



Document: ISO/TC 176/SC 2/N **731**

Our ref

Secretariat of ISO/TC 176/SC 2

Date: 30 June 2005

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

Design Specification for a *Revision* to ISO 9004:2000

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 revision.

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

30 September 2005

Thanking you in anticipation.

Yours sincerely

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

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0. Introduction

In 2004 ISO/TC 176/SC 2 conducted a formal Systematic Review of ISO 9004:2000 amongst its members, to determine if it should be withdrawn, left unchanged, amended or revised.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 revised.

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 a revision 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 revision to ISO 9004:2000.

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

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 revision to ISO 9004, and will also be used as the template for verifying the outputs of the drafting process.

1. User and interested parties needs and evaluation of impacts and benefits

1.1 General

ISO 9004:2008 will address the needs and expectations of users, customers and interested parties.

1.2 Users

Users of the standard are:

- Those people in an organization who are responsible for making plans and/or implementing measures to achieve the sustainable success of the organization by satisfying the needs and expectation of all interested parties.
- Those outside an organization who provide support to the making of plans and/or implementation of measures to achieve sustainable success.

1.3 User needs

All users require that ISO 9004:2008 be written in plain language and structured in an understandable and easy-to-use format. ISO 9004:2008 shall serve the changing needs of organizations for sustainable success.

Users expect that ISO9004:2008 will help them identify, evaluate, prioritize and satisfy the needs and expectations of interested parties.

Users expect that ISO 9004:2008 will facilitate the continual improvement of the capabilities of the organization to deliver value to their customers, and to satisfy the needs and expectations of other interested parties.

Users also expect that ISO 9004:2008 will facilitate improvement in their management systems, taking into account:

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- The need for continual adaptation by the organization to changes in its environment, such as coping with threats and exploiting new opportunities.
- The importance of alignment of the Vision, Mission, Objectives and the Culture of the organization. This includes the approach and steps needed to achieve and retain this alignment in the changing environment of an organization.
- The importance of risk management (related to Strategic and Operational issues).

1.4 Benefits for interested parties

The benefits for interested parties (including customers) are based on the organization's use of ISO9004:2008 to identify, evaluate and satisfy their needs and expectations in an appropriate manner.

ISO 9000:2000 Definition 3.3.7 , interested parties:
person or group having an interest in the performance or success of an organization

EXAMPLE Customers, owners, people in an organization, suppliers, bankers, unions, partners or society.

NOTE A group can comprise an organization, a part thereof, or more than one organization.

1.5 Benefits for the users

The primary benefit to the users of ISO 9004:2008 should be progress on their path to achieving sustainable success for their organization. Consequently, ISO 9004:2008 will contain different approaches that could be used by an organization to achieve its objectives or to close performance gaps that it may identify. It is not intended that an organization would implement all of the elements of the standard, but rather that the organization would have the flexibility to select and implement those approaches best suited for its purposes.

Assessment methods may be used by an organization to evaluate its performance, and such methods will be addressed in the standard.

The use of ISO 9004:2008 will help organizations to take into account any changes in the needs and expectations of interested parties and changes in the organization's processes.

1.6 The costs for users

ISO 9004:2008 should show that the investment in the implementation, maintenance and improvement of an effective and efficient management system, that is led by top management, is a way to achieve sustainable success for the organization. As such, ISO 9004:2008 should show that such an investment in a management system is a sound business decision and that potential benefits will far outweigh any associated costs.

2. Purpose of the revision

The purpose of this revision is to create a new ISO 9004:2008 standard that will provide guidance to an organization's strategic and operational management on achieving sustainable success.

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

3.1 Scope

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Guidance given in ISO 9004:2008 shall apply to the following items:

- Strategic and operational processes of the organization
- Continuous identification of opportunities for improvement and innovation
- Objectives for customer satisfaction, customer loyalty and product quality
- The performance of an organization in satisfying its customers and other interested parties
- Deployment of the 8 quality management principles beyond the requirements given in ISO 9001
- The effectiveness and efficiency of the quality management system
- The relationship of the quality management system to the other management systems within the organization
- Monitoring and measuring of an organization's performance against its vision, mission and objectives
- Achieving performance excellence.

ISO 9004:2008 shall consist of guidance and recommendations. It is not intended to be used:

- for certification or registration purposes,
- for regulatory or contractual use,
- or as a guide to the implementation of ISO 9001.

3.2 Purpose

ISO 9004:2008 shall provide guidance:

- To management on leading their organization towards the achievement of sustainable success.
- To convey to strategic management, the importance of the standard as useful guidance for the organization to achieve quality products and the resultant satisfaction of customers and other interested parties.
- On how to relate other management systems to the quality management system.
- On how management can use this standard in combination with the Performance Excellence Models (e.g. The European Foundation for Quality Management, Deming Prize Award, or Malcolm Baldrige National Quality Award, models) as a vehicle to achieve a higher level of performance.

3.3 Title

It is considered that a new title will need to be applied to ISO 9004:2008 to reflect its change of scope. Currently, the following titles have been proposed for consideration by the group that will draft ISO 9004:2008:

- Managing for Sustainable Success
- Managing for Sustainable Success through Quality
- Managing for Sustainable Success through Quality - Guidance
- Managing for Sustainable Success through Quality Centred Management
- Guidance on Managing for Sustainable Success through Quality Centred Management System

3.4 Field of application

All types and sizes of organizations, including public and private, profit and non-profit.

3.5 Guiding principles

ISO 9004:2008 shall be based on:

- a) The eight Quality Management Principles (as defined in ISO9000:2000)
 - Customer focus
 - Leadership

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- Involvement of people
- Process approach
- Systems approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

b) In addition to the eight Quality Management Principles given above, the following aspects shall also be considered within the scope of ISO 9004:2008:

- Ethics /social aspects
- Mission and Vision of the organization
- Adaptability / agility (ability to substantially change the organization, and its products and processes in response to changing opportunities / threats.
- Management of knowledge.
- Alignment with other management system elements; both for organizations that have a single "integrated" management system, as well as for those that employ multiple management systems (for different aspects of management), and need to ensure that they are aligned and linked effectively.
- Linking objectives and actions to results.

4. Compatibility

ISO 9004:2008 shall be written to facilitate compatibility with other relevant management system standards and models of management, such as the Performance Excellence Models and quality awards.

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.

5. Consistency

5.1 General

The text of ISO 9004:2008 shall be in accordance with the relevant provisions of existing basic documents published by ISO and IEC (see the ISO/IEC Directives, Part 2, clause 4.4).

5.2 Consistency between the ISO 9001:2008 and the ISO 9004:2008

To achieve consistency between the standards, ISO 9004:2008 shall be drafted to ensure:

- There is no conflict with ISO 9001:2008,
- The standards fit well together, 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 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 version of the

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standards this rigid alignment of the clauses will be relaxed so that ISO 9004 has more flexibility to meet the needs of its users.

6. Model and its features (Graphical illustration)

ISO 9004:2008 shall consider the inclusion of a graphical illustration of the guidance developed in the standard. Such representation shall be consistent with the model in ISO 9001:2008 and compatible with models used in other relevant management system standards or performance excellence models/quality awards.

[Secretariat Note: the initial draft Design Specification for ISO 9004:2008 (SC2/N706) presented a revised process approach diagram. On review, the revised diagram was considered to be too prescriptive, so has not been included in this version of the Design Specification]

7. Structure of the standard

7.1 General

ISO 9004:2008 shall be developed to include the following parts (within a single document)

- A Top management oriented part, with a compact writing style, focussing on strategic issues, and describing managerial processes
- An Operational management oriented part, with practical guidance for the implementation of operational processes and the improvement of those processes.

Other parts may also need to be included. There will be clear linkages between the different parts

7.2 Proposal for structure

The following shall be considered for the main clauses:

- Organizational environment - Identification of market scenarios, opportunities and risks
- Organizational identity – Principles, mission, vision and market position
- Strategic imperatives of an organization for sustainable success
- Management responsibility
- Resources management
- Product realization
- Measurement, analysis and improvements
- Results and sustainable organization
- Feedback and learning
- Strategic improvement and innovation of a quality management system.

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

8.1 General

During the development of ISO 9004:2008, the subjects listed within the scope and in this Section (section 8) shall be considered for inclusion in the standard. The extent of their inclusion will be dependent on their potential impact on the quality of an organization's products, and on the needs and expectations of its customers and other interested parties.

- The use of the eight quality management principles (see 3.5).
- The use of additional principles (see 3.5).
- The relationship of ISO 9004:2008 to the Performance Excellence Models.
- Information to executive management on the motivation for using ISO 9004:2008 in combination with the Performance Excellence Models, and on how to optimize its use.

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- The relationship of ISO 9004:2008 to sector specific standards; the standard should provide information to top management on the motivation to use ISO 9004:2008 in combination with sector specific standards, and on how to optimize its use.
- The applicability of ISO 9004:2008 to all product categories.
- ISO 9004:2008 will provide guidance to top management to enable diverse management systems to operate in harmony with each other.

8.2 Operating environment, identity and position of the Organization

ISO 9004:2008 shall address:

- The identification of the organization's operational environment, the needs and the expectations of its customers and other interested parties that materially affect its viability, and the definition of its strategic imperatives.
Note: Strategic imperatives are those issues that an organization needs to deal with in order to remain successful in the long term.
- The assessment of risks associated with the activities of the organization, to enable sustainable success and the facilitation of preventive actions.
- Compliance with applicable laws and statutory regulations.
- The adaptability of the organization to its operational environment (related to its culture, learning and innovation).
- The organization's profile in relation to its strategic vision and values.
- The way in which the organization makes decisions and takes actions to achieve its objectives for sustainable success.

8.3 Processes

ISO 9004:2008 shall address

- The need for the organization to identify and define the processes needed to facilitate the achievement of sustainable success.
- Integration of the processes in an overall model.

8.4 Measurements, Evaluation and Management of Improvement

ISO 9004:2008 shall address:

- The measurement, monitoring and evaluation of the effectiveness and efficiency of processes, the achievement of objectives, and improvement.

8.5 Results and Sustainability

ISO 9004:2008 shall address:

- How management assures that the organization's objectives and its actions will result in adding value.
- The achievement of the organization's objectives for sustainable success (such objectives should be derived from the strategic plan)
- How the organization's performance against achieving these objectives may be used as a measure of the maturity of its quality management system.
- The degree of improvement of adaptability, flexibility and responsiveness of the organization in relation to its vision and objectives.
- The perception of interested parties of their satisfaction with the organization's performance, and the results it achieved..
- The linking of results to objectives and actions, including the effects of lessons learned.

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9. Guidance on drafting (e.g. on marketing, format and style)

- A marketable title should be developed, that identifies clearly the purpose of the document (see 3.3).
- ISO 9004:2008 shall be written in simple, plain language that is familiar to managers, with the minimal use of technical terms and quality jargon. However, it should be recognized that the writing style required to engage and inform top management is different from the style required to engage the typical operational user of management system standards.
- ISO 9004:2008 shall be consistent with the concepts and terminology used in ISO 9001:2008 and compatible with other management system standards and excellence models / quality awards.

10. Liaisons

In order to achieve compatibility with relevant standards etc. it is essential that input is received from liaison members (both those that are internal and external to ISO), and that such input is given due consideration during the drafting process. Examples of such liaison members include:

- Applicable ISO and ISO/CASCO technical committees
- The other ISO/TC176/SC2/WG18 Task Groups
- ISO/TC176/SC1
- ISO/TC176/SC3
- Established liaisons within ISO/TC176 (e.g. the Performance Excellence Model owners)

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Annex A - Listing of reference input documents

- 1) The Systematic Reviews conducted on ISO 9001 and ISO 9004 (ISO/TC 176/SC 2 documents: N666, N667, N676R, N677R)
- 2) 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)
- 3) 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)
- 4) *Justification Study for an Amendment to ISO 9001:2000 and a Revision to ISO 9004:2000* (ISO/TC 176/SC2 document: N682)
- 5) ISO 9000:2000, *Quality management systems - Fundamentals and vocabulary*
- 6) ISO 9001:2000, *Quality management systems – Requirements*
- 7) ISO 9004:2000, *Quality management systems – Guidelines for performance improvements*
- 8) ISO/DIS 10014, *Quality management systems -- Guidelines for realizing financial and economic benefits*
- 9) ISO 14001:2004, *Environmental management systems – Requirements with guidance for use*
- 10) ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*
- 11) ISO Guide 72:2001, *Guidelines for the justification and development of management system standards*
- 12) The *ISO 9001:2000 Introduction & Support Package* guidance notes on *Guidance on the Concept and Use of the Process Approach for management systems* (ISO/TC 176/SC 2 document: N544R2)
- 13) Design Specification for ISO 9004:2000 (ISO/TC 176/SC 2 document: N308)
- 14) Design Specification for ISO 9001:2008 (ISO/TC 176/SC 2 document: N730)
- 15) Draft web page "Next Steps to Performance Excellence" (ISO/TC 176/SC 2 document: N708)
- 16) The ISO/IEC Directives:2001
- 17) The Japanese Standards Association Technical Report *TRQ0006- Guidelines for self assessment* (ISO/TC 176/SC 2 document: N644)
- 18) The Spanish national standard AENOR, *UNE 66174, ISO 9004 Tools and Plans for Improvement* (ISO/TC 176/SC 2 document: N671-1)
- 19) The French draft standard AFNOR, draft - Management System - Organization Management Guidelines (ISO/TC 176.SC 2 document : N689R)
- 20) The Japanese Standards Association (revised) Technical Report *TR Q0005 - Guideline to sustainable development* (ISO/TC 176/SC 2 document : N690)

Other suitable reference documents should be considered as necessary (e.g. sector specific standards, risk management standards and the Performance Excellence Models).

Appendix B: Self-Assessment tool(s)

ISO 9004:2008 shall give guidance on tools that are appropriate for assessing the sustainable success of the organization, based on the standard itself.

Two types of tools shall be considered:

- A Top management oriented self-assessment tool, with a compact writing style, focussing on strategic issues, and including managerial processes.
- An Operational management oriented self-assessment tool, focusing on the implementation of operational processes and the improvement of those processes.