

Key to colours	
New	Amended

ISO 9001:2015 vs ISO 9001:2008

This document has been prepared to assist clients and assessors with the new requirements, removed requirements and amended requirements. It will also give insight about the magnitude of change, which might assist clients to better plan their transition process. This document does not consider new structure, new number scheme and removed requirements as changes; rather the document only indicates new and amended requirements.

Summary of changes

Total number of ISO 9001:2015 requirements	298	Total number of ISO 9001:2008 requirements	233
Percentage of increase in 9001 requirements	22%	Number of new requirements	86

Key changes:

1. Requirements for a documented quality manual and for documented procedures have been removed.
2. Removal of the requirement for the role of "management representative". Top management are now required to demonstrate that they engage in key quality management system activities
3. Requirements to Identifying risks (potential mistakes) and opportunities and take appropriate actions accordingly to enhance customer satisfaction. As a result, the preventive action requirement has been removed.

Key changes clients DO NOT need to make:

1. Remove their management representatives
2. Withdraw their Quality Manuals and Documented Procedures
3. Restructure their management systems to follow the sequence of requirements as set out in the new version
4. Use the new terms.

Below table provides a clause by clause comparison.

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	ISO 9001:2015 Clause Number	Equivalent ISO 9001:2008 Clause Number
	4 Context of the organisation	
N	4.1 Understanding the organisation and its context	
N	4.2 Understanding the needs and expectations of interested parties	
A	4.3 Determining the scope of the quality management system	4.1 General requirements
A	4.4 Quality management system and its processes	4.1 General requirements
	5 Leadership	
	5.1 Leadership and commitment	
A	5.1.1 General	5.1 Management commitment
A	5.1.2 Customer focus	5.2 Customer focus
	5.2 Policy	
A	5.2.1 Establishing the quality policy	5.3 Quality policy
A	5.2.2 Communicating the quality policy	5.3 Quality policy
	5.3 Organisational roles, responsibilities and authorities	5.5.1 Responsibility and authority 5.5.2 Management representative

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	6 Planning	
N	6.1 Actions to address risks and opportunities	
A	6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
A	6.3 Planning of changes	5.4.2 Quality management system planning
	7 Support	
	7.1 Resources	
A	7.1.1 General	6.1 Provision of resources
	7.1.2 People	6.2 Human resources
	7.1.3 Infrastructure	6.3 Infrastructure
	7.1.4 Environment for the operation of processes	6.4 Work environment
	7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
N	7.1.6 Organisational knowledge	
	7.2 Competence	6.2.1 Human resources – General 6.2.2 Competence, training and awareness
A	7.3 Awareness	6.2.2 Competence, training and awareness
A	7.4 Communication	5.5.3 Internal communication
	7.5 Documented information	
	7.5.1 General	4.2.1 General 4.2.2 Quality Manual
	7.5.2 Creating and updating	4.2.3 Control of documents 4.2.4 Control of records
	7.5.3 Control of documented information	4.2.3 Control of documents 4.2.4 Control of records
	8 Operation	
A	8.1 Operational planning and control	7.1 Planning of product realisation
	8.2 Requirements for products and services	
A	8.2.1 Customer communication	7.2.3 Customer communication
	8.2.2 Determining the requirements for products and services	
A	8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to the product
	8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to the product
	8.3 Design and development of products and services	
	8.3.1 General	New clause. However, it is covered in 7.3.1 Design and development planning
A	8.3.2 Design and development planning	7.3.1 Design and development planning
A	8.3.3 Design and development inputs	7.3.2 Design and development inputs
	8.3.4 Design and development controls	7.3.1 Design and development planning 7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation
	8.3.5 Design and development outputs	7.3.3 Design and development outputs
	8.3.6 Design and development changes	7.3.7 Control of design and development changes
	8.4 Control of externally provided processes, products and services	
	8.4.1 General	7.4.1 Purchasing process
A	8.4.2 Type and extent of control	7.4.1 Purchasing process 7.4.3 Verification of purchased product
	8.4.3 Information for external providers	7.4.2 Purchasing information 7.4.3 Verification of purchased product
	8.5 Production and service provision	
A	8.5.1 Control of production and service provision	7.5.1 Control of production and service provision

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		7.5.2 Validation of processes for production and service provision
	8.5.2 Identification and traceability	7.5.3 Identification and traceability
	8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
	8.5.4 Preservation	7.5.5 Preservation of product
	8.5.5 Post-delivery activities	7.5.1 Control of production and service provision 7.2.1 Determination of requirements related to the product
N	8.5.6 Control of changes	
	8.6 Release of products and services	8.2.4 Monitoring and measurement of product
	8.7 Control of nonconforming outputs	8.3 Control of nonconforming product
	9 Performance evaluation	
	9.1 Monitoring, measurement, analysis and evaluation	
A	9.1.1 General	8.1 General
	9.1.2 Customer satisfaction	8.2.1 Customer satisfaction
	9.1.3 Analysis and evaluation	8.4 Analysis of data
	9.2 Internal audit	8.2.2 Internal audit
	9.3 Management review	
A	9.3.1 General	5.6.1 General
	9.3.2 Management review inputs	5.6.2 Review input
	9.3.3 Management review outputs	5.6.3 Review output
	10 Improvement	
A	10.1 General	8.5.1 Continual improvement
A	10.2 Nonconformity and corrective action	8.5.2 Corrective action
A	10.3 Continual improvement	8.5.1 Continual improvement 8.5.3 Preventive action

(Above table is based on Green, R, MacNee, C & Holt, A, 2015, *ISO 9001:2015 – Understanding the International Standard*, The Chartered Quality Institute (CQI), London.)

Contact us

Should you have any questions about your transition plan, please don't hesitate to contact DLCS International on 03 9863 7837

References:

1. International Organization for Standardization, *Quality management systems – Requirements*. 2015, ISO 9001:2015, International Organization for Standardization, Switzerland.
2. ISO TC / 176 / SC2, *Correlation matrices between ISO 9001:2008 and ISO 9001:2015*, [cited 2015 October 22], Available from <http://isotc.iso.org/livelink/livelink/open/tc176SC2public>
3. Green, R, MacNee, C & Holt, A, 2015, *ISO 9001:2015 – Understanding the International Standard*, The Chartered Quality Institute (CQI), London.
4. MacNee, C 2015, *ISO 9001:2015 Update*, IAF Technical Committee, The Chartered Quality Institute, London.