

ISO 9001:2015 TRANSITIONS

ISO 9001:2015 Overview

ISO 9001:2015 - Key Perspectives

- ISO 9001 needed to change, in order to:
 - adapt to a changing world;
 - reflect the increasingly complex environments in which organizations operate;
 - provide a consistent foundation for the future;
 - reflect the increasingly complex environments in which organizations operate;
 - ensure the new standard reflects the needs of all relevant interested parties, and
 - ensure alignment with other management system standards.

Key Feature Changes

- 10-clause structure and core text for all Management System Standards (MSS).
- More compatible with services and non-manufacturing users
 - Clearer understanding of the organization's context is required "one size doesn't fit all"
- Process approach strengthened/more explicit.
- Concept of preventive action now addressed throughout the standard by risk identification and mitigation.
- The term documented information replaces the terms document and record.
- Control of externally provided products and services replaces purchasing/outsourcing.
- Increased emphasis on seeking opportunities for improvement.

Beneficial Changes to ISO 9001

- Enhanced leadership involvement in the management system.
- Risk-based thinking.
- Simplified language, common structure and terms.
- Aligning QMS policy and objectives with the strategy of the organization.

Potential Benefits to the User

- Focus on achieving planned results.
- Flexibility for documented information.
- Improved risk control.
- Better process control leading to improved results.
- Improved customer satisfaction.
- Customer retention and loyalty.
- Improved image and reputation.
- Greater credibility.

Key Benefits - Common Clause Structure

- A new common format has been developed.
- All ISO management systems standards will look the same with the same structure (some deviations)
 - More efficient to address multiple management system requirements.
- Provides the option of integrating management systems.
- Standardized core definitions.

Structure of ISO 9001:2015 (1/3)

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 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
- 5 Leadership
 - 5.1 Leadership and commitment
 - 5.2 Policy
 - 5.3 Organizational roles, responsibilities and authorities
- 6 Planning
 - 6.1 Actions to address risks and opportunities
 - 6.2 Quality objectives and planning to achieve them
 - 6.3 Planning of changes

Structure of ISO 9001:2015 (2/3)

- 7 Support
 - 7.1 Resources
 - 7.2 Competence
 - 7.3 Awareness
 - 7.4 Communication
 - 7.5 Documented information
- 8 Operation
 - 8.1 Operational planning and control
 - 8.2 Requirements for products and services
 - 8.3 Design and development of products and services
 - 8.4 Control of externally provided processes, products and services
 - 8.5 Production and service provision
 - 8.6 Release of products and services
 - 8.7 Control of nonconforming outputs

Structure of ISO 9001:2015 (3/3)

- 9 Performance evaluation
 - 9.1 Monitoring, measurement, analysis and evaluation
 - 9.2 Internal audit
 - 9.3 Management review
- 10 Improvement
 - 10.1 General
 - 10.2 Nonconformity and corrective action
 - 10.3 Continual improvement

New Terminology

Table A.1 — Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management 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

Frequently Asked Questions

- 1. Why has it been decided to issue a new version of ISO 9001?
- 2. Does ISO 9001 still apply to all organizations - big, small, different sectors and different items – products, services?
- 3 .How has the structure of the standard changed?
- 4. What are the main differences in content between the old and new version?
- 5. How have the documentation requirements changed?
- 6. The standard does not mention a quality manual. Is it still required?
- 7. Why has management review been moved to performance evaluation?
- 8. The title of management representative has been removed. How is the performance of the system reported to top management?
- 9. Why has product been changed to products and services?
- 10. What is risk-based thinking and why has it been introduced into the standard?
- 11. What has been changed in terms of planning?
- 12. Are organizations still allowed to exclude requirements of ISO 9001?
- 13. What is the process approach and is it still applicable to ISO 9001:2015?
- 14. What are the benefits of the new version of ISO 9001?

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