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Our ref

Secretariat of ISO/TC 176/SC 2

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To the Members of
ISO/TC 176/SC 2 -
Quality Management and
Quality Assurance/
Quality Systems

Design Specification for an *Amendment* to ISO 9001:2000

Please find attached a copy of the above Design Specification.

In accordance with the recommendations of ISO Guide 72, this Design Specification is being circulated to the members of ISO/TC 176/SC 2 for ballot, to determine if there is approval for the basis of this work, prior to the start of any drafting work for the amendment.

Please return a ballot response of either: Approval, Disapproval or Abstain, before:

30 September 2005

Thanking you in anticipation.

Yours sincerely

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0. Introduction

In 2004 ISO/TC 176/SC 2 conducted a formal Systematic Review of ISO 9001:2000 amongst its members, to determine if it should be withdrawn, left unchanged, amended or revised. By a large majority, the response was that it should be **amended**.

In parallel with the Systematic Review, ISO/TC 176/SC 2 also conducted an extensive *ISO 9001:2000 and ISO 9004:2000 User Feedback Survey*.

In accordance with the recommendations of ISO/Guide 72:2001 *Guidelines for the justification and development of management system standards*, ISO/TC 176/SC 2 then presented a Justification Study to ISO/TC 176, to demonstrate that there was sufficient evidence of the need for an amendment to be developed.

Following discussions during its plenary meetings held in 2004, ISO/TC 176 endorsed the recommendations of the Justification Study and resolved that a project should be undertaken for a limited amendment to ISO 9001:2000.

This Design Specification translates the outputs of these events into requirements for producing the amendment.

ISO Guide 72 also recommends that a Design Specification is approved, prior to drafting of the standard commencing; consequently, this Design Specification will be circulated to the members of ISO/TC 176/SC 2 for review and for ballot.

This Design Specification will be used to guide the ISO/TC 176/SC 2 experts in the drafting of the amendment to ISO 9001, and will also be used as the template for verifying the outputs of the drafting process.

1. User needs and evaluation of impacts and benefits

The Justification Study identified user needs from the following:

- the results of the Systematic Review that was completed on ISO 9001:2000 during 2003-2004 (ISO/TC 176/SC 2 document: N676R),
- the feedback from ISO/TC 176/WG Interpretations (ISO/TC 176/SC 2 document: N683R),
- the extensive worldwide ISO/TC 176/SC 2/WG 18 *ISO 9001 and ISO 9004 User Feedback Survey* (ISO/TC 176/SC 2 document: N681), and similar national surveys,

Reference was also made to the original design specification for ISO 9001 (ISO/TC 176/SC 2 document: N307), which identified users and user needs.

The above documents and other inputs to the amendment process have been listed in Annex A.

The Justification Study also made use of the output on compatibility provided by the ISO/TC 176/SC 2 and ISO/TC 207/SC 1 Joint Task Group on Co-ordination (the JTG) as an important source for user needs. Requirements arising from that feedback are addressed in Section 4.0 *Compatibility*.

The above inputs have been reviewed and taken account of during the preparation of this design specification (see Section 8.0).

These inputs highlighted that in order to satisfy user needs, the amended standard shall remain generic and be applicable to all sizes and types of organization operating in any sector. However it was also noted that:

- The sample size and the geographic representation of the responses in the comments and surveys were limited.
- The total number of comments on specific sections of the standard in the *ISO 9001 and ISO 9004 User Feedback Survey* was sometimes small compared with the total number of survey responses.

- The limited number of interpretations may not be representative of the need for clarification by all the users of the standard.
- The development of the amended standard will affect associated management system standards

The Justification Study, by restricting the changes in ISO 9001 to the level of an amendment, requires that the impact on the users of this standard shall be limited, and also that changes will only be introduced where there are clear benefits to users. Consequently, analyses of the potential impacts and benefits arising from proposed changes will be undertaken using the tool described in Annex B.

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 following requirements shall apply to the amendment process:

- The model and process approach shall be maintained as defined in ISO 9001:2000 (see Sections 6.0 Model and 7.0 Structure).
- The amended standard shall remain generic and be applicable to all sizes and types of organization operating in any sector.
- The compatibility with ISO 14001:2004 shall be maintained and be enhanced, if possible.
- The consistency between ISO 9001 and ISO 9004 shall be maintained (see Section 5.0).
- 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 (see Section 8 and Annex B)
- 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

3. Scope, purpose, title and field of application of the amended standard and guiding principles

The current scope and purpose of the standard, the title and the field of application shall be unchanged from ISO 9001:2000.

The Quality Management Principles (as contained in ISO 9000:2000) shall be applied, unchanged, for this amendment.

4. Compatibility

There are two main areas where compatibility issues shall be addressed:

4.1 ISO 14001

The concept of compatibility developed jointly by ISO/TC176/SC2 and ISO/TC207/SC1 shall be used in this project. This definition is as follows:

> 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.

Noting that ISO 14001:2004 has been published and is highly compatible with ISO 9001:2000, the proposed amendment to ISO 9001:2000 shall maintain the current level of compatibility and strive to enhance this compatibility.

It is important to note when maintaining compatibility with ISO 14001:2004 that the following do not necessarily represent potential conflicts:

- Different text in common elements or terminology
- Different numbering of the clauses
- Different models and structure
- Inclusion of guidance, notes or annexes

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.

5. Consistency

Consistency between the amendment of ISO 9001:2000 and the revision of ISO 9004:2000 means:

- lack of conflict between the standards,
- the standards complement each other, but are able to stand alone,
- harmonized concepts and terminology,
- easy transition from one standard to the other,
- the two standards can be readily applied within the same quality management system.

In the 2000 versions of ISO 9001 and ISO 9004, the structural consistency between the standards was emphasized by aligning similar clauses to the greatest extent possible. In the next editions of the standards, this rigid alignment of the clauses will be relaxed so that ISO 9004 has more flexibility to meet the needs of its users.

Consistency with other standards of the ISO 9000 family shall also be maintained.

6. Model and its features

The process model as shown in ISO 9001:2000, Figure 1, shall remain unchanged.

7. Structure of the standard

To minimize the impact on users and to maintain or enhance the compatibility of ISO 9001 with other management system standards and relevant documents, the overall structure of the standard shall remain unchanged.

Some movement of requirements within or between clauses may be allowed if the intent of the standard is not changed, the impact on users is limited and the movement contributes to clearer understanding for users of the standard. The drafters of the amendment shall consider the limitations defined in clause 1.2 *Application* when moving requirements.

8. Subjects to be addressed in the text of the amended standard

An analysis was made of the documents listed in Annex A, to identify the clauses in ISO 9001:2000 that may be subjected to amendment. The table below shows the results of this analysis, and lists examples of the comments received against these particular clauses (however, it is important to recognize that these examples are a starting point for the identification of individual requirements that may need amending).

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Any further recommendations for change that are received during the development process (e.g. from Committee Draft, or Draft International Standard stage ballots) will be analysed by the drafting group using the tool given in Annex B.

It should be noted that it is likely that some of the changes recommended during the development process may have to be considered as being outside of the criteria for an amendment, following analysis using the tool in Annex B. In such cases, the recommendation will not be considered in this amendment but will be retained for consideration during the next revision of ISO 9001.

Any changes that are accepted will also be taken forward into the ISO TC176/SC2/WG18 process for maintaining and updating the design specification.

Clause	**Recommendation to the drafters**
General	- Eliminate the need for Introduction and Support Package documents identified in Annex A by clarifying related requirements.
General	- Review terminology to consider potential clarification or translation issues. - Determine if liaison with TC176/SC1 is necessary to address the following. 4.2 documentation - 6.4 work environment - 7.3 review, verification, validation - 7.5 product and service provision - 7.5.1.f post delivery activities 7.6 calibration - 7.6 monitoring and measuring device - Relationship of 8.3 nonconforming product and 8.5.2.a nonconformities - Methods used throughout the document
General	Clarify activities related to various clauses and sub-clauses of the standard that are carried out simultaneously.
General	• Clarify whether documents (procedures, quality manual) required by the standard can be combined; • Clarify the different styles for identifying required documented procedures (e.g. 8.5.2 and 4.2.3).
1.1	- Clarify the scope of application in relation to the intended product.
1.2	- Clarify the intent of this clause in relation to when exclusions can be made in clause 7 specifically for service organizations (e.g. 7.5.5 and 7.6)
4.1	- Clarify the requirement for “control required of outsourced processes.”
4.2.3.a 4.2.3.b	- Clarify the meaning of “review”, including the difference between “review” and the “need for review.” -
4.2.3.c 4.2.3.e 4.2.3.f 4.2.3.g	- Clarify the requirement by reviewing potential conflicts with “identification,” “identified,” and “identifiable.”
4.2.4 General	- Clarify the need for records by the identification of required records with the (see 4.2.4) notation and the statement in 4.2.4 that states you must have evidence of conformity to requirements.
5	- Consider clarification of application of the process approach to top management activities
5.4.2	- Consider the clarification of QMS planning in order to meet the

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Clause	Recommendation to the drafters
	Quality Objectives (5.4.1)
5.5.2	- Clarify the requirement for "appoint a member of management….."
5.6.2	- Clarify that inputs to the management review are not limited to the ones listed in this clause,
6.2.1	• Clarify the requirement that reads ¨personnel performing work affecting product quality."
6.2.2c	• Clarify the requirement for "the effectiveness of the actions taken."
6.4	• Clarify work environment in relation to the achievement of conformity to product requirements. •
7 General	• Clarify the relationship of clause 7 to clause 8.
7.2.1	• Clarify statutory and regulatory requirements.
7.2.1.c	• Clarify the requirement "requirements related to the product."
7.2.1.d	• Clarify the requirement "any additional requirements determined by the organization."
7.2.3	• Clarify the requirement for "effective arrangements" in the first sentence.
7.3	• Clarify requirements for service oriented organizations • Clarify the relationship of the requirements for 7.3.4, 7.3.5, and 7.3.6.
7.4.1	• Clarify the requirement for evaluation of supplier and associated records (e.g. small business).
7.5.2	• Clarify the intent of the first paragraph for when this clause should be applied, including relation with special processes of ISO9001:1994.
7.5.4	• Clarify the difference between protect and safeguard. • Clarify what is intellectual property.
7.5.5	• Clarify application of this requirement for all product types.
7.6	• Clarify the proper clause placemen for the first and second sentences of this clause. • Clarify the requirement for "when used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed." •
7.6.a	• Clarify the requirement in the third paragraph that uses the word "or."
8.2.1	• Clarify the requirement for customer perception in relation to monitoring versus measurement. • Clarify the requirement for "methods shall be determined"
8.2.2 Note	• Revise from 10011 to 19011
8.2.3	• Clarify that clause 8.2.3 focuses on processes. • Clarify the relationship of this clause with 8.2.4 • Clarify the relationship between QMS processes and product (last sentence).
8.2.4	• Clarify the requirement for "the release of product."
8.3	• Clarify this clause in relation to service organizations. •
8.4	• Review for redundancy and/or links to other clauses for

Clause	Recommendation to the drafters
	possible conflicts.
8.5	• Clarify the relationship between 8,5.1, 8.5.2, and 8.5.3 • Clarify the differences in concepts between corrective action and preventive action
8.5.1	• Clarify the requirement for product improvement in relation to continual improvement and clause 5.6.3.b.
8.5.2.f	• Clarify review.
8.5.3	• Clarify this clause in relation to service organizations.

7.0

9. Guidance on drafting

9.1 General

In order to maintain and further improve clarity, terminology and presentation style, and to increase user friendliness of the standard, the drafting group shall ensure that:

- the original intent of the standard is maintained.
- 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
- consistent use of terminology is maintained, and that terminology issues are resolved with the assistance of ISO/TC 176/SC 1
- 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.
- due consideration is given to the issue of compatibility and consistency with other management system standards and ISO/CASCO standards and guidelines.

9.2 Translation issues

Text where translation difficulties may occur should be identified by consultation with the various language speakers within the drafting group, and where appropriate, from language experts outside the drafting group; this may include technical writers, non-quality personnel and ISO/TC 176 members from non-English speaking countries. They should review the text of the draft standard for clarity and translatability.

10. Liaisons

As the amendment to ISO 9001:2000 is developed, the needs of liaison members to ISO TC176/SC2, and the impact of potential changes to ISO 9001 on their management system documents, shall be considered.

Annex A - List of reference input documents

The latest revision of the following documents shall be considered in the drafting of the amendment to ISO 9001:2000.

1) The ISO/TC 176 approved interpretations,
2) ISO/TC 176/WG Interpretations – Collation of Interpretations and inputs to SC2 (ISO/TC 176/SC 2 document: N 683R)
3) The Systematic Reviews conducted on ISO 9001 and ISO 9004 (ISO/TC 176/SC 2 documents: N666, N667, N676R, N677R)
4) The web based *ISO 9001 and ISO 9004 User Feedback Survey* conducted by ISO/TC 176/SC2, with the assistance of ISO Central Secretariat (ISO/TC 176/SC 2 documents: N631, N668, N681, N705)
5) National feedback surveys and research, including those from the USA, Japan, Germany and Canada (ISO/TC 176/SC 2 documents: N607-1, N607-2, N637, N680)
6) *Justification Study for an Amendment to ISO 9001:2000 and a Revision to ISO 9004:2000* (ISO/TC 176/SC2 document: N682)
7) ISO 14001:2004, *Environmental management systems – Requirements with guidance for use*
8) ISO Guide 72:2001, *Guidelines for the justification and development of management system standards*
9) The *ISO 9001:2000 Introduction & Support Package* set of documents.
10) Design Specification for ISO 9001:2000 (ISO/TC 176/SC 2 document: N307)
11) Design Specification for ISO 9004:2008 (ISO/TC 176/SC 2 document: N731)
12) ISO 9000:2000, *Quality management systems - Fundamentals and vocabulary*
13) The ISO/IEC Directives:2001

Annex B – Tool for assessing the impacts versus benefits for proposed changes

B.1 Introduction

ISO/TC 176/SC 2 has agreed that it is very important that any changes to ISO 9001:2000 for the next release of the standard in 2008 be relatively minor in nature with minimal impact and high benefit to the end user. The following tool was created to assist the drafters of the amendment in determining which proposed changes should be included.

B.2 Objective of the Tool

To help the drafters of the ISO 9001 amendment identify and evaluate the impact vs. benefits of each proposed change.

B.3 Categories of Impact

For each category below, select the appropriate level for each proposed change. When completed, take the highest number and apply it to the decision matrix.

a) Changes or creation of ISO 9001:2000 user documents, including records
1. Low – no change to documents
2. Medium – requires minimum changes to documents
3. High – requires extensive changes or creation to documents

b) Changes to existing processes of the organization
1. Low – no change to processes
2. Medium – requires minimum change to processes
3. High – requires extensive change to processes

c) Need for additional training for users of ISO 9001
1. Low – no additional training required
2. Medium – minimal training required (e.g. ½ day awareness training)
3. High – extensive 1 – 5 days of training required

d) Effect on certification
1. Low –no Effect on current certification
2. Medium – recertification within the certified organizations certification cycle
3. High – recertification required within a defined transition period

B.4 Categories of Benefits

For each category below, select the appropriate level for each proposed change. When completed, take the lowest number and apply it to the decision matrix.

a) Provides clarity
1. High – removes ambiguity in the requirements
2. Medium – provides better clarity then before
3. Low – does not improve the clarity

b) Increases compatibility with ISO 14001
1. High – Considerably increases compatibility with ISO 14001
2. Medium – Improves the compatibility with ISO 14001
3. Low – has no impact on the compatibility with ISO 14001

c) Maintains consistency with ISO 9000 family of standards
1. High – No evidence of inconsistency with the ISO 9000 family of standards
2. Medium – Improves consistency with the ISO 9000 family of standards
3. Low – has no impact on consistency with the ISO 9000 family of standards

d) Improves translatability
1. High – significant improvement on translatability
2. Medium – slight improvement on translatability
3. Low – no improvement on translatability

B.5 Decision Making Principles

No changes which are high impact should be incorporated into this amendment to the standard.

Changes which are medium impact can only be incorporated into this amendment if they provide a correspondingly medium or high benefit to users of the standard.

Even where a change is low impact, it must be justified by the benefits it delivers to users.

B.6 Decision Matrix

The following decision matrix is based on the principles above and shall be used by drafters of the revision to the standard to determine whether a proposed change should be considered in the next revision.

			Benefits		
			1	2	3
			High	Medium	Low
Impact	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.