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ISO 9001:2015 Draft (DIS)

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By Royal Charter

Seminar Benefits

- Be able to transition from ISO 9001:2008 to ISO 9001:2015
- Inform others about the new requirements intended for ISO 9001:2015
- Prepare for ISO 9001:2015 audits

Please be aware that this presentation is based upon the Draft International Standard (DIS) and may be subject to further changes.

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Welcome!

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Seminar Objectives

Upon completion of this Seminar, delegates will be able to:

- Identify the key envisaged changes to ISO 9001
- Explain the purpose and use of Annex SL Appendix 2
- Communicate any changes in QMS specific requirements arising as a result of transitioning from ISO 9001:2008 to ISO 9001:2015
- Identify what the changes will mean for organizations
- Explain the BSI certification transition arrangements

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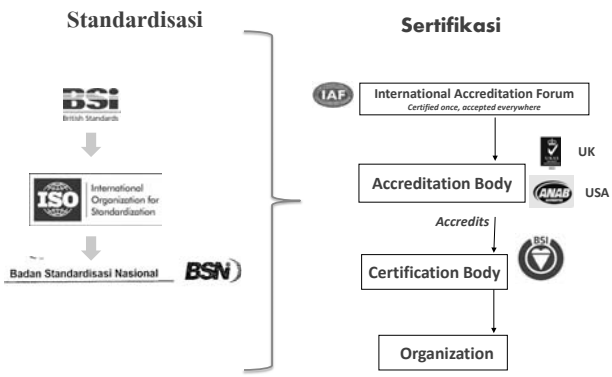
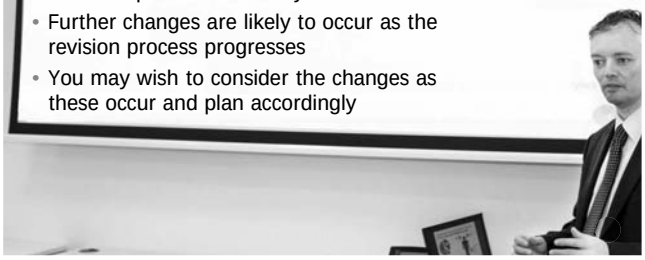


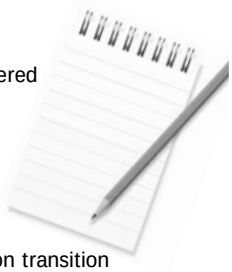
Disclaimers

- Statements made by the presenter may represent their own opinions and/or interpretations
- The presentation includes information related to the revisions process as of May 2014
- Further changes are likely to occur as the revision process progresses
- You may wish to consider the changes as these occur and plan accordingly



Agenda

- ISO facts
- ISO 9001 development process
- Key perspectives and what was considered
- Strategic changes to date
- High level structure
- Common terms and core definitions
- Quality management principles
- Significant and other changes
- ISO 9001:2015 timeline and certification transition
- Other important information



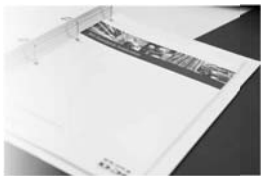
ISO Facts

- ISO = International Organization for Standardization
  - based in Switzerland, over 100 nations participate with approximately 20,000 standards
  - all ISO standards are based on consensus
- ISO standards are usually developed by its Technical Committees (“TCs”)
- Work involves international experts nominated by their national standards bodies

ISO 9001:2015 Development Process

There was broad international agreement on the need for revision.

There are different stages involved within the development of the international standard:



- Working Draft (“WD”)
- Committee Draft (“CD”)
- Draft International Standard (“DIS”)
- Final Draft International Standard (“FDIS”)
- International Standard (“IS”)
  - Published after approval of the FDIS
  - Subject to “systematic review” every 5 years

What Was Considered?

International experts considered:

- results from an extensive web-based user survey
- the increasing diversity of ISO 9001 users
- developments in knowledge and technologies
- broader user interests

Key Perspectives (1)

ISO 9001 needs to:

- Maintain its relevance
- Provide a consistent foundation for the next 10 years
- Integrate with other management systems
- Provide an integrated approach to organizational management

Key Perspectives (2)

ISO 9001 also needs to:

- Reflect the increasingly complex environments in which organizations’ operate
- Ensure the new standard reflects the needs of all potential user groups
- Enhance an organization’s ability to satisfy its customers

Strategic Changes to Date (in DIS)

- Adoption of a new High Level Structure (HLS)
- Enhanced emphasis on risk based thinking
- Common term: 'Documented information'

Customers remain the primary focus

High Level Structure

A new common ISO format has been developed for use across all management system standards:

- Common terms and core definitions
- Identical core text and numbering schemes

Organizations implementing an integrated system (e.g. QMS, EMS, ISMS etc.) should achieve optimum benefits.

The high level structure and common text is public information and can be found at www.iso.org/directives

Identical Core Text and Numbering Schemes

1) Scope

2) Normative references

3) Terms and definitions

Identical Core Text and Numbering Schemes

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 XXX MS
- 4.4 XXX management system

Identical Core Text and Numbering Schemes

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 XXX objectives and planning to achieve them

Identical Core Text and Numbering Schemes

7) Support

- 7.1 Resources
- 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

Identical Core Text and Numbering Schemes

8) Operation

- 8.1 Operational planning and control

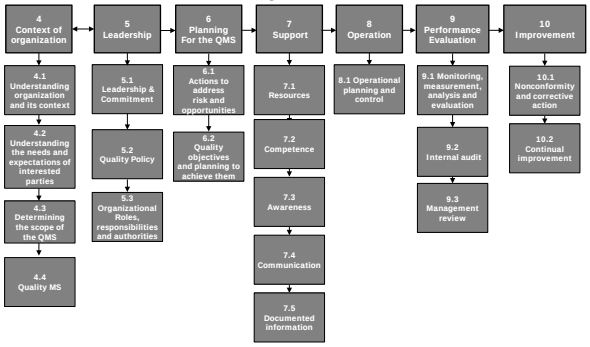
9) Performance evaluation

- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
  - 9.2.1 [Internal Audits]
  - 9.2.2 [Programmes(s)]
- 9.3 Management review

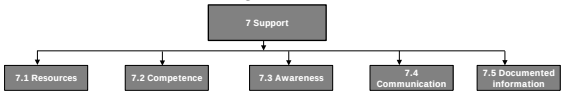
10) Improvement

- 10.1 Nonconformity and corrective action
- 10.2 Continual improvement

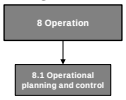
HLS and additional “QMS” Structure



HLS and additional “QMS” Structure: Clause 7



HLS and additional “QMS” Structure: Clause 8



Common Terms and Core Definitions

Difference to ISO 9000:2005 (some!)	Was not defined in 9000:2005 (some!)
Organization	Risk
Interested party	Documented information
Management system	Performance
Objective	Context of the organization
Competence	Monitoring
Corrective action	Improvement
Continual improvement	Knowledge

Areas of contention during development

- Allowing ‘applicability’ of specific requirements (exclusions)?
- Terms: Goods and services v product?
- Terms: Improvement v continual improvement?

Quality Management Principles

Was 8:	Now 7:
Customer focus	Customer focus
Leadership	Leadership
Involvement of people	Engagement of people
Process approach	Process approach
System approach to management	(Included in the process approach)
Continual improvement	Improvement
Factual approach to decision making	Evidence based decision making
Mutually beneficial supplier relationships	Relationship management

Significant Changes

1. High level structure (HLS) and terms/definitions
2. More generic and compatible with service industries
3. Organizational context must be understood
4. Process approach strengthened/more explicit
5. Preventive action replaced by risk
6. Documented information
7. Control of externally provided products and services (Purchasing/outsource)

4.1 Context of the Organization (1)

- Consider what the external and internal issues are for your organization.
- Where does this come from?
- Clause 4.1 states: "The organization shall determine external and internal issues, that are relevant to its purpose and its strategic direction and that effect its ability to achieve the intended result(s) of its QMS".

4.2 Context of the Organization (2)

- From the issues raised which relevant interested parties should you address and communicate with?
  - Where does this come from?

- Clause 4.2 states: "Due to their impact or potential impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine
  - a) the interested parties that are relevant to the quality management system;"

Other Changes:
4.3 Scope, 4.4 QMS/Processes

Scope to consider:

- External & internal issues
- Requirements of relevant interested parties
- The products and services covered (must also be stated in scope)
- Allowing “applicability” of specific requirements (already covered earlier)
- Clause 4.4 QMS – minor changes (processes already covered earlier)

Other Changes: 5.1 Leadership

Enhanced leadership requirements:

- Accountability of its effectiveness (QMS)
- Compatibility of policy & objectives with strategic direction and context
- Application of Policy
- Integration of the QMS into organization’s business processes
- Promoting awareness of the process approach
- Engaging, directing and supporting persons to contribute…..
- Promote continual improvement
- Supporting management to demonstrate their leadership

Other Changes: 5.1.2 Customer Focus

Demonstrate leadership and commitment:

- Ensuring risks and opportunities that can affect conformity of products and services, and the ability to enhance customer satisfaction, are determined and addressed

Other Changes: 5.2/5.3 Policy/Roles….

- 5.2 Quality Policy:
  - explicit requirement to ‘apply’ the policy
  - available to relevant interested parties, as appropriate
- 5.3 Roles, responsibilities and authorities:
  - explicit requirement for roles etc. to be ‘understood’
  - no requirement for a specific ‘Management representative’
  - requirement for defining responsibility & authority for ensuring processes are delivering their intended outputs
  - Top management do not need ‘themselves’ to ensure the integrity of the QMS is maintained when changes are made

Risk: 3.09 effect of uncertainty on an expected result

- Note 1 to entry: An effect is a deviation from the expected — positive or negative.
- Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- Note 3 to entry: Risk is often characterized by reference to potential events (ISO Guide 73, 3.5.1.3) and consequences (ISO Guide 73, 3.6.1.3), or a combination of these.
- Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (ISO Guide 73, 3.6.1.1) of occurrence.
- Note 5 to entry: The term “risk” is sometimes used when there is only the possibility of negative consequences.

Other Changes: 6.1.1 Actions to address risks and opportunities (1)

From the issues raised and relevant interested parties requirements identified, this clause requires:

- A consideration of these to determine the risks and opportunities that need to be addressed, specifically to –
  - a) give assurance that the quality management system can achieve its intended result(s);
  - b) prevent, or reduce, undesired effects;
  - c) achieve continual improvement.

Other Changes: 6.1.1 Actions to address risks and opportunities (2)

From the issues raised and relevant interested parties requirements identified, this clause requires:

- The organization to plan:
  - a) actions to address these risks and opportunities;

Other Changes: 6.2 Objectives

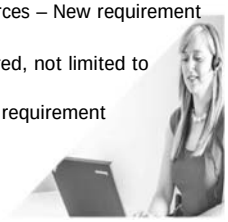
- Relevant processes require objectives
- Be relevant to conformity of products and services and the enhancement of customer satisfaction
- Explicit requirements to monitor, communicate & update
- Planning how to achieve the objectives is much more prescriptive
- How the results will be evaluated is now required

The addition of: ‘Changes’

- Planning/implementing QMS changes (6.3),
- Controlling operational changes, planned and unintentional (8.1)
- Addressing unplanned changes affecting products & services (8.5.6)
- See also 7.1.6 Organizational knowledge - for addressing changing needs and trends, with respect to knowledge

Other Changes: 7 Support (1)

- 7.1.1 a)/b) Additional resource considerations (explicit)
- 7.1.2 People to ensure the effectiveness of QMS/processes
- 7.1.3/4 Infrastructure/Environment - Minimal changes
- 7.1.5 Monitoring and measuring resources – New requirement (incudes old M/M equipment 7.6)
  - This extends to all resources required, not limited to equipment e.g. visual inspections
- 7.1.6 Organizational knowledge - New requirement
- 7.2 Competence – Minimal changes



Other Changes: 7 Support (2)

- 7.3 Awareness – relevant quality objectives (explicit)
- Implications of not conforming (explicit)
- 7.4 Communications – separate clause, external & internal of what, when, whom, how to communicate
- 7.5 Documented information – no Quality Manual, no mandated 6 documented procedures
- 7.5.2 Creating and updating – enhanced: description, format & suitability
- 7.5.3 Control of documented information – now includes confidentiality, integrity and access explicitly

Other Changes: 8 Operation (1)

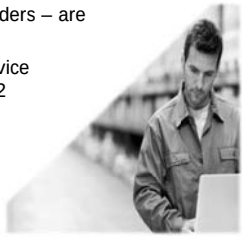
- 8.1 b) Explicit requirement for establishing criteria for the processes
- 8.2.1 Customer communications more explicit around customer property and contingency actions
- 8.2.2 Determination of requirements….requires a process & explicit in relation to potential customers
- 8.2.3 Review of requirements….. - Minimal changes
- 8.3.1 Design and development …. – Clarification of the application of design & development requirements
- 8.3.2 D & D Planning – uses the terms consider rather than determine

Other Changes: 8 Operation (2)

- 8.3.3 Design and development Inputs – explicit requirements for internal and external resource needs, potential consequences of failure, level of control expected by customers…
- 8.3.4 Design and development controls – new clause combining Reviews, Verification & Validation
- 8.3.5/6 Design and development outputs/changes – minor changes
- 8.4 Control of externally provided products and services – replaces Purchasing & Outsourcing, application of requirements clarified, otherwise minor changes

Other Changes: 8 Operation (3)

- 8.4.2 Type and extent of control of external provision – previous notes in 4.1 (2008) now turned into requirements and verification may be necessary
- 8.4.3 Information for external providers – are now more detailed and explicit
- 8.5.1 Control of production and service provision – amalgamation of 7.5.1/2 (2008), explicit M/M of criteria and competence
- 8.5.2 Identification and traceability – focus now on 'process outputs' rather than on 'product' (2008)



Other Changes: 8 Operation (4)

- 8.5.3 Property belonging to customers…. – minimal changes
- 8.5.4 Preservation – minimal changes
- 8.5.5 Post-delivery activities – new clause including new requirements for consideration
- 8.5.6 New requirement covered under 'Changes' slide
- 8.6 Release of products and services – minimal changes
- 8.7 Control of nonconforming process outputs…. – more explicit options to apply correction, corrective action, to include process outputs & products & services

Other Changes: 9 Performance evaluation (1)

- 9.1.1 General – In 8.1 (2008) there was a requirement for planning, this has been replaced with the determination of what needs monitoring & measuring, the methods to be used, when performing/analyzing/evaluating
- 9.1.2 Customer satisfaction – minor changes
- 9.1.3 Analysis and evaluation – explicit requirement to use results as inputs to management review, outputs from the analysis are now made clear

Other Changes: 9 Performance evaluation (2)

- 9.2 Internal audit – (Programme) explicit considerations of quality objectives, customer feedback and changes impacting the organization, management responsibility for action implicit now (was explicit)
- 9.3 Management review – Additional input requirements: changes in external & internal issues (including strategic direction), issues concerning external providers (and other interested parties), adequacy of resources for effective QMS and effectiveness of actions taken addressing risks & opportunities

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Other Changes: 10 Improvement (1)

- 10.1 General – This clause is not specifically about continual improvement, but improvement! And is NEW.
  - It provides emphasis now on: improving processes to prevent nonconformities
  - It provides emphasis now on: improving products and services to meet known and predicted requirements
- 10.2.1 Nonconformity and corrective action – enhances 8.5.2 Corrective action (2008). Correction/consequences now included. Actions taken is now recognizing the potential occurrence of a similar nonconformity elsewhere.

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Other Changes: 10 Improvement (2)

- 10.2.2 Documented information – new requirement to document the nature of the N/C and subsequent actions taken
- 10.3 Continual improvement – similar requirement, but with consideration of tools/methodologies for investigating underperformance/supporting C.I.

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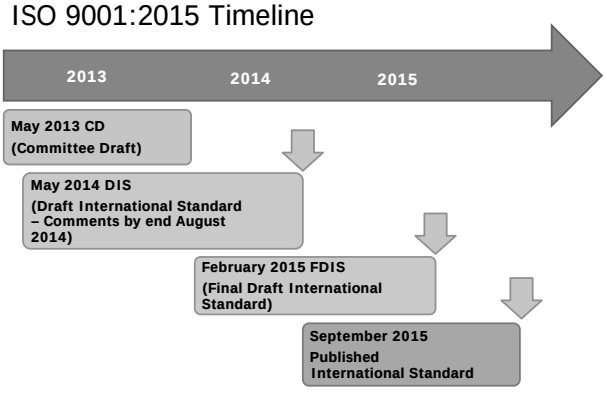
ISO 9001:2015 Timeline



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ISO 9001:2015 Certification Transition Timeline

Sept 2015 Publication

September 2015 start of 3 years transition period to September 2018

Summary - Key changes:

- Determining the organizational context (HLS)
- Greater emphasis on processes
- Greater alignment with strategic direction (HLS)
- Integration of the QMS into organization's business processes (HLS)
- Determining risks/opportunities within the context (HLS)
- Change management
- Knowledge management
- Communication expanded (HLS)
- Explicit performance evaluation requirements
- Improvement expanded (HLS)

Other Important Information

- Impact on other standards that are part of the family, expect changes to:
  - Industry-specific standards
  - Supporting documents
- BSI Transition course (1 day)
- BSI Lead Audit Transition course (2 days)
- Expect further news updates as this process evolves

How can clients keep up to date with the latest information?

Where can clients find the latest information?

A separate webpage has been set up for the revision from the main ISO 9001 webpage - www.bsigroup.com

This page will be constantly updated with articles and webinars as and when they are created. There is also an opportunity for clients to register to get priority information as it is available by registering for updates on our website. Clients can also connect to our LinkedIn groups for each revision – www.linkedin.com

How can clients keep up to date with the latest information?

Where can clients obtain a copy of the DIS?

The DIS is only available to purchase in the UK on the BSI Shop – http://shop.bsigroup.com/

How can clients keep up to date with the latest information?

How can clients make comments on the DIS?

Clients within the UK can make comments on the individual clauses through the draft review site – http://drafts.bsigroup.com/Home/Details/53029

All comments will be considered by the UK committee before submission to the ISO committee.
International clients will be able to make comments through their local National Standards Body.

Review and Final Questions

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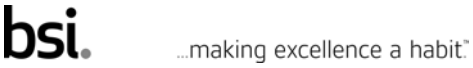
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