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ISO 9001: 2015

Understanding the changes

Why has **ISO 9001** been Revised?

ISO 9001, the world's leading Quality Management System has been revised to a new and updated standard, ISO 9001:2015.

Why?

All of the ISO Standards are reviewed every five years. This is to check whether a revision is needed to keep the standard up-to-date with the market and to other management systems such as ISO 14001. ISO 9001:2015 will therefore be compatible with other management systems and respond to the latest trends.

What are the key changes?

ISO 9001:2008 and ISO 9001:2015 both cover the same essential topics; there have been some important changes, some of which are mentioned below:

- ⇒ The new standard follows a higher level structure known as Annex SL. This is to make it easier to use in conjunction with other management system standards such as ISO 14001.
- ⇒ There is an increase in the importance of risk and identifications of opportunities
- ⇒ A commitment to quality through leadership has been enhanced
- ⇒ A focus on continual improvement to ensure that better results are achieved through the QMS.

New Structure Explained

As mentioned previously, the most significant change to the standard is the new structure, Annex SL. The 2015 version of ISO 9001 now has ten sections:

ISO 9001:2008

1. Scope
2. Normative Reference
3. Terms and Definitions
4. General Requirements
5. Management Responsibility
6. Resource Management
7. Product Realisation
8. Measurement, Analysis and Improvement

ISO 9001:2015

1. Scope
2. Normative Reference
3. Terms and Definitions
4. Context of the Organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

As can been seen from the comparison, the structure and terminology is now different and perhaps more definitive. Taking a closer look at the new sections of ISO 9001:2015, we can see that there are new requirements including:

Clause 4. is now 'Context of the Organisation', meaning that it is now necessary to understand the external and internal context of your organisation in relation to the Quality Management System. This means identifying the external and internal requirements that may influence your QMS.

Leadership is a new requirement and is defined in its own section within the new ISO 9001:2015 standard. This means that top management throughout the organisation are expected to take a more hands on approach to the QMS. This will ensure companywide motivation and commitment towards goals, a continued focus on improvement, and the effectiveness of the QMS.

Clause 6. 'Planning' - Risk and Opportunity based thinking is also a new requirement of the standard and is to be incorporated into all elements of the system. The organisation is required to develop objectives and plan to achieve them.

Clause 7. 'Support' is referring to the supporting processes (which includes resources, competence, communication, and documentation) of the organisation. Furthermore, support refers to the monitoring and measuring of resources to ensure valid and reliable results. Monitoring and measuring is also used to verify conformity of products and services to requirements.

The new section 8. 'Operation', is essentially about delivering your product or service to meet customer requirements and satisfaction. Section 8 has many of the previous elements of ISO 9001:2008 clause 7. Product Realisation, which includes, customer and product requirements, design and development of product/services, control of external providers, and the delivery of products/services.

The ninth clause ‘Performance Evaluation’ is ensuring that the QMS is operating and functioning to achieve its intended objectives. It is also about ensuring compliance to any legal requirements of the organisation. Internal audits and management reviews are included in this chapter.

The final clause ‘Improvement’ is about identifying what has gone wrong and why, and ensuring continual improvement of the management system. This section also covers the familiar territory of ‘nonconformity’ and ‘corrective action’.

Terminology Differences

ISO 9001:2008	ISO 9001:2015
Products	Products and Services
Exclusions	No Longer used
Management Representative	No Longer used. The same responsibilities are applicable in the new standard; however, it is no longer applied to a single person/representative
Documentation; Quality Manual; Documented Procedures; Records	Documented Information
Work Environment	Environment for the Operation of Processes
Monitoring and Measuring Equipment	Monitoring and Measuring Resources
Purchased Product	Externally Provided Products and Services
Supplier	External Provider

What are the Benefits?

Continued Improvement and Quality

The new standard aims to make sure that quality management is seamlessly combined with your organisations key business strategies; this will ensure continued improvement

Leadership

The organisations management/leadership team will have more hands on involvement with the management system. This will generate company wide motivation towards goals.

Risk Management

Improvements will be identified efficiently, therefore, business opportunities will come to light. Management system will be strengthened as a management tool.

Integrated Approach

The new structure will be relevant to all ISO management systems, this means that integration of multiple management systems will be more accessible.

What next?

If you are already certified against ISO 9001:2008, you have a three year transition period before you need to upgrade your system. This means that you must be certified against ISO 9001:2015 by September 2018.

If you are new to ISO 9001 certification, we suggest certifying to the new standard.

Support from Us

We can help you to understand the changes, guide you through the new concepts, and explain what you need to do. You can also keep an eye on our blog and follow us on Twitter to stay in touch. We will be providing on-going support and information. Our goal for the new standard transition is to have transferred all of our clients before the 2018 deadline.
Feel free to get in touch at any time, visit our website to fill in an enquiry form, or give us a call on

ISO 9001:2015 vs ISO 9001:2008

Comparison Table

New ISO 9001:2015 Clause	Previous ISO 9001:2008 Equivalent
1. Scope	**1. Scope**
2. Normative Reference	**2. Normative Reference**
3. Terms and Definitions	**3. Terms and Definitions**
4. Context of the Organisation	**N/A**
4.1 Understanding the Organisation and its context	N/A
4.2 Understanding the needs and expectations of interested parties	N/A
4.3 Determining the scope of the QMS	N/A
4.4 QMS and its Processes	4.1 QMS and its Processes
5. Leadership	**N/A**
5.1 *Leadership and Commitment (title only)*	5.1 Management Commitment and 5.2 Customer Focus
5.1.1 General	5.1 Management Commitment
5.1.2 Customer Focus	5.2 Customer Focus
5.2 *Policy (title only)*	5.3 Quality Policy
5.2.1 Establishing the Quality Policy	5.3 Quality Policy
5.2.2 Communicating the Quality Policy	5.3 Quality Policy
5.3 Organisational Roles, Responsibilities and Authorities	5.5.1 Responsibility and Authority
6. Planning	**N/A**
6.1 Actions to address Risk and Opportunities	N/A
6.2 Quality Objectives and Planning to achieve	5.4.1 Quality Objectives
6.3 Planning Changes	5.4.2 Quality Management System Planning
7. Support	**N/A**
7.1 *Resources (title only)*	6.1 Provision of Resources
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 (title only)*	7.6 Control of Monitoring and Measurement Equipment
7.1.5.1 General	7.6 Control of Monitoring and Measurement Equipment
7.1.5.2 Measurement Traceability	7.6 Control of Monitoring and Measurement Equipment
7.1.6 Organisational Knowledge	N/A
7.2 Competence	6.2 Human Resources
7.3 Awareness	6.2 Human Resources
7.4 Communication	5.5.3 internal Communication
7.5 *Documented Information (title only)*	4.2.3 Control of Documents and 4.2.4 Control of Records
7.5.1 General	4.2.3 Control of Documents and 4.2.4 Control of Records
7.5.2 Creating and Updating	4.2.3 Control of Documents and 4.2.4 Control of Records
7.5.3 Control of Documented Information	4.2.3 Control of Documents and 4.2.4 Control of Records
8. Operation	**N/A**

8.1 Operational Planning and Control	7.1 Planning and Product Realisation
8.2 Requirements for Products and Services	7.2 Customer Related Processes
8.2.1 Customer Communication	7.2.3 Customer Communication
8.2.2 Determination of Requirements related to Products and Services	7.2.1 Determination of Requirements related to the Product
8.2.3 Review of Requirements related to Products and Services	7.2.2 Review of the Requirements related to the Product
8.2.4 Changes to Requirements for Products and Procedures	7.2.2 Review of the Requirements related to the Product
8.3 *Design and Development for Products and Services (title only)*	7.3 Design and Development
8.3.1 General	N/A
8.3.2 Design and Development Planning	7.3.1 Design and Development Planning
8.3.3 Design and Development Inputs	7.3.2 Design and Development Inputs
8.3.4 Design and Development Controls	7.3.4 Design and Development review, 7.3.5 Design and Development Verification, and 7.3.6 Design and Development Validation
8.4 *Control of externally provided Processes, Products, and Services (title only)*	7.4.1 Purchasing Process
8.4.1 General	7.4.1 Purchasing Process
8.4.2 Type and extent of Control	7.4.1 Purchasing Process and 7.4.3 Verification of Purchased Product
8.4.3 Information for External Providers	7.4.2 Purchasing Information
8.5 *Production and Service provision (title only)*	7.5.1 Control of Production and Service provision and 7.5.2 Validation of processes for Production and Service provision
8.5.1 Control of Production and Service Provision	7.5.1 Control of Production and Service provision and 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 the 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 and 7.2.1 Determination of Requirements Related to the Product
8.5.6 Control Changes	4.2.3 Control of Documents, 5.4.2 QMS Planning and 7.3.7 Design and Development 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 Products
9. Performance Evaluation	**N/A**
9.1 *Monitoring, Measurement, Analysis and Evaluation (title only)*	8.1 General and 8.2 Monitoring and Measurement
9.1.1 General	8.1 General and 8.2 Monitoring and Measurement
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 (title only)*	5.6 Management Review
9.3.1 General	5.6.1 General
9.3.2 Management Review Inputs	5.6.2 Review Inputs
9.3.3 Management Review Outputs	5.6.3 Review Outputs
10. Improvement	**N/A**
10.1 General	8.3 Control of nonconforming Product and 8.5 Improvement
10.2 Nonconforming and Corrective Action	8.3 Control of nonconforming Products and 8.5.2 Corrective Action
10.3 Continual improvement	8.5.1 Continual Improvement