MANAGING RISK

The upcoming “changes” to ISO 9001:2008

Based on the ISO 9001 FDIS

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About DNV

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- DNV is celebrating our 144th anniversary this year.
- A progressive, forward-thinking organization
- A GLOBAL organization with a worldwide footprint
- Over 8,000 DNV'ers provide quality, safety and environmental services in over 100 countries, on a daily basis
- A leading International Certification Body
- Risk Based Certification™ - our proprietary protocol
- We are also a leader in Management System Training

Current ISO 9000 Family

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Standard/ document	Title	Edition	Publication Date	Comment	MSS Type
ISO 9000:2005	Quality management systems – Fundamentals and Vocabulary	Third	2005-09-15		C
ISO 9001:2000	Quality management systems – Requirements	Third	2000-12-15	Amendment in progress	A
ISO 9004:2000	Quality management systems – Guidelines for performance improvements	Second	2000-12-15	Revision in progress	B
ISO 10002	Quality management – Customer satisfaction – Guidelines for complaints handling in organizations	First	2004-07-01		C
ISO 10005:2005	Quality management - Guidelines for quality plans	Second	2005-06-01		C
ISO 10006:2003	Quality management - Guidelines for quality management in projects	Second	2003-06-15		B
ISO 10007:2003	Quality management - Guidelines for configuration management	Second	2003-06-15		C
ISO 10012:2003	Measurement management systems- Requirements for measurement processes and measuring equipment	Second	2003-04-14	Revised to merge ISO 10012-1 and ISO 10012-2	B
ISO/TR 10013:2001	Guidelines for quality management system documentation	Second	2001-07-15		C
ISO 10014:2006	Quality management – Guidelines for realizing financial and economic benefits	First	2006:06	Replaces ISO/TR 10014	B
ISO 10015:1999	Quality Management: Guidelines for training	First	1999-12-15	Confirmed 2005-09-08	C
ISO/TR 10017	Guidance on statistical techniques for ISO 9001:2000	Second	2003-05-15		C
ISO 10019	Guidelines for the selection of quality management system consultants and use of their services	First	2005-01-05		C
ISO/TS 16949:2002	Quality management systems, Automotive Suppliers, Particular requirements for the application of ISO 9001:2000	Second	2002-03-01		A
ISO 19011:2002	Guidelines on quality and/or environmental management systems auditing	First	2002-10-01		C
ISO/IEC 90003:2004	Software engineering – Guidelines for the application of ISO 9001:2000 to computer software	First	2004-02-11	Revised by ISO/IEC JTC1/SC7	B

The ISO 9001 Revision process

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- Under the auspices of the Technical Committee TC 176, the ISO 9000 “family of documents” is continually reviewed and revised.
  - First Edition – 1987
  - Second Edition – 1994
  - Third Edition – 2000
- Standards are revised because they must be kept up to date with stakeholder’s expectations. Quality Management is a dynamic process and evolves over time. Thus, the Standards should follow suit.
- For the upcoming revision <AMENDMENT> of ISO 9001, a design specification was balloted, back in 2005.
- By design, the 4th Edition of ISO 9001 is supposed to include only MINOR clarifications to the existing document. No significant changes are proposed nor expected.

Design Specification for an amendment of ISO 9001

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- **2. Purpose and scope of the amendment process**
- **2.1 Purpose**
  - **The purpose of the amendment is to enhance the clarity of ISO 9001:2000 and to enhance its compatibility with ISO 14001:2004.**
- **2.2 Scope**
  - **The amended standard shall remain generic and be applicable to all sizes and types of organization operating in any sector.**
  - **The changes shall be restricted so that the impact of the amendment on the users is limited, and also that changes will only be introduced where there are clear benefits to users The ISO 9001:2000 support package should be used to assist the writers in identifying issues for clarification.**
  - **Drafts of the amended standard shall be subjected to verification against the design specification, and to validation by users.**

Design Specification for an amendment of ISO 9001

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- **4. Compatibility**
  - **There are two main areas where compatibility issues shall be addressed:**
- **4.1 ISO 14001**
  - **In the case of a Management System Standard, "compatibility" shall mean that common elements of the standards can be implemented by organizations in a shared manner, in whole or in part, without unnecessary duplication or the imposition of conflicting requirements. "Compatibility" shall not mean that the text of the common elements of the standards needs to be identical, although it should be whenever this is possible in practice.**
- **4.2 Sector specific and other standards**
  - **A number of other management system standards are based on ISO 9001:2000 and have used its structure and text. The writers of the amendment need to be aware of the impact of changes on the compatibility of other management system standards to ISO 9001.**

Design Specification for an amendment of ISO 9001

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- **9. Guidance on drafting**
  - **the standard is free from cultural bias.**
  - **the standard is written in a clear style that avoids the excessive use of quality terms and jargon, and can be understood by all interested parties, not just quality specialists.**
  - **the standard is written to be unambiguous, to give a common understanding that prevents multiple interpretations.**
  - **sentences are kept short, to reduce excessive wordiness without becoming ambiguous**
  - **the effect of any proposed change on the other requirements of ISO 9001:2000 is considered before it is implemented.**
  - **requirements are written in such a manner as to enable them to be audited**
  - **the standard can be translated into other languages.**

Decision matrix

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			Benefits		
IMPACT			1	2	3
			High	Medium	Low
	1	Low	1	2	3
	2	Medium	2	4	6
	3	High	* 3	6	9

1-2	Incorporate the change.
3-4	Additional analysis should be conducted prior to making the decision. *Note: '*3 - high impact x high benefits' is treated as an exception, since no changes which are high impact should be incorporated into this amendment. In this instance the drafters should ensure that a record is retained of the proposed change, and their analysis of this change, to provide input into future revisions .*
6-9	Do not incorporate the change.

Changes to the Standard

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- The highlighted text shows the revised wording of the requirement on the Final Draft International Standard <FDIS> document.
- The examples shown here are not all inclusive.
  - For a full list, see Appendix B
- Remember that NOTES in the ISO 9001 Standard don't constitute requirements, but are meant to clarify them.
- Other input sources:
  - ISO/TC 176 APG papers (36)
  - ISO/TC 176 Support Documents (5)
  - ISO/TC 176 ISO 9001 Interpretation documents (37)
- Visit www.tc176.org

Proposed changes

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- **0.1 – Introduction**

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) 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.

NOTE 1 In this International Standard, the term "product" only applies to

— product intended for, or required by, a customer,

— any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

Proposed changes

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Outsourced processes

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

NOTE 2 An outsourced process is identified as one needed for the organization's quality management system but chosen to be performed by a party external to the organization.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the application of 7.4.

Proposed changes

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4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures and records required by this International Standard, and

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

Proposed changes

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4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Proposed changes

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4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

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5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

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2008

Proposed changes

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6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, training and awareness

The organization shall

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence,

c) ensure that the necessary competence has been achieved,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

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6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport, communication or information systems).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term "work environment" relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).

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7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery, and for post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements applicable to the product, and

d) any additional requirements considered necessary by the organization.

NOTE Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

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7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

Proposed changes

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7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

Proposed changes

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7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) have identification in order to determine its calibration status;

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

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8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.

8.2.2 Internal audit

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

Proposed changes

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8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where practicable, the organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

Next steps

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- **The underlying conclusion is that, as per the Design Specification, none of the proposed clarifications impact the nature of the requirements contained in ISO 9001:2000**
- **According to the ISO website, October 31st is the target date for release of ISO 9001:2008**
- **The IAF has decided that:**
  - **No accredited certificates might be issued to ISO 9001:2008 until the Standard is released AND the registrant undergoes an audit**
  - **Migration to ISO 9001:2008 certification can be accomplished during a regular surveillance audit or a re-certification audit.**
  - **Certificates to ISO 9001:2000 can be issued for 12 months, after ISO 9001:2008 is released**
  - **Twenty four months after publication by ISO of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid.**

THANK YOU!

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AS9100 Rev. C – Key Changes – October 30

Presenter: Sidney Vianna

Director of Aviation, Space & Defense Services,

Time: 1pm CST Duration: 1 hour

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THANK YOU!

Questions?