ISO/CD1 9001 and ISO/CD1 9004
Available for Review and Comment

ASQ, in partnership with international standards developers, is now circulating drafts of ISO/CD 9001 and ISO/CD 9004 for review and comment.

These two documents are not intended for use. They are only preliminary drafts, and are being circulated at an early stage of development only for public review and comment, in order to determine if the direction of the two standards is on-target with user needs.

For ISO 9001, the requirements standard, the development plan calls for making minor changes for clarification and compatibility with ISO 14001. However, even small changes to the standard can dramatically impact a user's QMS.

For ISO 9004, the guidelines document, the development plan calls for producing a major revision, with a focus on providing guidance on organizational sustainability rather than performance improvement.

All public comments must be submitted before March 31, 2007. When submitting your comments, you must use the forms provided so they can be collated and sent to the US committee members as input to the US position.

The comment forms are available for download from the web. Please download the corresponding form and when completed, send to standards@asq.org. Please use comment forms to submit your comments. Feedback in other formats will not be accepted.

9001 comment form: http://www.asq.org/docs/template-for-comments-ISO-CD-9001.doc
9004 comment form: http://www.asq.org/docs/template-for-comments-ISO-CD-9004.doc

If you have any questions on the use of the template, please contact ASQ's Jason Knopes at 800-414-298-8789 Ext. 7857 or write to standards@asq.org.

All properly submitted comments will be shared with the U.S. delegates to the international committees revising ISO/CD 9001 and ISO/CD 9004, for the purpose of strengthening the U.S. position on the documents.

Thank you,
Jason R. Knopes
ASQ
Administrator, ANSI-Accredited TAG to ISO/TC 176
414-298-8789 Ext 7857
standards@asq.org

ISO/TC 176/SC 2 N 786-1

Date: 2007-02-8

ISO/CD 9001

ISO/TC 176/SC 2/WG 18

Secretariat: BSI

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Warning

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

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

Document type: International Standard
Document subtype:
Document stage: (30) Committee
Document language: E

S:\Staff\Randy\Word Files-Standards\N786-1 ISO_CD_9001_(E).doc STD Version 2.2

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Foreword

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

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

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

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

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

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

The title of ISO 9001 has been revised in this edition and no longer includes the term “Quality assurance“. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annex A of this International Standard is for information only.

Notes to this Committee Draft:

1. The differences between ISO 9001:2000 and this draft are highlighted in yellow. Text with "~~strikethrough~~" indicates ISO 9001:2000 text proposed for deletion.

2. The former Annex B "Correspondence between ISO 9001:2000 and ISO 9001:1994" has been deleted.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision 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. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

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

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

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

For an organization to function effectively, 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, can be 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 of these processes, and their management, 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 over their combination and interaction.

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

a) understanding and meeting 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 customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act“ (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization‘s policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

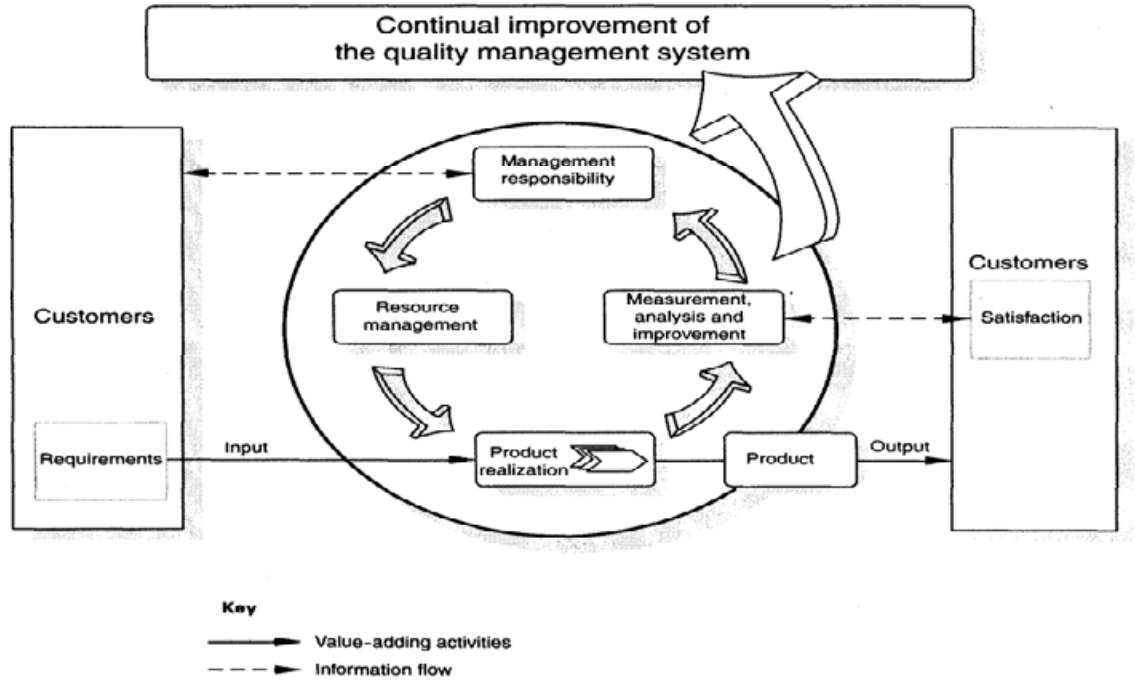

Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

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 organizations 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.

0.4 Compatibility with other management systems

During the development of this International Standard, due consideration has been taken of the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements 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 system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Quality management systems — Requirements

1 Scope

1.1 General

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

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

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" applies ~~only~~ to the product intended for, or required by, a customer. This also includes purchased product and product resulting from intermediate stages of the realization process.

NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

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~~ 2005 *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 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:~~

~~supplier → organization → customer~~

~~The term "organization" replaces the term "supplier" used in ISO 9001 :1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".~~

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

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~~ determine the processes needed for the quality management system and their application throughout the organization (see 1.2),

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~~ to requirements, the organization shall ensure control over such processes. The controls to be applied to these outsourced processes shall be defined within the quality management system.

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

NOTE 2 The requirements of Clause 7.4 of this international standard may also apply to outsourced processes.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

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

d) a quality manual,

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

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

~~g) records required by this International Standard (see 4.2.4).~~

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

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 (see 1.2),

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 necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

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

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 shall be controlled. ~~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.~~

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

Records shall be remain legible, readily identifiable and retrievable.

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 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

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

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], 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 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 shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of the organization's 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

Top management shall ensure that appropriate communication processes 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 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 (see 4.2.4).

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

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 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 Human resources

6.2.1 General

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

6.2.2 Competence, training and awareness

The organization shall

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

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

c) ~~ensure the effectiveness of the actions taken,~~ ensure that the necessary competence has been achieved,

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

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

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 or information systems).

6.4 Work environment

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

Note: The term work environment relates to conditions necessary to achieve conformity to product requirements such as clean rooms, anti-static precautions and hygiene controls.

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 (see 4.1).

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, measurement, 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 (see 4.2.4).

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.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

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

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

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

d) any additional requirements as needed ~~determined~~ by the organization.

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

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 (see 4.2.4)

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 Design and development planning

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

During the design and development planning, the organization shall determine

a) the design and development stages,

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

c) the responsibilities and authorities for design and development.

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

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

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

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (See 4.2.4). These inputs 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 suitable for 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.

NOTE Production and service provision includes preservation of the product.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

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 (4.2.4)

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) 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 (4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where 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 (4.2.4).

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 (see 4.2.4)

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. (see 4.2.4)

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 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 (see 4.2.4) and

e) revalidation.

NOTE 1 For many service organizations, the service provided does not readily allow the verification before the delivery of the service. These types of processes should be considered and identified during the planning stage (see 7.1)

NOTE 2. Processes such as welding, sterilization, training, heat treatment, call center service, or emergency response may need validation

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 throughout product realization.

Where traceability is a requirement, the organization shall control ~~and record~~ the unique identification of the product and maintain records (see 4.2.4)

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

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~~ the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.5 Preservation of product

The organization shall preserve the ~~conformity of~~ product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. ~~Where appropriate,~~ ~~This~~ As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

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 ~~(see 7.2.1)~~.

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 (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) ~~be identified~~ have identification to enable ~~the~~ their 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 (see 4.2.4).

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 1 See ISO 10012 for ~~ISO 10012-2 for guidance~~ further information.

NOTE 2 Monitoring and measurement devices, include measuring equipment (whether used for monitoring or measurement) and devices other than measuring equipment that are used for monitoring conformity to requirements.

NOTE 3 Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

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 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the ~~measurements~~ indicators 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.

8.2.2 Internal audit

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

a) conforms to the planned arrangements (see 7.1), 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.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

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 (see 4.2.4) shall be defined in a documented procedure.~~

Records of the audit and its results shall be maintained (see 4.2.4).

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 (see 8.5.2).

NOTE See ISO 19011 ~~ISO 10011-1, ISO 10011-2 and ISO 10011-3~~ for guidance.

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~~.

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

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 (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

~~Evidence of conformity with the acceptance criteria shall be maintained~~. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product ~~release~~ and service delivery to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

NOTE Evidence of conformity with acceptance criteria can be a record or as otherwise specified in the planned arrangements.

8.3 Control of nonconforming product

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

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

a) by taking action to eliminate the detected nonconformity;

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

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

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

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

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

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

~~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

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 (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

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

d) suppliers.

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

The organization shall take action to eliminate the causes 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 (see 4.2.4), and

f) reviewing the effectiveness of the corrective action taken.

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 (see 4.2.4), and

e) reviewing the effectiveness of the preventive action taken.

Annex A
(Informative)

Correspondence between ISO 9001:2000 and ISO 14001:2004

Table A.1 — Correspondence between ISO 9001:2000 and ISO 14001:2004

ISO 9001:2000		ISO 14001:2004	
Introduction General Process approach Relationship with ISO 9004 Compatibility with other management systems	 0.1 0.2 0.3 0.4		Introduction
Scope General Application	1 1.1 1.2	1	Scope
Normative reference	2	2	Normative references
Terms and definitions	3	3	Definitions
Quality management system (title only)	4	4	Environmental management system requirements (title only)
General requirements	4.1	4.1	General requirements
Documentation requirements (title only)	4.2		
General	4.2.1	4.4.4	Documentation
Quality manual	4.2.2		
Control of documents	4.2.3	4.4.5	Control of documents
Control of records	4.2.4	4.5.4	Control of records
Management responsibility (title only)	**5**		
Management commitment	5.1	4.2 4.4.1	Environmental policy Resources, roles, responsibility and authority
Customer focus	5.2	4.3.1 4.3.2 4.6	Environmental aspects Legal and other requirements Management review
Quality policy	5.3	4.2	Environmental policy
Planning (title only)	5.4	4.3	Planning
Quality objectives	5.4.1	4.3.3	Objectives, targets and programme(s)
Quality management system planning	5.4.2	4.3.3	Objectives, targets and programme(s)

Table A.1 – Correspondence between ISO 9001:2000 and ISO 14001:2004 (continued)

Responsibility, authority and communication (title only)	5.5		
Responsibility and authority	5.5.1	4.4.1	Resources, roles, responsibility and authority
Management representative	5.5.2	4.4.1	Resources, roles, responsibility and authority
Internal communication	5.5.3	4.4.3	Communication
Management review	5.6	4.6	Management review
General	5.6.1	4.6	Management review
Review input	5.6.2	4.6	Management review
Review output	5.6.3	4.6	Management review
Resource management (title only)	6		
Provision of resources	6.1	4.4.1	Resources, roles, responsibility and authority
Human resources (title only)	6.2		
General	6.2.1	4.4.2	Competence, training and awareness
Competence, awareness and training	6.2.2	4.4.2	Competence, training and awareness
Infrastructure	6.3	4.4.1	Resources, roles, responsibility and authority
Work environment	6.4		
Product realization (title only)	7	4.4	Implementation and operation
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes (title only)	7.2		
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.3.1 4.4.6	Environmental aspects Operational control
Customer communication	7.2.3	4.4.3	Communication
Design and development (title only)	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2	4.4.6	Operational control
Design and development outputs	7.3.3	4.4.6	Operational control
Design and development review	7.3.4	4.4.6	Operational control
Design and development verification	7.3.5	4.4.6	Operational control
Design and development validation	7.3.6	4.4.6	Operational control
Control of design and development changes	7.3.7	4.4.6	Operational control

Table A.1 – Correspondence between ISO 9001:2000 and ISO 14001:2004 (continued)

ISO 9001:2000		ISO 14001:2004	
Purchasing (title only)	7.4		
Purchasing process	7.4.1	4.4.6	Operational control
Purchasing information	7.4.2	4.4.6	Operational control
Verification of purchased product	7.4.3	4.4.6	Operational control
Production and service provision (title only)	7.5		
Control of production and service provision	7.5.1	4.4.6	Operational control
Validation of processes for production and service provision	7.5.2	4.4.6	Operational control
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5	4.4.6	Operational control
Control of monitoring and measuring devices	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement (title only)	8	4.5	Checking
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement (title only)	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.5	Internal audit
Monitoring and measurement of processes	8.2.3	4.5.1 4.5.2	Monitoring and measurement Evaluation of compliance
Monitoring and measurement of product	8.2.4	4.5.1 4.5.2	Monitoring and measurement Evaluation of compliance
Control of nonconforming product	8.3	4.4.7 4.5.3	Emergency preparedness and response Nonconformity, corrective action and preventive action
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement (title only)	8.5		
Continual improvement	8.5.1	4.2 4.3.4 4.6	Environmental policy Objectives, targets and programme(s) Management review
Corrective action	8.5.2	4.5.3	Nonconformity, corrective action and preventive action
Preventive action	8.5.3	4.5.3	Nonconformity, corrective action and preventive action

Table A.2 – Correspondence between ISO 14001:2004 and ISO 9001:2000

ISO 14001:2004		ISO 9001:2000	
Introduction	—	0 0.1 0.2 0.3 0.4	Introduction General Process approach Relationship with ISO 9004 Compatibility with other management systems
Scope	1	1 1.1 1.2	Scope General Application
Normative references	2	2	Normative reference
Terms and definitions	3	3	Terms and definitions
Environmental management system requirements (title only)	4	4	Quality management system (title only)
General requirements	4.1	4.1 5.5 5.5.1	General requirements Responsibility, authority and communication Responsibility and authority
Environmental policy	4.2	5.1 5.3 8.5.1	Management commitment Quality policy Continual improvement
Planning (title only)	4.3	5.4	Planning (title only)
Environmental aspects	4.3.1	5.2 7.2.1 7.2.2	Customer focus Determination of requirements related to the product Review of requirements related to the product
Legal and other requirements	4.3.2	5.2 7.2.1	Customer focus Determination of requirements related to the product
Objectives, targets and programme(s)	4.3.3	5.4.1 5.4.2 8.5.1	Quality objectives Quality management system planning Continual improvement
Implementation and operation (title only)	4.4	7	Product realization (title only)
Resources, roles, responsibility and authority	4.4.1	5.1 5.5.1 5.5.2 6.1 6.3	Management commitment Responsibility and authority Management representative Provision of resources Infrastructure
Competence, training and awareness	4.4.2	6.2.1 6.2.2	(Human resources) General Competence, awareness and training
Communication	4.4.3	5.5.3 7.2.3	Internal communication Customer communication
Documentation	4.4.4	4.2.1	(Documentation requirements) General

Table A.2 – Correspondence between ISO 14001:2004 and ISO 9001:2000 (continued)

ISO 14001:2004		ISO 9001:2000	
Control of documents	4.4.5	4.2.3	Control of documents
Operational control	4.4.6	7.1 7.2 7.2.1 7.2.2 7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7 7.4.1 7.4.2 7.4.3 7.5 7.5.1 7.5.2 7.5.5	Planning of product realization Customer-related processes Determination of requirements related to the product Review of requirements related to the product Design and development planning Design and development inputs Design and development outputs Design and development review Design and development verification Design and development validation Control of design and development changes Purchasing process Purchasing information Verification of purchased product Production and service provision Control of production and service provision Validation of processes for production and service provision Preservation of product
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking (title only)	4.5	8	Measurement, analysis and improvement (title only)
Monitoring and measurement	4.5.1	7.6 8.1 8.2.3 8.2.4 8.4	Control of monitoring and measuring devices (Measurement, analysis and improvement) General Monitoring and measurement of processes Monitoring and measurement of product Analysis of data
Evaluation of compliance	4.5.2	8.2.3 8.2.4	Monitoring and measurement of processes Monitoring and measurement of product
Nonconformity, corrective action and preventive action	4.5.3	8.3 8.4 8.5.2 8.5.3	Control of nonconforming product Analysis of data Corrective action Preventive action
Control of records	4.5.4	4.2.4	Control of records
Internal audit	4.5.5	8.2.2	Internal audit
Management review	4.6	5.1 5.6 5.6.1 5.6.2 5.6.3 8.5.1	Management commitment Management review (title only) General Review input Review output Continual improvement

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http://www.iso.org/tc176/ISO9001AuditingPracticesGroup

ISO/TC 176/SC 2 N 787-1

Date: 2007-02-8

ISO/CD 9004

ISO/TC 176/SC 2/WG 18

Secretariat: BSI

Managing for sustainability — A quality management approach

(French title to be added) — —

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Document type: International Standard
Document subtype:
Document stage: (30) Committee
Document language: E

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Foreword

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

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

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

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

ISO 9004 was prepared by Technical Committee ISO/TC 176, *Quality Management and Quality Assurance*, Subcommittee SC 2, *Quality Systems*.

This third edition cancels and replaces the second edition, ISO 9004:2000, which has been technically, and substantially, revised. It now addresses the sustainability of an organization, rather than its previous focus on performance improvements.

Introduction

Through advances in information and communications technology, the world is virtually becoming a smaller place. It is no longer enough for organizations to just make profits for their shareholders and to obey the law. They are increasingly accountable to more environmentally and socially aware shareholders, to civil society in general, to employees, to customers and to a variety of other stakeholders. The creation and sustainable development of organizations is now central to our economic and social lives.

Sustainability is the result of the continued satisfaction of an organization’s stakeholders; the stakeholders are those entities (organizations, individuals, institutions) that contribute to the functioning and value creation of an organization and without whom the organization's aims could not be achieved.

This International Standard provides guidance to organizations on how to achieve sustainability in a demanding, ever-changing, and uncertain environment.

This International Standard utilizes the same eight quality management principles that provide the foundations of ISO 9001:2000 (see ISO 9000:2005, Clause 0.2) and gives guidance on the application of the quality management principles to the purpose of achieving long term, sustainable, success for an organization, and on managing the movement of the whole of an organization, rather than just some of its constituent parts, towards sustainability.

This International Standard gives guidance that complements the use of ISO 9001 and other management system standards, but does not give guidance on their application, i.e. it is not a guide to ISO 9001..

Clauses 5 through 10 of this International Standard identify essential features of an organization. Within each section guidance is provided that relates to various aspects of each essential feature. Consideration is given to the interdependence of essential features, the risks and opportunities they present, processes typically related to managing the features, the resources required, and potential measurement and analysis methodologies.

Annexes A and B provide tools aimed at assessing an organization's strategy and its operations. The guidance given in this International Standard relates to the results of assessments of individual essential features.

Managing for sustainability — A quality management approach

1 Scope

This International Standard provides guidelines and tools for utilizing the principles of quality management to achieve sustainability. It is applicable to all organizations, regardless of their size, type and activity.

This International Standard is not intended for certification, regulatory or contractual use.

2 Normative references

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

ISO 9000:2005 Quality management systems — Fundamentals and vocabulary

ISO 9001:200X[1] Quality management systems — Requirements

[1] To be published

3 Terms and definitions

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

3.1 sustainability
<of an organization>
ability of an organization or activity to maintain or develop its performance in the long term.

Note 1: Sustainability emphasizes the need for a balance between the economic-financial interests of an organization and those of its social and ecological environment.

Note 2: Sustainability relates to both the direct and indirect stakeholders of an organization (such as shareholders, employees, customers, users, pressure groups and communities).

4 Managing for sustainability

4.1 General

The sustainability of the organization is reliant on its ability to autonomously monitor the external environment for opportunities, changes, trends and risks. At the same time, the organization needs to have the ability to learn, change and innovate in response to the results of monitoring, through cohesive, efficient and aligned processes that are based on quality management principles.

To achieve sustainability an organization should focus on its results as well as on its processes.

4.2 Essential features for sustainability

One of the most essential features for the achievement of sustainability is for the organization to be managed in an aligned and coherent manner, by:

— articulating a mission and vision;

— developing a strategic plan to achieve these; and

— implementing systems to support the realization of the strategic plan

In order to sustain the mission and vision, the organization should continuously strive to meet its environment using change and innovation. This will require continuous monitoring of the organization's environment, as well as its own situation.

The sequence of the steps needed for managing for sustainability follows the well known "Plan-Do-Check-Act" (or P-D-C-A) cycle (see 4.2). Aiming for sustainability means that the organization should always try to improve its ability to enhance the improvement part of the P-D-C-A cycle, supported by an autonomous management culture.

4.3 Managing for sustainability

The process of managing for sustainability generally follows the "Plan-Do-Check-Act" (or P-D-C-A) cycle. The relationships between the steps of the P-D-C-A cycle and managing for sustainability, is as follows:

a) Plan:

1) Intent

Is there a strategic aim related to the essential feature under consideration that reflects the needs of the organization and its stakeholders in a sustainable way?

2) Processes and structure

Are there appropriately well defined processes to address the aim for the essential feature being considered?

3) Resources

Are adequate resources planned and available for the working of this essential feature?

b) Do:

1) Implementation

Are the processes related to the essential feature implemented as planned? Are the processes cohesively linked to other organizational processes and features?

c) Check

1) Measurement

Are planned outcomes monitored and measured? Do the measures provide useful and efficient information concerning the working of the essential feature?

2) Check

Were processes and structures implemented or changed as planned? Were resources allocated and provided as planned?

3) Analysis

What has been achieved? Does the essential feature contribute to the sustainability of the organization? What needs to be improved?

4) Learning

What kind of learning did the organization acquire from its analyses?

d) Act:

1) Corrections

What kind of corrections were needed to ensure the achievement of the objectives the organization didn't meet initially.

2) Improvement

What kind of improvement activities were needed in processes, products, structures and systems?

3) Innovation

What kind of innovations and changes were needed to achieve the organization's articulated mission, vision and objectives?

A representation of sustainability improvement, based on the PDCA cycle, is given in figure 1 below.

4.4 Assessing sustainability

In order for an organization to determine its progress in the achievement of sustainability, it should perform an assessment of its strategy and operations. The results of such an assessment will indicate opportunities for enhancing sustainability, growth and improvement.

The results of an assessment are usually more balanced and complete when the assessments are conducted by teams.

Note Annexes A and B provide tools for assessing an organization's strategy and operations.

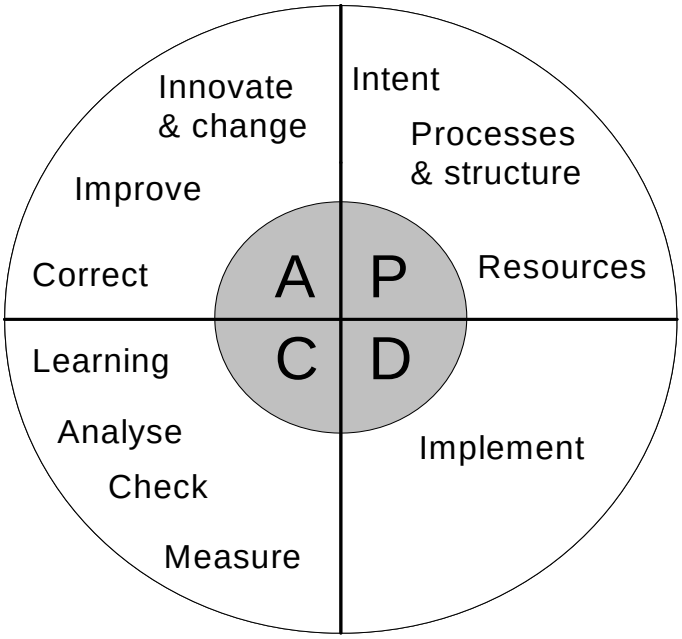


Figure 1. Sustainability improvement, based on the P-D-C-A cycle.

5 The organization's environment

5.1 General

All organizations, whether they are large or small, profit or not-for-profit, operate in external environments that are undergoing change. The monitoring and analysis of the environment in which an organisation operates are necessary to provide ongoing data and information, to enable decisions for organisational change that will maintain and improve the performance of the organisation.

5.2 Monitoring

Monitoring the environment of an organization usually includes, but is not limited to, collection and consideration of data that will help with:

— identifying and understanding the present and future expectations and needs of defined stakeholders (including Shareholders, Managers, Employees, Customers, Partners and Society),

— awareness of the threats and opportunities of alternative or competitive product offerings,

— assessing the threats and opportunities of emerging market/product opportunities that organisation may consider offering,

— understanding current customer trends, needs and expectations,

— obtaining an awareness of legislative and regulatory requirements and changes,

— understanding of the labour market and its effect on employee stakeholders,

— understanding the socio-economic trends and local cultural aspects relevant to the organization's areas of activities,

— spotting emergent technological changes,

— understanding current organisational and process capabilities,

— identifying and learning from good external practices in other organisations, especially for key processes that are similar to those used within the organisation..

5.3 Analysing

An organization should analyze relevant external data and propose scenarios as to their potential impacts, as essential inputs for the its policy and strategy formulation processes.

Data and information should be gathered in order to permit analysis of the following types of issues:

a) Whether the defined stakeholders have had their needs and expectations met as planned?

b) How the needs and expectations of customers and defined stakeholders might develop over time?

c) What functions of the organization's existing products provide most value for its customers now?

d) What products will the organization need to realize to meet the changing needs and expectations of customers and identified stakeholders?

e) How will the margins and the market for the organizations' existing products evolve in the mid and long term?

f) What new markets or opportunities may emerge?

g) What risks may emerge?

h) What changes can be expected in the legal and regulatory environment that will affect the organization?

i) How will the competitive environment develop during the mid and long term?

j) What distinctive features can the organisation offer to its chosen markets?

6 Strategy, policies and communication

6.1 Strategic orientations

The interaction between an organization and its environment is unique. Consequently, for sustainability, the organization needs to establish and deploy its own strategic orientations.

The organization should determine it's current and future capabilities needed for sustainability, through analysing its external and internal environment.. The strategic orientations should be based on filling the gaps between the organization's current capabilities, and those either needed to meet its current environment, or its predicted future environment. Additionally, the organization should develop strategic orientations based on the risks and opportunities identified from its understanding of those gaps.

The organization should review its strategic orientations and revise them as necessary, to ensure that the organization is capable of adapting to changes in its environment.

6.2 Mission and vision

By understanding and analysing the organisation's environment, its management should be able to establish a mission and vision for the organization, as well as the strategic orientations needed to achieve them.

A mission (why we exist?) and vision (what we want to be?) should be developed in light of external and internal analysis.

An organization should have an identified aim or purpose, within its social environment. The organization should identify its mission and vision on the basis of its understanding of its relationship to its stakeholders, their characteristics, and its own competencies.

The mission should describe the value which the organization seeks to create for its stakeholders.

The vision presents the state the organization wishes to achieve, once it is equipped with the necessary competencies.

6.3 Aspects of strategy

An organization should develop a strategy to fulfil its mission and vision, which is also directed towards the achievement of sustainability. This should include consideration of:

a) its external environment, including trends;

b) the needs and expectation of stakeholders;

c) its capabilities and resources; and

d) lessons learnt from previous experiences.

6.4 Policies and objectives

Policies and objectives define an organization's desired results and assist the organization to apply its resources to achieving these results.

The organization should establish policies and objectives, based on its strategy

— to provide a focus to direct the organization,

— to ensure that plans are communicated to all relevant stakeholders, and

— to assure that its policies and objectives are aiming for sustainability.

Policies that are based on the organization's mission, vision and strategy provide a framework for establishing and reviewing its objectives.

Objectives are used to put the policies into operation, i.e. they answer the question "what should be done to fulfil the policies"? The objectives need to be consistent with the policies and their achievement needs to be measurable. The achievement of objectives should have a positive impact on the organization's

— products,

— operational effectiveness,

— financial performance, as well as

— on the satisfaction, confidence and loyalty of stakeholders.

6.5 Strategic planning

In order to provide a framework for the proper allocation of resources, to incorporate success factors in the business domain, and to meet the needs and expectations of stakeholders, management should ensure that the organization's strategic plan gives consideration to the following:

— the organization’s environment;

— new opportunities;

— target markets and customers;

— products to be provided;

— the organization's capability profile;

— the allocation of resources;

— risk analyses.

6.6 Risk management

Any event that has the potential to affect the objectives of the organization negatively should be considered to be a risk for the organization; whereas an event that is able to affect the objectives of the organization positively should be considered an opportunity for improvement and innovation activities.

Risk identification should consider not only risks in cost, time and product quality, but also risks in areas such as organization’s reputation, security, dependability, professional liability, information technology, health and safety, and environment.

In order to develop its strategy, the organization should identify, analyse and understand the following, and identify the risks associated with them:

– technological trends;

– relevant needs of society;

– availability of natural resources;

– its capability profile, including the capabilities needed to realize its vision in the future; and

– its provision and allocation of resources.

6.7 Review of strategy for sustainability

In order to take account of the continual changes in the organization's environment, and to assess if it will achieve the mission and vision, management should periodically conduct reviews of the organization's strategy.

This review should focus on the following:

— whether the management system is effective, efficient and competitive;

— whether the strategy is translated into measurable objectives and guidance throughout the organization;

— whether the organization's structure and processes are appropriate for the intended strategy and able to meet potential changes in needs.

This should ensure that the strategy is appropriate and that the management system provides a useful method for obtaining external learning and insights on critical strategic processes. It should also enable a comparison and understanding of the organization's performance against competitors, or "world class" / "best in class" organizations, and that the risks of any identified differences or shortfalls are evaluated.

6.8 Communication

6.8.1 General

Experience shows that many costly problems in organizations have their root causes in poor communications, both internally and externally.

In order for relevant information (e.g. mission, vision, strategy, policies, objectives, operational data and feedback) to be conveyed effectively, the organization's management needs to establish a formal communications policy and associated internal and external communication processes.. This is important both for the organization’s identity and sustainability.

Internal communication considerations include

— keeping people informed and getting their commitment,

— gathering views on the organization and its performance,

— receiving and giving feedback and ideas for innovation,

— complying with statutory and regulatory requirements.

External communication considerations include

— keeping stakeholders informed and getting their feedback,

— promoting the organization’s identity,

— establishing contacts with other organizations, to facilitate learning,

— being proactive about building and maintaining relationships and networks,

— complying with statutory and regulatory requirements,

— influencing decision makers.

6.8.2 The effectiveness and efficiency of communication processes

The effectiveness and efficiency of the communication processes needs to be assessed and reviewed periodically to determine if there is a need for improvement or innovation.

Factors that influence the effectiveness of communications include

— planning and timing

— targeting communications to ensure that appropriate audiences will receive them,

— selectivity, adequacy and clarity of the information that is to be communicated,

— sufficient resources to support the communication channels and communication technologies,

— requiring confirmation that information was received and understood,

— integrity, confidentiality, security,

— the transmission of the communications in specific languages and formats (for example, electronic data exchange) appropriate for the specific stakeholders.

7 Resources

7.1 Management of resources

The organization should identify the resources that are critical to its development and achievement of sustainability, through its strategy and planning. This should include the resources needed for the operation and improvement of the systems for managing the organization and for the satisfaction of customers and other stakeholders.

In order to achieve sustainability, the organization should develop a plan for controlling, protecting and developing its resources.

Note 1 In order to achieve sustainability the organization will need to enhance its management of resources beyond the level required by ISO 9001.

Note 2 The resources available to the organization may not be limited to those inside of the organization, but may include external resources.

7.2 Planning

It is necessary for the organization to develop, implement and continually improve appropriate processes for the identification, development, provision, monitoring, maintenance and protection of resources. The extent of the protection needed to be applied to the resources depends on their associated risks of potential scarcity. The organization should periodically review the suitability of the identified resources.

7.3 Allocation of resources

Management should develop and implement processes to assess the resource needs of the organization and to establish the priorities for the allocation of the resources. In cases where a shortage of a resource cannot be resolved in an adequate time frame due to a systematic, recurrent, or concurrent cause, the resource planning process should be reviewed.

7.4 Human resources

7.4.1 General

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.

Human resource management should be performed through a planned, transparent and socially responsible approach.

The organization should motivate its people to understand the significance and importance of their responsibilities and activities in relation to the creation and provision of value for the organization and its stakeholders.

The organization should systematically seek to improve their competence to create such value through training, empowerment and knowledge exchange.

In order to ensure that people in the organization have the competence needed for the creation and provision of customer value, the organization should establish processes to develop and improve the competence of its people.

To enhance its people’s satisfaction, the organization should also consider

— developing a mechanism to share and use the wisdom of its people, e.g. a suggestion scheme,

— defining personnel systems, such as for reward and promotion,

— introducing an appropriate recognition system and assessing the people's accomplishments,

— establishing a skills qualification system to promote self-development, and

— continually reviewing the satisfaction and needs of its people.

To determine whether its people have the necessary competence, the organization should review the current competence of its people, analyzing it by using various competency assessment models, and identify the competence that needs to be developed.

To satisfy its competence development needs, the organization should establish an appropriate human resource development plan.

The development plan should consider training and strategic human resources management.

The organization should

— take a mid/long-term standpoint on competences needed in light of the organization's vision and business strategy,

— select learning techniques suitable for the development of competence,

— define indicators for evaluating effectiveness of the learning,

— implement the learning and keep relevant records,

— evaluate effectiveness of learning against their purposes in a timely manner, and

— evaluate the effectiveness of the implementation of the organization's key beliefs.

7.4.2 Involvement and motivation of people in the organization

The management should ensure that the people in the organization understand the importance of their contribution and roles in

— identifying constraints to their performance,

— accepting ownership and responsibility to solve problems,

— evaluating their performance against their own personal goals and objectives,

— actively seeking opportunities to enhance their competencies, knowledge and experience,

— freely sharing knowledge and experience.

7.5 Infrastructure

7.5.1 General

The organization should plan, provide and manage its infrastructure effectively and efficiently (e.g. physical assets such as buildings; information communications technology or ICT; machinery and equipment etc).

It should consider the dependability, safety, security, cost, and environmental impact of its infrastructure in relation to its objectives. The organization should review its infrastructure and its related management processes at defined intervals, in order to ensure that the infrastructure meets its current and expected future needs.

The organization should identify the risks associated with its infrastructure, consider their consequences, and protect the needs of its stakeholders.

7.5.2 Work environment

The organization should ensure that the work environment complies with all applicable regulatory and statutory requirements (including those for occupational health and safety). At the same time the organization should look for ways to maintain sustainability and competitiveness by encouraging productivity, creativity and well-being at work for the people in the organisation and all other personnel who may be working at, or visiting, the organization's premises (e.g. customers, suppliers, partners etc.).

7.6 Knowledge

The organization should treat information, knowledge and technology as essential resources. It should develop, implement and maintain processes to identify, obtain, maintain, protect, use and evaluate the information, knowledge and technology it needs. The organization should share such information, knowledge or technology with its partners or other stakeholders, as appropriate.

7.7 Financial resources

The organization should forecast and determine its financial needs and acquire the necessary financial resources (resources for actual operation and for future investments purposes) to meet those identified needs. The management should develop and implement processes for monitoring and controlling the use of financial resources, as well as for realizing their effective and efficient allocation.

7.8 Natural resources and life cycle management

The efficient use of natural resources (such as energy, water, oil, minerals, raw materials etc.) is indispensable for the sustainability of the organization and for conservation of the natural environment. It is necessary for the organization to consider the risks/opportunities related to the availability of such resources not only in the short, but also in the mid and long term. Additionally, the organization should analyze whether there may be any side effects from their exploitation, use and disposal.

Life Cycle Management (LCM) is a business decision-making approach that considers benefits, costs and risks over the full life cycle of a product. It covers areas such as: dependability (reliability, availability, maintenance, maintenance support), obsolescence and disposal.

Life Cycle Management puts information in front of decision makers that can contribute to the development of competitive advantages for the organization, e.g. through cost reductions. In addition, organizations that apply LCM are viewed as being in step with important environmental policy trends, which can enhance their public image.

The life cycle management approach examines all stages of the product or service (i.e. from initiation to final disposal).

Quality and dependability should be designed into a product. The design process should also consider aspects such as the need for low failure rates, easy maintenance, and the availability of spare parts (including their supporting logistics).

Minimizing the environmental burden should be considered for design, manufacturing of a product or execution of service, distribution, product use and disposal. Examples of tools that may be used to analyze the environmental burden include life cycle assessment (LCA), design for environment (DfE), and environmental benchmarking.

The organization should also consider the development of a plan to apply responsible practices and actions in terms of ensuring the uninterrupted continuous provision of energy as needed, while protecting the natural environment and saving its resources.

8 Processes

8.1 The process approach

An organization should use a "process approach" to facilitate the effective operation and interaction of its processes, and should develop the interrelating strategic and operational processes necessary for the achievement of sustainability. Benefits of the process approach include

a) the achievement of planned results,

b) the improvement of the effectiveness and efficiency of the organisation,

c) the provision of confidence to customers, and other stakeholders, about the consistent performance of the organization,

d) transparency of operations within the organization,

e) lower costs and shorter cycle times, through the effective use of resources,

f) improved, consistent and predictable results,

g) provision of opportunities for focused and prioritized improvement initiatives, and

h) encouragement of the involvement of people and the clarification of their responsibilities.

8.2 Types of processes

Processes are specific to the organization, and will vary depending on its type, size and degree of development. Process can be identified in terms of the following types:

a) Management processes

These include the processes relating to strategic planning, establishing policies, setting objectives, providing communication, ensuring availability of resources needed, life cycle management and management reviews. This includes all the processes for the provision of the resources that are needed for the realization of organization's objectives.

b) Realization processes

These include all the processes that provide the intended output of the organization. (e.g. design, manufacturing processes, service delivery processes, after-sales servicing).

c) Support processes

These include all those processes needed to contribute directly or indirectly to the realization processes (e.g. financial, training, maintenance, marketing, sales, quality management).

8.3 Managing the organization's processes

To achieve sustainability it is necessary that an organization identifies and manages all the processes that are necessary for achieving its objectives, and clearly defines how these processes interrelate and interact.

Note: for more information on the identification, planning, implementation and measurement of processes, see the paper giving "Guidance on the Concept and use of the Process Approach for management systems" available from www.iso.org/tc176/sc2.

8.4 Process responsibility and authority

It's crucial that the management appoint a person with defined responsibilities and authorities to implement, maintain and improve each process and its interaction with other processes This individual is usually referred to as a "process owner".

Management should ensure that the authority, role, mission, rights and duties of the process owner is recognized throughout the organization.

The organization should also establish arbitration procedures in case disputes arise over the management of the processes.

9 Measurements and analysis

9.1 Measurement approach

Reliable measurement data are an important input for an organization aiming for sustainability. This will also enable a factually based approach to management and priority setting. The organization should monitor and/or measure systematically the performance of all relevant processes. The measurement approach adopted should be related to the criticality of the processes involved and the objectives stated for these processes.

In planning its measurement approach, the organization should give consideration to the following:

— determining where, how and why measuring and monitoring should be applied. The aim should be to improve the performance of the organization's processes and to improve their outputs;

— recording the results of these activities;

— verifying that all process objectives are met; and

— taking corrective action when objectives are not met, for example by means of additional process activities, or new policies and objectives to improve the process.

9.2 Performance metrics

A robust set of performance metrics, put into context by the use of comparative data, allows the management to monitor trends in the performance of an organization. The organization should identify its key performance indicators. To be capable of signalling approaching risk or potential opportunity an organization needs to employ a broad set of performance metrics that address the desired outcomes and processes deployed.

The organization's management should consider:

— the performance indicators for the processes of the organization, including input, in-process and output measurements;

— the level of satisfaction and expectation(s) of all stakeholders;

— the correlation between process parameters and the desired results (outputs) that will enable specific, measurable, achievable, realistic and timely process objectives to be set;

— the performance gaps with other organizations;

— tracking results to identify trends in key process parameters.

Examples of performance metrics include customer satisfaction levels, supplier performance, on time delivery, lead times, failure rates, waste, process costs, incident frequencies etc.

The criteria for measuring the effectiveness and efficiency of a process should be consistent with the objectives set for its outputs. These should, in turn, be consistent with the strategy of the organization.

9.3 Measuring achievement of objectives

An organization should monitor carefully the degree and speed at which it achieves its objectives, by defining appropriate key indicators of performance, by using effective tools to gather information, and by comparing the information gathered against the established objectives.

9.4 Key indicators

Key indicators can relate to processes, products, customer satisfaction, and the satisfaction of other stakeholders (such as shareholders, people in the organization, partners, suppliers and society).

Key indicators can take many different forms, and typically relate to one of the above topics. The following list gives some examples:

— the effectiveness and efficiency of the organization's processes (including parameters such as speed, productivity and competitiveness);

— the "voice of the customer" (commendation or complaints);

— the performance of products (as identified through market share, sales, profit etc.);

— the loyalty of customers;

— the image of the organization (as identified through benchmarking, or brand image);

— opinion and dissatisfaction expressed in shareholders meetings;

— the organization's credit rating;

— evaluations of the organization performed by external bodies;

— impact on the natural environment;

— safety records;

— contribution to society (culture and community);

— degree of legal compliance;

— opportunities for sustainable employment; and

— the cost of non-quality.

9.5 Measurement tools

The methods used for collecting information regarding key indicators should be practicable and appropriate to the organisation’s circumstances. Typical examples are:

— interviews, questionnaires and surveys;

— monitoring trends in levels of nonconforming product;

— monitoring the time taken to deal with customers;

— monitoring levels of machine downtime;

— monitoring customers' reaction during meetings with their representatives;

— monitoring trends in sales figures;

— supplier reviews carried out by the customer;

— feedback from field visits to customers; and

— suggestion schemes.

9.6 Internal audit

Internal auditing is potentially the most important improvement tool available to an organization’s management, and great attention should be given to its planning and implementation. Internal audits are an important means of monitoring the level of achievement of objectives and the causality behind lower or slower improvements than expected.

The critical element of internal auditing is the effective closing out of non-compliances by identification of their root causes and the corrective actions taken to eliminate them.

9.7 Assessment

Assessments are a proven means of determining the degree of sustainability of an organization.

Assessments should examine whether the organization has the capability at an overall level and at the level of its individual processes to achieve the outputs expected, and evaluate whether sufficient physical, financial and human resources are available to support its achievement of those outputs.

In preparing an assessment (see Annex A) the organization should consider:

— the purposes and scope of the assessment,

— the competence needed by those who will perform the assessment, and

— the development of detailed implementation plans, including schedules and procedures.

The organization should include the results of the assessment as inputs to the management review of the strategy, to use them for continual improvement and innovation of the systems, management and leadership.

The results of the assessment should be communicated to those concerned in the organization, and be used to share understanding about its environment and the future direction of the organization.

9.8 Review and evaluation of processes

An organization should use a systematic approach to reviewing and evaluating its processes, for sustainability improvement (see Figure 1), as follows:

a) Intent

The organization's aims and approaches for the measurement and analysis of its processes should be evaluated against the impact, effectiveness and timeliness of the data collected, and whether these support the achievement of sustainability.

b) Process and structure

The process of measurement and analysis should be evaluated against the adequacy and availability of the resources used.

c) Resources

The resources used for the measurement and analysis process should be evaluated against the expected effectiveness and efficiency in measuring the degree of contribution of the processes, structures, resources and products, to the sustainability of the organization.

d) Implementation

The degree of the implementation of the chosen measurement and analysis process across the whole organization (inside all relevant processes or units) should be investigated.

e) Measurement

The effectiveness of the measurement process, for the performance of the measurement and analysis process itself, should be reviewed periodically. This is to ensure that it adequately supports the decision and priority setting process inside the organization. Benchmarking should also be used as a part of this review, in order to compare the organization's own process against similar “state of the art” processes.

f) Analyze

Periodically, the organization should review how good its measurement and analysis process is. This should include an analysis of the requirements on the data to be delivered by this process, and of the impact of the use of this data, on the abilities of the organization to achieve sustainability.

10 Learning, improvement and innovation

10.1 General

An organization should be able adapt to changes in its business environment in order to achieve sustainability. Consequently, it needs to have the capability to recognize when such changes are occurring, and to innovate in response to them. Its response should be guided by what it has learnt in the past, or from how other organizations have responded in similar situations

Sustainability requires the organization to have the ability to learn. In an organization with an advanced learning ability, it is possible to sophisticatedly and effectively use the wisdom gained by the organization from its people, to build up its core competence, and to promote continual improvement and innovation.

An organization should use innovation to continually improve its effectiveness and operational efficiency, as an additional route towards achieving sustainability.

10.2 Learning

10.2.1 Type of learning

The organization should understand the importance of learning for remaining aware of trends and changes that could impact on its sustainability and for obtaining necessary capabilities for sustainability.

Sustainability requires learning ability in the following two aspects:

a) the learning ability of an organization – i.e. the ability of an organization to collect information on, analyze, and gain insight from external events, including events in the business environment,

b) the ability to integrate personal competence and organizational competence – i.e the ability to integrate the knowledge and thinking/behavioural patterns of the people in the organization into the value system of the organization.

10.2.2 Sources of learning

The organization should find and take advantage of both internal and external sources that can be used as the basis of learning.

Internally, learning results from the sharing of experience, knowledge and information across functional divisions within the organization, on such matters as

— networking with external partners,

— best practice within the organization,

— problems, errors and “near mistakes”, and

— behavioural / thinking patterns in the organization.

External sources include

— market changes relating to changing customer needs,

— trends in all relevant fields,

— benchmarking against successful organizations,

— political changes,

— changes in technology,

— universities and other educational institutions, and

— experts and consultants.

10.2.3 Factors influencing learning effectiveness

Management should ensure that the organization promotes learning based on the autonomy of its people and that it establishes the culture of a learning organization.

In order to learn effectively, the organization should consider the following issues, and act on them appropriately

— management initiatives in learning and showing its leadership,

— stimulation of networking, connectivity, interactivity and sharing of knowledge

— establishing efficient channels of communication,

— respecting its people's competence and supporting improvement of it,

— appreciating creativity, accepting heterogeneity and tolerating failures,

— recognizing and rewarding positive outcomes,

— making available an open access system for learning,

— a readiness to accept lessons from internal and external sources,

— providing its people with opportunities to exchange ideas, knowledge and experience both inside and outside the organization,

— the effective use of information and knowledge of either internal or external origin, and

— being open to criticism.

In order to establish a culture of a learning organization, management should ensure that the organization promotes the integration of personal competence/knowledge into organization's capability/knowledge.

Management should ensure that the organization promotes the maximization and optimization of the results of learning.

10.2.4 Planning of the learning process

The organization should establish a process for learning that takes into account the following:

— the needs of customers and other stakeholders, and changes in those needs,

— changes in the technological capabilities necessary to meet needs of the stakeholders,

— changes in the competitive environment and factors affecting competitive advantage,

— the capability to collect and analyze various types of information, and

— the gaining of necessary capabilities.

10.3 Improvement

An organization's improvement activities should focus on the processes needed to improve the satisfaction of stakeholders, as well seeking to improve its products.

The organization should define objectives for the improvement of its products, processes and management system, and should seek to improve them continually and systematically.

Management should ensure that continual improvement becomes established as part of the organization's culture through:

— providing the opportunity to participate in effective improvement,

— recognition and reward, and

— small group activity.

10.4 Innovation

10.4.1 General

Innovation is essential for sustainability; it needs to be based on the organization's learning ability. The organization should carry out innovation in its capabilities and organizational constitution, as is necessary to ensure its future success. Innovation may mean entirely or partially eliminating the existing framework of the organization and constructing a new framework, which will require wisdom gained through its learning.

10.4.2 Type of innovation

Management should understand that major changes in the organization's environment may require breakthrough innovations, and not mere improvements to the organization's existing situation, for sustainability. Innovations should be allowed to be realized whenever necessary.

Innovation includes the following:

a) innovation in technology or product, i.e. innovation to respond to changes in the business environment and product lifecycle;

b) innovation in the business model, i.e. innovation to ensure that competitive advantage is maintained and new business opportunities are realized, when there are changes in the business environment;

c) innovation in the organization, i.e. innovation in the organization's constitution in response to changes in the business environment;

d) innovation in processes, i.e. innovation in the methods for product realization.

The design, implementation and management of processes for innovation within an organization will be influenced by its respective needs, particular objectives, products produced, processes used, size and structure.

10.4.3 Factors influencing the effectiveness of the innovation

Innovation by organizations is influenced by their respective needs, objectives, products produced, processes used, size and structure.

The organization should consider the following factors in identifying opportunities for sustainability

— detecting indications of change,

— understanding the reality accurately,

— management’s commitment to innovation,

— a willingness to challenge and change the status quo,

— identification of the barriers to innovation, and

— exchange of knowledge and expertise internally, and with partners/suppliers outside the organization.

10.4.4 Planning of the innovation process

In order to achieve sustainability, the organization should consider

— the possibility that its processes and/or products may become obsolete, thereby putting its very existence at risk,

— the need to innovate its processes and/or products, in order to meet customers' needs and expectations and to create new value for its stakeholders, and

— the possibility of identifying or creating new customer needs, and thereby creating new market opportunities.

The organization should take advantage of the following factors in the planning of innovation

— the results from reviews of its strategy for sustainability,

— the results of activities to improve its quality management system,

— the results from reviews of its business strategy,

— the organization's performance (such as market share, sales, profits, and rating),

— the results of assessments,

— the identification and prioritization of objectives,

— its internal situation, in terms of factors such as skills and knowledge, availability of resources, and existing functions within the organization that could be used for innovation,

— the external situation, in terms of considerations such as the availability of scientific or technical information,

— the availability of methods for innovation, and

— expected benefits and risk factors.

Innovation based on learning ability is essential for sustainability. Sustainability is made possible only when the organization detects changes in its business environment, understands its core competence and innovates in its capabilities and organizational constitution as necessary.

Annex A
(Informative)

Maturity assessment tool

A.1 Introduction

Organizations should use an assessment tool, similar to the one in A.2 below, to determine their maturity level, i.e. how well their essential capabilities are developing and growing towards the achievement of sustainability.

The use of such a tool (along with the guidance given in clauses 4 to 10) should enable an organization to identify specific areas for improvement and to establish any action plans needed for the organization's further development.

The results of an organization's assessments should be a valuable input into its management review process, for both strategic and operational issues; consequently such assessments should be conducted periodically.

Experience demonstrates that the results of assessment are more balanced and complete when the assessments are conducted by teams.

A.2 Description of the maturity levels

Prior to using this assessment tool, users should familiarize themselves with the maturity levels described in table A1 below.

The maturity levels describe the degree of development of the capabilities of an organization and are given on a rising scale from 1 to 5. The maturity levels are derived from the eight quality management principles (see ISO 9000:2005, clause 0.2).

Table A.1 – Description of the maturity levels

Level 1 **Beginner** organization	Level 2 **Proactive** organization	Level 3 **Flexible** organization	Level 4 **Innovative** organization	Level 5 **Sustainable** organization
Management focus on production and rendering the service. No systematic approach and planning of activities. Unpredictable results. Improvements as reactions to request or complaints	Customer oriented management. Quality Mgt System implemented. Some results are predictable. Corrective and preventive actions systematically performed.	The strategic plan addresses customers and stakeholders. Process based approach. Effective and agile Mgt.. Systems. Results are predictable.	Balanced focus on stakeholders Effective interrelated process approach. Consistent, positive, results and sustained trends. Continual improvement based on learning and culture of sharing.	Ability to maintain and develop its performance in the long term.

A.3 Strategic assessment

A strategic assessment is an activity that should be performed by top management, to obtain a quick overview of the organization's maturity.

It is based on four critical criteria (see figure A1) that are related to the guidance given in clauses 4 to 10 and in accordance with the "continual improvement" aspect of the "Plan-Do-Check-Act" (PDCA) cycle. The tool uses different scenarios (see annex B1) to describe the key characteristics that relate to the corresponding maturity levels.

Such a strategic assessment should only take approximately one to two hours to complete.

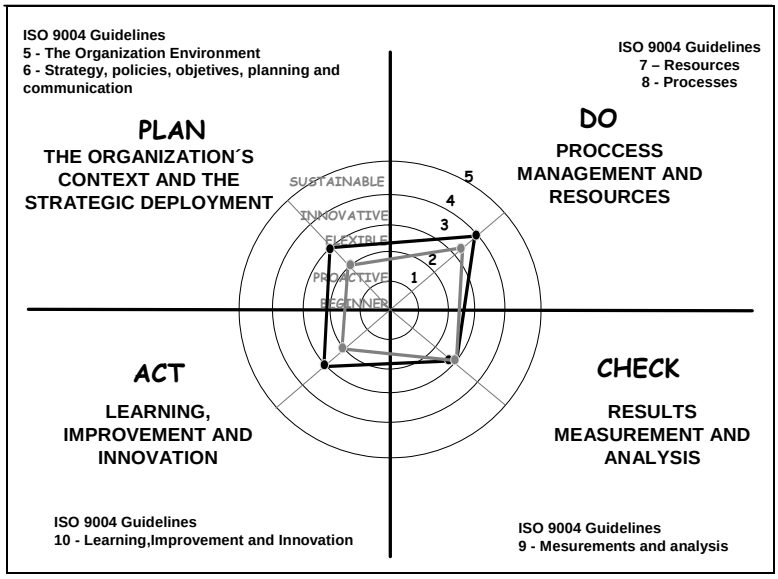


Figure A.1 — Example of the results of a strategic assessment

A.4 Operational assessment

An operational assessment is an activity that should be performed by process owners, to assess the essential capabilities of an organization, relative to the guidance given in clauses 4 to 10 (see figure A2).

It should take approximately 1 day to complete such an assessment, including the time needed for correlating the results against the relevant sections of this International Standard (see annex B2).

A.5 Using the assessment tool

The present situation in the organization should be compared to the descriptions of the maturity levels shown in annex B, starting with level 1 and "climbing" to higher levels as far as the capabilities described are clearly demonstrated. The current maturity level is the highest level fully achieved without there being any "gaps" in the required capabilities.

A review of the gaps between the current level and the next level will help the organization in planning and prioritizing the improvement actions needed to move towards sustainability.

A.6 Assessment results and improvement planning

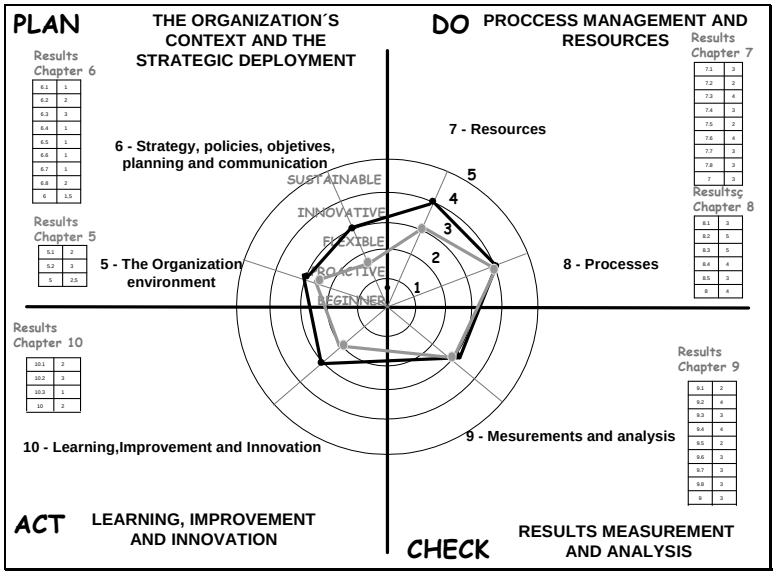


Figure A.2 — Example of the results of an operational assessment.

The completion of an assessment should be recognized as an important step in identifying opportunities for the future development of the organization

The information gained from such an assessment should be used to stimulate comparisons throughout the organization, between its processes and between its different business units, to identify opportunities for improvement. It should also be used as an input into the planning of future assessments.

For ease of understanding and communication, the results of assessments should be presented in a way that gives a quick visualization of the organization's maturity status against the guidance in clauses 4 to 10, and against the "continual improvement" aspect of the "Plan-Do-Check-Act" (PDCA) cycle. The types of graphs shown in Figures A1 and A2 are examples of such a presentation. This will assist in the identification and prioritization of opportunities for improvement, as well as in identifying those that may yield the maximum improvement at the lowest cost. The consistent use of this type of presentation will present an ongoing illustration of the organization's progress.

An analysis of the results, against the guidance in clauses 4 to 10, should be taken forward into the development of an improvement plan for the organization.

Annex B
(Informative)

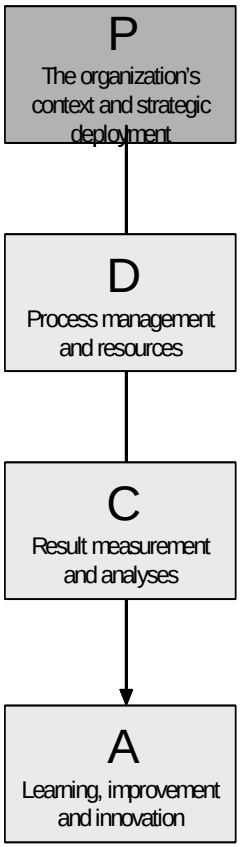
Maturity level assessment sheets

This annex contains descriptions of the maturity levels for the assessment tool detailed in Annex A.

Table B1 gives strategic maturity level assessment sheets, and Table B2 gives operational maturity level assessment sheets.

Note ISO 10014:2005 *Quality management systems — Guidelines for realizing financial and economic benefits* provides additional guidance that may be useful to organizations that wish to customize the assessment tool.

Table B.1 – Strategic maturity level assessment sheets

Level / Focus area	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
	The organization's focus is on its economic results, product performance, and compliance with some legal requirements. The organization's environment is not considered, except occasionally in a reactive approach. Information from the market is not systematically collected and the organization has no capability to anticipate on changes. The organization has not defined a formal strategy and only performance and economic objectives are stated. Departmental objectives are not aligned with the strategy. Communications only apply to financial, regulatory and legislative requirements, in a reactive way. Processes, resources and structure are not defined or planned in a systematic way. Tasks, responsibilities and authorities are unclear.	The organization has defined its Mission, Vision, Strategy and Objectives. Strategic intentions are limited to: financial results, regulatory and legislative requirements and customer satisfaction Objectives are aligned with the organization's strategies. Management communicates policies related to the quality management system to the entire organization. There is some monitoring and analysis of the organization's environment. The organization promotes communication with its main interested parties such as customers, suppliers, shareholders and personnel. Processes, resources and structure are defined, implemented and periodically reviewed according to the chosen strategies.	The organization has formally defined its Mission, Vision, Strategy and Objectives. Periodical reviews take place to ensure the flexibility of the organization in accordance with its environment, needs, and its strategy. The strategy takes into consideration the main interested parties. The objectives are aligned with the strategies and deployed. The organization has implemented a continuous improvement approach. The organization environment is monitored and analyzed, to improve the organization and to identify opportunities and risks. The organization has identified opportunities for communication and getting feed back as an input for improvement. Processes and structure are defined and seen as a system. . The organization plans and provides the necessary resources to achieve the objectives, accordingly to its strategies.	The organization environment is monitored and analyzed, to improve the organization and to identify opportunities and risks. Customer needs, legislative and regulatory requirements, its own experience and information related to internal and external environment opportunities and risks are collected and considered as inputs for innovation The strategy takes into account all interested parties, and is reviewed to improve continuously its efficiency and effectiveness. Periodical reviews of Mission, Vision, Strategy and Objectives take place to determine the capabilities needed for improvement and innovation. Gap identification and risk management are taken into consideration. The organization plans and provides the necessary resources to achieve the objectives. Communication processes are effective and efficient, and include contacts with other organizations to facilitate effective learning, Communications support the building of relationships and networks for innovation. .	Customer needs, legislative and regulatory requirements, its own experience and information related to internal and external opportunities and risks are collected and considered as inputs for sustainability. Periodical reviews of Mission, Vision, Strategy and Objectives take place to determine the capability needed for sustainability through external and internal environmental analysis and experience. The strategic orientation covers all gaps between the capabilities needed and the ones currently available, as well as the opportunities and risks being identified, based on an understanding of the organization's gaps. The strategy is the main tool to manage the organization and its results towards sustainability. The strategy includes specific policies and objectives related to specific interested parties triggering excellent results for the organization. The organization's main indicators are continuously benchmarked to maintain a competitive advantage. The organization plans and provides the necessary resources to achieve the objectives and sustainability.

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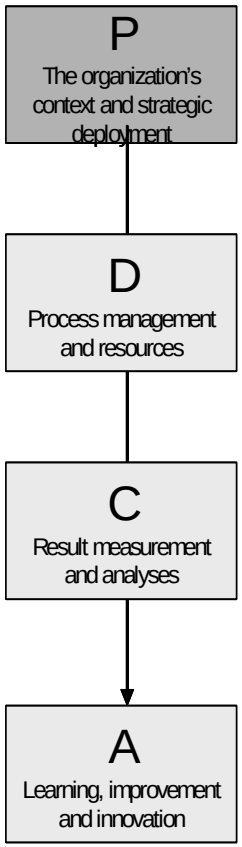
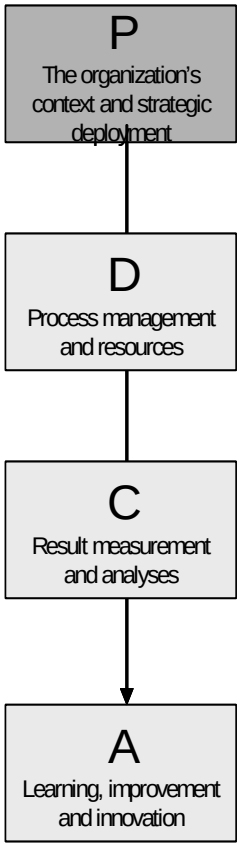
	Resources are identified for operational processes only. The organization determines its needs and necessary resources without monitoring and controlling. No identification or plans regarding natural resources and the impact on natural environment. The processes are not identified and there are no objectives for these processes.	The organization has identified resources for operational processes and for the customer related processes. There are processes to identify natural resources (e.g. energy, water, oil, minerals) The management has defined objectives for improving the effectiveness of the processes. Processes are aligned with strategy and policies.	The organization has implemented managerial, operational and supporting processes and has identified the necessary resources. Process for improvement of the management system is in place, related to the expectations of the main stakeholders. Plans are made for use, control, protection and development of the resources including the natural resources. Objectives for improving the effectiveness of the processes are stated. Objectives are aligned with some of the strategies and policies.	The processes are aligned with mission, vision, strategies of the organization. The organization has implemented and improved effective and efficient strategic, operational and support processes, including relations with all relevant interested parties. The processes work in integrated way; the process owners have defined objectives deployed from the strategic plan, which includes innovation and improvement. The organization has developed an effective and efficient plan for controlling, protecting and developing its resources. The organization has developed and implemented a process to use the natural resources efficiently, considering the availability of these resources. This process takes into account the environment issues during the entire life cycle of the products. Processes and structures, seen as the parts of a system, are defined, implemented and periodically reviewed according to organization strategies.	The organization has identified strategic resources to develop and achieve sustainability through its strategy and planning. The organization has developed an effective and efficient plan for controlling, protecting and developing its internal and external resources. The efficient use of natural resources, the minimization of the environment impacts and the conservation of the natural environment contributes to sustainability of the organization. Processes and structures, seen as a part of a system, are defined, implemented, maintained and periodically reviewed according to strategies, with aim to achieve and ensure sustainability.

Table B.1 – Strategic maturity level assessment sheets

Level / Focus area	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
	Only financial indicators are used, in combination with some basic non-financial indicators (like on-time delivery, number of customers complaints, basic customer satisfaction surveys.).	Periodical Quality Management System review meeting includes qualitative goals, quantitative targets, main processes performance, product quality indicators and customer satisfaction measurements. There is not clear link between goals and performance indicators. Accuracy of data that made up indicators is not known and data analysis is very basic. Capability studies of main realization processes are conducted, mostly based on customer requirements, conclusions are of limited use.	Management decisions are data driven. The organization relates the important goals to performance indicators. New plans are followed by metrics and indicators. Managers are trained and skilled in basic statistical analysis. If necessary, managers are supported by data analysis specialists. This leads to data brake-down to meaningful conclusions. In addition to Formal Quality Management System Review, a data analysis report is issued monthly or even weekly. This report is considered as a useful "navigation compass" by managers. Data accuracy is audited. R&R studies are performed, particularly when data comes from judgements, opinions, etc. Statistical analysis made to support decisions. Data is deeply analysed in order to identify root causes and to define action plans. The organization has business intelligence tools to "mine data" as required by changing situations. The capability (i.e. variability) of new, critical processes is systematically studied and variation components are known. When appropriate advanced statistical techniques as Robust Design are used.	Organization policies, goals and vision are deployed to the organization structure and processes. This deployment links the policy, goals and vision to consistent performance metrics and process indicators and covers all significant aspect of the organization. These indicators are stratified through the organizational levels covering all significant financial, operational aspects but not the full aspects related to the stakeholders (e.g. employee satisfaction index). Main operational indicators are reported in official reports (e.g. letter to shareholders). Most of the main organization indicators show competitive levels against the reference information. These results are considered in future objectives setting.	The organization includes indicators for all sustainability constraints for the organizations and these indicators are highlighted. Indicators used cover all significant aspects of the organization related to the stakeholders. Aspects critical for sustainability of the organization are the cornerstones of policies and strategies. These aspects are monitored and related to strategies designed to reduce the impact of these constraints upon the organization.

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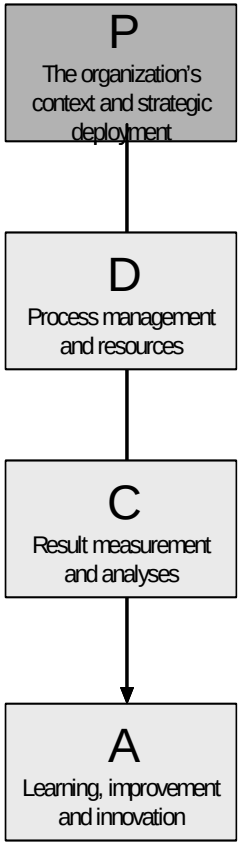
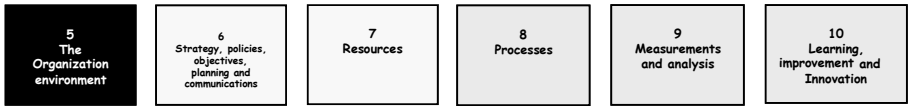
Level / Focus area	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
	Learning, improvement and innovation of the organization is not covered by strategies and policies. The organization has not defined a way how to take advantage of the internal knowledge. The improvement of products and processes is realized in ad-hoc way, following the regulatory requirements or the customers' complaints. The organization creates and introduces new products solely based on the ad-hoc requests from sales process.	The organization has defined its policies for learning and improvement of processes and products. The organization has established a management system for continuous improvement of processes. Results are evident via measurements and audits. Training programme is defined and adapted to the changing technologies used in the products and processes. Analyses of the customer needs and expectations are systematically performed to improve the existing and to generate new products. The organization uses external references to improve the management system, as for example the norm ISO 9001.	The organization demonstrates continuous stream of improvements, with implication for the development of personnel. Improvements are based on wide participation of personnel. Some people in the organization are involved in the management of the knowledge, but process is not formalized. The organization favours an environment of work suitable for improvement, innovation and the learning. Vertical and horizontal communication exist and support the evolution of the innovation and improvement processes in the organization The training programme is adapted to the changing needs both of the processes and of the products of the organization, concerning most of the personnel	The organization has defined and implemented an appropriate innovation process, which affects both the processes and the products. Knowledge management system is in place, using information and communication technology, focused on the sharing of the experiences of the personnel The system of management is improved, using approaches and tools for excellent management, based on the assessments of own situation. Training and learning programme of the organization is based on current and future needs defined in collaboration with the relevant, chosen interested parties.	The processes and products have been improved up to top level, being considered the best in class inside its sector. The knowledge management is considered to be the key for the success of the organization on strategic and operative level. Building and sharing of knowledge is seen as being the base for effective and efficient innovation process. The organization has defined a plan for innovation, which forms a part of strategic plan developed by works teams, formed and focused on establishment of new concepts, innovative products and efficient processes. The organization is considered sustainable leader, for its aptitude to generate innovative products, efficient and respectful processes, with good economic results, and appropriate social and environmental impact

Table B.2 – Operational maturity level assessment sheets



Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
5.2 Monitoring	The organization has not identified its stakeholders and/or the organization has not defined key information channels to monitor the environment in which it operates beyond its commercial relations with clients The organization only looks for external information when management and/or product and/or service related problems arise.	The organization has identified its stakeholders and has established channels of information with its clients and suppliers The organization updates the information about applicable legislative and regulatory requirements and commits to comply with them. The organization has information on its operating market and uses it to design its long term strategic plan. The organization knows and develops its current capabilities across processes	The organization has established communication channels with its stakeholders and obtains from them relevant information to focus better on products and/or services The organization updates information on technology and innovation that can affect its products, services and processes The organization collects and keeps updated relevant macroeconomic information for later analysis	The organization searches for information about good external practices in other organizations and learns from them for improvement purposes. The organization innovates both its products/services and its processes, always looking for differentiation and added value The organization updates information on local cultural aspects that can affect its activities	The organization pro-actively investigates the current and future needs of stakeholders The organization is recognized as the best in class regarding innovation, technology, competitiveness and social impact
5.3 Analysing	The organization has not defined its policy and strategy in a formal way The organization does not investigate in a systematic way external relevant information Only economic and financial objectives have been defined.	The organization has defined its policy and strategy, on the basis of information of the market, its customers and suppliers The organization evaluates the level of fulfilment of its customer needs.	The organization analyzes the possible areas of future operating markets and the keys for differentiation The organization analyzes the possible legislative and regulatory changes and their possible impact on its processes, products and services	The organization evaluates and checks in a constant way its aptitude to satisfy and to go beyond the needs of its stakeholders The processes of the organization ensure the quality and the innovation of its processes, products and services, measured across results indicators	The organization extensively analyzes possible situations on the basis of different emergent risks and opportunities and is prepared for potential changes. The sustainable level of the organization is analyzed in a constant way as well as the value added of products and / or services for the stakeholders

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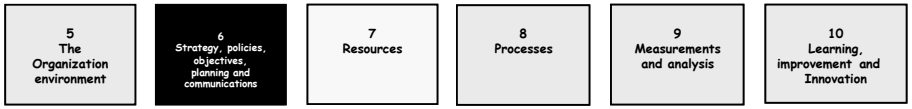
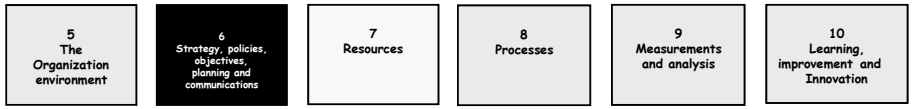


Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
6.1 Strategic orientations	The organization has not performed an analysis of its environment's evolution, nor defined future strategies.	The organization has made an analysis of its environment's evolution and of its internal capabilities that are necessary to satisfy it, while establishing and unfolding necessary strategies.	The organization systematically analyses its environment's evolution and its internal capabilities to satisfy it, while establishing and unfolding the necessary strategies. The organization evaluates periodically its defined strategic orientations to ensure that they are adequate and effective, modifying them when necessary.	The organization systematically analyses its environment's evolution and its internal capabilities to satisfy it, while establishing and unfolding the necessary strategies based on the necessities and expectations of the stakeholders, learning and experiences. The organization evaluates periodically the strategies defined to ensure that they are effective and efficient.	The organization has monitoring mechanisms in place which allow to identify at any moment the trends in its internal and external environment and to adapt continually its strategies and capabilities.
6.2 Mission and vision	The organization has not defined its mission or vision.	The organization has defined its vision, and counts on strategies to achieve it, although not the mission.	The organization has information about its environment, internal and external, which allows establishing the mission, the vision and the strategic directions to achieve them. The organization periodically reviews and evaluates the effectiveness of the mission and the vision adapting it to the needs of the environment.	The mission and the vision besides of being based on the knowledge of the relations with the stakeholders, also consider the competition. The vision and the mission are reviewed in terms of effectiveness and efficiency and adapted continuously on the basis of the changing needs and expectations of the market and stakeholders.	The mission and the vision of the organization provide continually value for all the stakeholders, is dynamic, lean on the information technologies and it is committed as much with the social responsibility of nowadays as in the future at all the levels.

Table B.2 – Operational maturity level assessment sheets



Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
6.3 Aspects of strategy	The organization has not identified the different parameters on which to base its strategy.	As a foundation, the organization bases its strategy on the products/services related customers' needs and expectations.	The organization does not only base its strategy on the products/services related customers' needs and expectations but also considers its capabilities and necessary resources in order to satisfy them.	The organization has established an agile and dynamic process to develop the strategy, based on aspects such as: the work environment, the needs and expectations of the stakeholders, the capabilities and the availability of resources and the learned lessons from previous experiences.	The strategy is a faithful reflection of the vision and mission of the organization and it is translated in policies and objectives in short, half and long term, which assures the sustainability of the company in all its scopes.
6.4 Policies and objectives	The policies and the objectives of the organization are not based on a strategy nor are aligned with the vision and mission.	The organization has policies based on the mission of the organization and measurable objectives unfolded in the main levels of the organization.	The policies and the objectives of the organization are based on a strategy aligned with the vision and mission of the organization,. The objectives are measurable and they unfold at all the levels of the organization. Effective realization of objectives and policies is evident through all the different processes of the organization.	The policies and the objectives are adapted permanently to provide an answer to the changing needs and expectations of the market and other interested groups. Effective realization of objectives and policies is evident through all the different processes of the organization and stakeholders. Policies and objectives are effectively communicated to the main groups of interest	The policies and the objectives provide a continued approach to direct the organization towards the maintenance of the sustainability. In addition, realizing objectives has a positive impact on the product, the effectiveness of the operations, the financial yield and the satisfaction, the confidence and the loyalty of the stakeholders.

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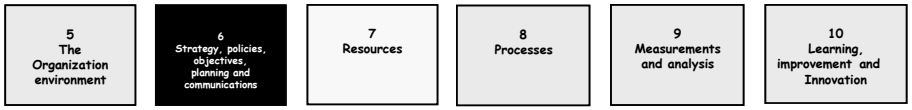

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
6.5 Strategic planning	The organization has not developed a framework that allows it to plan actions in short, half and long term	The organization, taking the vision as a reference, defines the objectives and short term actions, being reviewed as part of the quality management system.	The organization taking, the vision and the mission as a reference, develops strategic plans that are oriented to satisfy the customers' needs and expectations. These plans are evaluated periodically to measure the effectiveness and to undertake improvement actions.	The organization, taking the vision, the mission, the needs and expectations of the present and future stakeholders, the threats, the risks, the markets, the competition and the success factors, the new technologies, etc. as a reference, develops strategic plans which allow to improve continuously and to ensure its permanent presence in the market. These plans are evaluated for their effectiveness and efficiency whenever situations take place that can affect positive or negatively the organization's results. This evaluation allows undertaking actions of improvement or innovation.	The organization has an observatory which allows, based on the continuous analysis of environment's data, to develop and to update its short, half and long term strategic plans to ensure its permanent presence in the market. In obtaining such data, the following aspects are considered: positioning of the company compared to the competition and to companies considered like the best ones, future evolution of the markets and products, risks to which it can be put under, economic and demographic trends, data relative to social questions, new models of management, new technologies, necessities and expectations of the interested parties, etc.

Table B.2 – Operational maturity level assessment sheets

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
6.6 Risk management	The organization has not identified nor analyzed nor understood the factors of its environment which condition its evolution or permanent presence in the market.	Based on the customer's satisfaction, the organization has identified, analyzed and understood the factors of its environment which fundamentally condition its evolution or permanent presence in the market	The organization systematically identifies, analyzes and understands the factors of its environment which condition its evolution or permanent presence in the market and identifies the associated risks and derived actions.	The organization systematically identifies, analyzes and understands the factors of its environment which condition its evolution or permanent presence in the market. It identifies and selects the associated risks and manages with the experience and learned lessons the changes necessary to introduce. The organization reviews and measures the effectiveness and efficiency of the introduced changes.	The identification, the related analysis of the factors of the environment and risks are a practice integrated in all the activities and a permanent objective of the organization.
6.7 Review of strategy for sustainability	The organization does not review its strategy.	The organization performs scheduled reviews of its quality management system, focusing on the fulfilment of requirements and the customer's satisfaction.	The organization, besides performing the scheduled reviews of its quality management system to assure that it is continuously effective, also reviews and evaluates if the strategy is coherent with the vision and mission and if this has been translated in measurable objectives and in structures and processes able to provide answers to the changes of the environment.	The organization reviews and adapts permanently the strategy to ensure that the management system is continuously effective, efficient and competitive and the structure and the processes of the organization are able to provide answers to the present and future necessities of the stakeholders and changes of the environment.	Through the performance indicators of the organization, the perception of the stakeholders and the pursuit of the evolution of the technology and markets and the comparisons with its referring competitors or companies at national or international level, management reviews and updates the organization's strategy in order to remain aligned with the standards of the market.

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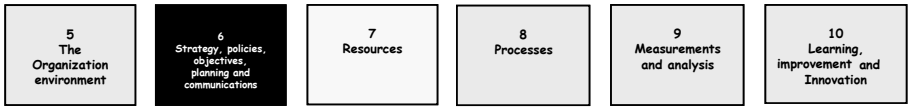

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
6.8. Communication	The organization has not defined a communication process and only communicates in a reactive way when legally, financially or internally required.	The organization has defined and implemented a systematic process for external and internal communication which complies with legislative, regulatory and quality management system requirements. The process focuses on customer satisfaction, shareholders and internal operational needs.	The organization has identified and implemented communication opportunities and improvements, in relation with the main interested parties. It is getting feedback from them which is used to improve the organization and therefore supporting the development of its adaptability and flexibility.	The organization communication process is being improved by including contacts with other organizations to facilitate an effective and efficient learning capability and being proactive while building relationship and networks for innovation. The effectiveness and efficiency of the communication process are continuously reviewed to analyze its ability to forecast the new opportunities and needs for innovation.	The organization has implemented effective internal and external communication processes to convey information related to mission, vision, strategy, policies, objective, operational data and feedback. The effectiveness and efficiency of the communication process are aligned with the sustainability of the organization.

Table B.2 – Operational maturity level assessment sheets

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
7.1 Management of resources	The organization has only identified resources for operational processes.	The organization has identified resources for operational processes and for customer satisfaction.	The organization has identified resources for operational processes, improvement of the management system and for the satisfaction of customers and main interested parties. The organization has developed an effective plan for controlling, protecting and developing its resources.	The organization has identified resources for operation and improvement of the integrated management system and for the satisfaction of customers and all interested parties. The organization has developed an effective and efficient plan for controlling, protecting and developing its resources.	The organization has identified strategic resources to develop and achieve sustainability through its strategy and planning. The organization has developed an effective and efficient plan for controlling, protecting and developing its resources and external resources.
7.2 Planning	The organization has no defined a process for planning of resources and it only identifies and provides main resources.	The organization has defined and implemented a process for planning of resources, including identification, provision, monitoring of resources.	The organization has defined, implemented and improved an effective process for planning of resources, including identification, development, provision, monitoring, maintenance and protection of resources. The organization reviews periodically the suitability of the identified resources.	The organization has defined, implemented and improved an effective and efficient process for planning of resources, including identification, development, provision, monitoring, maintenance and protection of resources and associated risks of potential scarcity. The organization reviews periodically the suitability of the identified resources.	The planning of resources process conducts the organization to the sustainability. The actions to avoid potential scarcity of the resources have been successful.
7.3 Allocation of resources	The organization provides resources after a simple assessment of resource needs.	The management has developed and implemented a process to assess the resource needs of the organization.	The management has developed and implemented an effective process to assess the resource needs of the organization and to establish the priorities for the allocation of the resources.	The management has developed and implemented an effective and efficient process to assess the resource needs of the organization and to establish the priorities for the allocation of the resources and it is periodically reviewed.	The resource allocation process is effective and efficient and totally aligned with strategic planning process to lead for sustainability.

Table B.2 – Operational maturity level assessment sheets

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
7.4 Human resources	The organization provides training and other aspects to human resources without a systematic process.	The organization has defined and implemented a process to manage human resource competences and training,	The organization has developed, implemented and improved an effective process to manage human resource competences, training, awareness, motivation needs and expectations.	The organization has developed, implemented and improved an effective and efficient process to manage human resource integrated competences, training, empowerment, knowledge, awareness, motivation, needs and expectations. The organization has implemented a strategic human resource management process.	The competences and satisfaction of human resources and the strategic planning permit the sustainability of the organization in the long term.

Table B.2 – Operational maturity level assessment sheets

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
7.5 Infrastructure	The infrastructure is provided by requirement of the departments without plans or processes. The organization is not taking care, in a formal way, of the work environment. The organization tries to fulfil some requirements like regulatory and statutory and only improves the wok environment after mandatory requirements from the customers or authorities	The organization has planned, provided and managed the infrastructure. The organization has defined a process to ensure that the work environment complies with all applicable regulatory and statutory requirements (including those for occupational health and safety).	The organization has effectively planned, provided and managed the infrastructure. This infrastructure and related processes are periodically reviewed. The organization has identified potential risk for the infrastructure. The organization has implemented and improved an effective process to ensure that the work environment complies with all applicable regulatory and statutory requirements (including those for occupational health and safety).	The organization has effectively and efficiently planned, provided and managed the infrastructure. This infrastructure and related processes are periodically reviewed, taking into account all interested parties needs and future expectations. The organization has identified potential risk for the infrastructure and proposed preventive actions in an effective and efficient manner. The organization has implemented and improved an effective and efficient process to ensure that the work environment complies with all applicable regulatory and statutory requirements (including those for occupational health and safety). The process encourages productivity, creativity and well-being at work for people in the organization and other interested parties working for or visiting the organization.	The infrastructure is effective and efficient to conduct the organization to sustainability. The infrastructure is totally aligned with mission, vision, strategies and interested parties need and expectations. The process implemented for the work environment maintains sustainability competitiveness.

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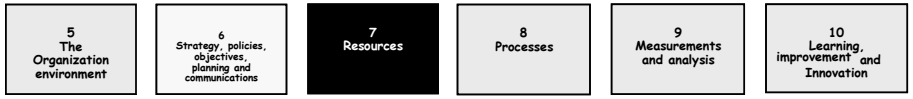
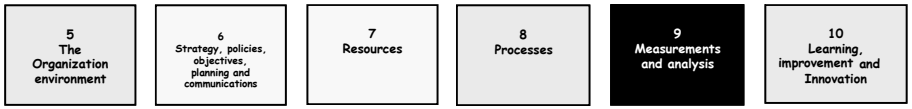


Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
7.6 Knowledge	The organization treats information, knowledge and technology without taking care as intellectual resources.	The organization treats information, knowledge and technology as essential resources. The organization has developed, implemented and improved a process to identify, obtain, protect, use and evaluate information, knowledge and technology it needs.	The organization has developed, implemented and improved an effective process to identify, obtain, protect, use and evaluate information, knowledge and technology it needs. The organization shares information, knowledge and technology with its partners.	The organization has developed, implemented and improved an effective and efficient process to identify, obtain, protect, use and evaluate information, knowledge and technology it needs. The organization shares information, knowledge and technology with its partners and other interested parties.	The organization has a knowledge management process that ensures sustainability.
7.7 Financial resources	The organization determines its financial needs and acquires necessary financial resources without monitoring and controlling.	The organization has developed and implemented a process to determine its financial needs and to acquire necessary financial resources without monitoring and controlling.	The organization has developed and implemented an effective process to forecast and determine its financial needs, to acquire necessary financial resources, to monitor and to control the financial resources.	The organization has developed and implemented an effective and efficient process to forecast and determine its financial needs, to acquire necessary financial resources, to monitor and to control the financial resources.	The effective and efficient process to manage financial resources is totally aligned with the needs and expectations of all interested parties and it leads to sustainability.
7.8 Natural resources and life cycle management	The organization has no policies or plans regarding utilization of natural resources and the impact on natural environment.	The organization has developed and implemented a process to use efficiently the natural resources (energy, water, oil, minerals, ...)	The organization has developed and implemented a process to use efficiently and to consider the availability of the natural resources.	The organization has developed, implemented and improved a process to use efficiently and to consider the availability of the natural resources. This process takes into account the environment in all life cycle of the products.	The efficient use of natural resources, the minimization of the environment impacts and the conservation of the natural environment conducts to the sustainability of the organization.

Table B.2 – Operational maturity level assessment sheets

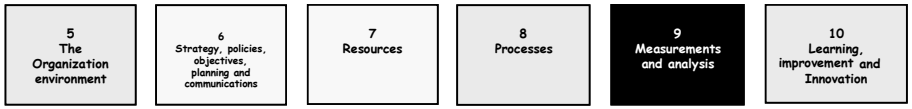
Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
8.1 The process approach	The organization has not adopted a process approach The organization has not targeted objectives for processes..	The organization has implemented a process approach at least in operational processes. The management has defined objectives for improving effectiveness of the processes and are aligned with policy commitments.	The organization has implemented and improved an effective process approach in strategic, operational and support processes. The management has defined objectives for improving effectiveness of the processes and are aligned with policy commitments and some strategies.	The organization has implemented and improved an effective and efficient process approach in strategic, operational and support processes, related with all interested parties. The management and process owners have defined objectives for improving effectiveness and efficiency or innovation of the processes and are aligned with policy commitments and strategies.	The effective and efficient process approach between all kind of processes and transparency with all interested parties conducts the organization to sustainability. The effectiveness and efficiency of the processes of the organization are aligned with mission, vision, strategies, values and sustainability.
8.2 Types of processes	The organization has not identified processes.	The organization has identified at least operational processes related to product realization.	The organization has identified management, managing resources, realization and support processes related to customers.	The organization has identified management, managing resources, realization and support processes related to all interested parties.	All the activities are included in some type of process to permit the sustainability of the organization.
8.3 Managing the organization's processes	The organization has not identified processes.	The organization has identified at least processes related to product realization and customers.	The organization has identified all kind of processes related to customers.	The organization has identified all kind of processes related to all interested parties and all management systems (e.g. quality, environmental, health and safety)	All the activities are included in some type of process to permit the sustainability of the organization.
8.4 Process responsibility and authority	The role of process owner is not defined.	The management of the organization has appointed owners of processes related to product realization and customers.	The management of the organization has appointed owners of all processes related to customers. The owners improve the effectiveness of their processes. The management has an effective policy to avoid and clarify potential disputes in the process management.	The management of the organization has appointed owners of all processes related to all interested parties and all management systems (e.g. quality, environmental, health and safety) The owners improve the effectiveness and efficiency of their processes and policies.	The responsibilities and authorities are clearly documented and assessed to leads the processes and the organization to the sustainability.

Table B.2 – Operational maturity level assessment sheets



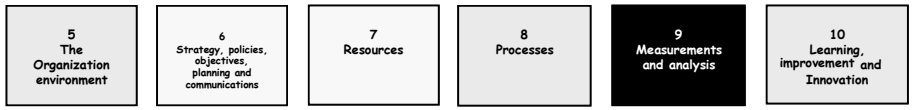
Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
9.1 Measurement approach	Only basic financial indicators, on-time deliveries, customers complaints, basic customer satisfaction surveys, etc.	Formal Quality Management System Review is taken, but sometimes conclusions are not followed.	A mature Quality Management System is in place. Management decisions are data driven and therefore management supports measurement improvement.	Management Systems are coordinated or integrated with other organization systems, therefore measurement systems is company wide and comprehensive.	The measurement system is considered by management a "navigation radar" since the information provided is reliable, accurate, timeline and pertinent for organization sustainability
9.2 Performance metrics	Very Basic data available and the accuracy is doubtful.	Periodical Quality Management System Review is in place. This system requires formal metrics for some objectives and processes. Often these metrics are very basic and not related to organization sustainability. Often the organization has difficulties to define metrics for the objectives and most of them are qualitative. Often Operational definition for indicators is with some "fuzzy points" that could lead to inconsistencies. Data that constitute indicators is supposed to be "good"	Management uses reliable metrics. Main sustainability constraints are identified and related to performance metrics that generate indicators. The organization relates the important goals to performance indicators. New plans are followed by metrics and indicators. Clear operational definition for indicators. Data accuracy is controlled. R&R studies are performed, particularly when data comes from judgements, opinions, etc. Performance measurement is analysed by qualified people (statistician, quality engineer, "black belt") reporting formal conclusions.	Management Systems are coordinated or integrated with other organization systems which allow a clear identification of sustainability constraints and performance metrics are extended company wide as appropriate. This performance metrics system supports a reliable Business Score Card.	The performance metrics provides clear guidelines to design policies and objective to improve organization sustainability.

Table B.2 – Operational maturity level assessment sheets



Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
9.3 Measuring achievement of objectives	No formal approach. Basic objective related to financial aspects, customers complains, leading times, etc.	Periodical review of quality objectives through Quality Management System Review meeting. Often these objectives are very basic and not related to organization sustainability.	Main sustainability constraints are identified and some objectives and policies are issued to improve sustainability.	There are a clear identification of sustainability constraints and a company wide approach to objectives related to sustainability.	Organization objectives are clearly aligned with organization of sustainability constraints.
9.4 Key indicators	No formal approach. Basic customer requirements and main process key indicators are known.	Formal definition of main process key indicators. Often, the use of these indicators is reduced since they are not accurate or timeline.	When appropriate advanced quality engineering techniques such as Robust Design, FMEA, DFSS, Lean, TOC, etc. are used to identify key indicators and key process parameters indicators, Y=F(X). When possible, direct reading (e.g. electronic link to a computer) from the key process parameters and outputs is in place.	The key indicators are integrated with other systems of key indicators (accountability, HR, etc.) and often constitute a Business Score Card.	Key indicators are clearly highlighted in the Business Score Card (BSC) monitoring tendencies that could endanger sustainability of the organization.
9.5 Measurement tools	No formal approach.	Measurements of processes and achievement of quality objectives are not including sustainability constraints.	Measurement of processes and achievement of quality objectives are effective. Measurement approach is evolving to include sustainability constraints, since it is a considered by management as a useful tool. When necessary. R&R studies are performed, particularly when data comes from judgements, opinions, etc. which makes these measures “reliable”.	Quality measures are coordinated or even integrated with other areas.	Measurements are extended and cover all significant aspects related to the stakeholders highlighting tendencies that could endanger sustainability of the organization

Table B.2 – Operational maturity level assessment sheets



Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
9.6 Internal audit	No audit performed on periodical basis. At most in response to problems, customer complaints, etc.	Audits of Quality Management System are in place. Quality audits are not coordinated or combined with safety audits, operational audits, etc. The results of these audits are not considered by management as a "golden mine". Sometimes auditors are very formalistic and do not provide improvement guidelines.	Management understand the benefit of audits and they support audit improvements. Audits ensure data and indicators accuracy. Audit reports are analysed and generate effective improvement actions. Planning for new important projects, business, branches, etc includes systematically audits to track their evolution. Quality audits are somehow coordinated with safety audits, operational audits, etc.	Management System Audits are often coordinated or even integrated and provide a good view of the "state of the art" and signal improving opportunities.	Audit reports are one of the main inputs used for designing and reviewing organization policies, strategies and contingency plans. The audit process is an effective tool to identify the problems, their root causes and to establish improvement actions to eliminate them.
9.7 Assessment	No idea about the degree of sustainability of the organization.	Assessment is only related with quality management system.	Main sustainability constraints of the organization and key activities are known. An assessment plan is in place and generates effective improvement actions.	Assessment results are systematic input for the strategic plan.	The assessment outputs are main inputs used for designing and reviewing organization's capabilities and the strategic plan.
9.8 Review and evaluation of processes	Not sustainability improvement loop is in place, or a quality improvement loop.	The sustainability improvement loop is only related with the quality system.	The assessment process is reviewed periodically regarding its effectiveness and timeliness of the data collected and the aim to support achievement of sustainability	The evaluation of the assessment process includes the contribution to sustainability, the degree of support of the decision and priority making process.	The evolution of the analysis of the assessment process indicates a good performance. Assessment process is an accurate and recognized tool for improvement in the organization.

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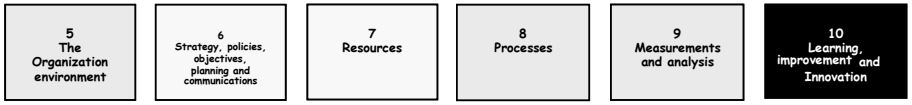

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
10.1 Learning	The organization has not developed educational/training plans. The organization has not understood the necessity of learning. Learning process has not been implemented.	Education/training programs are found and evaluated, and their effects are confirmed. Learning is only received by part of the organization.	Effective plan based on organizational knowledge is planned and implemented. Organizational knowledge is focused around a small knowledge base dependent only on certain personal. The appropriate Environment is created for organizational learning. The effect of learning is transmitted to part of the employee.	Organizational knowledge is utilized generally in management policy regarding to realization planning. In order to developed full integration of personal Knowledge into organisational knowledge, the company has mechanism and forums for sharing information. Learning continues throughout the organization towards improvements in performance.	Plans for continual improvement and innovation founded on knowledge gained through organizational learning. Learning is entrenched in organizational culture. The effect of learning leads to continual improvement in organizational performance.
10.2 Improvement	Organization does not have defined specific policies for improvement. The focus of the organization is on corrective actions.	The organization has a few defined specific policies for improvement. The focus is still on corrective actions although some preventive actions are implemented.	Organization has formally defined specific programs for improvement. Although there are some corrective actions, the focus is now on prevention. Some evidence of improvement is perceived.	Organization has formally defined and implemented specific strategies for improvement. Still having some corrective and preventive actions, but focus is on continual improvement	Organization has formally defined and implemented a Continual Improvement approach, widely applied by all employees. Continual Improvement and Innovation are part of the Strategy and Policies. Evidence of a strong causal relationship between the improvement and innovation and the organizational results. Some corrective and preventive actions with strong focus on innovation.

Table B.2 – Operational maturity level assessment sheets

Level / Clause	1 Beginner	2 Proactive	3 Flexible	4 Innovative	5 Sustainable
10.3 Innovation	Procedures for continual improvement are not established. No awareness of innovation. Inadequate planning for policy items. Results from plans are not assessed	Procedures for continual improvement are established, but any specifically for innovation. Slow reaction to change.	Effective planning of policy items is planed and implemented. Innovation planning is conducted in part of organization. Responses are made to visible and rapid changes but not to gradual changes.	Presence of mechanisms to measure and analyze environmental changes. Effective and efficient planning on policy items is developed and implemented. Change is being forecast, or action taken ahead of change. Organization wide innovation is taking place	Innovative planning is developed and implemented. Knowledge gathered and shared in the planning process is utilized in organizational knowledge. Results of continuing innovation are improving performance continually, placing the organization at the top ahead of other competitors. Environmental change through self-innovation and corporate culture of innovation is rooted in the organization.