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ISO 9001:2015 vs. ISO 9001:2008

9001 Academy
ISO 9001 Online Consultation Center

ISO 9001:2015	ISO 9001:2008	Explanation
Introduction	Introduction	
0.1 General	0.1 General	These clauses are almost the same; the new version explains the context of the organization and its influence on the structure of the quality management system (QMS), while pointing out that the standard does not imply a need for uniformity in the structure of the QMS. Additionally, enhancing customer satisfaction is pointed out in this clause.
0.2 Quality management principles		The 2008 revision of the standard only mentions that the quality management principles are taken into consideration; the 2015 revision lists the quality management principles, pointing out that detailed descriptions of the principles are given in ISO 9000.
0.3 Process approach	0.2 Process approach	The clause name is the same, but the 2015 revision has three sections that explain the process approach, PDCA cycle, and risk-based thinking. For more information, read Plan-Do-Check-Act in the ISO 9001 Standard.
0.4 Relationships with other management system standards	0.4 Compatibility with other management systems	This clause of the new version of the standard refers to ISO 9000, ISO 9004, and Annex B of the standard, which provides more details of other standards on quality management.
Quality Management Systems – Requirements	Quality Management Systems – Requirements	
1 Scope	1 Scope	These clauses are almost the same for both versions of the standard.
2 Normative references	2 Normative references	
3 Terms and definitions	3 Terms and definitions	The new version refers to ISO 9000:2015.

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4 Context of the organization		
4.1 Understanding organization and its context		This is a completely new requirement; the organization will need to determine the external and internal context that affects the organization. For more information, read How to identify the context of the organization in ISO 9001:2015.
4.2 Understanding needs and expectations of interested parties		Interested parties are introduced in the new version of the standard. The previous version was only focused on the customer.
4.3 Determining the scope of the quality management system	4.2.2 Quality manual	This requirement was related to the Quality Manual in the previous version. The Quality Manual is not mandatory anymore, but the requirement for determining and documenting the scope remains. For more information, read What clauses can be excluded in ISO 9001:2015? and The future of the Quality Manual in ISO 9001:2015.
4.4 Quality management system and its processes	4.1 General requirements	The requirements from the previous version remain; the new requirements are related to determining the risks and opportunities and inputs and outputs of the processes, as well as assigning responsibilities and authorities for the processes.
5 Leadership		
5.1 Leadership and commitment	5.1 Management commitment 5.4.2 Quality management system Planning	The clauses are very similar; the emphasis in the new version is on promoting awareness and support of other persons who contribute to the effectiveness of the QMS. The main difference between the clauses is that the new version requires the top management to take accountability for the effectiveness of the QMS. For more information, read How to comply with new leadership requirements in ISO 9001:2015.
5.1.1 Leadership and commitment for the quality management system		

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5.1.2 Customer focus	5.2 Customer focus	The old requirements remain the same. Determination of the risks and opportunities regarding conformity of products and services is a new requirement, as well as the consideration of the statutory and regulatory requirements.
5.2 Quality policy	5.3 Quality Policy	The requirements remain the same. An additional requirement is to be available to interested parties, as appropriate. See the sample document here: Quality Policy. For more information, read How to Write a Good Quality Policy.
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and authority	The main difference is that the new standard does not require appointing a management representative; however, the new clause describes in more detail the roles, responsibilities and authorities within the QMS, implying that they can be allocated to different persons.
6 Planning for the quality management system		
6.1 Actions to address risks and opportunities		This is a completely new requirement. When planning the QMS, the organization will need to determine the risks and opportunities affecting the organization. For more information, read this article: The Role of Risk Assessment in the QMS.
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives	The requirements remain the same, but are further elaborated in the new version. See the sample document here: Quality Objectives. For more information, read How to Write Good Quality Objectives.
6.3 Planning of changes	5.4.2 Quality management system planning	The new version of the standard defines how the changes in the QMS should be managed by considering the purpose of the change, the potential consequences, and availability of resources and allocation of responsibilities.

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7 Support		
7.1 Resources	6.1 Provision of resources	The old requirements remain, but new version emphasizes consideration of capabilities and constraints of the organization, as well as resources obtained from external providers.
7.1.1 General		
7.1.2 People	6.2.1 General	The requirements of both clauses are pretty much the same.
7.1.3 Infrastructure	6.3 Infrastructure	The requirements of both clauses are pretty much the same.
7.1.4 Environment for the operation of process	6.4 Working environment	The requirements of both clauses are pretty much the same.
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment	The new version of the standard emphasizes the provision of resources for monitoring and measurement. The organization must retain the documented information as evidence of fitness for purpose of monitoring and measurement resources. The old standard only focuses on the measuring equipment. See the sample document here: Maintenance and Calibration Record.
7.1.6 Organizational knowledge		This is a completely new requirement, which acknowledges the organizational knowledge as an important resource. The organization will need to determine the knowledge necessary to run its processes and achieve conformity of products and services.
7.2 Competence	6.2.2 Competence, training and awareness	Competence and awareness are split into different clauses to emphasize their importance and provide more detailed requirements. See the sample document here: Procedure for Human Resources. For more information, read Using Competence, Training and Awareness to Replace Documentation in your QMS.
7.3 Awareness		

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7.4 Communication	5.5.3 Internal communication	The new clause includes both external and internal communication and requires definition of responsibility and methods of communication.
7.5 Documented information	4.2.3 Control of documents 4.2.4 Control of records	Documents and records now belong to the same category – documented information. The requirements of both versions are equivalent. See the sample document here: Procedure for Document and Record Control. For more information, read New approach to document and record control in ISO 9001:2015.
7.5.1 General		
7.5.2 Creating and updating		
7.5.3 Control of documented information		
8 Operation	7 Product realization	
8.1 Operational planning and control	7.1 Planning product realization	The requirements of both clauses are equivalent. See the sample document here: Procedure for Production and Service Provision.
8.2 Requirements for products and services	7.2 Customer-related processes	The requirements are almost the same, but the new version emphasizes communication about treatment of customer property. See the sample document here: Notification to a Customer about Changes on his Property.
8.2.1 Customer communication	7.2.3 Customer communication	
8.2.2 Determining the requirements related to products and services	7.2.1 Determination of requirements related to the product	The requirements of both clauses are pretty much the same. See the sample document here: Sales Procedure.
8.2.3 Review of requirements related to products and services	7.2.2 Review of requirements related to the product	The requirements of both clauses are pretty much the same. See the sample document here: Customer Requirement Review Checklist.
8.2.4 Changes to requirement for product and services		This new clause defines requirements related to changes in requirements related to products and services.

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8.3 Design and development of products and services	7.3 Design and development	The requirements of both clauses are pretty much the same. See the sample document here: Procedure for Design and Development.
8.3.1 General		This clause defines when the design and development process is necessary.
8.3.2 Design and development planning	7.3.1 Design and development planning	The requirements of both clauses are pretty much the same. See the sample document here: Procedure for Design and Development.
8.3.3 Design and development inputs	7.3.2 Design and development inputs	The requirements of both clauses are pretty much the same. See the sample document here: Project Task.
8.3.4 Design and development controls	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation	The new clause sublimates the requirements of the three old clauses, keeping the old requirements and emphasizing the consideration of nature, duration, and complexity of design and development activities. See the sample document here: Project Plan and Review. For more information read ISO9001 Design Verification vs Design Validation.
8.3.5 Design and development outputs	7.3.3 Design and development outputs	The requirements of both clauses are pretty much the same. See the sample document here: Design Review Minutes.
8.3.6 Design and development changes	7.3.7 Control of design and development changes	The requirements of both clauses are pretty much the same. See the sample document here: Change Review Record.
8.4 Control of externally provided products and services	7.4.1 Purchasing process	Although the name of the clause has changed, the requirements are pretty much the same. See the sample document here: Procedure for Purchasing and Evaluation of Suppliers.
8.4.1 General		
8.4.2 Type and extent of control of external provision	7.4.3 Verification of purchased product	The requirements of both clauses are pretty much the same. See the sample document here: Procedure for Purchasing and Evaluation of Suppliers. For

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		more information, read How to control outsourced processes using ISO 9001.
8.4.3 Information for external providers	7.4.2 Purchasing information	The requirements of both clauses are pretty much the same. The new version emphasizes the monitoring and control of external providers' performance.
8.5 Production and service provision	7.5 Production and service provision	The requirements are almost the same, but the new standard points out that the implemented controlled conditions are for delivery and post-delivery activities. See the sample document here: Procedure for Production and Service Provision. For more information, read Understanding Product & Service Provision in ISO 9001.
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision	
8.5.2 Identification and traceability	7.5.3 Identification and traceability	The requirements of both clauses are pretty much the same. See the sample document here: Record of Traceability.
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property	The requirements of both clauses are the same, but in the new standard the requirements are extended to property belonging to external providers as well. See the sample document here: Notification to a Customer about Changes on his Property.
8.5.4 Preservation	7.5.5 Preservation of product	The requirements of both clauses are the same.
8.5.5 Post-delivery activities		The post-delivery activities are mentioned in several places in the old version, but in the new standards they are set apart as a separate sub clause.
8.5.6 Control of changes		The control of changes is mentioned in several places in the old version; however, the importance of controlling changes is stressed in the new standard by defining a separate sub clause.

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8.6 Release of products and services		This is a new requirement, dealing with verification of product and ensuring that product or service meets requirements.
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product	The requirements are equivalent. See the sample document here: Procedure for Control of Nonconforming Product.
9 Performance evaluation		
9.1 Monitoring, measurement, analysis and evaluation	8.2.3 Monitoring and measurement of processes	The new clause sublimates all requirements for processes and products or services monitoring and measurement.
9.1.1 General	8.2.4 Monitoring and measurement of product	
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction	The requirements are the same. See the sample document here: Procedure for Measuring Customer Satisfaction.
9.1.3 Analysis and evaluation	8.4 Analysis of data	The requirements are equivalent. See the sample document here: Data Analysis Report.
9.2 Internal audit	8.2.2 Internal audit	The requirements are equivalent. The main difference is that the new standard does not require a documented procedure. See the sample document here: Procedure for Internal Audit. For more information, read Five Main Steps in ISO 9001 Internal Audit.
9.3 Management review	5.6 Management review	The requirements are equivalent. See the sample document here: Procedure for Management Review. For more information, read How to Make Management Review More Practical.

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10 Improvement	8.5 Improvement	
10.1 General		The requirements in the new standard explain what should be considered in the process of improvement.
10.2 Nonconformity and corrective action	8.5.2 Corrective action	The requirements are equivalent. See the sample document here: Procedure for Corrective and Preventive Action. For more information, read Understanding dispositions for ISO 9001 nonconforming product.
10.3 Continual improvement	8.5.1 Continual improvement	The new standard points out the need to use all available information for continually improving the QMS. For more information, read Seven Steps for Corrective and Preventive Actions to support Continual Improvement.
Annex A – Clarification of new structure, terminology and concepts		Annex A explains the new structure of the 2015 revision together with key new terms and concepts.
Annex B - Other International Standards on quality management and quality management systems developed by ISO/TC 176		Annex B lists all ISO standards related to ISO 9001 and clauses to which each of the listed standards is referring.

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9001 Academy
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EPPS Services Ltd.
for electronic business and business consulting
Zavizanska 12, 10000 Zagreb
Croatia, European Union

Email: support@advisera.com
Phone: +1 (646) 759 9933
Toll-Free (U.S. and Canada): 1-888-553-2256
Toll-Free (United Kingdom): 0800 808 5485
Fax: +385 1 556 0711

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