AMERICAN NATIONAL STANDARD

Quality management systems— Guidelines for performance improvements

Approved as a American National Standard by:
American Society for Quality

An American National Standard Approved on December 13, 2000

American National Standards: An American National Standard implies a consensus of those substantially concerned with its scope and provisions. An American National Standard is intended as a guide to aid the manufacturer, the consumer, and the general public. The existence of an American National Standard does not in any respect preclude anyone, whether he or she has approved the standard or not, from manufacturing, purchasing, or using products, processes, or procedures not conforming to the standard. American National Standards are subject to periodic review and users are cautioned to obtain the latest edition.

Caution Notice: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

©2000 by ASQ

Copyright Protection Notice for the ANSI/ISO/ASQ Q9004-2000 Standard.
This standard is subject to copyright claims of ISO, ANSI, and ASQ. Not for resale. No part of this publication may be reproduced in any form, including an electronic retrieval system, without the prior written permission of ASQ. All requests pertaining to the ANSI/ISO/ASQ Q9004-2000 Standard should be submitted to ASQ.

Note: As used in this document, the term "International Standard" refers to the American National Standard adoption of this and other International Standards.

ASQ will consider requests for change and information on the submittal of such requests regarding this Standard. All requests should be in writing to the attention of the Standards administrator at the address below.

ASQ Mission: The American Society for Quality advances individual and organizational performance excellence worldwide by providing opportunities for learning, quality improvement, and knowledge exchange.

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be viewed but shall not be edited or printed. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. ASQ accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by our customers. In the unlikely event that a problem relating to it is found, please inform ASQ at the address below.

Published by:

American Society for Quality

ASQ®

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

Contents

Page

1 Scope **1**
2 Normative reference **1**
3 Terms and definitions **1**
4 Quality management system **2**
4.1 Managing systems and processes **2**
4.2 Documentation **3**
4.3 Use of quality management principles **4**
5 Management responsibility **5**
5.1 General guidance **5**
5.2 Needs and expectations of interested parties **7**
5.3 Quality policy **9**
5.4 Planning **10**
5.5 Responsibility, authority and communication **11**
5.6 Management review **12**
6 Resource management **14**
6.1 General guidance **14**
6.2 People **15**
6.3 Infrastructure **17**
6.4 Work environment **18**
6.5 Information **18**
6.6 Suppliers and partnerships **19**
6.7 Natural resources **19**
6.8 Financial resources **19**
7 Product realization **20**
7.1 General guidance **20**
7.2 Processes related to interested parties **23**
7.3 Design and development **24**
7.4 Purchasing **29**
7.5 Production and service operations **31**
7.6 Control of measuring and monitoring devices **33**
8 Measurement, analysis and improvement **34**
8.1 General guidance **34**
8.2 Measurement and monitoring **35**
8.3 Control of nonconformity **40**
8.4 Analysis of data **41**
8.5 Improvement **42**

Annexes

A Guidelines for self-assessment **46**
B Process for continual improvement **53**
Bibliography **55**

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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9004 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition of ISO 9004 cancels and replaces ISO 9004-1:1994, which has been technically revised. The title has been modified to reflect the comprehensiveness of the quality management system. Many of the existing International Standards within the ISO 9000 family will be reviewed for withdrawal, or for re-issue as Technical Reports, as many of their provisions are incorporated into this International Standard.

In comparison to previous editions, ISO 9001 and ISO 9004 now form a consistent pair of standards on quality management. ISO 9001 aims to give quality assurance of product and to enhance customer satisfaction, while ISO 9004 uses a broader perspective of quality management to give guidance for performance improvement.

Annexes A and B of this International Standard are for information only.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision by the top management of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. This International Standard is based on eight quality management principles. However, it is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The purpose of an organization is

— to identify and meet the needs and expectations of its customers and other interested parties (people in the organization, suppliers, owners, society), to achieve competitive advantage, and to do this in an effective and efficient manner, and

— to achieve, maintain, and improve overall organizational performance and capabilities.

The application of quality management principles not only provides direct benefits but also makes an important contribution to managing costs and risks. Benefit, cost and risk management considerations are important for the organization, its customers and other interested parties. These considerations on overall performance of the organization may impact

— customer loyalty,

— repeat business and referral,

— operational results such as revenue and market share,

— flexible and fast responses to market opportunities,

— costs and cycle times through effective and efficient use of resources,

— alignment of processes which will best achieve desired results,

— competitive advantage through improved organizational capabilities,

— understanding and motivation of people towards the organization's goals and objectives, as well as participation in continual improvement,

— confidence of interested parties in the effectiveness and efficiency of the organization, as demonstrated by the financial and social benefits from the organization's performance, product life cycle, and reputation,

— ability to create value for both the organization and its suppliers by optimization of costs and resources as well as flexibility and speed of joint responses to changing markets.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness and efficiency of a quality management system to enhance interested party satisfaction by meeting interested party requirements.

For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, is considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions and managing of these processes can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and fulfilling the requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to whether the organization has met their requirements. The model shown in Figure 1 does not show processes at a detailed level.

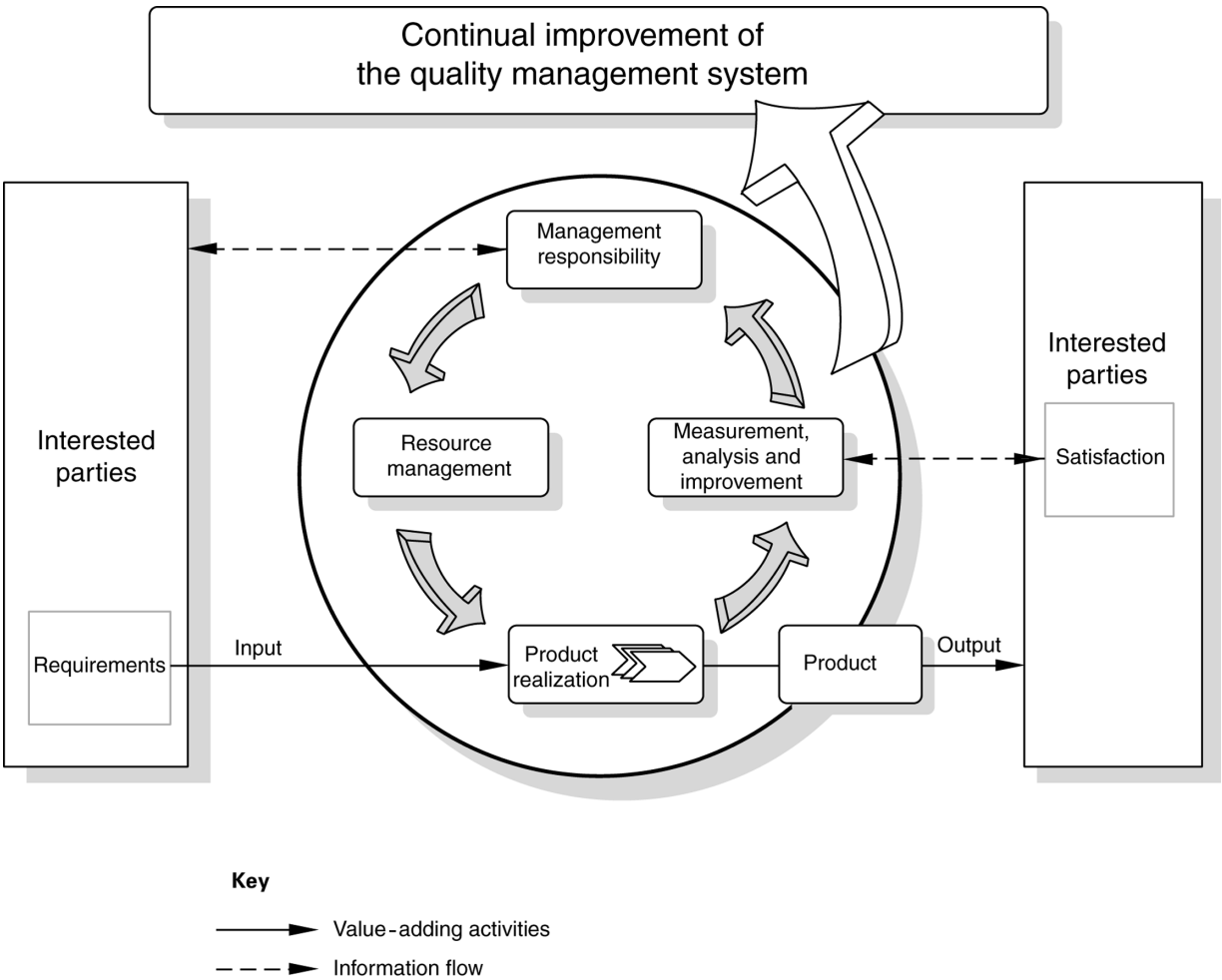

Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9001

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

For further benefit to the user, the basic content of the ISO 9001 requirements are included in boxed text following the comparable clause in this International Standard. Information marked “NOTE” is for guidance in understanding or clarification.

0.4 Compatibility with other management systems

This International Standard does not include guidance specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management, or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management systems. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that follows the guidelines of this International Standard.

Quality management systems — Guidelines for performance improvements

1 Scope

This International Standard provides guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.

This International Standard is applicable to the processes of the organization and consequently the quality management principles on which it is based can be deployed throughout the organization. The focus of this International Standard is the achievement of ongoing improvement, measured through the satisfaction of customers and other interested parties.

This International Standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use, nor as a guide to the implementation of ISO 9001.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

3 Terms and definitions

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

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

supplier → **organization** → **customer (interested parties)**

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

4 Quality management system

4.1 Managing systems and processes

Leading and operating an organization successfully requires managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization's performance by considering the needs of interested parties. Managing an organization includes quality management, among other management disciplines.

Top management should establish a customer-oriented organization

a) by defining systems and processes that can be clearly understood, managed and improved in effectiveness as well as efficiency, and

b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization.

Examples of activities to establish a customer-oriented organization include

— defining and promoting processes that lead to improved organizational performance,

— acquiring and using process data and information on a continuing basis,

— directing progress towards continual improvement, and

— using suitable methods to evaluate process improvement, such as self-assessments and management review.

Examples of self-assessment and continual improvement processes are given in annexes A and B respectively.

ISO 9001:2000, Quality management systems — Requirements

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization,

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

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

4.2 Documentation

Management should define the documentation, including the relevant records, needed to establish, implement and maintain the quality management system and to support an effective and efficient operation of the organization's processes.

The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers and other interested parties and should be appropriate to the organization. Documentation may be in any form or medium suitable for the needs of the organization.

In order to provide documentation to satisfy the needs and expectations of interested parties management should consider

— contractual requirements from the customer and other interested parties,

— acceptance of international, national, regional and industry sector standards,

— relevant statutory and regulatory requirements,

— decisions by the organization,

— sources of external information relevant for the development of the organization's competencies, and

— information about the needs and expectations of interested parties.

The generation, use and control of documentation should be evaluated with respect to the effectiveness and efficiency of the organization against criteria such as

— functionality (such as speed of processing),

— user friendliness,

— resources needed,

— policies and objectives,

— current and future requirements related to managing knowledge,

— benchmarking of documentation systems, and

— interfaces used by organization's customers, suppliers and other interested parties.

Access to documentation should be ensured for people in the organization and to other interested parties, based on the organization's communication policy.

ISO 9001:2000, Quality management systems — Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

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

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions,

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

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

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

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

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

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

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

f) to ensure that documents of external origin are identified and their distribution controlled, and

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

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.3 Use of quality management principles

To lead and operate an organization successfully, it is necessary to manage it in a systematic and visible manner. The guidance to management offered in this International Standard is based on eight quality management principles.

These principles have been developed for use by top management in order to lead the organization toward improved performance. These quality management principles are integrated in the contents of this International Standard and are listed below

a) **Customer focus**

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) **Leadership**

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) **Involvement of people**

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

d) **Process approach**

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) **System approach to management**

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

f) **Continual improvement**

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) **Factual approach to decision making**

Effective decisions are based on the analysis of data and information.

h) **Mutually beneficial supplier relationships**

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Successful use of the eight management principles by an organization will result in benefits to interested parties, such as improved monetary returns, the creation of value and increased stability.

5 Management responsibility

5.1 General guidance

5.1.1 Introduction

Leadership, commitment and the active involvement of the top management are essential for developing and maintaining an effective and efficient quality management system to achieve benefits for interested parties. To achieve these benefits, it is necessary to establish, sustain and increase customer satisfaction. Top management should consider actions such as

— establishing a vision, policies and strategic objectives consistent with the purpose of the organization,

— leading the organization by example, in order to develop trust within its people,

— communicating organizational direction and values regarding quality and the quality management system,

— participating in improvement projects, searching for new methods, solutions and products,

— obtaining feedback directly on the effectiveness and efficiency of the quality management system,

— identifying the product realization processes that provide added value to the organization,

— identifying the support processes that influence the effectiveness and efficiency of the realization processes,

— creating an environment that encourages the involvement and development of people, and

— provision of the structure and resources that are necessary to support the organization's strategic plans.

Top management should also define methods for measurement of the organization's performance in order to determine whether planned objectives have been achieved.

Methods include

— financial measurement,

— measurement of process performance throughout the organization,

— external measurement, such as benchmarking and third-party evaluation,

— assessment of the satisfaction of customers, people in the organization and other interested parties,

— assessment of the perceptions of customers and other interested parties of performance of products provided, and

— measurement of other success factors identified by management.

Information derived from such measurements and assessments should also be considered as input to management review in order to ensure that continual improvement of the quality management system is the driver for performance improvement of the organization.

5.1.2 Issues to be considered

When developing, implementing and managing the organization's quality management system, management should consider the quality management principles outlined in 4.3.

On the basis of these principles, top management should demonstrate leadership in, and commitment to, the following activities:

— understanding current and future customer needs and expectations, in addition to requirements;

— promoting policies and objectives to increase awareness, motivation and involvement of people in the organization;

— establishing continual improvement as an objective for processes of the organization;

— planning for the future of the organization and managing change;

— setting and communicating a framework for achieving the satisfaction of interested parties.

In addition to small-step or ongoing continual improvement, top management should also consider breakthrough changes to processes as a way to improve the organization's performance. During such changes, management should take steps to ensure that the resources and communication needed to maintain the functions of the quality management system are provided.

Top management should identify the organization's product realization processes, as these are directly related to the success of the organization. Top management should also identify those support processes that affect either the effectiveness and efficiency of the realization processes or the needs and expectations of interested parties.

Management should ensure that processes operate as an effective and efficient network. Management should analyse and optimize the interaction of processes, including both realization processes and support processes.

Consideration should be given to

— ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively and efficiently,

— ensuring process inputs, activities and outputs are clearly defined and controlled,

— monitoring inputs and outputs to verify that individual processes are linked and operate effectively and efficiently,

— identifying and managing risks, and exploiting performance improvement opportunities,

— conducting data analysis to facilitate continual improvement of processes,

— identifying process owners and giving them full responsibility and authority,

— managing each process to achieve the process objectives, and

— the needs and expectations of interested parties.

ISO 9001:2000, Quality management systems — Requirements

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Needs and expectations of interested parties

5.2.1 General

Every organization has interested parties, each party having needs and expectations. Interested parties of organizations include

— customers and end-users,

— people in the organization,

— owners/investors (such as shareholders, individuals or groups, including the public sector, that have a specific interest in the organization),

— suppliers and partners, and

— society in terms of the community and the public affected by the organization or its products.

5.2.2 Needs and expectations

The success of the organization depends on understanding and satisfying the current and future needs and expectations of present and potential customers and end-users, as well as understanding and considering those of other interested parties.

In order to understand and meet the needs and expectations of interested parties, an organization should

— identify its interested parties and maintain a balanced response to their needs and expectations,

— translate identified needs and expectations into requirements,

— communicate the requirements throughout the organization, and

— focus on process improvement to ensure value for the identified interested parties.

To satisfy customer and end-user needs and expectations, the management of an organization should

— understand the needs and expectations of its customers, including those of potential customers,

— determine key product characteristics for its customers and end-users,

— identify and assess competition in its market, and

— identify market opportunities, weaknesses and future competitive advantage.

Examples of customer and end-user needs and expectations, as related to the organization's products, include

— conformity,

— dependability,

— availability,

— delivery,

— post-realization activities,

— price and life-cycle costs,

— product safety,

— product liability, and

— environmental impact.

The organization should identify its people's needs and expectations for recognition, work satisfaction, and personal development. Such attention helps to ensure that the involvement and motivation of people are as strong as possible.

The organization should define financial and other results that satisfy the identified needs and expectations of owners and investors.

Management should consider the potential benefits of establishing partnerships with suppliers to the organization, in order to create value for both parties. A partnership should be based on a joint strategy, sharing knowledge as well as gains and losses. When establishing partnerships, an organization should

— identify key suppliers, and other organizations, as potential partners,

— jointly establish a clear understanding of customers' needs and expectations,

— jointly establish a clear understanding of the partners' needs and expectations, and

— set goals to secure opportunities for continuing partnerships.

In considering its relationships with society, the organization should

— demonstrate responsibility for health and safety,

— consider environmental impact, including conservation of energy and natural resources,

— identify applicable statutory and regulatory requirements, and

— identify the current and potential impacts on society in general, and the local community in particular, of its products, processes and activities.

ISO 9001:2000, Quality management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.2.3 Statutory and regulatory requirements

Management should ensure that the organization has knowledge of the statutory and regulatory requirements that apply to its products, processes and activities and should include such requirements as part of the quality management system. Consideration should also be given to

— the promotion of ethical, effective and efficient compliance with current and prospective requirements,

— the benefits to interested parties from exceeding compliance, and

— the role of the organization in the protection of community interests.

5.3 Quality policy

Top management should use the quality policy as a means of leading the organization toward improvement of its performance.

An organization's quality policy should be an equal and consistent part of the organization's overall policies and strategy.

In establishing the quality policy, top management should consider

— the level and type of future improvement needed for the organization to be successful,

— the expected or desired degree of customer satisfaction,

— the development of people in the organization,

— the needs and expectations of other interested parties,

— the resources needed to go beyond ISO 9001 requirements, and

— the potential contributions of suppliers and partners.

The quality policy can be used for improvement provided that

— it is consistent with top management's vision and strategy for the organization's future,

— it permits quality objectives to be understood and pursued throughout the organization,

— it demonstrates top management's commitment to quality and the provision of adequate resources for achievement of objectives,

— it aids in promoting a commitment to quality throughout the organization, with clear leadership by top management,

— it includes continual improvement as related to satisfaction of the needs and expectations of customers and other interested parties, and

— it is effectively formulated and efficiently communicated.

As with other business policies, the quality policy should be periodically reviewed.

ISO 9001:2000, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

The organization's strategic planning and the quality policy provide a framework for the setting of quality objectives. Top management should establish these objectives, leading to improvement of the organization's performance. The objectives should be capable of being measured in order to facilitate an effective and efficient review by management. When establishing these objectives, management should also consider

— current and future needs of the organization and the markets served,

— relevant findings from management reviews,

— current product and process performance,

— levels of satisfaction of interested parties,

— self-assessment results,

— benchmarking, competitor analysis, opportunities for improvement, and

— resources needed to meet the objectives.

The quality objectives should be communicated in such a way that people in the organization can contribute to their achievement. Responsibility for deployment of quality objectives should be defined. Objectives should be systematically reviewed and revised as necessary.

ISO 9001:2000, Quality management systems — Requirements

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality planning

Management should take responsibility for the quality planning of the organization. This planning should focus on defining the processes needed to meet effectively and efficiently the organization's quality objectives and requirements consistent with the strategy of the organization.

Inputs for effective and efficient planning include

— strategies of the organization,

— defined organizational objectives,

— defined needs and expectations of the customers and other interested parties,

— evaluation of statutory and regulatory requirements,

— evaluation of performance data of the products,

— evaluation of performance data of processes,

— lessons learned from previous experience,

— indicated opportunities for improvement, and

— related risk assessment and mitigation data.

Outputs of quality planning for the organization should define the product realization and support processes needed in terms such as

— skills and knowledge needed by the organization,

— responsibility and authority for implementation of process improvement plans,

— resources needed, such as financial and infrastructure,

— metrics for evaluating the achievement of the organization's performance improvement

— needs for improvement including methods and tools, and

— needs for documentation, including records.

Management should systematically review the outputs to ensure the effectiveness and efficiency of the processes of the organization.

ISO 9001:2000, Quality management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management should define and then communicate the responsibility and authority in order to implement and maintain an effective and efficient quality management system.

People throughout the organization should be given responsibilities and authority to enable them to contribute to the achievement of the quality objectives and to establish their involvement, motivation and commitment.

ISO 9001:2000, Quality management systems — Requirements

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

A management representative should be appointed and given authority by top management to manage, monitor, evaluate and coordinate the quality management system. This appointment is to enhance effective and efficient operation and improvement of the quality management system. The representative should report to top management and communicate with customers and other interested parties on matters pertaining to the quality management system.

ISO 9001:2000, Quality management systems — Requirements

5.5.2 Management representative

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

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

The management of the organization should define and implement an effective and efficient process for communicating the quality policy, requirements, objectives and accomplishments. Providing such information can aid in the organization's performance improvement and directly involves its people in the achievement of quality objectives. Management should actively encourage feedback and communication from people in the organization as a means of involving them.

Activities for communicating include, for example

— management-led communication in work areas,

— team briefings and other meetings, such as for recognition of achievement,

— notice-boards, in-house journals/magazines,

— audio-visual and electronic media, such as email and websites, and

— employee surveys and suggestion schemes.

ISO 9001:2000, Quality management systems — Requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management should develop the management review activity beyond verification of the effectiveness and efficiency of the quality management system into a process that extends to the whole organization, and which also evaluates the efficiency of the system. Management reviews should be platforms for the exchange of new ideas, with open discussion and evaluation of the inputs being stimulated by the leadership of top management.

To add value to the organization from management review, top management should control the performance of realization and support processes by systematic review based on the quality management principles. The frequency of review should be determined by the needs of the organization. Inputs to the review process should result in outputs that extend beyond the effectiveness and efficiency of the quality management system. Outputs from reviews should provide data for use in planning for performance improvement of the organization.

ISO 9001:2000, Quality management systems — Requirements

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review input

Inputs to evaluate efficiency as well as effectiveness of the quality management system should consider the customer and other interested parties and should include

— status and results of quality objectives and improvement activities,

— status of management review action items,

— results of audits and self-assessment of the organization,

— feedback on the satisfaction of interested parties, perhaps even to the point of their participation,

— market-related factors such as technology, research and development, and competitor performance,

— results from benchmarking activities,

— performance of suppliers,

— new opportunities for improvement,

— control of process and product nonconformities,

— marketplace evaluation and strategies,

— status of strategic partnership activities,

— financial effects of quality related activities, and

— other factors which may impact the organization, such as financial, social or environmental conditions, and relevant statutory and regulatory changes.

ISO 9001:2000, Quality management systems — Requirements

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

By extending management review beyond verification of the quality management system, the outputs of management review can be used by top management as inputs to improvement processes. Top management can use this review process as a powerful tool in the identification of opportunities for performance improvement of the organization. The schedule of reviews should facilitate the timely provision of data in the context of strategic planning for the organization. Selected output should be communicated to demonstrate to the people in the organization how the management review process leads to new objectives that will benefit the organization.

Additional outputs to enhance efficiency include, for example

— performance objectives for products and processes,

— performance improvement objectives for the organization,

— appraisal of the suitability of the organization's structure and resources,

— strategies and initiatives for marketing, products, and satisfaction of customers and other interested parties,

— loss prevention and mitigation plans for identified risks, and

— information for strategic planning for future needs of the organization.

Records should be sufficient to provide for traceability and to facilitate evaluation of the management review process itself, in order to ensure its continued effectiveness and added value to the organization.

ISO 9001:2000, Quality management systems — Requirements

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 General guidance

6.1.1 Introduction

Top management should ensure that the resources essential to the implementation of strategy and the achievement of the organization's objectives are identified and made available. This should include resources for operation and improvement of the quality management system, and the satisfaction of customers and other interested parties. Resources may be people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources.

6.1.2 Issues to be considered

Consideration should be given to resources to improve the performance of the organization, such as

— effective, efficient and timely provision of resources in relation to opportunities and constraints,

— tangible resources such as improved realization and support facilities,

— intangible resources such as intellectual property,

— resources and mechanisms to encourage innovative continual improvement,

— organization structures, including project and matrix management needs,

— information management and technology,

— enhancement of competence via focused training, education and learning,

— development of leadership skills and profiles for the future managers of the organization,

— use of natural resources and the impact of resources on the environment, and

— planning for future resource needs.

ISO 9001:2000, Quality management systems — Requirements

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 People

6.2.1 Involvement of people

Management should improve both the effectiveness and efficiency of the organization, including the quality management system, through the involvement and support of people. As an aid to achieving its performance improvement objectives, the organization should encourage the involvement and development of its people

— by providing ongoing training and career planning,

— by defining their responsibilities and authorities,

— by establishing individual and team objectives, managing process performance and evaluating results,

— by facilitating involvement in objective setting and decision making,

— by recognizing and rewarding,

— by facilitating the open, two-way communication of information,

— by continually reviewing the needs of its people,

— by creating conditions to encourage innovation,

— by ensuring effective teamwork,

— by communicating suggestions and opinions,

— by using measurements of its people's satisfaction, and

— by investigating the reasons why people join and leave the organization.

ISO 9001:2000, Quality management systems — Requirements

6.2 Human resources

6.2.1 General

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

6.2.2 Competence, awareness and training

6.2.2.1 Competence

Management should ensure that the necessary competence is available for the effective and efficient operation of the organization. Management should consider analysis of both the present and expected competence needs as compared to the competence already existing in the organization.

Consideration of the need for competence includes sources such as

— future demands related to strategic and operational plans and objectives,

— anticipated management and workforce succession needs,

— changes to the organization's processes, tools and equipment,

— evaluation of the competence of individual people to perform defined activities, and

— statutory and regulatory requirements, and standards, affecting the organization and its interested parties.

6.2.2.2 Awareness and training

Planning for education and training needs should take account of change caused by the nature of the organization's processes, the stages of development of people and the culture of the organization.

The objective is to provide people with knowledge and skills which, together with experience, improve their competence.

Education and training should emphasize the importance of meeting requirements and the needs and expectations of the customer and other interested parties. It should also include awareness of the consequences to the organization and its people of failing to meet the requirements.

To support the achievement of the organization's objectives and the development of its people, planning for education and training should consider

— experience of people,

— tacit and explicit knowledge,

— leadership and management skills,

— planning and improvement tools,

— teambuilding,

— problem solving,

— communication skills,

— culture and social behaviour,

— knowledge of markets and the needs and expectations of customers and other interested parties, and

— creativity and innovation.

To facilitate the involvement of people, education and training also include

— the vision for the future of the organization,

— the organization's policies and objectives,

— organizational change and development,

— the initiation and implementation of improvement processes,

— benefits from creativity and innovation,

— the organization's impact on society,

— introductory programmes for new people, and

— periodic refresher programmes for people already trained.

Training plans should include

— objectives,

— programmes and methods,

— resources needed,

— identification of necessary internal support,

— evaluation in terms of enhanced competence of people, and

— measurement of the effectiveness and the impact on the organization.

The education and training provided should be evaluated in terms of expectations and impact on the effectiveness and efficiency of the organization as a means of improving future training plans.

ISO 9001:2000, Quality management systems — Requirements

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

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

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

6.3 Infrastructure

Management should define the infrastructure necessary for the realization of products while considering the needs and expectations of interested parties. The infrastructure includes resources such as plant, workspace, tools and equipment, support services, information and communication technology, and transport facilities.

The process to define the infrastructure necessary for achieving effective and efficient product realization should include the following:

a) provision of an infrastructure, defined in terms such as objectives, function, performance, availability, cost, safety, security and renewal;

b) development and implementation of maintenance methods to ensure that the infrastructure continues to meet the organization's needs; these methods should consider the type and frequency of maintenance and verification of operation of each infrastructure element, based on its criticality and usage;

c) evaluation of the infrastructure against the needs and expectations of interested parties;

d) consideration of environmental issues associated with infrastructure, such as conservation, pollution, waste and recycling.

Natural phenomena that cannot be controlled can impact the infrastructure. The plan for the infrastructure should consider the identification and mitigation of associated risks and should include strategies to protect the interests of interested parties.

ISO 9001:2000, Quality management systems — Requirements

6.3 Infrastructure

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

a) buildings, workspace and associated utilities,

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

c) supporting services (such as transport or communication).

6.4 Work environment

Management should ensure that the work environment has a positive influence on motivation, satisfaction and performance of people in order to enhance the performance of the organization. Creation of a suitable work environment, as a combination of human and physical factors, should include consideration of

— creative work methods and opportunities for greater involvement to realize the potential of people in the organization,

— safety rules and guidance, including the use of protective equipment,

— ergonomics,

— workplace location,

— social interaction,

— facilities for people in the organization,

— heat, humidity, light, airflow, and

— hygiene, cleanliness, noise, vibration and pollution.

ISO 9001:2000, Quality management systems — Requirements

6.4 Work environment

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

6.5 Information

Management should treat data as a fundamental resource for conversion to information and the continual development of an organization's knowledge, which is essential for making factual decisions and can stimulate innovation. In order to manage information, the organization should

— identify its information needs,

— identify and access internal and external sources of information,

— convert information to knowledge of use to the organization,

— use the data, information and knowledge to set and meet its strategies and objectives,

— ensure appropriate security and confidentiality, and

— evaluate the benefits derived from use of the information in order to improve managing information and knowledge.

6.6 Suppliers and partnerships

Management should establish relationships with suppliers and partners to promote and facilitate communication with the aim of mutually improving the effectiveness and efficiency of processes that create value. There are various opportunities for organizations to increase value through working with their suppliers and partners, such as

— optimizing the number of suppliers and partners,

— establishing two-way communication at appropriate levels in both organizations to facilitate the rapid solution of problems, and to avoid costly delays or disputes,

— cooperating with suppliers in validation of the capability of their processes,

— monitoring the ability of suppliers to deliver conforming products with the aim of eliminating redundant verifications,

— encouraging suppliers to implement programmes for continual improvement of performance and to participate in other joint improvement initiatives,

— involving suppliers in the organization's design and development activities to share knowledge and effectively and efficiently improve the realization and delivery processes for conforming products,

— involving partners in identification of purchasing needs and joint strategy development, and

— evaluating, recognizing and rewarding efforts and achievements by suppliers and partners.

6.7 Natural resources

Consideration should be given to the availability of natural resources that can influence the performance of the organization. While such resources are often out of the direct control of the organization, they can have significant positive or negative effects on its results. The organization should have plans, or contingency plans, to ensure the availability or replacement of these resources in order to prevent or minimize negative effects on the performance of the organization.

6.8 Financial resources

Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans, and taking necessary action.

Management should plan, make available and control the financial resources necessary to implement and maintain an effective and efficient quality management system and to achieve the organization's objectives. Management should also consider the development of innovative financial methods to support and encourage improvement of the organization's performance.

Improving the effectiveness and efficiency of the quality management system can influence positively the financial results of the organization, for example

a) internally, by reducing process and product failures, or waste in material and time, or

b) externally, by reducing product failures, costs of compensation under guarantees and warranties, and costs of lost customers and markets.

Reporting of such matters can also provide a means of determining ineffective or inefficient activities, and initiating suitable improvement actions.

The financial reporting of activities related to the performance of the quality management system and product conformity should be used in management reviews.

7 Product realization

7.1 General guidance

7.1.1 Introduction

Top management should ensure the effective and efficient operation of realization and support processes and the associated process network so that the organization has the capability of satisfying its interested parties. While realization processes result in products that add value to the organization, support processes are also necessary to the organization and add value indirectly.

Any process is a sequence of related activities or an activity that has both input and output. Management should define the required outputs of processes, and should identify the necessary inputs and activities required for their effective and efficient achievement.

The interrelation of processes can be complex, resulting in process networks. To ensure the effective and efficient operation of the organization, management should recognize that the output of one process may become the input to one or more other processes.

7.1.2 Issues to be considered

Understanding that a process can be represented as a sequence of activities aids management in defining the process inputs. Once the inputs have been defined, the necessary activities, actions and resources required for the process can be determined, in order to achieve the desired outputs.

Results from verification and validation of processes and outputs should also be considered as inputs to a process, to achieve continual improvement of performance and the promotion of excellence throughout the organization. Continual improvement of the organization's processes will improve the effectiveness and efficiency of the quality management system and the organization's performance. Annex B describes a “Process for continual improvement” that can be used to assist in the identification of actions needed for continual improvement of the effectiveness and efficiency of processes.

Processes should be documented to the extent necessary to support effective and efficient operation. Documentation related to processes should support

— identifying and communicating the significant features of the processes,

— training in the operation of processes,

— sharing knowledge and experience in teams and work groups,

— measurement and audit of processes, and

— analysis, review and improvement of processes.

The role of people within the processes should be evaluated in order

— to ensure the health and safety of people,

— to ensure that the necessary skills exist,

— to support coordination of processes,

— to provide for input from people in process analysis, and

— to promote innovation from people.

The drive for continual improvement of the organization's performance should focus on the improvement of the effectiveness and efficiency of processes as the means by which beneficial results are achieved. Increased benefits, improved customer satisfaction, improved use of resources and reduction of waste are examples of measurable results achieved by greater effectiveness and efficiency of processes.

7.1.3 Managing processes

7.1.3.1 General

Management should identify processes needed to realize products to satisfy the requirements of customers and other interested parties. To ensure product realization, consideration should be given to associated support processes as well as desired outputs, process steps, activities, flows, control measures, training needs, equipment, methods, information, materials and other resources.

An operating plan should be defined to manage the processes, including

— input and output requirements (for example specifications and resources),

— activities within the processes,

— verification and validation of processes and products,

— analysis of the process including dependability,

— identification, assessment and mitigation of risk,

— corrective and preventive actions,

— opportunities and actions for process improvement, and

— control of changes to processes and products.

Examples of support processes include

— managing information,

— training of people,

— finance-related activities,

— infrastructure and service maintenance,

— application of industrial safety/protective equipment, and

— marketing.

7.1.3.2 Process inputs, outputs and review

The process approach ensures that process inputs are defined and recorded in order to provide a basis for formulation of requirements to be used for verification and validation of outputs. Inputs can be internal or external to the organization.

Resolution of ambiguous or conflicting input requirements can involve consultation with the affected internal and external parties. Input derived from activities not yet fully evaluated should be subject to evaluation through subsequent review, verification and validation. The organization should identify significant or critical features of products and processes in order to develop an effective and efficient plan for controlling and monitoring the activities within its processes.

Examples of input issues to consider include

— competence of people,

— documentation,

— equipment capability and monitoring, and

— health, safety and work environment.

Process outputs that have been verified against process input requirements, including acceptance criteria, should consider the needs and expectations of customers and other interested parties. For verification purposes, the outputs should be recorded and evaluated against input requirements and acceptance criteria. This evaluation

should identify necessary corrective actions, preventive actions or potential improvements in the effectiveness and efficiency of the process. Verification of the product can be carried out in the process in order to identify variation.

The management of the organization should undertake periodic review of process performance to ensure the process is consistent with the operating plan. Examples of topics for this review include

— reliability and repeatability of the process,

— identification and prevention of potential nonconformities,

— adequacy of design and development inputs and outputs,

— consistency of inputs and outputs with planned objectives,

— potential for improvements, and

— unresolved issues.

ISO 9001:2000, Quality management systems — Requirements

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements.

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

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.3.3 Product and process validation and changes

Management should ensure that the validation of products demonstrates that they meet the needs and expectations of customers and other interested parties. Validation activities include modelling, simulation and trials, as well as reviews involving customers or other interested parties.

Issues to consider should include

— quality policy and objectives,

— capability or qualification of equipment,

— operating conditions for the product,

— use or application of the product,

— disposal of the product,

— product life cycle,

— environmental impact of the product, and

— impact of the use of natural resources including materials and energy.

Process validation should be carried out at appropriate intervals to ensure timely reaction to changes impacting the process. Particular attention should be given to validation of processes

— for high value and safety critical products,

— where deficiency in product will only be apparent in use,

— which cannot be repeated, and

— where verification of product is not possible.

The organization should implement a process for effective and efficient control of changes to ensure that product or process changes benefit the organization and satisfy the needs and expectations of interested parties. Changes should be identified, recorded, evaluated, reviewed, and controlled in order to understand the effect on other processes and the needs and expectations of customers and other interested parties.

Any changes in the process affecting product characteristics should be recorded and communicated in order to maintain the conformity of the product and provide information for corrective action or performance improvement of the organization. Authority for initiating change should be defined in order to maintain control.

Outputs in the form of products should be validated after any related change, to ensure that the change has had the desired effect.

Use of simulation techniques can also be considered in order to plan for prevention of failures or faults in processes.

Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in processes. The results should be used to define and implement preventive actions to mitigate identified risks. Examples of tools for risk assessment include

— fault modes and effects analysis,

— fault tree analysis,

— relationship diagrams,

— simulation techniques, and

— reliability prediction.

7.2 Processes related to interested parties

Management should ensure that the organization has defined mutually acceptable processes for communicating effectively and efficiently with its customers and other interested parties. The organization should implement and maintain such processes to ensure adequate understanding of the needs and expectations of its interested parties, and for translation into requirements for the organization. These processes should include identification and review of relevant information and should actively involve customers and other interested parties. Examples of relevant process information include

— requirements of the customer or other interested parties,

— market research, including sector and end-user data,

— contract requirements,

— competitor analysis,

— benchmarking, and

— processes due to statutory or regulatory requirements.

The organization should have a full understanding of the process requirements of the customer, or other interested party, before initiating its action to comply. This understanding and its impact should be mutually acceptable to the participants.

ISO 9001:2000, Quality management systems — Requirements

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

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

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

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

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product 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) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues, or advertising material.

7.2.3 Customer communication

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

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 General guidance

Top management should ensure that the organization has defined, implemented and maintained the necessary design and development processes to respond effectively and efficiently to the needs and expectations of its customers and other interested parties.

When designing and developing products or processes, management should ensure that the organization is not only capable of considering their basic performance and function, but all factors that contribute to meeting the product and process performance expected by customers and other interested parties. For example, the organization should consider life cycle, safety and health, testability, usability, user-friendliness, dependability, durability, ergonomics, the environment, product disposal and identified risks.

Management also has the responsibility to ensure that steps are taken to identify and mitigate potential risk to the users of the products and processes of the organization. Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in products or processes. The results of the assessment should be used to define and implement preventive actions to mitigate the identified risks. Examples of tools for risk assessment of design and development include

— design fault modes and effects analysis,

— fault tree analysis,

— reliability prediction,

— relationship diagrams,

— ranking techniques, and

— simulation techniques.

ISO 9001:2000, Quality management systems — Requirements

7.3 Design and development

7.3.1 Design and development planning

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

During the design and development planning the organization shall determine

a) the design and development stages,

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

c) the responsibilities and authorities for design and development.

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

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

7.3.2 Design and development input and output

The organization should identify process inputs that affect the design and development of products and facilitate effective and efficient process performance in order to satisfy the needs and expectations of customers, and those of other interested parties. These external needs and expectations, coupled with those internal to the organization, should be suitable for translation into input requirements for the design and development processes.

Examples are as follows:

a) external inputs such as

— customer or marketplace needs and expectations,

— needs and expectation of other interested parties,

— supplier's contributions,

— user input to achieve robust design and development,

— changes in relevant statutory and regulatory requirements,

— international or national standards, and

— industry codes of practice;

b) internal inputs such as
   - policies and objectives,
   - needs and expectations of people in the organization, including those receiving the output of the process,
   - technological developments,
   - competence requirements for people performing design and development,
   - feedback information from past experience,
   - records and data on existing processes and products, and
   - outputs from other processes;

c) inputs that identify those characteristics of processes or products that are crucial to safe and proper functioning and maintenance, such as
   - operation, installation and application,
   - storage, handling and delivery,
   - physical parameters and the environment, and
   - requirements for disposal of the products.

Product-related inputs based on an appreciation of the needs and expectations of end users, as well as those of the direct customer, can be important. Such inputs should be formulated in a way that permits the product to be verified and validated effectively and efficiently.

The output should include information to enable verification and validation to planned requirements. Examples of the output of design and development include

- data demonstrating the comparison of process inputs to process outputs,
- product specifications, including acceptance criteria,
- process specifications,
- material specifications,
- testing specifications,
- training requirements,
- user and consumer information,
- purchase requirements, and
- reports of qualification tests.

Design and development outputs should be reviewed against inputs to provide objective evidence that outputs have effectively and efficiently met the requirements for the process and product.

ISO 9001:2000, Quality management systems — Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained. These shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.3 Design and development review

Top management should ensure that appropriate people are assigned to manage and conduct systematic reviews to determine that design and development objectives are achieved. These reviews may be conducted at selected points in the design and development process as well as at completion.

Examples of topics for such reviews include

— adequacy of input to perform the design and development tasks,

— progress of the planned design and development process,

— meeting verification and validation goals,

— evaluation of potential hazards or fault modes in product use,

— life-cycle data on performance of the product,

— control of changes and their effect during the design and development process,

— identification and correction of problems,

— opportunities for design and development process improvement, and

— potential impact of the product on the environment.

At suitable stages, the organization should also undertake reviews of design and development outputs, as well as the processes, in order to satisfy the needs and expectations of customers and people within the organization who receive the process output. Consideration should also be given to the needs and expectations of other interested parties.

Examples of verification activities for output of the design and development process include

— comparisons of input requirements with the output of the process,

— comparative methods, such as alternative design and development calculations,

— evaluation against similar products,

— testing, simulations or trials to check compliance with specific input requirements, and

— evaluation against lessons learned from past process experience, such as nonconformities and deficiencies.

Validation of the output of the design and development processes is important for the successful reception and use by customers, suppliers, people in the organization and other interested parties.

Participation by the affected parties permits the actual users to evaluate the output by such means as

— validation of engineering designs prior to construction, installation or application,

— validation of software outputs prior to installation or use, and

— validation of services prior to widespread introduction.

Partial validation of the design and development outputs may be necessary to provide confidence in their future application.

Sufficient data should be generated through verification and validation activities to enable design and development methods and decisions to be reviewed. The review of methods should include

— process and product improvement,

— usability of output,

— adequacy of process and review records,

— failure investigation activities, and

— future design and development process needs.

ISO 9001:2000, Quality management systems — Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, when known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1 Purchasing process

Top management of the organization should ensure that effective and efficient purchasing processes are defined and implemented for the evaluation and control of purchased products, in order that purchased products satisfy the organization's needs and requirements, as well as those of interested parties.

Use of electronic linkage with suppliers should be considered in order to optimize communication of requirements.

To ensure the effective and efficient performance of the organization, management should ensure that purchasing processes consider the following activities:

— timely, effective and accurate identification of needs and purchased product specifications;

— evaluation of the cost of purchased product, taking account of product performance, price and delivery;

— the organization's need and criteria for verifying purchased products;

— unique supplier processes;

— consideration of contract administration, for both supplier and partner arrangements;

— warranty replacement for nonconforming purchased products;

— logistic requirements;

— product identification and traceability;

— preservation of product;

— documentation, including records;

— control of purchased product which deviates from requirements;

— access to suppliers' premises;

— product delivery, installation or application history;

— supplier development;

— identification and mitigation of risks associated with the purchased product.

Requirements for suppliers' processes and product specifications should be developed with suppliers in order to benefit from available supplier knowledge. The organization could also involve suppliers in the purchasing process in relation to their products in order to improve the effectiveness and efficiency of the organization's purchasing process. This could also assist the organization in its control and availability of inventory.

The organization should define the need for records of purchased product verification, communication and response to nonconformities in order to demonstrate its own conformity to specification.

7.4.2 Supplier control process

The organization should establish effective and efficient processes to identify potential sources for purchased materials, to develop existing suppliers or partners, and to evaluate their ability to supply the required products in order to ensure the effectiveness and efficiency of overall purchasing processes.

Examples of inputs to the supplier control process include

— evaluation of relevant experience,

— performance of suppliers against competitors,

— review of purchased product quality, price, delivery performance and response to problems,

— audits of supplier management systems and evaluation of their potential capability to provide the required products effectively and efficiently and within schedule,

— checking supplier references and available data on customer satisfaction,

— financial assessment to assure the viability of the supplier throughout the intended period of supply and cooperation,

— supplier response to inquiries, quotations and tendering,

— supplier service, installation and support capability and history of performance to requirements,

— supplier awareness of and compliance with relevant statutory and regulatory requirements,

— the supplier's logistic capability including locations and resources, and

— the supplier's standing and role in the community, as well as perception in society.

Management should consider actions needed to maintain the organization's performance and to satisfy interested parties in the event of supplier failure.

ISO 9001:2000, Quality management systems — Requirements

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service operations

7.5.1 Operation and realization

Top management should go beyond control of the realization processes in order to achieve both compliance with requirements and provide benefits to interested parties. This may be achieved through improving the effectiveness and efficiency of the realization processes and associated support processes, such as

— reducing waste,

— training of people,

— communicating and recording information,

— developing supplier capability,

— improving infrastructure,

— preventing problems,

— processing methods and process yield, and

— methods of monitoring.

ISO 9001:2000, Quality management systems — Requirements

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records, and

e) revalidation.

7.5.2 Identification and traceability

The organization can establish a process for identification and traceability that goes beyond the requirements in order to collect data which can be used for improvement.

The need for identification and traceability may arise from

— status of products, including component parts,

— status and capability of processes,

— benchmarking performance data, such as marketing,

— contract requirements, such as product recall capability,

— relevant statutory and regulatory requirements,

— intended use or application,

— hazardous materials, and

— mitigation of identified risks.

ISO 9001:2000, Quality management systems — Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product.

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.3 Customer property

The organization should identify responsibilities in relation to property and other assets owned by customers and other interested parties and under the control of the organization, in order to protect the value of the property. Examples of such property are

— ingredients or components supplied for inclusion in a product,

— product supplied for repair, maintenance or upgrading,

— packaging materials supplied directly by the customer,

— customer materials handled by service operations such as storage,

— services supplied on behalf of the customer, such as transport of customer property to a third party, and

— customer intellectual property, including specifications, drawings and proprietary information.

ISO 9001:2000, Quality management systems — Requirements

7.5.4 Customer property

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

NOTE Customer property can include intellectual property.

7.5.4 Preservation of product

Management should define and implement processes for handling, packaging, storage, preservation and delivery of product that prevent damage, deterioration or misuse during internal processing and final delivery of the product. Management should involve suppliers and partners in defining and implementing effective and efficient processes to protect purchased material.

Management should consider the need for any special requirements arising from the nature of the product. Special requirements can be associated with software, electronic media, hazardous materials, products requiring special people for service, installation or application, and products or materials that are unique or irreplaceable.

Management should identify resources needed to maintain the product throughout its life cycle to prevent damage, deterioration or misuse. The organization should communicate information to the interested parties involved about the resources and methods needed to preserve the intended use of the product throughout its life cycle.

ISO 9001:2000, Quality management systems — Requirements

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of measuring and monitoring devices

Management should define and implement effective and efficient measuring and monitoring processes, including methods and devices for verification and validation of products and processes to ensure the satisfaction of customers and other interested parties. These processes include surveys, simulations, and other measurement and monitoring activities.

In order to provide confidence in data, the measuring and monitoring processes should include confirmation that the devices are fit for use and are maintained to suitable accuracy and accepted standards, as well as a means of identifying the status of the devices.

The organization should consider means to eliminate potential errors from processes, such as "fool-proofing", for verification of process outputs in order to minimize the need for control of measuring and monitoring devices, and to add value for interested parties.

ISO 9001:2000, Quality management systems — Requirements

7.6 Control of monitoring and measuring devices

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

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

Where necessary to ensure valid results, measuring equipment shall

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

b) be adjusted or re-adjusted as necessary;

c) be identified to enable calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8 Measurement, analysis and improvement

8.1 General guidance

8.1.1 Introduction

Measurement data are important for making fact-based decisions. Top management should ensure effective and efficient measurement, collection and validation of data to ensure the organization's performance and the satisfaction of interested parties. This should include review of the validity and purpose of measurements and the intended use of data to ensure added value to the organization.

Examples of measurement of performance of the organization's processes include

— measurement and evaluation of its products,

— capability of processes,

— achievement of project objectives, and

— satisfaction of customer and other interested parties.

The organization should continually monitor its performance improvement actions and record their implementation, as this can provide data for future improvements.

The results of the analysis of data from improvement activities should be one of the inputs to management review in order to provide information for improving the performance of the organization.

8.1.2 Issues to be considered

Measurement, analysis and improvement include the following considerations:

a) measurement data should be converted to information and knowledge to be of benefit to the organization;

b) measurement, analysis and improvement of products and processes should be used to establish appropriate priorities for the organization;

c) measurement methods employed by the organization should be reviewed periodically, and data should be verified on a continual basis for accuracy and completeness;

d) benchmarking of individual processes should be used as a tool for improving the effectiveness and efficiency of processes;

e) measurements of customer satisfaction should be considered as vital for evaluation of the organization's performance;

f) use of measurements, and the generating and communicating of the information obtained, are essential to the organization and should be the basis for performance improvement and the involvement of interested parties; such information should be current, and its purpose should be clearly defined;

g) appropriate tools for the communication of information resulting from the analyses of the measurements should be implemented;

h) the effectiveness and efficiency of communicating with interested parties should be measured to determine whether the information is timely and clearly understood;

i) where process and product performance criteria are met, it may still be beneficial to monitor and analyse performance data in order to understand better the nature of the characteristic under study;

j) the use of appropriate statistical or other techniques can help in the understanding of both process and measurement variation, and can thereby improve process and product performance by controlling variation;

k) self-assessment should be considered on a periodic basis to assess the maturity of the quality management system and the level of the organization's performance, as well as to define opportunities for performance improvement (see annex A).

ISO 9001:2000, Quality management systems — Requirements

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Measurement and monitoring

8.2.1 Measurement and monitoring of system performance

8.2.1.1 General

Top management should ensure that effective and efficient methods are used to identify areas for improvement of the quality management system performance. Examples of methods include

— satisfaction surveys for customers and other interested parties,

— internal audits,

— financial measurements, and

— self-assessment.

8.2.1.2 Measurement and monitoring of customer satisfaction

Measurement and monitoring of customer satisfaction is based on review of customer-related information. The collection of such information may be active or passive. Management should recognize that there are many sources of customer-related information, and should establish effective and efficient processes to collect, analyse and use this information for improving the performance of the organization. The organization should identify sources of customer and end-user information, available in written and verbal forms, from internal and external sources. Examples of customer-related information include

— customer and user surveys,

— feedback on aspects of product,

— customer requirements and contract information,

— market needs,

— service delivery data, and

— information relating to competition.

Management should use measurement of customer satisfaction as a vital tool. The organization's process for requesting, measuring and monitoring feedback of customer satisfaction should provide information on a continual basis. This process should consider conformity to requirements, meeting needs and expectations of customers, as well as the price and delivery of product.

The organization should establish and use sources of customer satisfaction information and should cooperate with its customers in order to anticipate future needs. The organization should plan and establish processes to listen effectively and efficiently to the “voice of the customer”. Planning for these processes should define and implement data-collection methods, including information sources, frequency of collection, and data-analysis review. Examples of sources of information on customer satisfaction include

— customer complaints,

— communicating directly with customers,

— questionnaires and surveys,

— subcontracted collection and analysis of data,

— focus groups,

— reports from consumer organizations,

— reports in various media, and

— sector and industry studies.

ISO 9001:2000, Quality management systems — Requirements

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

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

8.2.1.3 Internal audit

Top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weaknesses of the quality management system. The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that the existing requirements have been met, since the internal audit evaluates the effectiveness and efficiency of the organization.

It is important that management ensure improvement actions are taken in response to internal audit results. Planning for internal audits should be flexible in order to permit changes in emphasis based on findings and objective evidence obtained during the audit. Relevant input from the area to be audited, as well as from other interested parties, should be considered in the development of internal audit plans.

Examples of subjects for consideration by internal auditing include

— effective and efficient implementation of processes,

— opportunities for continual improvement,

— capability of processes,

— effective and efficient use of statistical techniques,

— use of information technology,

— analysis of quality cost data,

— effective and efficient use of resources,

— process and product performance results and expectations,

— adequacy and accuracy of performance measurement,

— improvement activities, and

— relationships with interested parties.

Internal audit reporting sometimes includes evidence of excellent performance in order to provide opportunities for recognition by management and motivation of people.

ISO 9001:2000, Quality management systems — Requirements

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.1.4 Financial measures

Management should consider the conversion of data from processes to financial information in order to provide comparable measures across processes and to facilitate improvement of the effectiveness and efficiency of the organization. Examples of financial measures include

— prevention and appraisal costs analysis,

— nonconformity cost analysis,

— internal and external failure cost analysis, and

— life-cycle cost analysis.

8.2.1.5 Self-assessment

Top management should consider establishing and implementing self-assessment. This is a careful evaluation, usually performed by the organization's own management, that results in an opinion or judgement of the effectiveness and efficiency of the organization and the maturity of the quality management system. It can be used by the organization to benchmark its performance against that of external organizations and world-class performance. Self-assessment also aids in evaluating the performance improvement of the organization, whereas the internal audit process of an organization is an independent audit used to obtain objective evidence that existing

policies, procedures or requirements have been met, as it evaluates the effectiveness and efficiency of the quality management system.

The range and depth of self-assessment should be planned in relation to the organization's objectives and priorities. The self-assessment approach described in annex A focuses on determining the degree of the effectiveness and efficiency of the implementation of the organization's quality management system. Some of the advantages of using the self-assessment approach given in annex A are that

— it is simple to understand,

— it is easy to use,

— it has minimal impact on the use of management resources, and

— it provides input for enhancing the performance of the organization's quality management system.

Annex A is only one example of self-assessment. Self-assessment should not be considered as an alternative to internal or external quality auditing. Use of the approach described in annex A can provide management with an overall view of the performance of the organization and the degree of maturity of the quality management system. It can also provide input for identifying areas in the organization requiring performance improvement and in helping to determine priorities.

8.2.2 Measurement and monitoring of processes

The organization should identify measurement methods and should perform measurements to evaluate process performance. The organization should incorporate these measurements into processes and use the measurements in process management.

Measurements should be used for managing daily operations, for evaluation of the processes that may be suitable for small-step or ongoing continual improvements, as well as for breakthrough projects, according to the vision and strategic objectives of the organization.

Measurements of process performance should cover the needs and expectations of interested parties in a balanced manner. Examples include

— capability,

— reaction time,

— cycle time or throughput,

— measurable aspects of dependability,

— yield,

— the effectiveness and efficiency of the organization's people,

— utilization of technologies,

— waste reduction, and

— cost allocation and reduction.

ISO 9001:2000, Quality management systems — Requirements

8.2.3 Monitoring and measurement of processes

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

8.2.3 Measurement and monitoring of product

The organization should establish and specify the measurement requirements (including acceptance criteria) for its products. The measurement of product should be planned and performed in order to verify that the requirements of interested parties have been achieved and used to improve the realization processes.

When selecting measurement methods for ensuring that products conform to requirements and when considering customer needs and expectations, the organization should consider the following:

a) the types of product characteristics, which then determine the types of measurement, suitable measurement means, the accuracy required and skills needed;

b) equipment, software and tools required;

c) the location of suitable measurement points in the realization process sequence;

d) characteristics to be measured at each point, and the documentation and acceptance criteria to be used;

e) customer established points for witness or verification of selected characteristics of a product;

f) inspections or testing required to be witnessed or performed by statutory and regulatory authorities;

g) where, when and how the organization intends, or is required by the customer or statutory and regulatory authorities, to engage qualified third parties to perform

   — type testing,

   — in-process inspections or testing,

   — product verification,

   — product validation, and

   — product qualification;

h) qualification of people, materials, products, processes, and the quality management system;

i) final inspection to confirm that verification and validation activities have been completed and accepted;

j) recording the results of product measurements.

The organization should review the methods used for measuring products and the planned records of verification, to consider opportunities for performance improvement. Typical examples of product measurement records that could be considered for performance improvement include

— inspection and test reports,

— material release notices,

— product acceptance forms, and

— certificates of conformity as required.

ISO 9001:2000, Quality management systems — Requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.2.4 Measurement and monitoring the satisfaction of interested parties

The organization should identify the measurement information required to meet the needs of interested parties (other than customers), in relation to the processes of the organization in order to balance the allocation of resources. Such information should include measurements relating to the people in the organization, owners and investors, suppliers and partners, as well as society. Measurement examples are as follows.

a) For people in the organization, the organization should

— survey the opinions of its people regarding how well the organization satisfies their needs and expectations, and

— assess individual and collective performances and their contribution to organizational results.

b) For owners and investors, the organization should

— assess its capacity to attain defined objectives,

— assess its financial performance,

— evaluate the impact of external factors on its results, and

— identify the value contributed by the actions taken.

c) For suppliers and partners, the organization should

— survey the opinions of suppliers and partners on their satisfaction with the purchasing processes of the organization,

— monitor and supply feedback on the performance of suppliers and partners and their compliance with the organization's purchasing policy, and

— assess the quality of product purchased, contributions from suppliers and partners, and mutual benefits derived from the relationship.

d) For society, the organization should

— define and track suitable data relative to its objectives, in order to achieve satisfactory interaction with society, and

— periodically assess the effectiveness and efficiency of its actions and the perceptions of its performance by relevant parts of society.

8.3 Control of nonconformity

8.3.1 General

Top management should empower people in the organization with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities. Authority for response to nonconformities should be defined to maintain achievement of process and product requirements. The organization should effectively and efficiently control nonconforming product identification, segregation and disposition in order to prevent misuse.

Where practical, nonconformities should be recorded, together with their disposition, to assist learning and to provide data for analysis and improvement activities. The organization may also decide that nonconformities to both product realization and support processes should be recorded and controlled.

The organization can also consider recording information on those nonconformities that are corrected in the normal course of work. Such data can provide valuable information for improving the effectiveness and efficiency of processes.

8.3.2 Nonconformity review and disposition

The management of the organization should ensure the establishment of an effective and efficient process to provide for review and disposition of identified nonconformities. Review of nonconformities should be conducted by authorized people to determine if any trends or patterns of occurrence require attention. Negative trends should be considered for improvement, and as input to management review where reduction goals and resource needs are considered.

People carrying out the review should have the competence to evaluate the total effects of the nonconformity and should have the authority and resources to disposition the nonconformity and to define appropriate corrective action. Acceptance of nonconformity disposition may be a contractual requirement of the customer, or a requirement of other interested parties.

ISO 9001:2000, Quality management systems — Requirements

8.3 Control of nonconforming product

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

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

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

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

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

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

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

Decisions should be based on analysis of data obtained from measurements and information collected as described in this International Standard. In this context, the organization should analyse data from its various sources to assess performance against plans, objectives and other defined goals, and to identify areas for improvement including possible benefits for interested parties.

Decisions based on facts require effective and efficient actions such as

— valid analysis methods,

— appropriate statistical techniques, and

— making decisions and taking actions based on results of logical analyses, as balanced with experience and intuition.

Analysis of data can help to determine the root cause of existing or potential problems, and therefore guide decisions about the corrective and preventive actions needed for improvement.

For an effective evaluation by management of the total performance of the organization, data and information from all parts of the organization should be integrated and analysed. The organization's overall performance should be

presented in a format that is suitable for different levels of the organization. The results of this analysis can be used by the organization to determine

— trends,

— customer satisfaction,

— satisfaction of other interested parties,

— effectiveness and efficiency of its processes,

— supplier contribution,

— success of its performance improvement objectives,

— economics of quality, financial and market-related performance,

— benchmarking of its performance, and

— competitiveness.

ISO 9001:2000, Quality management systems — Requirements

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction,

b) conformity to product requirements,

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

8.5 Improvement

8.5.1 General

Management should continually seek to improve the effectiveness and efficiency of the processes of the organization, rather than wait for a problem to reveal opportunities for improvement. Improvements can range from small-step ongoing continual improvement to strategic breakthrough improvement projects. The organization should have a process in place to identify and manage improvement activities. These improvements may result in change to the product or processes and even to the quality management system or to the organization.

ISO 9001:2000, Quality management systems — Requirements

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

Top management should ensure that corrective action is used as a tool for improvement. Corrective action planning should include evaluation of the significance of problems, and should be in terms of the potential impact on such

aspects as operating costs, costs of nonconformity, product performance, dependability and the safety and satisfaction of customers and other interested parties. People from appropriate disciplines should participate in the corrective action process. Also, the effectiveness and efficiency of processes should be emphasized when actions are taken and the actions should be monitored to ensure that desired goals are met. Corrective actions should be considered for inclusion in management review.

In pursuing corrective action, the organization should identify sources of information, and collect information to define the necessary corrective actions. The defined corrective action should be focused on eliminating causes of nonconformities in order to avoid recurrence. Examples of sources of information for corrective action consideration include

— customer complaints,

— nonconformity reports,

— internal audit reports,

— outputs from management review,

— outputs from data analysis,

— outputs from satisfaction measurements,

— relevant quality management system records,

— the organization's people,

— process measurements, and

— results of self-assessment.

There are many ways to determine the causes of nonconformity, including analysis by an individual or the assignment of a corrective-action project team. The organization should balance the investment in the corrective action against the impact of the problem being considered.

In evaluating the need for actions to ensure that nonconformities do not recur, the organization should consider providing appropriate training for people assigned to corrective-action projects.

The organization should incorporate root-cause analysis, as appropriate, into the corrective-action process. Root-cause analysis results should be verified by testing prior to defining and initiating corrective action.

ISO 9001:2000, Quality management systems — Requirements

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken, and

f) reviewing corrective action taken.

8.5.3 Loss prevention

Management should plan to mitigate the effects of loss to the organization in order to maintain the performance of processes and products. Loss prevention in the form of planning should be applied to realization and support processes, activities and products to ensure the satisfaction of interested parties.

To be effective and efficient, planning for loss prevention should be systematic. This should be based on data from appropriate methods, including evaluation of historical data for trends, and criticality relative to the performance of the organization and its products, in order to generate data in quantitative terms. Data can be generated from

— use of risk analysis tools such as fault mode and effects analysis,

— review of customer needs and expectations,

— market analysis,

— management review output,

— outputs from data analysis,

— satisfaction measurements,

— process measurements,

— systems that consolidate sources of information from interested parties,

— relevant quality management system records,

— lessons learned from past experience,

— results of self-assessment, and

— processes that provide early warning of approaching out-of-control operating conditions.

Such data will provide information to develop an effective and efficient plan for loss prevention and prioritization appropriate to each process and product, in order to satisfy the needs and expectations of interested parties.

Results of the evaluation of the effectiveness and efficiency of loss prevention plans should be an output from management review, and should be used as an input for the modification of plans and as input to the improvement processes.

ISO 9001:2000, Quality management systems — Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken, and

e) reviewing preventive action taken.

8.5.4 Continual improvement of the organization

To aid in ensuring the future of the organization and the satisfaction of interested parties, management should create a culture which involves people actively seeking opportunities for improvement of performance in processes, activities and products.

To involve people, top management should create an environment where authority is delegated so that people are empowered and accept responsibility to identify opportunities where the organization can improve its performance. This can be achieved by activities such as

— setting of objectives for people, projects and the organization,

— benchmarking competitor performance and best practice,

— recognition and reward for achievement of improvement, and

— suggestion schemes including timely reaction by management.

To provide a structure for improvement activities, top management should define and implement a process for continual improvement that can be applied to realization and support processes and activities. To ensure the effectiveness and efficiency of the improvement process, consideration should be given to realization and support processes in terms of

— effectiveness (such as outputs meeting requirements),

— efficiency (such as resources per unit in terms of time and money),

— external effects (such as statutory and regulatory change),

— potential weakness (such as lack of capability and consistency),

— the opportunity to employ better methods,

— control of planned and unplanned change, and

— measurement of planned benefits.

Such a process for continual improvement should be used as a tool for improving the organization's internal effectiveness and efficiency, as well as to improve the satisfaction of customers and other interested parties.

Management should support improvements in the form of small-step ongoing activities integral to existing processes as well as breakthrough opportunities, in order to gain maximum benefit for the organization and interested parties.

Examples of inputs to support the improvement process include information derived from

— validation data,

— process yield data

— test data,

— data from self-assessment,

— stated requirements and feedback from interested parties,

— experience of people in the organization,

— financial data,

— product performance data, and

— service delivery data.

Management should ensure that product or process changes are approved, prioritized, planned, provisioned and controlled to satisfy interested party requirements and avoid exceeding the capability of the organization.

A process presenting continual process improvement for implementation by an organization is described in annex B.

Annex A
(informative)

Guidelines for self-assessment

A.1 Introduction

Self-assessment is a carefully considered evaluation resulting in an opinion or judgement of the effectiveness and efficiency of the organization and the maturity of the quality management system. Self-assessment is usually performed by the organization's own management. The intent of self-assessment is to provide fact-based guidance to the organization regarding where to invest resources for its improvement.

It also can be useful in measuring progress against objectives, and to reassess the continuing relevance of those objectives.

Many models currently exist for the self-assessment of organizations to quality management system criteria. The most widely recognized and used models are national and regional quality award models, also referred to as organizational excellence models.

The self-assessment approach described in this annex is intended to provide a simple, easy-to-use approach to determine the relative degree of maturity of an organization's quality management system and to identify the main areas for improvement.

Specific features of the ISO 9004 self-assessment approach are that it can

— be applied to the entire quality management system, or to a part of the quality management system, or to any process,

— be applied to the entire organization or part of the organization,

— be completed quickly with internal resources,

— be completed by a multi-discipline team, or by one person in the organization who is supported by top management,

— form an input to a more comprehensive management system self-assessment process,

— identify and facilitate the prioritization of opportunities for improvement, and

— facilitate maturing of the quality management system towards world-class performance.

The ISO 9004 self-assessment approach is to evaluate the maturity of the quality management system for each major clause in ISO 9004 on a scale ranging from 1 (no formal system) to 5 (best-in-class performance). This annex provides guidance in the form of typical questions that the organization can ask in order to evaluate its performance for each of the main clauses in ISO 9004.

Another advantage to this approach is that results monitored over time can be used to appraise the maturity of an organization.

This approach to self-assessment is neither a substitute for internal audit of the quality management system nor for the use of existing quality award models.

A.2 Performance maturity levels

The performance maturity levels used in this self-assessment approach are shown in Table A.1.

Table A.1 — Performance maturity levels

Maturity level	Performance level	Guidance
1	No formal approach	No systematic approach evident, no results, poor results or unpredictable results.
2	Reactive approach	Problem- or corrective-based systematic approach; minimum data on improvement results available.
3	Stable formal system approach	Systematic process-based approach, early stage of systematic improvements; data available on conformance to objectives and existence of improvement trends.
4	Continual improvement emphasized	Improvement process in use; good results and sustained improvement trends.
5	Best-in-class performance	Strongly integrated improvement process; best-in-class benchmarked results demonstrated.

A.3 Self-assessment questions

The award models as well as other self-assessment models have a wide range of detailed criteria for assessing the performance of management systems. Self-assessment provides an easy approach for evaluating the maturity of an organization based on clauses 4 to 8 of this International Standard. Each organization should develop a set of questions for those clauses of this International Standard that are suitable to its needs. Examples of typical questions for self-assessment are provided below. The subclause numbers are given in parentheses.

Question 1: Managing systems and processes (4.1)

a) How does management apply the process approach to achieve the effective and efficient control of processes, resulting in performance improvement?

Question 2: Documentation (4.2)

a) How are documents and records used to support effective and efficient operation of the processes of the organization?

Question 3: Management responsibility — General guidance (5.1)

a) How does top management demonstrate its leadership, commitment and involvement?

Question 4: Needs and expectations of interested parties (5.2)

a) How does the organization identify customers' needs and expectations on a continual basis?

b) How does the organization identify people's need for recognition, work satisfaction, competence and personal development?

c) How does the organization consider the potential benefits of establishing partnerships with its suppliers?

d) How does the organization identify other interested parties' needs and expectations that can result in setting objectives?

e) How does the organization ensure that statutory and regulatory requirements have been considered?

Question 5: Quality policy (5.3)

a) How does the quality policy ensure that the needs and expectations of customers and other interested parties are understood?

b) How does the quality policy lead to visible and expected improvements?

c) How does the quality policy consider the organization's vision of the future?

Question 6: Planning (5.4)

a) How do the objectives translate the quality policy into measurable goals?

b) How are the objectives deployed to each management level to assure individual contribution to achievement?

c) How does management ensure the availability of resources needed to meet the objectives?

Question 7: Responsibility, authority and communication (5.5)

a) How does top management ensure that responsibilities are established and communicated to people in the organization?

b) How does communicating quality requirements, objectives and accomplishments contribute to improvement of the organization's performance?

Question 8: Management review (5.6)

a) How does top management ensure valid input information is available for the management review?

b) How does the management review activity evaluate information to improve the effectiveness and efficiency of the processes of the organization?

Question 9: Resource management — General guidance (6.1)

a) How does top management plan for resources to be available in a timely manner?

Question 10: People (6.2)

a) How does management promote involvement and support of people for improvement of the effectiveness and efficiency of the organization?

b) How does management ensure that the competence of people in the organization is adequate for current and future needs?

Question 11: Infrastructure (6.3)

a) How does management ensure that the infrastructure is appropriate for the achievement of the objectives of the organization?

b) How does management consider environmental issues associated with the infrastructure?

Question 12: Work environment (6.4)

a) How does management ensure that the work environment promotes motivation, satisfaction, development and performance of people in the organization?

Question 13: Information (6.5)

a) How does management ensure that appropriate information is easily available for fact-based decision making?

Question 14: Suppliers and partnerships (6.6)

a) How does management involve suppliers in the identification of purchasing needs and joint strategy development?

b) How does management promote partnership arrangements with suppliers?

Question 15: Natural resources (6.7)

a) How does the organization ensure the availability of necessary natural resources for its realization processes?

Question 16: Financial resources (6.8)

a) How does management plan, provide, control and monitor the financial resources necessary to maintain an effective and efficient quality management system and to ensure the achievement of the objectives of the organization?

b) How does management ensure awareness of people in the organization about the link between product quality and costs?

Question 17: Product realization — General guidance (7.1)

a) How does top management apply the process approach to ensure the effective and efficient operation of the realization and support processes and the associated process network?

Question 18: Processes related to interested parties (7.2)

a) How has management defined customer-related processes to ensure consideration of customers' needs?

b) How has management defined other interested-party-related processes to ensure consideration of interested parties' needs and expectations?

Question 19: Design and development (7.3)

a) How has top management defined design and development processes to ensure they respond to the needs and expectations of the organization's customers and other interested parties?

b) How are design and development processes managed in practice, including the definition of design and development requirements and the achievement of planned outputs?

c) How are activities such as design review, verification, validation and configuration management considered in the design and development processes?

Question 20: Purchasing (7.4)

a) How has top management defined purchasing processes that ensure purchased products satisfy the organization's needs?

b) How are purchasing processes managed?

c) How does the organization ensure conformity of purchased products from specification through to acceptance?

Question 21: Production and service operations (7.5)

a) How does top management ensure that the input to the realization processes takes account of customers' and other interested parties' needs?

b) How are realization processes managed from inputs to outputs?

c) How are activities such as verification and validation considered in realization processes?

Question 22: Control of measuring and monitoring devices (7.6)

a) How does management control the measuring and monitoring devices to ensure that correct data are being obtained and used?

Question 23: Measurement, analysis and improvement — General guidance (8.1)

a) How does management promote the importance of measurement, analysis and improvement activities to ensure that the organization's performance results in satisfaction of interested parties?

Question 24: Measurement and monitoring (8.2)

a) How does management ensure collection of customer-related data for analysis, in order to obtain information for improvements?

b) How does management ensure the collection of data from other interested parties for analyses and possible improvements?

c) How does the organization use self-assessment of the quality management system for improving the overall effectiveness and efficiency of the organization?

Question 25: Control of nonconformity (8.3)

a) How does the organization control process and product nonconformity?

b) How does the organization analyse nonconformity for lessons learned and process and product improvement?

Question 26: Analysis of data (8.4)

a) How does the organization analyse data to assess its performance and identify areas for improvement?

Question 27: Improvement (8.5)

a) How does management use corrective action for evaluating and eliminating recorded problems affecting its performance?

b) How does management use preventive action for loss prevention?

c) How does the management ensure the use of systematic improvement methods and tools to improve the organization's performance?

A.4 Documentation of self-assessment results

There are many ways to format self-assessment questions to evaluate performance, to indicate maturity ratings and to record possible improvement actions. One approach is shown in Table A.2.

Table A.2 — Example of the recording of self-assessment results

Subclause	Question No.	Actual performance observations	Rating	Improvement action
5.2	4 a)	Our process is better than any other process in the world for this item	5	None required
5.2	4 b)	We have no system for this item	1	Need to structure a process to address this — by WHOM and by WHEN ?

Self-assessment can be used in a flexible way according to the needs of the organization. One approach would be to perform the self-assessment on an individual basis for all or part of the quality management system and then to pursue improvement. Another approach would be to have a cross-functional group of people perform self-assessment on all or part of the quality management system, followed by group review and analysis, then consensus building to determine improvement priorities and action plans. How self-assessment can be effectively and efficiently used in an organization is only limited by the imagination and ingenuity of the individuals in the organization who have an interest in achieving excellence.

A.5 Linking potential benefits of ISO 9004 to self-assessment

There are many different ways to decide what actions should be taken as a result of self-assessment. One approach is to consider the self-assessment output together with the potential key benefits to be gained from a robust quality management system. This approach would enable an organization to identify and initiate improvement projects that would potentially provide the best benefits based on the priority needs of the organization. To facilitate the use of such an approach, examples of potential benefits are given below relating to the questions in A.3 and to particular subclauses of this International Standard. These examples may be used as a starting point to construct a list that is appropriate for the organization. Examples of potential benefits are as follows.

Benefit 1: Managing systems and processes (4.1)

Provides a systematic and visible way to lead and operate an organization that continually improves performance.

Benefit 2: Documentation (4.2)

Provides information and supporting evidence of the effectiveness and efficiency ot the quality management system.

Benefit 3: Management responsibility — General guidance (5.1)

Ensures the consistent and visible involvement of top management.

Benefit 4: Needs and expectations of interested parties (5.2)

Ensures that the quality management system considers, in a balanced way, the needs and expectations of all interested parties, to get an effective and efficient system.

Benefit 5: Quality policy (5.3)

Ensures all interested parties' needs are understood and provides direction to the total organization leading to visible and expected results.

Benefit 6: Planning (5.4)

Translates the quality policy into measurable objectives and plans to provide clear focus on important areas throughout the organization.

Enhances learning from previous experiences.

Benefit 7: Responsibility, authority and communication (5.5)

Provides an organization-wide, consistent and comprehensive approach and clarifies roles and responsibilities and linkages to all interested parties.

Benefit 8: Management review (5.6)

Involves top management in the improvement of the quality management system.

Assesses whether plans have been achieved and indicates appropriate action for improvement.

Benefit 9: Resource management — General guidance (6.1)

Ensures the availability of adequate resources in terms of people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources so that the objectives of the organization can be achieved.

Benefit 10: People (6.2)

Provides better understanding of roles, responsibilities and goals and enhances involvement at all levels in the organization in order to achieve performance improvement objectives.

Encourages recognition and reward.

Benefits 11, 12, 13 and 15 to: Infrastructure (6.3), Work environment (6.4), Information (6.5) and Natural resources (6.7)

Provide for effective use of resources other than human resources.

Enhance understanding of restrictions and opportunities to ensure that objectives and plans are achievable.

Benefit 14: Suppliers and partnerships (6.6)

Promotes partner relationships with suppliers and other organizations for mutual benefit.

Benefit 16: Financial resources (6.8)

Provides better understanding of the relationship between cost and benefits.

Encourages improvement towards effective and efficient achievement of the organization's objectives.

Benefit 17: Product realization — General guidance (7.1)

Structures the operations of the organization to achieve a desired result.

Benefit 18: Processes related to interested parties (7.2)

Ensures that resources and activities are managed as processes.

Ensures that all interested parties' needs and expectations are understood throughout the organization.

Benefit 19: Design and development (7.3)

Structures the design and development processes to respond effectively and efficiently to the needs and expectations of customers and other interested parties.

Benefit 20: Purchasing (7.4)

Ensures that suppliers are aligned with the organization's quality policy and objectives.

Benefit 21: Production and service operations (7.5)

Ensures sustained customer satisfaction by producing products, delivering services and providing support functions that meet customers' needs and expectations.

Benefit 22: Control of measuring and monitoring devices (7.6)

Ensures the accuracy of data for analysis.

Benefit 23: Measurement, analysis and improvement — General guidance (8.1)

Ensures effective and efficient measurement, collection and validation of data for improvement.

Benefit 24: Measurement and monitoring (8.2)

Provides controlled methods for measurement and monitoring of processes and products.

Benefit 25: Control of nonconformity (8.3)

Provides for effective disposition of nonconformity in products and processes.

Benefit 26: Analysis of data (8.4)

Provides for factual decision making.

Benefit 27: Improvement (8.5)

Increases the effectiveness and efficiency of the organization.

Focuses on prevention and improvement based on trends.

Annex B
(informative)

Process for continual improvement

A strategic objective of an organization should be the continual improvement of processes in order to enhance the organization's performance and benefit its interested parties.

There are two fundamental ways to conduct continual process improvement, as follows:

a) breakthrough projects which either lead to revision and improvement of existing processes or the implementation of new processes; these are usually carried out by cross-functional teams outside routine operations;

b) small-step ongoing improvement activities conducted within existing processes by people.

Breakthrough projects usually involve significant redesign of existing processes and should include

— definition of the objectives and an outline of the improvement project,

— analysis of the existing process (the “as-is” process) and realizing opportunities for change,

— definition and planning of improvement to the process,

— implementation of the improvement,

— verification and validation of the process improvement, and

— evaluation of the improvement achieved, including lessons learned.

Breakthrough projects should be conducted in an effective and efficient way using project management methods. After completion of the change, a new project plan should be the basis for continuing process management.

People in the organization are the best source of ideas for small-step or ongoing process improvement and often participate as work groups. Small-step ongoing process improvement activities should be controlled in order to understand their effect. The people in the organization that are involved should be provided with the authority, technical support and necessary resources for the changes associated with the improvement.

Continual improvement by either of the methods identified should involve the following.

a) Reason for improvement: a process problem should be identified and an area for improvement selected, noting the reason for working on it.

b) Current situation: the effectiveness and efficiency of the existing process should be evaluated. Data to discover what types of problems occur most often should be collected and analysed. A specific problem should be selected and an objective for improvement should be set.

c) Analysis: the root causes of the problem should be identified and verified.

d) Identification of possible solutions: alternative solutions should be explored. The best solution should be selected and implemented; i.e. the one that will eliminate the root causes of the problem and prevent the problem from recurring.

e) Evaluation of effects: it should then be confirmed that the problem and its root causes have been eliminated or their effects decreased, that the solution has worked, and the objective for improvement has been met.

f) Implementation and standardization of the new solution: the old process should be replaced with the improved process, thereby preventing the problem and its root causes from recurring.

g) Evaluation of the effectiveness and efficiency of the process with the improvement action completed: the effectiveness and efficiency of the improvement project should be evaluated and consideration should be given for using its solution elsewhere in the organization.

The process for improvement should be repeated on remaining problems, developing objectives and solutions for further process improvement.

In order to facilitate the involvement and awareness of people in improvement activities, management should consider activities such as

— forming small groups and having leaders elected by the group members,

— allowing people to control and improve their workplace, and

— developing people's knowledge, experience and skills as a part of the overall quality management activities of the organization.

Bibliography

[1] ISO 9000-3:1997, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software*.

[2] ISO 9001:2000, *Quality management systems — Requirements*.

[3] ISO 9004-4:1993, *Quality management and quality system elements — Part 4: Guidelines for quality improvement*.

[4] ISO 10005:1995, *Quality management — Guidelines for quality plans*.

[5] ISO 10006:1997, *Quality management — Guidelines to quality in project management*.

[6] ISO 10007:1995, *Quality management — Guidelines for configuration management*.

[7] ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*[1)].

[8] ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*[1)].

[9] ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes*[1)].

[10] ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*.

[11] ISO 10012-2:1997, *Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes*.

[12] ISO 10013:1995, *Guidelines for developing quality manuals*.

[13] ISO/TR 10014:1998, *Guidelines for managing the economics of quality*.

[14] ISO 10015:1999, *Quality management — Guidelines for training*.

[15] ISO/TR 10017:1999, *Guidance on statistical techniques for ISO 9001:1994*.

[16] ISO 10576-1:—[2)], *Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles*.

[17] ISO/TR 13425:1995, *Guide for the selection of statistical methods in standardization and specification*.

[18] ISO 14001:1996, *Environmental management systems — Specification with guidance for use*.

[19] ISO 14004:1996, *Environmental management systems — General guidelines on principles, systems and supporting techniques*.

[20] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*[3)].

[21] IEC 60300-1:—[4)], *Dependability management — Part 1: Dependability programme management*.

1) To be revised as ISO 19011, *Guidelines on quality and/or environmental management auditing*.

2) To be published.

3) Formerly designated ISO/IEC Guide 25.

4) To be published. (Revision of ISO 9000-4:1993)

[22] *Statistical methods for quality control — Vol.1: Terminology and symbols — Acceptance sampling*. ISO Handbook, 4th edition, 1995.

[23] *Statistical methods for quality control — Vol.2: Measurement methods and results Interpretation of statistical data — Process control*. ISO Handbook, 4th edition, 1995.

[24] *Quality Management Principles Brochure*[5].

[25] *ISO 9000 + ISO 14000 News* (a bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world)[6].

[26] Reference websites: http://www.iso.ch
http://www.bsi.org.uk/iso-tc176-sc2

5) Available from website: http://www.iso.ch

6) Available from ISO Central Secretariat (sales@iso.ch).

Additional resources on the ANSI/ISO/ASQ Q9000:2000 Standards available from ASQ Quality Press:

ISO 9001:2000 Explained, Second Edition
Charles A. Cianfrani, Joseph J. Tsiakals, and John E. (Jack) West
http://qualitypress.asq.org/perl/catalog.cgi?item=H1104

The ISO Lesson Guide 2000: Pocket Guide to Q9001:2000, Second Edition
Dennis Arter and J. P. Russell
http://qualitypress.asq.org/perl/catalog.cgi?item=H1102

ISO 9001:2000 – An Audio Workshop and Master Slide Presentation
John E. (Jack) West and Charles A. Cianfrani
http://qualitypress.asq.org/perl/catalog.cgi?item=H1106

ISO 9001:2000 Quick Reference
Jeanne Ketola and Kathy Roberts
http://qualitypress.asq.org/perl/catalog.cgi?item=H1107

ISO 9000 at the Front Line
William A. Levinson
http://qualitypress.asq.org/perl/catalog.cgi?item=H0987

After the Quality Audit: Closing the Loop on the Audit Process, Second Edition
J. P. Russell and Terry Regel
http://qualitypress.asq.org/perl/catalog.cgi?item=H1070

Internal Quality Auditing
Denis Pronovost
http://qualitypress.asq.org/perl/catalog.cgi?item=H1069

Quality Press has created an ISO 9000:2000 Resource Materials web page. This convenient online resource contains links to all the books, journals, standards, and courses that are available through ASQ (as well as general information and FAQs) on this important revision to the standards. You can visit this page from our Online Bookstore at http://qualitypress.asq.org.

To request a complimentary catalog of ASQ Quality Press publications, call 800-248-1946, or visit our Online Bookstore at http://qualitypress.asq.org.

American Society for Quality

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

T2104E