

NSAI

WELCOME
An insight to changes in ISO 9001
ISO 9001:2015
Quality Management System
June 2014

NSAI

NSAI Certification
ISO 9001:2015
Quality Management Systems

DIS 9001:2015

**An opportunity for
Ireland to comment**



Draft Transition policy

- Copy of transition policy provided
- Keep an eye on www.NSAI.ie for changes





Standards Development

ISO DIS 9001 Insight into changes

Background – reasons for change

ISO 9001 needs to:

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



Background – reasons for change

- 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



Requirements for the revision

- Standard to remain generic and relevant to all sizes and types of organization
- Capable of being applied by the widest possible range of organizations with varying degrees of maturity of their quality systems
- Intent of clause 1.2 of ISO 9001:2008 shall be maintained
- Use simplified language and writing styles



Requirements for the revision

- Apply Annex SL to the ISO/IEC Directives - (hereafter referred to as Annex SL) to ISO 9001, to enhance compatibility and alignment with other ISO management system standards.
- Consistent phrasing and terms should be maintained to facilitate understanding and translation
- Focus on effective process management to produce the desired outcomes shall be maintained.



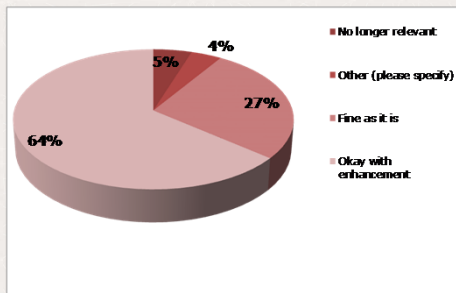
Inputs for the revision

- The results of the "systematic review" completed on ISO 9001:2008 during 2011-2012
- Analysis of the results of the extensive worldwide ISO 9000 User Survey
- Others – New quality principles & other ISO TC 176 SC2 documents



Future Relevance of ISO 9001:2008

(9001 WW Survey Result)



ISO 9001 - New Concept Importance

How important is it to incorporate the following concepts into ISO 9001?

Concept	% in Favor
Resource Management	75
Voice of Customer	74
Measures (performance, satisfaction, ROI)	72
Knowledge Management	72
Integration of Risk Mgmt.	73
Systematic problem solving & learning	73
Self-assessment tool	71
Strategic Planning	68
Innovation	65
Use of technology to develop/implement the reqs. Of the Standard	63
Life Cycle Management	62
Use of technology to run your business	61
Financial resources of the organization	55
Supporting Quality Tools (Six sigma Lean, SPC)	55

World-wide Survey - Key User Inputs

- ISO 9001, as it is, must change to continue be relevant
- Integrate with other MSS (EMS etc.)
- Provide one integral approach to the management of the organization for Leadership commitment & understanding, strategic planning, management buy-in
- Need to work with ISO/CASCO and IAF to ensure efficiency/effectiveness of audits and address problems in certification audits
- Include tools and risk management



**Annex SL – High level text
– common core text and definitions****Content**

- | | |
|---------------------------------|----------------------------|
| • 1 Scope | • 6 Planning |
| • 2 Normative references | • 7 Support |
| • 3 Definitions | • 8 Operation |
| • 4 Context of the organization | • 9 Performance evaluation |
| • 5 Leadership | • 10 Improvement |



ISO DIS 9001**ISO 9001:2008**

- 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

ISO DIS 9001

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



Overview of changes to requirements

- Quality manual
- Documented information
- Management representative
- Product and service
- Preventative action
- Risk based thinking
- Context of the organization considered in developing QMS



Overview of changes to requirements

- Interested parties and customers
- More focus on processes of QMS
- Exemptions → Applicability
 - Generic standard all requirements to be applied - justifications needed where requirement cannot be applied
- Planning of changes to the QMS
- Organizational Knowledge
- Externally providers



Scope - unchanged

• **Providing product and services that meet customers and statutory requirements still the primary focus**

- Meeting Customer Requirements
- Aims to enhance customer satisfaction






ISO 9001 DIS changes at a glance:

- **High Level Structure** and common text (**HLS**)- reinforcement of compatibility and ease of integration
- Better applicability for services and other sectors
- Less prescriptive requirements...more performance based requirements
- Organizational context and relevant requirements for relevant interested parties
- (A)



ISO 9001 DIS changes at a glance:

- Scope: boundaries of the QMS clearly defined
- Exclusions replaced by extent of application : what an organization can apply shall apply
- Risk based thinking throughout the standard replaces a specific section on preventive actions
- More leadership requirements and **accountability concept introduced**



ISO 9001 DIS changes at a glance:

- No management representative
- Documented information replaces documents and records
- Outsourcing is external provision
- Objectives with reference to who, what and when
- Planning of changes



ISO 9001 DIS changes at a glance:

- Requirements for organisational knowledge
- No explicit quality manual requirement
- More emphasis on processes to deliver the required results as stated in the scope of the standard
- Process to determine requirements for products and services to be offered to potential customers and...



ISO 9001 DIS changes at a glance:

- Design and development requirements where P&S requirements are not defined in a way adequate for production and service provision
- Property belonging to customers and external providers
- Post delivery activities
- Release of products and services
- Control of non conforming processes, outputs, products and services



ISO 9001 DIS changes at a glance:

- Reference to 9000 disappears
- Applicable terminology within the standard
- **Annex A** informative regarding important concepts and changes
- **Annex B** informative with the NEW 7 QMP
- **Annex C** informative with a display of 9000 family and 10 000 and relation to 9001



SCOPE

- Specifies requirements for a QMS system where an organization:
- a) needs to demonstrate its ability to consistently provide product or service that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.



SCOPE (cont'd...)

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided



Terms & Definitions

69 Terms & Definitions set out in clear language



ISO/DIS 9001:2015 Annex A

- Structure & terminology
- Products & Services
- Context of the organisation
- Risk based approach
- Applicability – a form of exclusions
- Documented information
- Organisational knowledge
- Control of externally provided products & services.

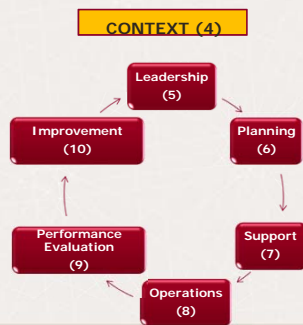


ISO/DIS 9001:2015 Annex B – 7 QMP

- Customer focus
- Leadership
- Engagement of people (*was involvement*)
- Process Approach
- Improvement
- Evidence based Decision Making (*was Factual..*)
- Relationship Management (*was Mutually Beneficial supplier Relationships*).
- Systems approach – now integrated in to the standard as a whole.



High level structure (1).



High Level Structure (2)

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



High Level Structure (3)

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
 - Improvement



ISO/DIS 9001:2015 Significant Changes

4.0 Context of the organisation

- HLS introduced
- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- Identify impacts on planning the quality system
- Scope of the QMS



ISO/DIS 9001:2015 Significant Changes

4.4 QMS & it's Processes

- Process approach is more explicit than in 2008 edition
- 4.4.2 (in 4.4 Quality management system) specifies essential requirements



Leadership

5.1 Leadership and commitment

With respect to the quality
management system
and

5.2 Quality Policy

With respect to the needs and
expectations of customers

Quality policy reviewed by top
management: purpose, context,
satisfy requirements



Leadership

5.3

Organisational roles, responsibilities and authorities

Top management *shall ensure that the responsibility & authorities for relevant roles & responsibilities are assigned & understood...*

QMS conforms

Processes are delivering..

Reporting on performance ..

Promoting of customer focus ..

Integrity of QMS when changes occur.





Standards Development Cont'd

ISO DIS 9001 Content

Clause 6: Planning for the QMS

6.1 Actions to address risk and opportunities

Risk – Effect of uncertainty on an expected result

Need to consider risk qualitatively when defining rigor and control needed in setting up the QMS



ISO DIS 9001 Content

Clause 6: Planning for the QMS

- Need to plan actions to address risk and opportunities and integrate into QMS and its processes
- Actions taken to be proportionate to the potential impact on conformity of products and services



ISO DIS 9001 Content

6.2 Quality Objectives and planning to achieve them

- Established at relevant functions, levels and processes
- Documented information on quality objectives required
- When planning to achieve them determine: what will be done, what resources are required, who is responsible, how results will be evaluated and when will it be completed.



ISO DIS 9001 Content

6.3 Planning of changes

- Determines need for change to QMS - to be carried out in planned and systematic manner.
- To consider purpose and potential consequences
- Integrity of QMS
- Availability of resources
- Allocation or re-allocation of responsibilities and authorities



ISO DIS 9001 Content**7 Support****7.1 Resources**

7.1.1 General – determine and provide the resources needed for establishment, implementation, maintenance and continual improvement of the QMS

Shall consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers



ISO DIS 9001 Content**7.1.2 People**

- Provide the persons necessary for the effective operations of the QMS including the processes needed

7.1.3 Infrastructure

- Determine provide and maintain the infrastructure for the operations of its processes to achieve conformity of products and services



ISO DIS 9001 Content**7.1.4 Environment for the operation of processes**

- Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services



ISO DIS 9001 Content**7.1.5 Monitoring and measuring resources**

- Where used for evidence of conformity of product and services, need to determine the resources required to ensure valid results.
- Ensure resources are:
 - a) Suitable for type of monitoring and measuring
 - b) Maintained to ensure fitness of purpose
- Retain appropriate documented information



ISO DIS 9001 Content**7.1.5 Monitoring and measuring resources**

- Where measurement traceability is an essential part of providing confidence in the validity of measurement results measuring instruments shall be:
 - verified or calibrated at specified intervals
 - identified to determine calibration status
 - safeguard from adjustments, damage or deterioration so as to invalidate results
- When an instrument is found to be defective the validity of previous measurement results needs to be determined and appropriate action taken as necessary



ISO DIS 9001 Content**7.1.6 Organizational knowledge**

- Determine the knowledge necessary for the operations of its processes and to achieve conformity of products and services
- Knowledge to be maintained and made available to the extent necessary
- When addressing changing needs and trends, consider current knowledge and determine how to acquire or access the necessary additional knowledge



ISO DIS 9001 Content

7.2 Competence

- Determine the necessary competence of persons doing work under organization's control that affect quality performance
- Ensure persons are competent
- Take action to acquire necessary competence & evaluate effectiveness of actions taken
- Retain appropriate documented information



ISO DIS 9001 Content

7.3 Awareness

Persons doing work under organizations control shall be aware of:

- Quality policy
- Relevant quality objectives
- Contribution to effectiveness of QMS & benefits of improved quality performance
- Implications of not conforming with QMS requirements



ISO DIS 9001 Content

7.4 Communication

Determine internal and external communications relevant to the QMS including:

- What to communicate
- When to communicate
- With whom
- How to communicate



ISO DIS 9001 Content

7.5 Documented information

7.5.1 General

The organizational QMS shall include:

- Documented Information (**DI**) required by this standard
- DI determined by the organization as necessary for the effectiveness of the QMS



ISO DIS 9001 Content

7.5.2 Creating and updating

When creating and updating DI the organization shall ensure appropriate:

- Identification and description
- Format
- Review and approval for suitability and adequacy



ISO DIS 9001 Content

7.5.3 Control of documented information

DI required by the QMS & this standard shall be controlled to ensure:

- a) it is available and suitable for use where and when it is needed
- b) is adequately protected



ISO DIS 9001 Content

7.5.3 Control of documented information

For control of documented information the organization shall address:

- a) distribution, access, retrieval & use
- b) Storage and preservation
- c) Control of changes
- d) Retention and disposition





NSAI Certification Cont'd

Operational (8)

- 8.1 Operational planning and control (HLS)
- 8.2 Determination requirements for products & services.
- 8.3 Design & development of products & services
- 8.4 **Control of external provision of products and services**
- 8.5 Production and service provision
- 8.6 Release of products & services
- 8.7 Control of nonconforming process outputs, products & services



Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal Audit

9.3 Management Review

- Clarified text on measurement.
- Requirement for performance of QMS including trends.
- Analysis of data reinforced and clarified



Improvement (10)

10.1 General

Select opportunities for improvement – meet customer requirements & enhance customer satisfaction.

10.2 Nonconformity & Corrective Action a proactive CAR system.

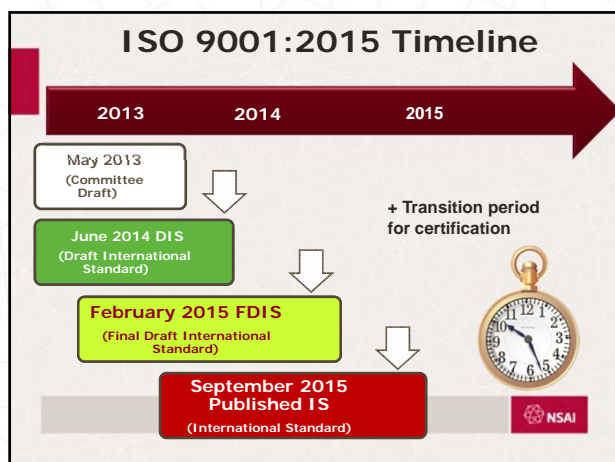


Improvement (10)

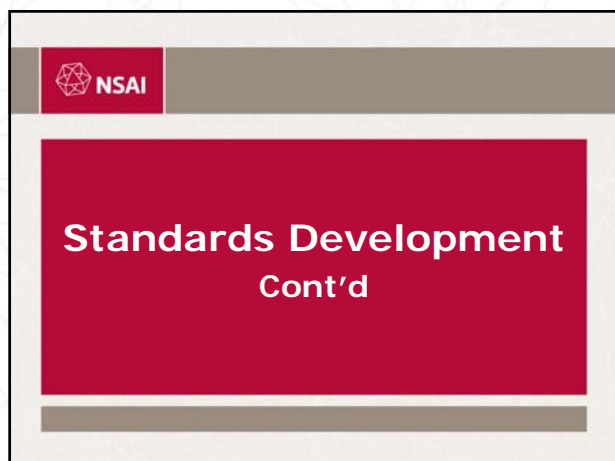
10.3 Continual Improvement

A key tool in driving the QMS to enhance customer satisfaction.









ISO TS 9002:2015

- Most current users are from a large, hardware, manufacturing industry background
- Software and services sectors, and SMEs have difficulty interpreting a lot of ISO 9001:2008
- ISO 9001:2015 should be more readily applicable in all sectors, and by all sizes of organization, to meet the strategic intent that the standard should be "generic".
- Need to explain the changes to current and new users
- Provide examples on the interpretation of the requirements by specific sectors or sizes of organization.



ISO TS 9002 Timeline

2014	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
					ISO/DIS 9001	ISO/DIS 9001	ISO/DIS 9001	ISO/DIS 9001	ISO/DIS 9001	ISO/DIS 9001	TC 176 Meeting	
					Translation	Translation	Ballot	Ballot	Ballot	Ballot		
							ISO/WD TS 9002				TC 176 Meeting	
2015	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
							ISO/FDIS 9001	ISO/FDIS 9001	ISO/FDIS 9001	ISO 9001 Published		
							Ballot	Ballot	Ballot	ISO TS 9002 Published		
	ISO/DTS 9002					ISO/DTS 9002	ISO/DTS 9002	ISO/DTS 9002	ISO/DTS 9002			
						Ballot	Ballot	Ballot				

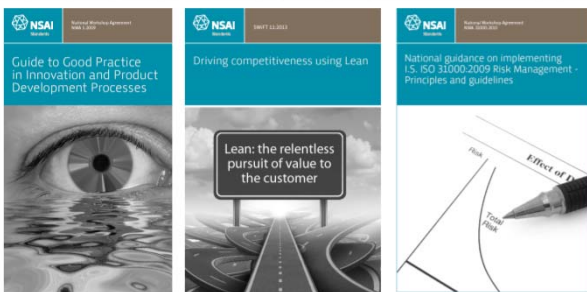
Scope of ISO TS 9002

- Guidelines for the application of ISO 9001:2015
- It is **not** a requirements document (it doesn't add / delete / modify requirements of ISO 9001:2015)
- **IF** there is a perceived conflict in interpretation, ISO 9001:2015 takes precedence.
- The guidance is for suppliers, customers and third parties.
- Although generic, it includes examples of the application of ISO 9001 to :
 - specific types of organization (e.g. SMEs)
 - specific types of outputs (e.g. services or software)



Other NSAI Publications

www.standards.ie



Other NSAI Publications

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- Guide to Good Practice in Innovation and Product Development Processes
- Driving competitiveness using Lean
- National guidance on implementing I.S. ISO 31000:2009 Risk Management – Principles and Guidelines