



ISO 9001:2015 OVERVIEW

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WHAT IS ISO 9001

- ISO 9001 is the international standard for a quality management system (“QMS”). In order to be certified to ISO 9001, a company must follow the requirements set forth in the ISO 9001 Standard.
- The standard is designed to help companies at many levels, including a focus on customer requirements, improving leadership within the company, finding ways to continually improve, and more

ISO 9001:2015 - KEY PERSPECTIVES

ISO 9001 needed to change from ISO 9001:2008 to ISO 9001:2015, 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

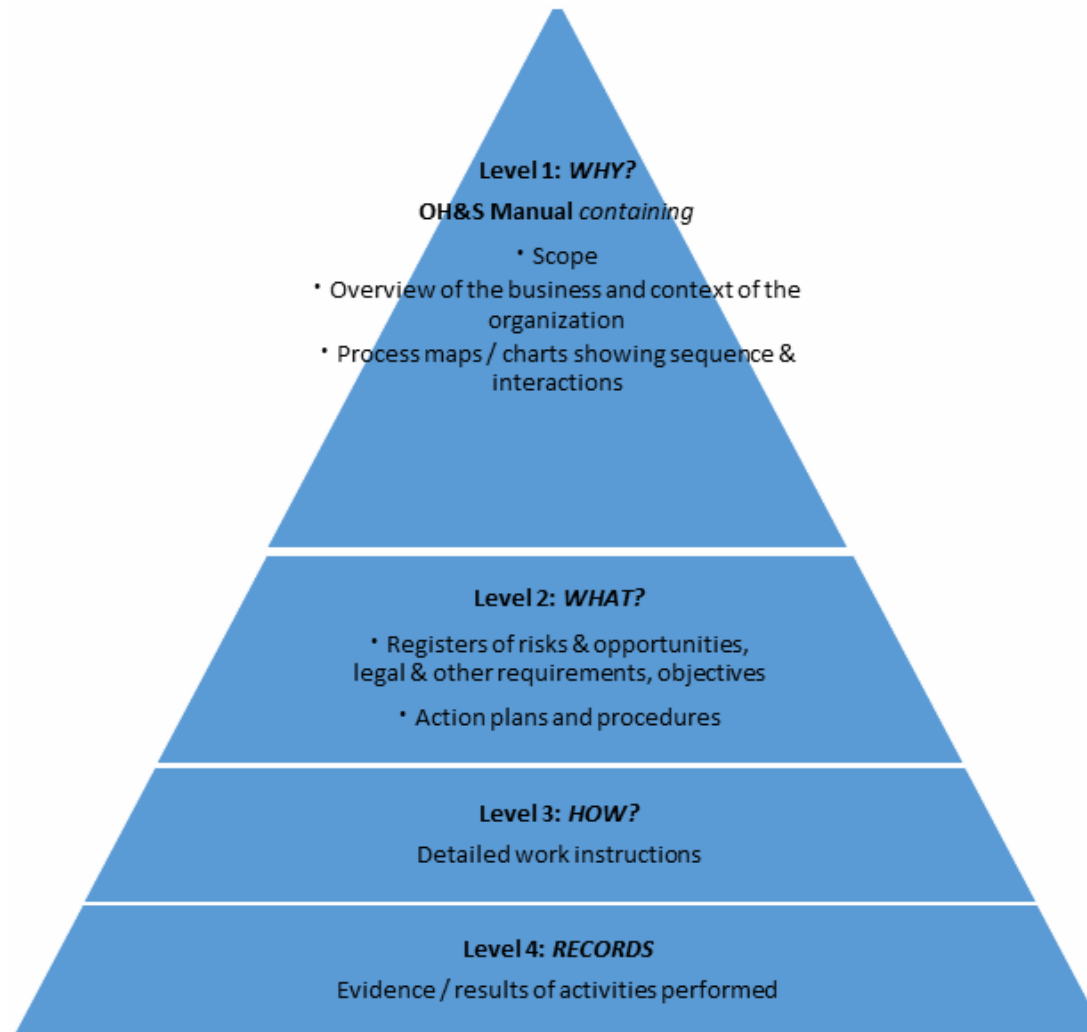
- 8 Operation

- 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

STRUCTURE OF THE DOCUMENTATION



THE CERTIFICATION JOURNEY

The Certification Journey

Stage 1

This initial assessment determines if the mandatory requirements of the standard are being met and if the management system is capable of proceeding to stage 2.

Stage 2

This second assessment determines the effectiveness of the system, and seeks to confirm that the management system is implemented and operational.

Recommendation for Certification

At this point in the process we review any corrective actions taken to address findings raised at Stage 1 & 2. Certification may be recommended.

Certification Review & Decision

The organisation's files are reviewed by an independent and impartial panel and the certification decision is made.

Certification Achieved

Successful certification is communicated to the client. Certificates are issued.

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