



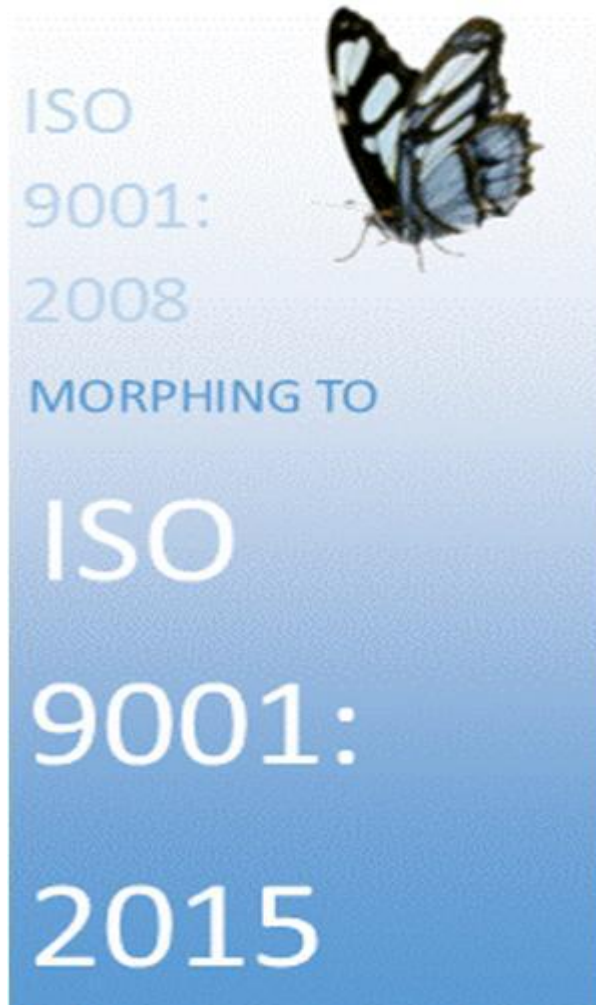
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Choose certainty.
Add value.

Updates on CD/ISO 9001:2015

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30th January 2014



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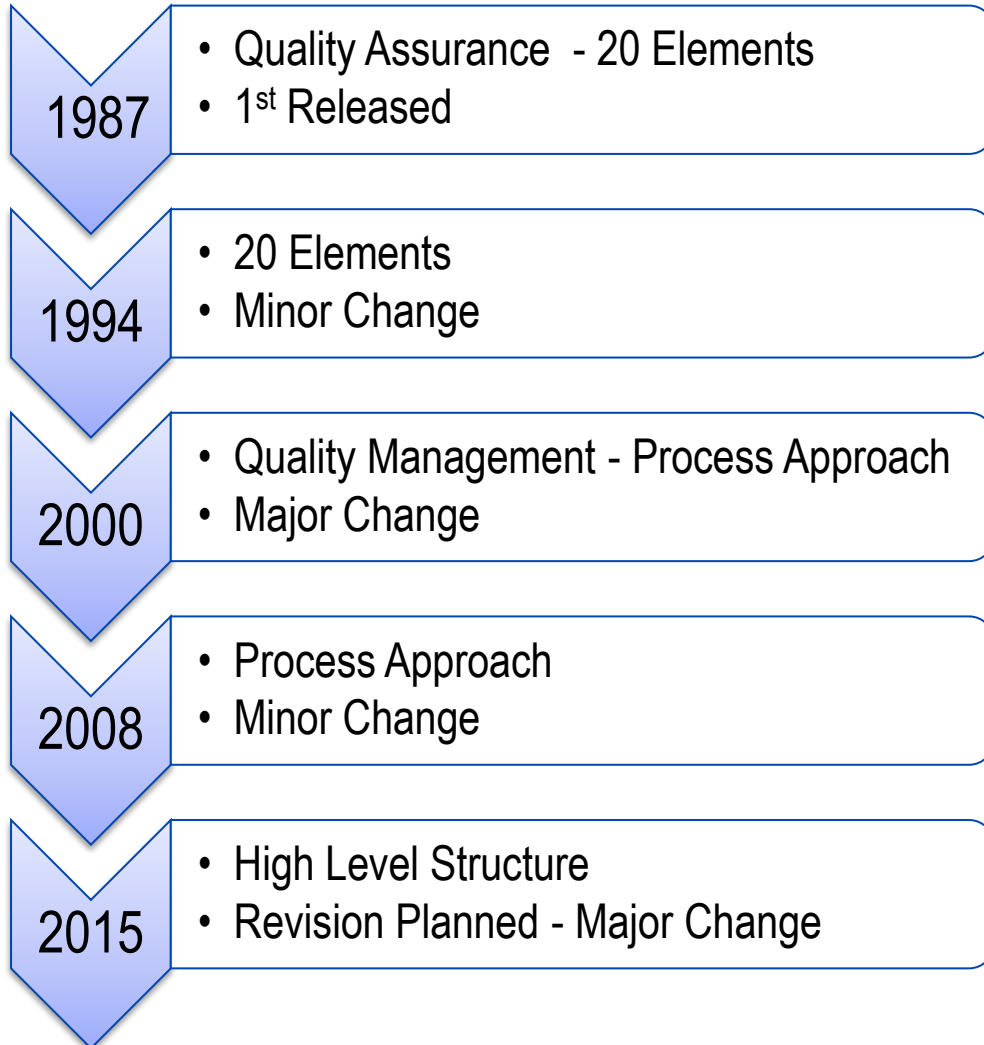


- ISO 9001 – Quality Management System (QMS) Standard
- Users – over 1 million registered organizations
- Aims of the QMS Standard
- ISO 9000 Family of Standards

Revision History



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ISO 9001:2015 Timeline



May 2013 CD
(Committee Draft)



February 2014 DIS
(Draft International Standard)



February 2015 FDIS
(Final Draft International Standard)



September 2015 Published IS
(International Standard)

+ Transition period
for certification





- Demand for a **Common Format and Language** that is aligned between those standards
- Decrease the emphasis on **Documentation**
- Increase the emphasis on **Achieving Value** for the Organization and its customers
- Increase emphasis on **Risk Management** to achieve objectives

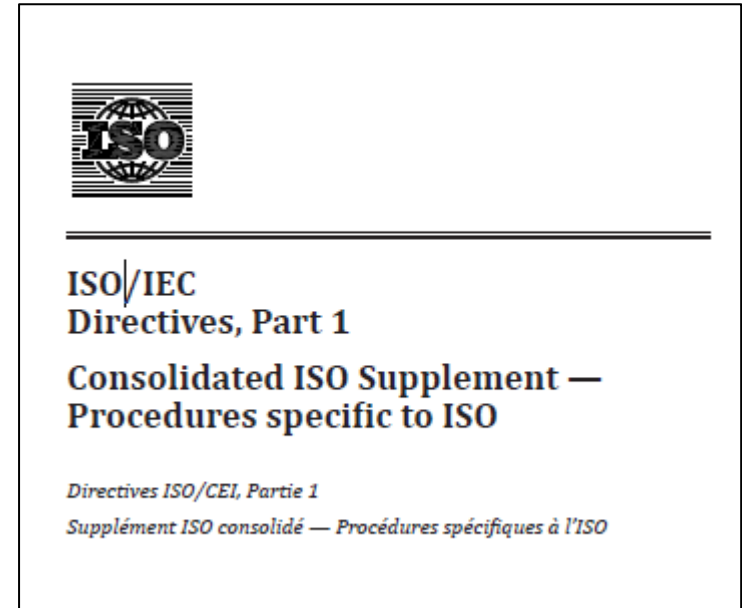


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ISO 9001:2015 Revision

Annex SL - High Level Structure

- The ISO/IEC Directives define the basic procedures to be followed in the development of International Standards and other publications
- Mandated by ISO's Technical Management Board (TMB)





Annex SL

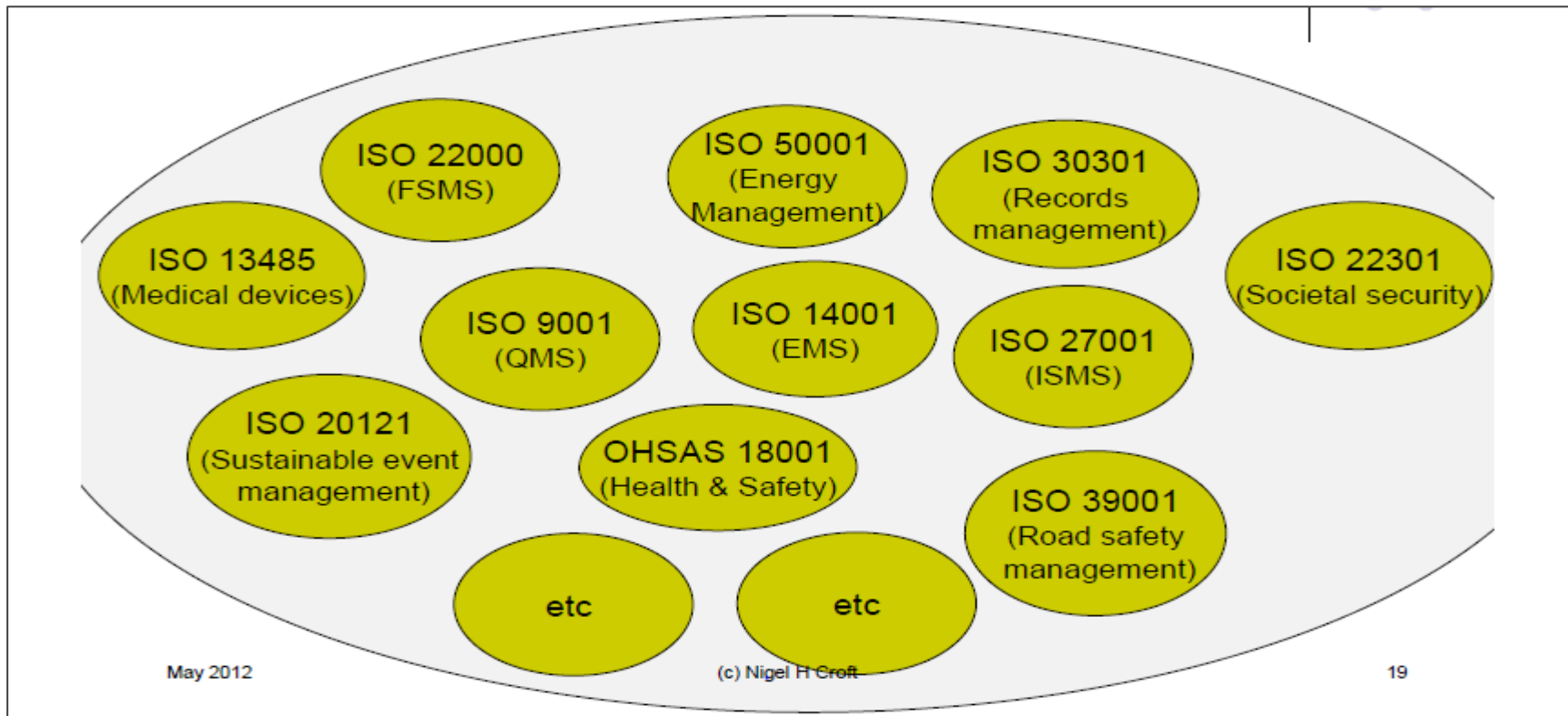
- High level structure, identical core text and common terms and core definitions for use in all Management System Standards
- Enhance the consistency and alignment of different management system standards

ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2013

**Annex SL
(normative)**

Proposals for management system standards

Organizations who implement a single system addressing multiple standards (e.g. QMS, EMS, ISMS etc) will see the most potential benefit





- The objective is to develop the revised ISO 9001 standard using the new structure as the foundation.
- TC 176/SC2 plays an active role in ISO's Joint Technical Coordination Group that is responsible for the development of Annex SL and any difficulties in applying Annex SL will be referred back to this group and to ISO/TMB.



- The high level structure and common text without ISO 9001:2015 management specific text is public information
- It can be found at www.iso.org/directives

Please note that Annex SL on its own should not be used to make changes to your management system

Comparing ISO 9001 and high-level structures / TABLE 1

ISO 9001:2008	Common high-level structure
1. Scope	1. Scope
2. Normative reference	2. Normative reference
3. Terms and definitions	3. Terms and definitions
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 and improvement	8. Operation
—	9. Performance evaluation
—	10. Improvement

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
 - Understanding the organization and its context
 - Needs and requirements
 - Scope
 - Management System
5. Leadership
 - General
 - Management commitment
 - Policy
 - Roles, responsibility and authority
6. Planning
 - Actions to address risks & opportunities
 - Objectives and plans to achieve them
7. Support
 - Resources
 - Competence
 - Awareness
 - Communication
 - Documented information
8. Operation
 - Operational planning and control
9. Performance evaluation
 - Monitoring, measurement, analysis & evaluation
 - Internal audit
 - Management review
10. Improvement
 - Non conformity and corrective action
 - Continual Improvement



- Clause 4.1 Understanding the organization and its context
- The organization shall determine **external and internal issues** that are relevant to its purpose and that affects its ability to achieve the **intended outcome(s)** of its “XXX” management system.
- Note: “XXX” = “quality”, “environmental”, information security”
etc



- Clause 4.4 XXX management system
- The organization shall determine establish, implement, maintain and continually improve an XXX management system, **including the processes needed and their interactions**, in accordance with the requirements of this International Standard.
- (Note: This is key to maintaining the “process approach”, which will now be embedded in ALL ISO management system standards)
- (Current clause 4.1 of ISO 9001:2008 likely to be incorporated into this clause).



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CD/ISO 9001:2015 Significant Changes

Please note that since the contents are under development, there may be further changes



8 QMP

1. Customer focused organization
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual Improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationship

7 QMP

1. Customer focus
2. Leadership
3. Engagement of people
4. Process Approach
5. Improvement
6. Evidence based Decision Making
7. Relationship Management



- a) Redrafting to make the standard more generic and more easily applicable by service industries.**
- Explicit reference to goods and services
 - Revision on measurement equipment and design and development



b) Context of the organization

- HLS introduced
- Clause 4.1 Understanding the organization and its context and
- Clause 4.2 Understanding the needs and expectations of interested parties
- Identify impacts on planning the quality system
- In 9001:2015 the scope is unchanged



c) Process Approach

- More explicit
- Clause 4.4.2 Process approach – specifying requirements considered essential to the adoption of a process approach.

Clause 4.4.2 Process Approach

The organization shall apply a process approach

- a) Determine the processes...
- b) Determine the inputs & outputs from each process
- c) Determine their sequence and interaction
- d) Determine the risks to conformity and customer satisfaction if unintended outputs are delivered or process interaction is ineffective
- e) Determine criteria, methods, measurements and related performance indicators needed to ensure that both the operation and control of these processes are effective
- f) Determine the resources and ensure availability
- g) Assign responsibilities and authorities
- h) Implement actions required to achieve results
- i) Monitor, analyze.....these processes ensuring they continue to deliver the intended outputs
- j) Ensure improvement of these processes.



d) Risk and Preventive Action

- Risk Analysis concepts are introduced
- Preventive Action is no longer a clause (8.5.3)
- Preventive Action concepts are deployed throughout the Standard (e.g. New clauses 4.1 and 6.1)
- No requirement for formal risk management



- Clause 6.1 Address Risks and Opportunities
- Determine Risks and opportunities that need to be addressed to:
 - a.) Assure the QMS can achieve its intended outcomes
 - b.) ...achieve conformity & customer satisfaction
 - c.) Prevent or reduce undesired effects
- The organization shall plan actions to address these Risks & Opportunities and integrate actions into the QMS and evaluating the effective of actions



e) Documented information

- HLS adopted without significant change and addition
- Document and record replaced by documented information.
- No specific requirement for Quality Manual or 6 mandatory documented procedures.



f) Control of external provision of goods and services

- Addresses all forms of external provision
- Risk based approach to determine type and extent of control



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ISO 9001:2015 Revision

What organizations can do



- Knows what is going on and is ready to implement the new requirements
- Takes full advantage of the revision of ISO 9001 to improve business performance
- ✓ Remember, don't make any changes yet!



- Integrate their activities within the scope of multiple Management System Standards
- Decrease the emphasis on documentation when this is not mandated or does not add value



- The new version is expected to be published by the September 2015.
- A transition period (usually two years) before ISO 9001:2008 officially becomes out of date.



Stay Tuned!

Additional updates and information will be made available as the change process proceeds



Thank you for your attention!

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