

# ISO 9001:2015

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## ISO



- The International Organization for Standardization based in Geneva, Switzerland
- Worldwide federation of national standards bodies (ISO member bodies)
- First approached subject of quality in 1979
- Derived from the Greek word “isos” meaning equal



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## ISO 9001

- 1979 – BS 5750 Quality Assurance Standards
- 1987 – ISO 9001, ISO 9002, ISO 9003 Quality Assurance Standards
- 1994 – ISO 9001, ISO 9002, ISO 9003 Quality Assurance Standards Revision
- 2000 – ISO 9001 Quality Management Systems – Series Revisions
- 2008 – ISO 9001 Quality Management Systems – Requirements

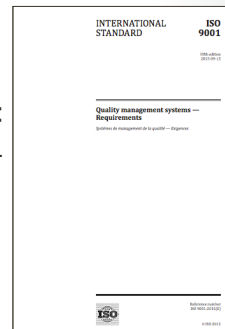
2015 – ISO 9001 Quality Management Systems – Requirements



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## ISO 9001:2015

- Fifth edition of ISO 9001 standard.
- Based on the Common Framework: Appendix 3 of ISO/IEC Directives, Part 1 Annex SL
  - “Annex SL” is the generally used shorthand
  - New Clause numbers
- Published on September 15, 2015.
- Deadline for the transition from ISO 9001:2008 version is September 14, 2018.



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## What was changed?



### ISO 9001:2008

0. Introduction
1. Scope
2. Normative references
3. Terms and definitions
4. Quality Management System
5. Management Responsibility
6. Resource Management
7. Product Realization
8. Measurement, Analysis and Improvement



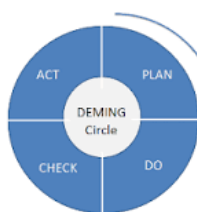
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### ISO 9001:2015

0. Introduction
1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

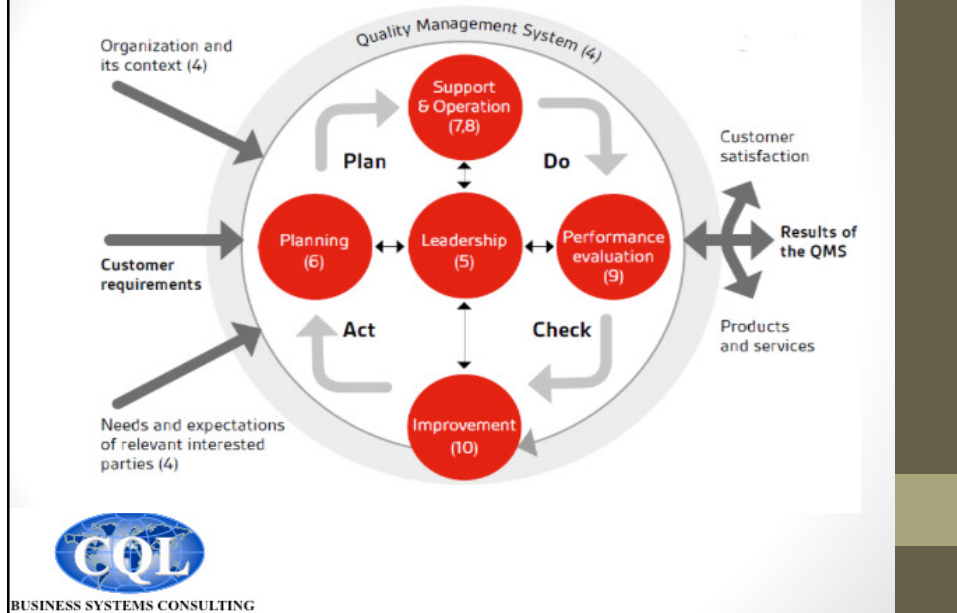
## ISO 9001:2015

Employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.



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## ISO 9001:2015 – PDCA Cycle



## Quality Management Principles

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence-based decision making
7. Relationship management



## Major Differences in Terminology

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used
Management representative	Not used
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measurement equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider



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\*Table A.1 of ISO 9001:2015

## Key Changes



- Emphasis on Risk-based management (Preventive Action)
- Increase emphasis on achieving value for organization and its customer
- Documented Information
  - Decreased emphasis on documentation
  - Expands concept of documentation
  - Replaces Documents and Records



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## Key Changes



- Organizational Context
  - Responsiveness to business environment
- Outsourcing is now External Provision
- Enhanced leadership requirements
- No requirement for Management Representative
- No requirement for Quality Manual



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Understanding  
ISO 9001:2015  
Requirements



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## 4. Context of the Organization

- 4.1 Understanding the organization and its context
- 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 and its processes



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## 5. Leadership

- 5.1 Leadership and commitment
  - 5.1.1 General
  - 5.1.2 Customer focus
- 5.2 Policy
  - 5.2.1 Establishing the quality policy
  - 5.2.2 Communicating the quality policy
- 5.3 Organizational roles, responsibilities and authorities



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## 6. Planning

**6.1 Actions to address risks and opportunities**



**6.2 Quality objectives and planning to achieve them**

**6.3 Planning of changes**



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## 7. Support

**7.1 Resources**

**7.1.1 General**

**7.1.2 People**

**7.1.3 Infrastructure**

**7.1.4 Environment for the operation of processes**

**7.1.5 Monitoring and measuring resources**

**7.1.5.1 General**

**7.1.5.2 Measurement traceability**



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## 7. Support

### 7.1.6 Organizational knowledge

### 7.2 Competence

### 7.3 Awareness

### 7.4 Communication

### 7.5 Documented information



#### 7.5.1 General

#### 7.5.2 Creating and updating

#### 7.5.3 Control of documented information



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## 8. Operation

### 8.1 Operational planning and control

### 8.2 Requirements for products and services

#### 8.2.1 Customer communication

#### 8.2.2 Determining the requirements for products and services

#### 8.2.3 Review of the requirements for products and services

#### 8.2.4 Changes to requirements for products and services



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## 8. Operation

### 8.3 Design and development of products and services

#### 8.3.1 General

#### 8.3.2 Design and development planning

#### 8.3.3 Design and development inputs

#### 8.3.4 Design and development controls

#### 8.3.5 Design and development outputs

#### 8.3.6 Design and development changes



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## 8. Operation

### 8.4 Control of externally provided processes, products and services

#### 8.4.1 General

#### 8.4.2 Type and extent of control

#### 8.4.3 Information for external providers



### 8.5 Production and service provision

#### 8.5.1 Control of production and service provision



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## 8. Operation



**8.5.2 Identification and traceability**

**8.5.3 Property belonging to customers or external providers**

**8.5.4 Preservation**

**8.5.5 Post-delivery activities**

**8.5.6 Control of changes**

**8.6 Release of products and services**

**8.7 Control of nonconforming outputs**



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## 9. Performance evaluation

**9.1 Monitoring, measurement, analysis and evaluation**



**9.1.1 General**

**9.1.2 Customer satisfaction**

**9.1.3 Analysis and evaluation**

**9.2 Internal audit**

**9.3 Management review**

**9.3.1 General**

**9.3.2 Management review inputs**

**9.3.3 Management review outputs**



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## 10. Improvement

### 10.1 General

### 10.2 Nonconformity and corrective action

### 10.3 Continual improvement



## Benefits

- Enhancing continuous improvement
- More emphasis on Leadership
- Managing risk and opportunities
- Performance measurement
- Integration




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Open Forum




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It is not enough to do your best; you must know what to do, and then do your best.

*W. Edwards Deming*




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Source: quotes.deming.org

# Thank You!!!

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