See 9.1	
8.5.	Improvement		**10.**	**Improvement**
			10.1.	Nonconformity and corrective action
			10.2.	Improvement