Document: ISO/TC 176/SC 2/N 1147

Secretariat of ISO/TC 176/SC 2 Date: 3 June 2013

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

ISO/CD 9001

In accordance with the approved project plan for the revision of ISO 9001 (see SC2/N1089), please find the Committee Draft of ISO 9001 attached. This is being circulated to members for commenting and ballot (a ballot has been established on the ISO Balloting Portal for this). The closing date for the submission of comments and votes is:

10 September 2013

Please use the ISO commenting template for the submission of comments, and ***include the relevant CD line number against each comment, in the 2nd column***. We know from past experience with previous revisions to ISO 9001 that we can expect a large number of comments at the CD stage. We may therefore have to return any comments that are submitted without reference to line numbers, or if other parts of the template have not been completed correctly, as we might not be able to process them adequately.

During the development of this CD, ISO/TC 176/SC2/WG24 encountered three issues on which it needs specific input from SC2:

- the need to maintain the concept of allowing "exclusions" of specific requirements
- the use of the term "goods and services" instead of the term "product"
- the use of the term "improvement" instead of the term "continual Improvement"

A subsidiary ballot on these issues has been posted on the ISO Balloting Portal, also with a closing date of 10 September 2013. Attachment 1 provides additional information to give the context to these issues:

Please also note that whilst member bodies may choose to comment on any part of the text:

- any comments received on the revised quality management principles given in Annex A to the CD are likely to be rejected, as the QMPs have previously been approved by a separate SC2 and SC1 joint ballot.
- any proposed changes to specific elements of the “Annex SL” identical text should be supported by very clearly stated justifications, which, if considered by WG24 to be appropriate, will be referred back to SC2 for decision

We look forward to receiving your votes and comments on the CD.

Yours sincerely

Charles Corrie
For the BSI Secretariat of
ISO/TC 176/SC 2

Attachment 1 to SC2/N1147

a) Exclusions

The current "exclusions" clause 1.2 in ISO 9001 was originally introduced following the decision to withdraw the ISO 9002 and ISO 9003 standards in 2000. A means had to be found to enable organizations with quality management systems that did not include all of the requirements of ISO 9001:2000 for technical reasons, but which had previously been able to meet the requirements of ISO 9002 or ISO 9003, to be able to claim conformity to the standard. The resulting solution was clause 1.2.

This Committee Draft has taken a different approach to the way in which its requirements are stated, when compared to the earlier editions of ISO 9001; consequently, there should no longer be any technical reasons for an organization's QMS not to be able to meet all the requirements of the future standard. This makes the need for such an exclusions clause redundant. For the time being, this Committee Draft includes text to permit "exclusions" (see lines 387 to 391), but this can be modified depending on the ballot results.

Please review the CD and decide if these requirements need to be maintained, or if they can now be removed. Note that if the results of the ballot indicate that the exclusions clause should no longer be maintained, then this will also require the Design Specification for this revision of ISO 9001 (see document SC2/N1088) to be amended, as Section 3, bullet e) states "The intent of clause 1.2 of ISO 9001:2008 shall be maintained in the revised standard.". This bullet e) would need to be deleted.

b) Goods and services

ISO 9001 has sought to be generic and applicable to all types of organization producing any type of product. However, feedback received on the current version of the standard has indicated that there is a perception that it continues to be biased towards manufacturing-type organizations with "hardware" products. The feedback has also indicated that the use of the single term "product" to cover services as well as physical products has been a hindrance to service organizations understanding and applying the standard.

In developing the Committee Draft ISO/TC 176/SC2/WG24 has therefore attempted to make it more truly generic, with a particular emphasis for organizations that provide services.

Noting that the ISO/IEC Directives themselves use the term "goods and services", ISO/TC 176/SC2/WG 24 has recommended that this term be adopted in place of the term "product".

The Committee Draft has been prepared using "goods and services".

Please review whether this change is acceptable to you.

c) Improvement

The recent revision of the Quality Management Principles (see SC2/N1145) has led to a change of one of the principles from "continual improvement" to just "improvement". ISO 9001 is being developed to make more explicit use of the quality management principles, so would need to move to just using the term "improvement" to be in alignment with them.

However, the text for management systems standards given in Annex SL of the ISO/IEC Directives, Procedures specific to ISO, uses the term "continual improvement", as do other ISO management system standards. Moving to just using "improvement" would result in a deviation from the Annex SL text.

The CD has been prepared using "continual improvement", but with the "continual" being given in strike-though text format.

Please review whether the deletion of "continual" is acceptable to you.

ISO/TC 176/SC 2/N1147

Date: 2013-06-3

ISO/CD 9001

ISO/TC 176/SC 2/WG 24

Secretariat: BSI

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Warning

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and Quality Assurance*, Subcommittee SC 2, *Quality Systems*.

This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised to adopt the unifying and agreed high level structure, identical core text and common terms and core definitions of Annex SL of the ISO Directives, redraft many sections to make them more generic and more easily applicable by service industries, and to change from using ‘product’ to ‘goods and services’.

The transition period for users of ISO 9001:2008 to transfer to using ISO 9001:20XX has been set for three years (***Note to this CD: this 3 year period is still subject to agreement by ISO/CASACO and the IAF***)

Introduction to this Committee Draft

0.1 General

This introduction is specific to this committee draft (CD) and it is not intended for incorporation to the final version of the standard. The introduction to ISO 9001:2008 has not been included in this committee draft. It will be revised as part of the response to the CD comments and ballots and incorporated into the draft international standard (DIS).

0.2 Annex SL

ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2013, Annex SL, Appendix 2 sets out the high level structure, identical core text and common terms and core definitions that are to form, when possible, the nucleus of future and revised management system standards such as ISO 9001.

'All MSS (whether they are Type A or Type B MSS) shall, in principle, use consistent structure, common text and terminology so that they are easy to use and compatible with each other. The guidance and structure given in Appendix 2 to this Annex SL shall, in principle, also be followed (based on ISO/TMB Resolution 18/2012)'.

Accordingly, ISO/CD 9001 has adopted the structure, common text and terminology provided in Annex SL, Appendix 2 as the nucleus of this revision and highlighted this in the document by the use of a *red italic* font.

Annex SL, Appendix 2 allows discipline specific additions to the core text and this has been utilised for the following:

a) specific quality management system requirements considered essential to meet the scope of the standard;
b) requirements that may appear to be generic but are considered essential to reflect use of the Quality Management Principles that form the basis for the quality management system standards within the ISO 9000 family;
c) requirements and notes that enhance or clarify the core text.

0.3 Significant Changes

a) Redrafting to make the standard more generic and more easily applicable by service industries.

Continued omission of specific reference to 'services' was considered to be unsustainable if relevance to the service sector was to be enhanced. On that basis 'product' has been replaced by 'goods and services' when

specifically referring to the deliverables for the customer. This proposed change will be subject to a specific briefing note and a request for ballot input from ISO/TC 176/SC 2 member bodies.

Where possible, clauses of the standard have been revised to reduce the prescriptive nature of some requirements which were originally derived from practices for the hardware sector, in particular clauses **7.1.4 Monitoring and measuring devices** and **8.5 Development of goods and services**.

b) Context of the organisation

Annex SL, Appendix 2 High Level Structure and core text has introduced two new clauses relating to the context of the organisation, **4.1 Understanding the organization and its context** and 4**.2 Understanding the needs and expectations of interested parties**. Together these clauses require the organisation to determine the issues and requirements that can impact on the planning of the quality management system and can be used as an input into the development of the quality management system.

Although there is now reference to determining the requirements of relevant interested parties there is no new requirement to ensure goods and services meet the needs and expectations of external parties other than those already identified in ISO 9001:2008, i.e. customers, regulators, etc. Such a change would require a change to the scope of the standard which is not permitted by the design specification for the revision.

c) Process approach

ISO 9001:2008 promoted the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system. This proposed revision to the standard makes this more explicit by including clause **4.4.2 Process approach** – specifying requirements considered essential to the adoption of a process approach.

d) Risk and Preventive Action

Annex SL, Appendix 2 High Level Structure and core text does not include a clause giving specific requirements for ‘preventive action’. This is because one of the key purposes of a formal management system is to act as a preventive tool. Consequently, the High Level Structure and Identical text require an assessment of the organization’s ‘external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s)’ in clause 4.1, and to ‘determine the risks and opportunities that need to be addressed to: assure the quality management system can achieve its intended outcome(s); prevent, or reduce, undesired effects; achieve ~~continual~~ improvement.’ in clause 6.1. These two sets of requirements are considered to cover the concept of ‘preventive action’, and also to take a wider view that looks at risks and opportunities. This approach is continued in the discipline specific text added to the Annex SL core text to require risk based thinking and a risk driven approach to preventive action throughout the development and implementation of the quality management system. This has also facilitated some reduction in prescriptive

requirements and their replacement by performance based requirements. Although risks have to identified and acted upon there is no requirement for formal risk management.

e) Documented information

The Annex SL Appendix 2 clause on Documented Information has been adopted without significant change or addition. Where appropriate, text elsewhere in the standard has been aligned with its requirements. Consequently the terms 'document' and 'record' have both been replaced throughout the requirements text by 'documented information'.

f) Control of external provision of goods and services

Clause **8.6 Control of external provision of goods and services** – addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organisation or by any other means. The organisation is required to take a risk based approach to determine the type and extent of controls appropriate to each external provider and all external provision of goods and services.

{Drafting Note The sources of text in this revision can be identified by the font colour as follows:

Red italics - Annex SL text

Black **– Text taken from existing ISO 9001: 2008 and text developed by WG24.}**

Quality management systems — Requirements

1 Scope

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

a) needs to demonstrate its ability to consistently provide goods and services that meet 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

a) goods and services intended for, or required by, a customer, and

b) any intended output resulting from the operational processes.

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

{**Drafting note: The Annex SL terms are currently incorporated to assist reviewers of the committee draft. At this time there is no agreement to incorporate such terms in ISO 9001, and they will be moved later into ISO 9000. Changes to definitions being developed by ISO/TC176/SC1 have not yet been incorporated.**}

3.01
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its ***objectives*** *(3.08)*

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.02

interested party *(preferred term)*

stakeholder *(admitted term)*

person or ***organization*** *(3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity*

3.03
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information.

3.04
management system
set of interrelated or interacting elements of an ***organization*** *(3.01) to establish* ***policies*** *(3.07) and* ***objectives*** *(3.08) and* ***processes*** *(3.12) to achieve those objectives*

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning, operation, etc.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.05
top management
person or group of people who directs and controls an ***organization*** *(3.01) at the highest level*

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the ***management system*** *(3.04) covers only part of an organization then top management refers to those who direct and control that part of the organization.*

3.06
effectiveness
extent to which planned activities are realized and planned results achieved

3.07
policy
intentions and direction of an ***organization*** *(3.01) as formally expressed by its* ***top management*** *(3.05)*

3.08
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and ***process*** *(3.12)). An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective or by the use of other words with similar meaning (e.g. aim, goal, or target).*

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of quality management systems standards quality objectives are set by the organization, consistent with the quality policy, to achieve specific results.

3.09
risk
effect of uncertainty

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 efficiency 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.

3.10
competence
ability to apply knowledge and skills to achieve intended results

3.11
documented information
*information required to be controlled and maintained by an **organization** (3.01) and the medium on which it is contained*

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to

*– the management system (3.04), including related **processes** (3.12);*

– information created in order for the organization to operate (documentation);

– evidence of results achieved (records).

3.12
process
set of interrelated or interacting activities which transforms inputs into outputs

3.13
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

*Note 2 to entry: Performance can relate to the management of activities, **processes** (3.12), products (including services), systems or **organizations** (3.01).*

3.14
***outsource** (verb)*
*make an arrangement where an external **organization** (3.01) performs part of an organization's function or **process** (3.12)*

*Note 1 to entry: An external organization is outside the scope of the **management system** (3.04), although the outsourced function or process is within the scope.*

3.15
monitoring
*determining the status of a system, a **process** (3.12) or an activity*

Note 1 to entry: To determine the status there may be a need to check, supervise or critically observe.

3.16
measurement
***process** (3.12) to determine a value*

3.17
audit
*systematic, independent and documented **process** (3.12) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled*

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

3.18
conformity
*fulfilment of a **requirement** (3.03)*

3.19
nonconformity
*non-fulfilment of a **requirement** (3.03)*

3.20
correction
*action to eliminate a detected **nonconformity** (3.19)*

3.21
corrective action
*action to eliminate the cause of a **nonconformity** (3.19) and to prevent recurrence*

3.22
continual improvement
*recurring activity to enhance **performance** (3.13)*

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues, that are relevant to its purpose and its strategic direction *and that affect its ability to achieve the intended outcome(s) of its quality management system.*

The organization shall update such determinations when needed.

When determining relevant external and internal issues, the organization shall consider those arising from:

a) changes and trends which can have an impact on the objectives of the organization;

b) relationships with, and perceptions and values of relevant interested parties;

c) governance issues, strategic priorities, internal policies and commitments; and

d) resource availability and priorities and technological change.

Note 1 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, cultural, social, economic and natural environment, whether international, national, regional or local.

Note 2 When understanding the internal context the organization could consider those related to perceptions, values and culture of the organization.

4.2 *Understanding the needs and expectations of interested parties*

The organization shall determine

a) the interested parties that are relevant to the quality management system, and

b) the requirements of these interested parties

The organization shall update such determinations in order to understand and anticipate needs or expectations affecting customer requirements and customer satisfaction.

The organization shall consider the following relevant interested parties:

a) direct customers;
b) end users;
c) suppliers, distributors, retailers or others involved in the supply chain;
d) regulators; and
e) any other relevant interested parties.

Note Addressing current and anticipated future needs can lead to the identification of improvement and innovation opportunities.

4.3 *Determining the scope of the quality management system*

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider

a) the external and internal issues referred to in 4.1, and

b) the requirements referred to in 4.2.

The scope shall be stated in terms of goods and services, the main processes to deliver them and the sites of the organization included.

When stating the scope, the organization shall document and justify any decision not to apply a requirement of this International Standard and to exclude it from the scope of the quality management system. Any such exclusion shall be limited to clause 7.1. 4 and 8 and shall not affect the organization's ability or responsibility to assure conformity of goods and services and customer satisfaction, nor can an exclusion be justified on the basis of a decision to arrange for an external provider to perform a function or process of the organization.

Note: An external provider can be a supplier or a sister organization (such as a headquarters or alternate site location) that is outside of the organization's quality management system.

The scope shall be available as documented information.

4.4 *Quality management system*

4.4.1 General

The organization shall establish, implement, maintain and ~~continually~~ improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

4.4.2 Process approach

The organization shall apply a process approach to its quality management system. The organization shall:

a) determine the processes needed for the quality management system and their application throughout the organization;
b) determine the inputs required and the outputs expected from each process;
c) determine the sequence and interaction of these processes;
d) determine the risks to conformity of goods and services 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 their availability;
g) assign responsibilities and authorities for processes;
h) implement actions necessary to achieve planned results;
i) monitor, analyse and change, if needed, these processes ensuring that they continue to deliver the intended outputs; and
j) ensure ~~continual~~ improvement of these processes.

5 *Leadership*

5.1 *Leadership and commitment*

5.1.1 Leadership and commitment with respect to the quality management system

Top management shall demonstrate leadership and commitment with respect to the quality management system by

a) ensuring that quality policies and quality objectives are established for the quality management system and are compatible with the strategic direction of the organization;
b) ensuring the quality policy is understood and followed within the organization;

c) *ensuring the integration of the quality management system requirements into the organization's business processes;*

d) promoting awareness of the process approach;

e) *ensuring that the resources needed for the quality management system are available*

f) *communicating the importance of effective quality management and of conforming to the quality management system requirements* and the requirements of goods and services*;*

g) *ensuring that the quality management system achieves its intended ~~outcomes~~* outputs*;*

h) engaging, *directing and supporting persons to contribute to the effectiveness of the quality management system;*

i) *promoting ~~continual~~ improvement* and innovation*;* and

j) *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.*

5.1.2 Leadership and commitment with respect to the needs and expectations of customers

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that

a) the risks which can affect conformity of goods and services and customer satisfaction are identified and addressed;

b) customer requirements are determined and met;

c) the focus on consistently providing goods and services that meet customer and applicable statutory and regulatory requirements is maintained;

d) the focus on enhancing customer satisfaction is maintained;

NOTE Reference to "business" in this International Standard should be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 *Quality policy*

Top management shall establish a quality policy that:

a) is appropriate to the purpose of the organization;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements, and

d) includes a commitment to ~~continual~~ improvement of the quality management system.

The quality policy shall:

a) be available as documented information;

b) be communicated within the organization;

c) be available to interested parties, as appropriate; and

d) be reviewed for continuing suitability.

NOTE Quality Management Principles can be used as the basis for the quality policy.

5.3 *Organizational roles, responsibilities and authorities*

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization.

Top management shall be accountable for the effectiveness of the quality management system and *shall assign the responsibility and authority for:*

a) *ensuring that the quality management system conforms to the requirements of this International Standard ~~and,~~*
b) ensuring that the processes interact and are delivering their intended outputs,
c) *reporting on the performance of the quality management system to top management* and any need for improvement, and
d) ensuring the promotion of awareness of customer requirements throughout the organization.

6 *Planning*

6.1 *Actions to address risks and opportunities*

When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to

a) assure the quality management system can achieve its intended outcome(s),
b) assure that the organization can consistently achieve conformity of goods and services and customer satisfaction,
c) prevent, or reduce, undesired effects, and
d) achieve ~~continual~~ improvement.

The organization shall plan:

a) actions to address these risks and opportunities, and
b) how to
  1) integrate and implement the actions into its quality management system processes (see 4.4), and
  2) evaluate the effectiveness of these actions.

Any actions taken to address risks and opportunities shall be proportionate to the potential effects on conformity of goods and services and customer satisfaction.

Note Options to address risks can include for example risk avoidance, risk mitigation or risk acceptance

6.2 *Quality objectives and planning to achieve them*

The organization shall establish quality objectives at relevant functions, levels and processes*.*
The quality objectives shall

a) be consistent with the quality policy,

b) be relevant to conformity of goods and services and customer satisfaction,

c) be measurable ~~(if practicable)~~,

d) take into account applicable requirements,

e) be monitored,

f) be communicated, and

g) be updated as appropriate.

The organization shall retain documented information on the quality objectives.

When planning how to achieve its quality objectives, the organization shall determine

a) what will be done,

b) what resources will be required (see 7.1),

c) who will be responsible,

d) when it will be completed, and

e) how the results will be evaluated.

6.3 Planning of changes

The organization shall determine the needs and opportunities for change to maintain and improve the performance of the quality management system.

The organization shall undertake change in a planned and systematic manner, identifying risks and opportunities and reviewing the potential consequences of change.

NOTE Specific requirements on control of changes are included in clause 8.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and ~~continual~~ improvement of the quality management system.

The organization shall consider

a) what are existing internal resources, capabilities and limitations, and

b) which goods and services are to be sourced externally.

7.1.2 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for its operations and to assure conformity of goods and services and customer satisfaction.

Note Infrastructure can include,

a) buildings and associated utilities,
b) equipment including hardware and software, and
c) transportation, communication and information systems.

7.1.3 Process environment

The organization shall determine, provide and maintain the process environment necessary for its operations and to assure conformity of goods and services and customer satisfaction.

NOTE Process environment can include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).

7.1.4 Monitoring and measuring devices

The organization shall determine, provide and maintain the monitoring and measuring devices needed to verify conformity to product requirements and shall ensure that the devices are fit for purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of monitoring and measuring devices.

NOTE 1 Monitoring and measurement devices can include measuring equipment and assessment methods such as surveys.

NOTE 2 Monitoring and measurement devices can be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.

7.1.5 Knowledge

The organization shall determine the knowledge necessary for the operation of the quality management system and its processes and to assure conformity of goods and services and customer satisfaction. This knowledge shall be maintained, protected and made available as necessary.

Where addressing changing needs and trends the organization shall take into account its current knowledge base and determine how to acquire or access the necessary additional knowledge.(See also 6.3)

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects its quality performance, and

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) *where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, and*

d) *retain appropriate documented information as evidence of competence.*

NOTE Applicable actions may include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 *Awareness*

Persons doing work under the organization's control shall be aware of

a) *the quality policy,*

b) relevant quality objectives,

c) *their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance, and*

d) *the implications of not conforming with the quality management system requirements.*

7.4 *Communication*

The organization shall determine the need for internal and external communications relevant to the quality management system including

a) *on what it will communicate,*

b) *when to communicate,* and

c) *with whom to communicate.*

7.5 *Documented information*

7.5.1 General

The organization's quality management system shall include

a) *documented information required by this International Standard,*

b) *documented information determined by the organization as being necessary for the effectiveness of the quality management system.*

NOTE The extent of documented information for a quality management system can differ from one organization to another due to

a) *the size of organization and its type of activities, processes,* ~~*products*~~ goods *and services,*

b) *the complexity of processes and their interactions, and*

c) *the competence of persons.*

7.5.2 Creating and updating

When creating and updating documented information the organization shall ensure appropriate

a) *identification and description (e.g. a title, date, author, or reference number),*

b) *format (e.g. language, software version, graphics) and media (e.g. paper, electronic),*

c) *review and approval for suitability and adequacy.*

7.5.3 Control of documented Information

Documented information required by the quality management system and by this International Standard shall be controlled to ensure

a) it is available and suitable for use, where and when it is needed, and

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable

a) distribution, access, retrieval and use,

b) storage and preservation, including preservation of legibility,

c) control of changes (e.g. version control), and

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled.

NOTE Access implies a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information, etc.

8 *Operation*

8.1 *Operational planning and control*

The organization shall plan, implement and control the processes needed to meet requirements and to implement the actions determined in 6.1, by

a) establishing criteria for the processes

b) implementing control of the processes in accordance with the criteria, and

c) keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that ~~*outsourced processes are*~~ the operation of a function or process of the organization by an external provider is *controlled (see 8.4).*

Note Operation of a function or process of the organization by an external provider is often referred to as outsourcing.

8.2 Determination of market needs and interactions with customers

8.2.1 General

The organization shall implement a process for interacting with customers to determine their requirements relating to goods and services.

Note 1 A “customer” means an existing or potential customer

Note 2 The organization can interact with other relevant interested parties to determine additional requirements for goods and services (see 4.2).

8.2.2 Determination of requirements related to the goods and services

The organization shall determine as applicable

a) requirements specified by the customer including the requirements for delivery and 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 goods and services, and
d) any additional requirements considered necessary by the organization.

Note: Additional requirements can include those arising from relevant interested parties

8.2.3 Review of requirements related to the goods and services

The organization shall review the requirements related to the goods and services. This review shall be conducted prior to the organization's commitment to supply goods and services to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) goods and services requirements are defined and agreed,
b) contract or order requirements differing from those previously expressed are resolved, and
c) the organization is able to meet the defined requirements.

Documented information describing the results of the review shall be maintained.

Where the customer does not provide documented statement of their requirements, the customer requirements shall be confirmed by the organization before acceptance.

Where requirements for goods and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations a formal review is impractical for each order. Instead the review can cover other relevant information available to the customer.

8.2.4 Customer communication

The organization shall determine and implement planned arrangements for communicating with customers in relation to:

a) goods and services information,
b) enquiries, contracts or order handling, including amendments,
c) customer feedback, including customer complaints (see 9.1),
d) the handling of customer property, if applicable, and
e) the specific requirements for contingency actions, where relevant.

8.3 Operational planning process

In preparing for the realization of goods and services, the organization shall implement a process to determine the following, as appropriate,

a) requirements for the goods and services taking into consideration relevant quality objectives;
b) actions to identify and address risks related to achieving conformity of goods and services to requirements;
c) the resources that will be required arising from the requirements for the goods and services;
d) the criteria for the acceptance of goods and services;
e) required verification, validation, monitoring, measurement, inspection and test activities specific to the goods and services;
f) how the performance data will be established and communicated; and
g) requirements for traceability, preservation, goods and services delivery and post delivery activities.

The output of this planning process shall be in a form suitable for the organization's operations.

NOTE 1 Documented information specifying the processes of the quality management system (including the realization of goods and services processes) and the resources to be applied to a specific good and service, project or contract can be referred to as a quality plan.

NOTE 2 The organization can also apply the requirements given in 8.5 to the development of processes for the realization of goods and services.

8.4 Control of external provision of goods and services

8.4.1 General

The organization shall ensure that externally provided goods and services conform to specified requirements.

Note Where the organization has arranged for an external provider to perform a function or process of the organization it is assumed this will result in the provision of goods, services or both goods and services.

8.4.2 Type and extent of control of external provision

The type and extent of control applied to the external providers and the externally-provided processes, goods and services shall be dependent upon

a) the risks identified and the potential impacts,

b) the degree to which the control of an externally provided process is shared between the organization and the provider, and
c) the capability of potential controls.

The organization shall establish and apply criteria for the evaluation, selection, and re- evaluation of external providers based on their ability to provide~~,~~ goods and services in accordance with the organization's requirements.

Documented information describing the results of evaluations shall be maintained.

8.4.3 Documented information for external providers

Documented information shall be provided to the external provider describing, where appropriate:
a) the goods and services to be provided or the process to be performed,
b) the requirements for approval or release of goods and services, procedures, processes or equipment,
c) the requirements for competence of personnel, including necessary qualification,
d) the quality management system requirements,
e) the control and monitoring of the external provider's performance to be applied by the organization,
f) any verification activities that the organization, or its customer, intends to perform at the external provider's premises, and
g) the requirements for handling of external provider's property provided to the organization.

The organization shall ensure the adequacy of specified requirements prior to their communication to the external provider.

The organization shall monitor the performance of external providers. Documented information describing ~~on~~ the results of monitoring shall be maintained.

8.5 Development of goods and services

8.5.1 Development processes

The organization shall plan and implement processes for the development of goods and services consistent with the process approach.
In determining the stages and controls for the development processes, the organization shall take account of:
a) the nature, duration and complexity of the development activities,
b) customer, statutory and regulatory requirements specifying particular process stages or controls,
c) requirements specified by the organization as essential for the specific type of goods and services being developed,
d) standards or codes of practice that the organization has committed to implement,
e) the determined risks and opportunities associated with the development activities with respect to

1) the nature of the goods and services to be developed and potential consequences of failure,
2) the level of control expected of the development process by customers and other relevant interested parties, and
3) the potential impact on the organization's ability to consistently meet customer requirements and enhance customer satisfaction.

f) internal and external resource needs for the development of goods and services,
g) the need for clarity with respect to the responsibilities and authorities of the individuals and parties involved in the development process,
h) the need for the management of the interfaces between individuals and parties involved in the development task or opportunity,
i) the need for involvement of customer groups and user groups in the development process and their interface with management of the development process,
j) the necessary documented information on the application of development processes, the outputs and their suitability, and
k) the activities needed to transfer from development to production or service provision.

8.5.2 Development controls

The controls applied to the development process shall ensure that

a) the result to be achieved by the development activities is clearly defined,
b) inputs are defined to a level sufficient for the development activities being undertaken and do not give rise to ambiguity, conflict or lack of clarity,
c) outputs are in a form suitable for subsequent use for production of goods and provision of services and related monitoring and measurement,
d) problems and issues arising during the development process are resolved or otherwise managed before committing to further development work or setting priorities for that work,
e) the planned development processes have been followed, the outputs are consistent with the inputs and the objective of the development activity has been met,
f) goods produced or services provided as a consequence of the development undertaken are fit for purpose, and
g) appropriate change control and configuration management is maintained throughout the development of goods and services and any subsequent modifications to goods and services.

8.5.3 Development transfer

The organization shall ensure that transfer from development to production or service provision only takes place when actions outstanding or arising from development have been completed or are otherwise managed such that there is no adverse impact on the organization's ability to consistently meet customer requirements, statutory or regulatory requirements, or to enhance customer satisfaction.

8.6 Production of goods and provision of services

8.6.1 Control of production of goods and provision of services

The organization shall implement production of goods and provision of services under controlled conditions. Controlled conditions shall include, as applicable:

a) the availability of documented information that describes the characteristics of the goods and services;
b) the implementation of controls;
c) the availability of documented information that describes the activities to be performed and the results achieved, as necessary;
d) the use of suitable equipment;
e) the availability, implementation and use of monitoring and measuring devices;
f) the competence of personnel or their qualification;
g) the validation and approval, and periodic revalidation, of any process for production of goods and provision of services where the resulting output cannot be verified by subsequent monitoring or measurement;
h) the implementation of goods and services release, delivery and post-delivery activities; and
i) prevention of nonconformity due to human error, such as unintentional mistakes and intentional rule violations.

NOTE Validation demonstrates the ability of these processes to achieve planned results through:

a) definition of criteria for review and approval of the processes;
b) approval of equipment and qualification of personnel;
c) use of specific methods and procedures; and
d) definition of requirements for documented information.

8.6.2 Identification and traceability

Where appropriate, the organization shall identify process outputs by suitable means.

The organization shall identify the status of process outputs with respect to monitoring and measurement requirements throughout realization of goods and services.

Where traceability is a requirement, the organization shall control the unique identification of the process outputs, and maintain it as documented information.

Note: Process outputs are the results of any activities which are ready for delivery to the customer (external or internal) or become the inputs to the next process. They can include products, services, intermediate parts, components, etc.

8.6.3 Property belonging to customers or external providers.

The organization shall exercise care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify,

protect and safeguard the customer or external provider's property provided for use or incorporation into the goods and services.

If any property of the customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and maintain documented information.

NOTE Property belonging to customer or external providers can include intellectual property and confidential or personal data.

8.6.4 Preservation of goods and services

The organization shall ensure preservation of goods and services, including any process outputs, during processing and delivery to the intended destination in order to maintain conformity to requirements. Preservation shall also apply to process outputs that constitutes parts of the goods or any physical process output that is needed for the provision of the service.

NOTE Preservation can include identification, handling, packaging, storage and protection.

8.6.5 Post delivery activities

Where applicable, the organization shall determine and meet requirements for post delivery activities associated with the nature and intended lifetime of the goods and services.

The extent of post delivery activities that are required shall take account of

a) the risks associated with the goods and services,
b) customer feedback, and
c) statutory and regulatory requirements.

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

8.6.6 Control of changes

The organization shall undertake change in a planned and systematic manner, taking account of the review of the potential consequences of changes (see 6.3) and taking action as necessary, to ensure the integrity of goods and services are maintained.

Documented information describing the results of the review of changes, the personnel authorizing the change and any necessary actions shall be maintained.

8.7 Release of goods and services

The organization shall implement the planned activities at appropriate stages to verify that goods and services requirements have been met (see 8.3). Evidence of conformity with the acceptance criteria shall be maintained.

The release of goods and services to the customer shall not proceed until the planned arrangements for verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. Documented information shall indicate the person(s) authorizing release of goods and services for delivery to the customer.

8.8 Nonconforming goods and services

The organization shall ensure that goods and services which do not conform to requirements are identified and controlled to prevent their unintended use or delivery that will have a negative impact on the customer.

The organization shall take actions (including corrections if needed) appropriate to the nature of the nonconformity and its effects. This applies also to nonconforming goods and services detected after delivery of the goods or during the provision of the service.

When the nonconforming goods and services have been delivered to the customer, the organization shall also take appropriate correction to assure that customer satisfaction is achieved.
Appropriate corrective actions shall be implemented (see 10.1).

NOTE The appropriate actions can include:

a) segregation, containment, returning and suspension of provision of goods and services;
b) informing the customer as appropriate; and
c) obtaining authorization for repair, regrade, use as it is, release, continuation or re-provision of the service, acceptance under concession.

When the nonconforming goods and services are corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Documented information describing the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained

9 *Performance evaluation*

9.1 *Monitoring, measurement, analysis and evaluation*

9.1.1 General

The organization shall ~~determine~~ take into consideration the determined risks and opportunities and shall:

a) *determine what needs to be monitored and measured* in order to:
   - demonstrate conformity of goods and services to requirements,
   - evaluate the performance of processes (see 4.4),
   - ensure conformity and effectiveness of the quality management system, and
   - evaluate customer satisfaction; and

b) evaluate the performance of external provider(s) (see 8.4);

c) determine *the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;*

d) determine *when the monitoring and measuring shall be performed;*

e) determine *when the results from monitoring and measurement shall be analysed and evaluated;* and

f) determine what performance indicators of the quality management system are needed.

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.

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the ~~quality~~ performance and the effectiveness of the quality management system.

9.1.2 Customer satisfaction

The organization shall monitor data relating to customer perceptions of the degree to which requirements have been met.

As appropriate, the organization shall obtain data relating to:

a) customer feedback , and

b) customer views and perceptions of the organization, its processes and its goods and services.

The methods for obtaining and using this data shall be determined.

The organization shall evaluate the data obtained to determine opportunities to enhance customer satisfaction.

9.1.3 Analysis and evaluation of data

The organization shall analyse and evaluate appropriate data arising from monitoring, measurement (see 9.1.1 and 9.1.2) and other relevant sources. This shall include determination of applicable methods.

The results of analysis and evaluation shall be used:

a) to determine the suitability, adequacy and effectiveness of the quality management system,

b) to assure that the goods and services can consistently meet customer requirements,

c) to ensure that the operation and control of processes is effective, and

d) to identify improvements within the quality management system.

The results of analysis and evaluation shall be used as an input to the management review.

9.2 *Internal Audit*

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system;

a) conforms to

1) the organization's own requirements for its quality management system; and

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

The organization shall:

a) plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting. The audit programme(s) shall take into consideration the quality objectives, *the importance of the processes concerned,* the related risks, *and the results of previous audits;*

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management for evaluation*,*

e) take appropriate action without undue delay; and

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.3 *Management review*

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness.

Management review shall be planned and carried out, taking into account the changing business environment and in alignment with the strategic direction of the organization.

The management review shall include consideration of:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance of the quality management system*, including trends and indicators for:*

1) nonconformities and corrective actions;

2) monitoring and measurement results;

3) *audit results;*
4) customer feedback;
5) supplier and external provider issues; and
6) process performance and product conformity;

d) *opportunities for ~~continual~~ improvement.*

The outputs of the management review shall include decisions related to:

a) *~~continual~~ improvement opportunities, and*
b) *any need for changes to the quality management system.*

The organization shall retain documented information as evidence of the results of management reviews including actions taken.

10 ~~*Continual*~~ *improvement*

10.1 *Nonconformity and corrective action*

When a nonconformity occurs, the organization shall:

a) *react to the nonconformity, and as applicable*
   1) *take action to control and correct it; and*
   2) *deal with the consequences;*
b) *evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by*
   1) *reviewing the nonconformity;*
   2) *determining the causes of the nonconformity, and*
   3) *determining if similar nonconformities exist, or could potentially occur;*
c) *implement any action needed;*
d) *review the effectiveness of any corrective action taken; and*
e) *make changes to the quality management system, if necessary.*

Corrective actions shall be appropriate to the effects of the nonconformities encountered.
The organization shall retain documented information as evidence of

a) *the nature of the nonconformities and any subsequent actions taken; and*
b) *the results of any corrective action.*

10.2 *Improvement*

The organization shall ~~continually~~ improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall improve the quality management system, processes and goods and services, as appropriate, through responding to:

a) results of analysis of data;
b) changes in the context of the organization;
c) changes in identified risk (see 6.1); and
d) new opportunities.

The organization shall evaluate, prioritise and determine the improvement to be implemented.

Annex A
Quality management principles
(Informative)

A.1 Introduction

This document introduces the seven quality management principles on which the quality management system standards of the ISO 9000 series are based.

The principles were developed and updated by international experts of ISO/TC 176, which is responsible for developing and maintaining the ISO 9000 series on quality management standards.

This annex provides a “statement” describing each principle and a “rationale” explaining why an organization should address the principle.

A.2 QMP 1 – Customer Focus

a) Statement

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

b) Rationale

Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organization

A.3 QMP 2 – Leadership

a) Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives of the organization.

b) Rationale

Creation of unity of purpose, direction and engagement enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

A.4 QMP 3 – Engagement of People

a) Statement

It is essential for the organization that all people are competent, empowered and engaged in delivering value.

Competent, empowered and engaged people throughout the organization enhance its capability to create value.

b) Rationale

To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of skills and knowledge facilitate the engagement of people in achieving the objectives of the organization.

A.5 QMP 4 – Process Approach

a) Statement

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

b) Rationale

The quality management system is composed of interrelated processes. Understanding how results are produced by this system, including all its processes, resources, controls and interactions, allows the organization to optimize its performance.

A.6 QMP 5 – Improvement

a) Statement

Successful organizations have an ongoing focus on improvement.

b) Rationale

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

A.7 QMP 6 – Evidence-based Decision Making

a) Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

b) Rationale

Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decisions made.

A.8 QMP 7 – Relationship Management

a) Statement

For sustained success, organizations manage their relationships with interested parties, such as suppliers.

b) Rationale

Interested parties influence the performance of an organization. Sustained success is more likely to be achieved when an organization manages relationships with its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner network is often of particular importance.

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[2] Published in English and French, ten times per year, ISO Focus+ covers the complete range of ISO International Standards: technical, management, good practice and conformity assessment, and for products, services, processes, systems, materials and professionals. Available at http://www.iso.org/isofocus+

附件 2

Template for comments(征求意见表)

Comments on ISO/CD 9001 Quality management systems - Requirements

Date : 2013-06-04	Document: ISO/TC 176/SC 2/WG 24/N XX

MB/ NC[1]	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment[2]	Comments	Proposed change	Observations of the secretariat
		General					
		General					
		General					
		Title					
		Contents					
		Foreword					
		Introduction					
		1					
		2					
		3					

		4					
		4.1					
		4.2					
		4.3					
		4.4					
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		Annex A					
		Bibliography					

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Document: ISO/TC 176/SC 2/N 1088

Secretariat of ISO/TC 176/SC 2 Date: 28 June 2012

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

Design Specification for the revision of ISO 9001:2008

Please find attached a copy of the above Design Specification.

This was initially drafted by the SC2 Secretariat, and then reviewed and revised by ISO/TC 176/SC 2/WG 24 during its meeting of 18 - 22 June 2012 in Bilbao.

Further editing of the draft has been undertaken by the SC2 Secretariat since then.

This is now being circulated to SC2's member bodies to support a New Work Item Proposal for the revision of ISO 9001

Yours sincerely

Charles Corrie
For the BSI Secretariat of
ISO/TC 176/SC 2

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Design Specification for the revision of ISO 9001

1. Introduction

This Design Specification provides principles and general expectations for the revision of ISO 9001, and not a fixed list of specific items or requirements to be considered in the standard. This will allow ISO/TC 176/SC 2 to communicate to its Members and the members of ISO/TC 176/SC 2/WG 24 the following:

- Purpose and direction with regard to the strategic intent of the revision,
- Clear boundaries in terms of the purpose of the revised standard and the scope of the revision process

ISO/TC 176/SC 2 is the owner of this Design Specification and has the authority to review and revise this Design Specification.

Once ISO/TC 176/SC2 has agreed on its preferred timeframe and development track for the revision (expected to be the three year "default" track), WG24 shall seek to maintain its development of the revision to the agreed timeframe. WG24 should be aware that the revision of associated standards will depend on the timeliness of the completion of this revision.

2. Strategic intent and purpose of the revision

This revision of the standard is being undertaken to reflect the changes in the environment in which it is used and ensure the standard is fit for its purpose.

The revision will:

a) take account of changes in quality management systems practices and technology since the last major revision to ISO 9001 (in the year 2000) and to provide a stable core set of requirements for the next 10 years or more.
b) ensure that requirements in this standard reflect the changes in the increasingly complex, demanding, and dynamic environments in which organizations operate.
c) ensure that requirements are stated to facilitate effective implementation by organizations and effective conformity assessment by 1st, 2nd and 3rd parties, as applicable.
d) ensure that the standard is adequate to provide confidence in those organizations meeting the standard's requirements

Accordingly, the changes to ISO 9001 should:

- be relevant to quality management system requirements and the strategic intent (as stated above)
- increase confidence in an organization's ability to provide conforming product and/or service
- enhance an organization's ability to satisfy its customers
- enhance customer confidence in quality management systems based on ISO 9001.

3. Requirements for the revision process

WG 24 is required to identify, develop and reach consensus on solutions to meet the strategic purpose and intent stated in section 2 above. The following provisions apply:

a) The revised standard will remain generic and be relevant to all sizes and types of organization operating in any sector
b) The revised standard needs to be capable of being applied by the widest possible range of organizations with varying degrees of maturity of their quality systems.
c) The current purpose of the standard, the title and the field of application shall in general be unchanged from ISO 9001:2008.
d) Amendments to the scope of the standard will only be accepted where they are consistent with the strategic intent in section 2 above.
e) The intent of clause 1.2 of ISO 9001:2008 shall be maintained in the revised standard.

f) The revised standard will apply Annex SL to the ISO/IEC Directives - Procedures Specific to ISO, 3rd edition, 2012 (hereafter referred to as Annex SL) to ISO 9001, in order to enhance its compatibility and alignment with other ISO management system standards.
g) The standard will use simplified language and writing styles so as to improve the ease of understanding and consistency of interpretations of the requirements.
h) The use of consistent phrasing and terms should be maintained to facilitate both translation into other languages and understanding of the original standard.
i) Input documents, comments and other information will be evaluated in relation to the strategic intent of the revision.
j) The focus on effective process management to produce the desired outcomes shall be maintained.
k) The revised standard shall conform to the requirement that: "the text of every document shall be in accordance with the relevant provisions of existing basic documents published by ISO and IEC" (ISO/IEC Directives, Part 2, clause 4.4).

4. Design Inputs

The documents listed below have been considered in the development of this Design Specification.

User needs have been determined from the following:
- the results of the "systematic review" that was completed on ISO 9001:2008 during 2011-2012 (document SC2/N1066),
- analysis of the results of the extensive worldwide ISO 9000 User Survey (document SC2/N1017).

Other inputs include:
- ISO/TC176/SC2 Vision and Mission (SC2/N1014).
- ISO/TC 176/SC2 Strategic Objective A.2.3 (2011) – SC2 portfolio of products for the next decade (SC2/N1016).
- ISO/TC 176/SC 2/WG 18/TG1.19 Project Review Report (SC2/N845; WG 24/N26).
- the work on developing "Future Concepts for use in the work of ISO/TC 176/SC2" (SC2/N1013).
- the work of the Ad Hoc Group that examined whether the requirements of ISO 9001 support clause 1.1 (SC2/N789-1).
- preliminary outputs from the joint SC1/SC2 Task Group on the revision to the Quality Management Principles.
- the work of the ISO/TMB/TAG13 - JTCG (now formalized as Annex SL).
- the Design Specifications for the 2000 and 2008 editions of ISO 9001, (SC 2/N307 and SC2/N707-1), which identified users and user needs.
- the comments received through the "systematic review", and on the "proposed actions" papers (SC2/N1068 and SC2/1075).

A list of documents to be considered in the revision of ISO 9001 is given in Annex A.

5. Background and guidance on strategic and other key issues

Prior to ISO 9001:2000 three different models of quality assurance standards (ISO 9001, ISO 9002 and ISO 9003) were available for users to choose from, depending on the nature of their products and processes. However, the 2000 revision eliminated ISO 9002 and ISO 9003, with "exclusions" to ISO 9001 being permitted through clause 1.2 of that standard. The latest ISO 9000 User Survey tested the idea of returning to having three different models available, based on risk and the criticality of the products being provided. The response given was a strong indication that the market preferred to remain with a single standard.

ISO 9001 is intended to be applicable to all types and sizes of organization, regardless of the nature of the products and services they provide. In some cases the standard's requirements may still not be sufficiently generic to meet the needs of the ever widening range of users. However, the generic nature of the standard can also sometimes be a barrier to understanding and its application to some product types and types of organizations. Where

possible the requirements of the standard should not only be generic but should be improved to increase clarity and precision in its application. The revision may consider the guidance given in CEN Guide 17 “Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs” helpful in this respect.

During the period 2009 -2011 ISO/TC 176/SC2 conducted an exercise to examine existing and new concepts that could be considered within the portfolio of SC2 products. These concepts, published in SC2/N1013 (WG24/N27), were analyzed and provide information on current application, and the potential application and impacts if implemented. SC2/N1013 is identified in Annex A as useful input to the revision. However, the concepts were not meant to be limited to ISO 9001 and consequently not all of the concepts may be applicable to the revision to ISO 9001.

ISO/TC 176/SC 2 has and continues to work closely with other ISO and IEC TCs, and Liaison partners, to ensure compatibility between their standards, e.g. a process has been established between ISO/TC 176/SC 2 and ISO TC 207/SC 1 to liaise as each progresses with the revision of their respective management system requirement standards.

During the past decade, ISO has published a number of other management system standards, with yet more under development. Consequently, ISO has responded to user requests for greater alignment by developing Annex SL for use in all of its management system standards. WG 24 should draw on the experience of other TCs that have already applied or are applying Annex SL.

A number of standards have been developed based upon ISO 9001. Where practicable, consideration of the content of those standards may be used as input into the revision of ISO 9001. WG24 may also need to consider the impact of changes to ISO 9001 upon the compatibility and alignment of these other management system standards.

Consistency with other standards in the ISO 9000 family should be maintained, particularly with respect to the definitions given in ISO 9000.

WG24 is expected to work in close liaison with ISO/TC176/SC1 to ensure consistency of approach, using an iterative process to ensure compatibility between the Fundamentals of ISO 9000 (Clause 2), ISO 9001 requirements, and the Terms and Definitions of ISO 9000 Clause 3.

The "process approach" adopted during the development of ISO 9001:2000 has not been fully understood by many users. At the same time the results of ISO 9000 User Survey (document SC 2/N1017) show significant support for maintaining the focus of ISO 9001 on the “management of processes”. This focus should result in an holistic system with the primary objective of meeting customer requirements and enhancing customer satisfaction.

6. Liaisons

As the ISO 9001 revision progresses, the needs of, and the impact on other interested parties shall be considered. This may include, but is not limited to the following liaison relationships:

- Applicable ISO technical committees and ISO/CASCO working groups

- The ISO/TMB/TAG 13 – Joint Technical Co-ordination Group for Management System Standards (the JTCG)
- ISO/TC 176/SC 1 Concepts and Terminology
- ISO/TC 176/SC 2/WG 22 Interpretations
- ISO/TC 176/SC 2/WG 23 Communications and Product Support
- ISO/TC 176/IAF/ISO 9001 Auditing Practices Group
- ISO/TC 207/SC 1 Environmental Management Systems
- ISO/PC 259 Outsourcing
- International Accreditation Forum (IAF)
- Established liaisons within ISO/TC 176/SC 2
- ISO/TC 176/SC 3 Supporting technologies
- ISO/IEC JTC 1/SC 7
- ISO/TC 210 Medical Devices
- ISO/TC 46/SC 11 (Management of records)

Annex A – List of reference input documents

The following have already been identified as input documents which may be useful in determining inputs into the revision process. It is anticipated that further documents may be identified as the revision progresses.

1) ISO/TC176/SC2 Vision and Mission (SC2/N1014)
2) ISO/TC 176/SC2 Strategic Objective A.2.3 (2011) – SC2 portfolio of products for the next decade (SC2/N1016)
3) The results of the Systematic Review conducted on ISO 9001:2008 (SC 2 documents: N1065, N1066, N1067)
4) The results of the ballot on the "Proposed action following the systematic review of ISO 9001:2008" (SC 2 documents: N1068, N1073, N1075)
5) The ISO 9000 User Survey Report (SC 2/N1017)
6) Future Concepts for the work of ISO/TC 176/SC2 (SC 2/N1013)
7) Annex SL to the ISO/IEC Directives - Procedures Specific to ISO, 3rd edition; 2012
8) The revised Quality Management Principles, (which are due to be available in the near future)
9) The Project Review Report from ISO/TC 176/SC2/WG18/TG 1.19 (SC 2/N 845)
10) The ISO/TC 176/SC 2 sanctioned interpretations of ISO 9001:2008
11) The ISO 9001:2008 Introduction & Support Package set of documents and Frequently Asked Questions.
12) Paper: "Do the requirements of ISO 9001 support clause 1.1" (SC 2/ N789-1)
13) The Design Specifications for ISO 9001:2000 and for ISO 9001:2008 (SC 2 documents: N307, N707-1)
14) Drafts of ISO 14001 as they become available during the current revision of that standard
15) Drafts of ISO 37500 *Outsourcing* as they become available during the current development of that standard
16) ISO 31000 *Risk Management*
17) CEN Guide 17 "*Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs*"
18) Sector standards based on ISO 9001
19) ISO 30301 *Information and documentation – Management systems for records – Requirements*

Annex B – Guidance on drafting

B.1 General

In order to maintain and further improve clarity, terminology and presentation style, and to increase user friendliness of the standard, ISO/TC 176/SC2 shall ensure that:

- the original intent of the standard is maintained.
- the standard is free from cultural bias.
- the standard is written in a style that can be understood by all interested parties, not just quality functional specialists.
- the standard is written in a clear style that can be easily translated into other languages.
- liaison is established with other TCs as required to achieve compatibility, consistency with other management system standards and ISO/CASCO guidelines
- consideration is given to the auditability of all requirements. (This should focus on the need to eliminate or reduce ambiguity rather than produce prescriptive requirements for documents or records that are of minimal value to those implementing the standard).
- requirements are clearly separated from any explanatory guidance information
- the use of cross referencing within the standard enhances user friendliness.
- the standard is written to be unambiguous to give a common understanding that avoids multiple interpretations.
- consistent use of terminology is maintained avoiding the excessive use of quality terms and jargon.
- terminology issues are resolved with the assistance of ISO/TC 176/SC 1
- terms that cannot be quantified (e.g. “significant”) are avoided
- sentences are kept short to reduce excessive wordiness (but statements of requirements should not be made so short as to be ambiguous).

B.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/SC 2 members from non-English speaking countries to review the text of the draft standard for clarity and translatability.