




## Transition

### ISO 9001:2008 to ISO 9001:2015



A look inside the Revised Standard

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### ISO 9001:2008 vs ISO 9001:2015

New Clause Layout

| ISO 9001:2008                        | ISO 9001:2015                 |
|--------------------------------------|-------------------------------|
| 4 Quality Management System          | 4 Context of the Organization |
| 5 Management Responsibility          | 5 Leadership                  |
| 6 Resource Management                | 6 Planning                    |
| 7 Product Realization                | 7 Support                     |
| 8 Measurement, Analysis, Improvement | 8 Operation                   |
|                                      | 9 Performance Evaluation      |
|                                      | 10 Improvement                |

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### ISO 9001:2008 vs ISO 9001:2015

| ISO 9001:2008                  | ISO 9001:2015  |
|--------------------------------|--|
| 4 Quality management system    | 4 Quality management system  |
| 4.1 General requirements       | 4.4 Quality management system and its Processes  |
| 4.2 Documentation requirements | 7.5 Documented information   |
| 4.2.1 General                  | 7.5.1 General  |
| 4.2.2 Quality manual           | 4.3 Determining the scope of the quality management system<br>7.5.1 General<br>4.4 Quality management system and its processes |
| 4.2.3 Control of documents     | 7.5.2 Creating and updating<br>7.5.3 Control of documented information   |
| 4.2.4                          | 7.5.2 Creating and updating<br>7.5.3 Control of documented information   |

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### ISO 9001:2008 vs ISO 9001:2015

| ISO 9001:2008                            | ISO 9001:2015   |
|--|---|
| 5 Management responsibility              | 5 Leadership  |
| 5.1 Management commitment                | 5.1 Leadership and commitment<br>5.1.1 Leadership and commitment for the quality management system                        |
| 5.2 Customer focus                       | 5.1.2 Customer focus  |
| 5.3 Quality policy                       | 5.2 Quality policy  |
| 5.4 Planning                             | 6 Planning for the quality management system  |
| 5.4.1 Quality objectives                 | 6.2 Quality objectives and planning to achieve them   |
| 5.4.2 Quality management system planning | 6 planning for the quality management system<br>6.1 Actions to address risks and opportunities<br>6.3 Planning of changes |

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### ISO 9001:2008 vs ISO 9001:2015

| ISO 9001:2008                                   | ISO 9001:2015  |
|---|--|
| 5.5 Responsibility, authority and communication | 5 Leadership   |
| 5.5.1 Responsibility and authority              | 5.3 Organizational roles, responsibilities and authorities                         |
| 5.5.2 Management representative                 | <b>Title Removed</b><br>5.3 Organizational roles, responsibilities and authorities |
| 5.5.3 Internal communication                    | 7.4 Communication  |
| 5.6 Management review                           | 9.3 Management review  |
| 5.6.1 General                                   |  |
| 5.6.2 Review input                              |  |

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### ISO 9001:2008 vs ISO 9001:2015

| ISO 9001:2008                            | ISO 9001:2015                                    |
|--|--|
| 6 Resource management                    | 7.1 Resources                                    |
| 6.1 Provision of resources               | 7.1.1 General<br>7.1.2 People                    |
| 6.2 Human resources                      | <b>Title Removed</b><br>7.2 Competence           |
| 6.2.1 General                            | 7.2 Competence                                   |
| 6.2.2 Competence, training and awareness | 7.2 Competence<br>7.3 Awareness                  |
| 6.3 Infrastructure                       | 7.1.3 Infrastructure                             |
| 6.4 Work environment                     | 7.1.4 Environment for the operation of processes |

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**ISO 9001:2008 vs ISO 9001:2015**

| ISO 9001:2008  | ISO 9001:2015  |
|--|--|
| 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          |
| 7.2.1 Determination of requirements related to the product | 8.2.2 Determination of requirements related to products and services |
| 7.2.2 Review of requirements related to the product        | 8.2.3 Review of requirements related to the products and services    |
| 7.2.3 Customer communication                               | 8.2.1 Customer communication   |
| 7.3 Design and development                                 | 8.5 Design and development of products and services                  |
| 7.3.1 Design and development planning                      | 8.3 Design and development of products and services                  |
|  | 8.3.1 General  |
|  | 8.3.2 Design and development planning                                |

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**ISO 9001:2008 vs ISO 9001:2015**

| ISO 9001:2008                                   | ISO 9001:2015  |
|---|--|
| 7.3 .2Design and development inputs             | 8.3.3 Design and development inputs                      |
| 7.3.3 Design and development outputs            | 8.3.5 Design and development outputs                     |
| 7.3.4 Design and development review             | 8.3.4 Design and development controls                    |
| 7.3.5 Design and development verification       |  |
| 7.3.6 Design and development validation         |  |
| 7.3.7 Control of design and development changes | 8.3.6 Design and development changes                     |
| 7.4 Purchasing                                  | 8.4 Control of externally provided products and services |
| 7.4.1 Purchasing process                        | 8.4.1 General  |
|   | 8.4.2 Type and extent of control of external provisions  |
| 7.4.2 Purchasing information                    | 8.4.3 Information for external providers                 |

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**ISO 9001:2008 vs ISO 9001:2015**

| ISO 9001:2008   | ISO 9001:2015   |
|---|---|
| 7.4.3 Verification of purchased products                            | 8.6 Release of products and services                        |
| 7.5 Production and services provision                               | 8.5 Production and services provision                       |
| 7.5.1 Control of productions and services provision                 | 8.5.1 Control of production and services provision          |
|   | 8.5.5 Post-delivery activities                              |
| 7.5.2 Validation of processes for production and services provision | 8.5.1 Control of production and services provision          |
| 7.5.3 Identification and traceability                               | 8.5.2 Identification and traceability                       |
| 7.5.4 Customer property   | 8.5.3 Property belonging to customers or external providers |
| 7.5.5 Preservation of Product                                       | 8.5.4 Preservation  |
| 7.6 Control of monitoring and measuring equipment                   | 7.1.5 Monitoring and measuring resources                    |

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**ISO 9001:2008 vs ISO 9001:2015**

| ISO 9001:2008                                 | ISO 9001:2015  |
|---|--|
| 8.0 Measurement, analysis and improvement     | 9.1 Monitoring, measurement, analysis and evaluation |
| 8.1 General                                   | 9.1.1 General  |
| 8.2 Monitoring and measurement                | 9.1 Monitoring, measurement, analysis and evaluation |
| 8.2.1 Customer satisfaction                   | 9.1.2 Customer satisfaction                          |
| 8.2.2 Internal audit                          | 9.2 Internal audit                                   |
| 8.2.3 Monitoring and measurement of processes | 9.1.1 General  |
| 8.2.4 Monitoring and measurement of product   | 8.6 Release of products and services                 |

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**ISO 9001:2008 vs ISO 9001:2015**

| ISO 9001:2008                        | ISO 9001:2015   |
|--------------------------------------|---|
| 8.3 Control of nonconforming product | 8.7 control of nonconforming process outputs, products and services |
| 8.4 Analysis of data                 | 9.1.3 Analysis and evaluation                                       |
| 8.5 Improvement                      | 10 Improvement  |
| 8.5.1 Continual improvement          | 10.1 General  |
|                                      | 10.3 Continual improvement  |
| 8.5.2 Corrective action              | 10.2 Nonconformity and corrective action                            |
| 8.5.3 Preventive action              | <b>Clause Removed</b>   |
|                                      | 6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2)   |

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**Quality principles**

Change 8 Quality Principles to 7

| Current 8 QMPs                                | Proposed 7 QMPs                        |
|---|--|
| 1. Customer focus                             | 1. Customer focus                      |
| 2. Leadership                                 | 2. Leadership                          |
| 3. Involvement of people                      | 3. Engagement and competence of people |
| 4. Process approach                           | 4. Process approach                    |
| 5. System approach to management              | 5. Improvement                         |
| 6. Continual improvement                      |  |
| 7. Factual approach to decision making        | 6. Informed decision making            |
| 8. Mutually beneficial supplier relationships | 7. Relationship management             |

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**Documented information:**  
Mandatory documented information previously known as records

|  |   |
|--|---|
| 1 Operation of processes (4.4)                 | 10 Externally provided products and services (8.4.1)                      |
| 2 Quality objectives (6.2.1)                   | 11 Traceability (8.5.2)   |
| 3 Monitoring and measurement resources (7.1.6) | 12 Control of changes (8.5.6)   |
| 4 Competence (7.2)                             | 13 Release of products and services (8.6)                                 |
| 5 General (7.5.1)                              | 14 Control of non-conforming process outputs, products and services (8.7) |
| 6 Operational planning and control (8.11)      | 15 Monitoring, measurement, analysis and evaluation (9.1.1)               |
| 7 Requirements review (8.2.3)                  | 16 Internal audit (9.2)   |
| 8 Design and development (.3.5)                | 17 Management review (9.3)  |
| 9 Design and development changes (8.3.6)       | 18 NC and corrective action (10.2)  |

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**Annex SL and management systems**

The mandatory HLS clauses


|                                      |             |
|--------------------------------------|-------------|
| <b>1 Scope</b>                       |             |
| <b>2 Normative references</b>        |             |
| <b>3 Terms and references</b>        |             |
| <b>4 Context of the organization</b> | <b>PLAN</b> |
| <b>5 Leadership</b>                  |             |
| <b>6 Planning</b>                    |             |
| 7 Support                            | DO          |
| 8 Operation                          | CHECK       |
| 9 Performance evaluation             | ACT         |
| 10 Improvement                       |             |

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**Terms and Definitions: clause 3**

Terms and Definitions

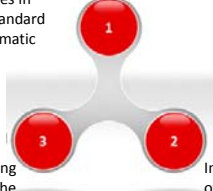
- Since ISO 9000 is not anymore a reference in Normative References section of the 2015 version of the standard, all the terms and definitions are included in the standard itself.
- Some of the new terms that have been added to the standard include monitoring, performance, outsource, involvement, risk, and so on.



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**Actions to address risks and opportunities**  
ISO 9001:2015, clause 6.1

One of the key changes in the ISO 9001:2015 standard is to establish a systematic approach to risk.



By preventing or reducing the undesired effects, the organization becomes proactive. Preventive action is automatic in risk-based approach system.

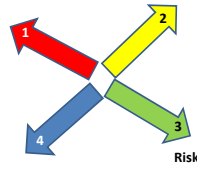
Instead of being only part of the preventive action procedure, risk is considered throughout the quality management system.

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**Actions to address risks and opportunities**  
Where is risk addressed in ISO 9001:2015

**Introduction**  
Risk-based thinking concept is explained in clause 0.5.

**ISO 31000**  
The reference which is a standard that provides guidance to risk management.



**Definitions**  
Risk is defined in clause 3 of ISO 9001:2015, as the effect of uncertainty on an expected result.


**Risk can be found in all clauses of ISO 9001:2015**  
The risk-based approach is used throughout the revised quality management system standard.

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**Plan how to deal with risks and opportunities**  
ISO 9001:2015, clause 6.1.2


- Identify and plan the treatment of risk
- Activities should be classified in order of priority
- The necessary resources must be allocated to the treatment plan

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**Transition**

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**Implementation:**

**What should I do?**

Look into the ISO 9001:2015 document and start working on understanding and including the changes.

Transition period began in September 2015

ISO 9001:2008 becomes outdated in October 2018

Certify to ISO 9001:2015 before transition period ends (expected late 2018)

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**Implementation:**

For assistance in:


- Transitioning to the new standard
- Auditor Training
- Documentation formatting
- Management responsibilities
- Risk analysis options

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**Changes to be aware of:**

- No need for a “Quality Manual”**
- Non-conforming material = Corrective action**
- Need for documented information (not processes)**
- Document and Record control are combined**
- Risk Assessment done on all processes and goals**

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**Questions**

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