International Workshop Agreement

IWA 2

Quality management systems — Guidelines for the application of ISO 9001:2000 in education

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Based on ISO 9001:2000, Second edition, 2000-12-15

Quality management systems — Requirements

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ISO's technical work is normally carried out through ISO technical committees in which each ISO member body has the right to be represented. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

In order to respond to urgent market requirements, ISO has also introduced the possibility of preparing documents through a workshop mechanism, external to its normal committee processes. These documents are published by ISO as International Workshop Agreements. Proposals to hold such workshops may come from any source and are subject to approval by the ISO Technical Management Board which also designates an ISO member body to assist the proposer in the organization of the workshop. International Workshop Agreements are approved by consensus amongst the individual participants in such workshops. Although it is permissible that competing International Workshop Agreements exist on the same subject, an International Workshop Agreement shall not conflict with an existing ISO or IEC standard.

An International Workshop Agreement is reviewed after three years, under the responsibility of the member body designated by the Technical Management Board, in order to decide whether it will be confirmed for a further three years, transferred to an ISO technical body for revision, or withdrawn. If the International Workshop Agreement is confirmed, it is reviewed again after a further three years, at which time it must be either revised by the relevant ISO technical body or withdrawn.

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

International Workshop Agreement IWA 2 was approved at a workshop held in Acapulco, Mexico, in October 2002, and hosted by the General Bureau of Standards (DGN), with the support and cooperation of the organizations in charge of coordinating the Mirror Subcommittee for Quality Management Systems within the Mexican ISO Committee, the Mexican Institute for Standardization and Certification (IMNC) and the National Committee for Standardization on Quality Management Systems (COTENNSISCAL). The meeting was facilitated by the Latin-American Institute for Quality (INLAC).

The text which is in italics and not boxed represents the text approved at the workshop. For the benefit of the user, the ISO 9001 requirements are included in boxed text before the comparable clause in this International Workshop Agreement. Information marked “NOTE” is for guidance in understanding or clarification.

The text of ISO 9004 is also provided to allow those users who wish to move beyond the requirements of ISO 9001 to enhance the efficiency of their quality management system in pursuit of continual improvement of performance. The ISO 9004 text is in dashed boxes following the comparable clause.

This corrected version of IWA 2:2003 incorporates a second page to the Supplement, which was omitted by mistake.

Supplement

This proposal was prepared in Mexico during the workshop held in Acapulco, and was created under the leadership of the National Committee for Standardization on Quality Management Systems (COTENNSISCAL) with the participation of the following organizations:

ASECAD de México
Centro de Investigación y Desarrolo de la Formación para el Trabajo (CIDFORT)
Colegio de Calidad Empresarial, S.C.
Consultoría Profesional en Sistemas de Calidad
CAAP
CSC
Grupo Raloy
Instituto de Ciencias, Humanidades y Technologías de Guanajuato (ICYTEG)
Instituto Latinoamericano para la Calidad (INLAC)
Instituto Mexicano de Normalización y Certificación (IMNC)
Instituto Politécnico Nacional (IPN)
— Centro de Estudios Científicos y Tecnológicos No. 7 “Cuauhtémoc”
— Centro de Investigación e Innovación Tecnológica
— División de Metrología, Normas y Calidad Industrial
— Unidad Profesional Interdisciplinaria de Biotecnología
Instituto Tecnológico de Oaxaca
Instituto Tecnológico y de Estudios Superiores de Monterrey (ITESM)
Qualitec Internacional, S.A. de C.V.
Secretaría de Educación Pública (SEP)
— Coordinación de Asesores de la Subsecretaría de Educación Superior e Investigación Científica
— Coordinación General de Universidades Tecnológicas
— Unidad Administradora del Proyecto para la Modernización de la Educación Técnica y la Capacitación
Sindicato Nacional de Trabajadores de la Educación
Tecno-Ingeniería Computacional, S.A. de C.V.
Universidad Nacional Autónoma de México, UNAM
— Facultad de Ingeniería
Universidad de Colima
Universidad Tecnológica de Tula Tepeji
Universidad Tecnológica Fidel Velázquez

Delegates and observers from the following countries and organizations participated during the workshop held in Acapulco.

Delegates:

Argentina, Instituto Argentino de Normalización (IRAM)
Australia, Standards Australia International (SAI)
Brazil, Petrobras and DS
Canada, Canadian Center for Management Development
Colombia, Instituto Colombiano de Normalización Técnica y Calidad (ICONTEC)
Denmark, TQM I/S
Germany, DIN
México, COTENNSISCAL, IPN, SEP, INLAC and ITESM

Spain, AENOR
Sweden, RFK AB
United Kingdom, British Standards Institution
United States, DPA Training and INFORM
Venezuela, FONDONORMA

Observers:

Centro de Investigación y Desarrollo de la Formación para el Trabajo (CIDFORT)
Colegio Nacional de Educación Profesional Técnica (CONALEP)
Det Norske Veritas
Instituto Argentino de Normalización (IRAM)
Instituto Chapultepec
Instituto de Ciencias, Humanidades y Tecnologías de Guanajuato (ICYTEG)
Instituto Latinoamericano para la Calidad (INLAC)
Instituto Politécnico Nacional
— ESIME Azcapotzalco
INTERPRO Consultores
Secretaría de Educación del Estado de Tabasco
Secretaría de Educación Pública
— Coordinación General de Universidades Tecnológicas
— Dirección General de Centros de Formación para el Trabajo
— Dirección General de Educación Tecnológica Agropecuaria
— Dirección General de Educación Tecnológica Industrial
— Unidad Administradora del Proyecto para la Modernización de la Educación Técnica y la Capacitación
Colegio de Posgraduados
TESCAP
Universidad ETAC
Universidad Nacional Autónoma de México
— Facultad de Ingeniería
Universidad Tecnológica de Aguascalientes
Universidad Tecnológica de Tula Tepeji
Universidad Tecnológica de Tecámac
Universidad Tecnológica de Torreón

Quality management systems — Guidelines for the application of ISO 9001:2000 in education

Introduction

ISO 9001:2000, Quality management systems — Requirements

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, regulatory 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.

0.1 General

The objective of this International Workshop Agreement is to provide guidelines to assist organizations that provide educational products to implement an effective quality management system that meets the requirements of ISO 9001:2000.

NOTE 1 The text of ISO 9004:2000 is provided without comment for those educational organizations that wish to go beyond meeting the requirements of ISO 9001:2000 to enhance the efficiency of their quality management system. It is well known that the cost of implementing an efficient and effective quality management system is a single cost whereas the consequent benefits continue indefinitely. Educational organizations are encouraged to have a good understanding of the ISO 9004:2000 guidelines and the eight quality management system principles when implementing the quality management system that suits their needs.

NOTE 2 To ensure that the overall cost of implementation is properly rewarded by the success of organization-wide continual gain, the implementation should be planned and carried out as a project or programme of projects depending on the size and individual circumstances of the educational organization.

The following general guidance is provided to help educational organizations to relate the concepts in ISO quality management system standards to education practices.

A curriculum can specify what is expected to be learnt and how the learning is to be assessed. However, the curriculum by itself does not ensure that needs and expectations will be met if deficient processes exist in educational organizations. The need to prevent these deficiencies has led to the provision of this International Workshop Agreement to help educational organizations implement a quality management system that is

known to be effective. Continuing assessment of the curriculum and educational processes that support instruction can ensure the effectiveness of the learning process. Internal quality audits provide verification of the fulfilment of requirements, for example, stated claims of achievements

The quality management system should be the simplest one that works well. It need only be comprehensive enough to meet the quality objectives for the educational organization. Quality control is an essential process in a quality management system. Accurate measurement is not easy when assessing human performance, and appraisal is usually conducted during the educational process.

ISO 9001:2000, Quality management systems — Requirements

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.

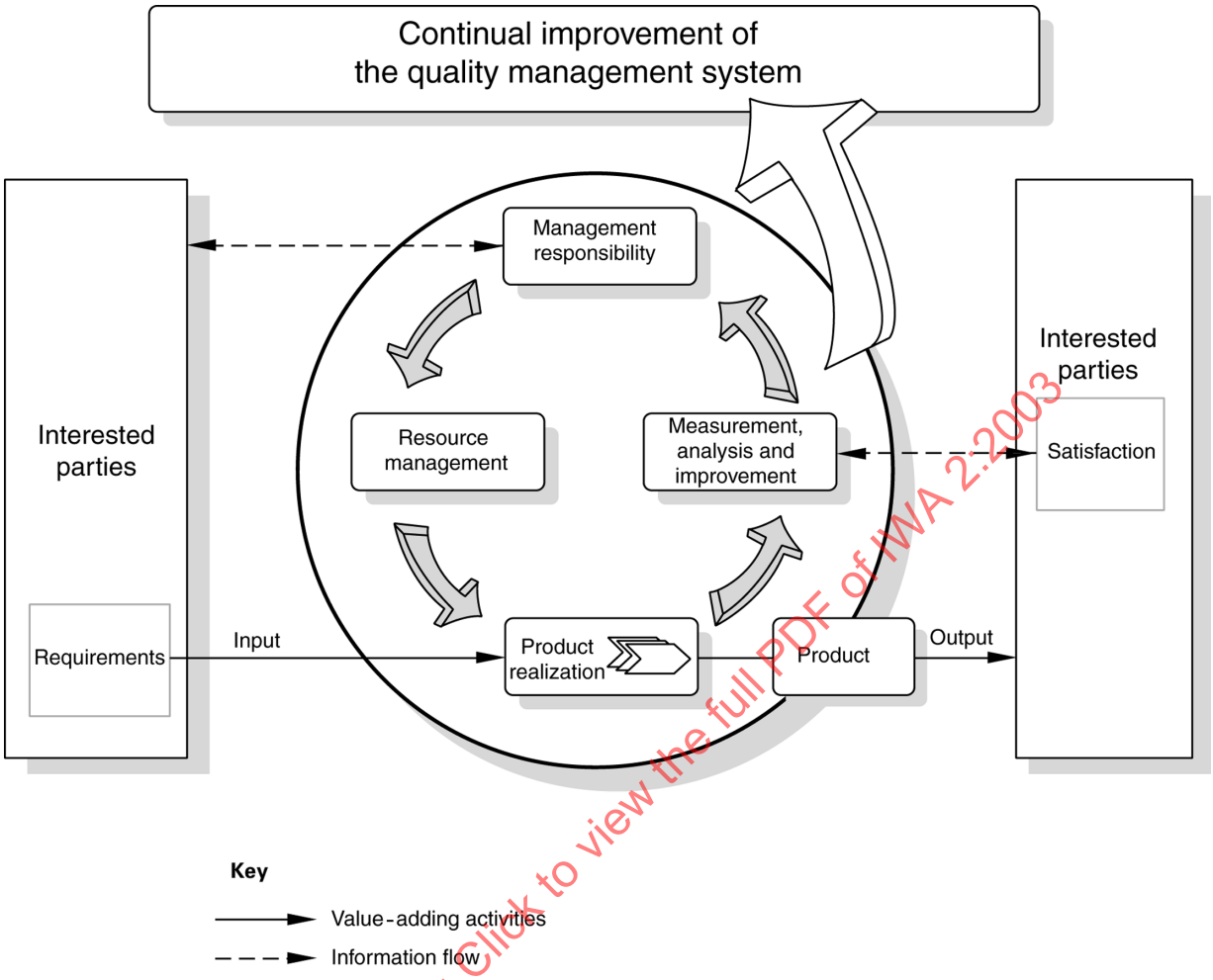

Figure 1 — Model of a process-based quality management system

0.2 Process approach in educational organizations

Educational organizations that provide educational products should define their processes. These processes, which are generally multidisciplinary, include administrative services and other forms of support, as well as those concerning assessment, such as:

- *a strategic process to determine the role of the educational organization in the socio-economic environment;*
- *provision of the teaching capability of the learning providers;*
- *maintenance of the working environment;*
- *developing, reviewing and updating study plans and curricula;*
- *admission and selection of applicants;*
- *student's education follow-up and assessment;*
- *final assessment aimed to grant the student an academic degree, a degree that will be supported by a diploma, acknowledgement, bachelor's degree or certificate of competencies;*
- *support services for the teaching-learning process carried out for the satisfactory accomplishment of their curricula, and support to the student until he/she can succeed in obtaining his/her academic degree or certificate;*
- *internal and external communication; and*
- *measurement of educational processes.*

ISO 9001:2000, Quality management systems — Requirements

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 organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order 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.

ISO 9001:2000, 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 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 regulatory requirements.

NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

1 Scope for educational organizations

This International Workshop Agreement (IWA) provides guidelines for the application of ISO 9001:2000 in educational organizations providing educational products.

These guidelines do not add to, change or modify the requirements of ISO 9001:2000, and are not intended for use in contracts for conformity assessment or for certification.

Each clause of ISO 9001:2000, framed with a continuous solid line, appears before the corresponding text of this IWA. The whole text of ISO 9004:2000, framed with a dashed line, is included to provide a complete vision of the continual performance improvement of organizations.

ISO 9004:2000, Quality management systems — Guidelines for performance improvements

1 Scope

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

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

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

ISO 9001:2000, Quality management systems — 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 organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

ISO 9001:2000, Quality management systems — 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, *Quality management systems — Fundamentals and vocabulary*.

ISO 9001:2000, Quality management systems — Requirements

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".

3 Terms and definitions in educational organizations

For the purposes of this IWA, the terms and definitions given in ISO 9000:2000 and the following apply.

3.1
customer
organization (3.3.2) or person that receives a product (3.4.2)

[ISO 9000:2000]

*EXAMPLE A customer can be a **consumer** (in education, generally a learner), a **client** or **purchaser** (in education, generally a person or body funding the learner who may also be the learner), an **end-user** (in education, generally the person or organization that benefits from the learning achieved by the learner).*

3.2
interested party
person or group having an interest in the performance or success of an organization

[ISO 9000:2000]

*EXAMPLE An interested party can be a **customer** (3.1), parents' association, other related **educational organization** (3.5) or society.*

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

3.3
educational process
*process resulting in **educational product** (3.4)*

3.4
educational product
product concerned with education

NOTE An educational product generally involves the provision of a service that includes intellectual software of information and some form of computer software or paper-based hardware assisting the transfer of information and retention for continuing reference.

3.5
educational organization
*organization that provides an **educational product** (3.4)*

3.6
education provider
*person who delivers an **educational product** (3.4) to learners*

NOTE The education provider is referred to by customary titles which vary on national and educational hierarchical grounds including for example, teacher, trainer, lecturer or professor.

ISO 9001:2000, Quality management systems — Requirements

4 Quality management system

4.1 General requirements

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

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (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 requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

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

4 Quality management system

4.1 General requirements in the educational organization

Due to the fundamental character of this clause and the fact that it sets the basis for the rest of ISO 9001, the guidelines are limited to the following:

a) educational organizations should define and manage those processes included in the educational design, educational development, and the educational delivery processes, the procedures for implementation, and the measurement of results;

b) the conditions for the acceptance of the education at the time of delivery; and

c) continual improvement of these processes and provision of resources.

The educational organization should define very clearly the intended "organization" to which the proposed quality management system is to apply. For example, is it to be a department or school within a larger educational organization, an entire educational organization or all the educational organizations in a given government or local government division.

Establishing the intent will help the educational organization to identify who serves as "top management" and the nature of the systems and processes that have to be understood if continual improvement and customer satisfaction are to be achieved.

They will also help to identify what services are delivered, which is essential in the identification and separation of customers and other interested parties.

An instructional quality management system should be understood in terms of the curriculum, a system of learning processes, the organizational structure, responsibilities, processes, and resources that ensure the quality of instruction. This includes most activities of the educational organization's employees or appropriate suppliers. Control of instruction may be exercised during the following processes:

a) instructional needs analysis;

b) instructional design;

c) instructional development;

d) delivery of instruction;

e) instructional evaluation;

f) educational faculty organization development; and

g) operation of libraries, workshops, and laboratories.

ISO 9004:2000, Quality management systems — Guidelines for performance improvements

4 Quality management system

4.1 Managing systems and processes

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

Top management should establish a customer-oriented organization

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

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

Examples of activities to establish a customer-oriented organization include

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

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

— directing progress towards continual improvement, and

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

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

ISO 9001:2000, Quality management systems — Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

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

b) a quality manual,

c) documented procedures required by this International Standard,

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

e) records required by this International Standard (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.

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 are identified and their distribution controlled, and

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

4.2.4 Control of records

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

4.2 Documentation requirements

4.2.1 General

When planning a quality management system, educational organizations developing their quality manual could include or make reference to issues other than the ones established by ISO 9001 (see ISO/TR 10013) such as but not limited to:

- *the terms and definitions required by the organization;*
- *regulatory and organizational policies;*
- *applicable laws and regulations;*
- *the competencies of the teaching staff (educational providers);*
- *accreditation and certification programmes;*
- *study plans and curricula;*
- *competence programmes, awareness, education, training and updating; and*
- *support services.*

4.2.2 Documentation in the educational organization

4.2.2.1 Quality manual

The quality manual should describe the scope of the educational organization's quality management system and interactions of its educational and support processes. It should include, or contain, references to all applicable documented procedures required by ISO 9001 and other criteria upon which the quality management system is based.

4.2.2.2 Control of documents in the educational organization

The purpose of document control is to ensure that documents from the quality management system are continually updated and are available for use. To achieve this objective the educational organization should establish a documented procedure describing the arrangements:

- *for editing, reviewing and approving internal documents, including their identification and revision status;*
- *for controlling external documents, mainly the relevant regulations that should be continuously updated;*
- *which ensure that documents are available to the organization's personnel; and*
- *for managing and controlling the student's legal documents, for ensuring the traceability of educational services and verifying the fulfilment of requirements in the established educational stages.*

Documents used to define, direct, and control instruction and support activities should be controlled (see 7.1). Documents generated internally should be reviewed and approved for adequacy and conformity.

Information about the edition of textbooks or learning material, text supplements, workbooks or other instruction resources should be controlled and traceable to the design and development process.

Procedures for course registration, formats for lesson plans, instructions on research report formats, etc. should be maintained to provide complete and current documents needed.

The document control system should include provisions for control of external document (for example, but not limited to, legislation, rules, government circulars, accreditation regulations).

4.2.2.3 Control of records in the educational organization

A record provides information about the activities carried out in the organization, such as the results obtained in each stage of the teaching/learning process (education provision).

The educational organization should give attention to retention times and record disposal, generally well established by legislation or regulation.

Student records and instructional records are typically maintained by educational organizations within the guidelines of privacy protection, such as:

- *design report;*
- *development report;*
- *instructor certifications or qualifications;*
- *impact evaluation;*
- *student performance records and instruction reviews;*
- *evidence of completion (certificate, credit, diploma, etc.);*
- *loss, damage, or unsuitable use of student supplied materials;*
- *complaints;*
- *participation in research;*
- *prerequisite skills; and*
- *copyright records or permission to use information.*

The specific requirements for records within an educational organization quality management system are defined in clauses 5 to 8 by reference to 4.2.4.

ISO 9004:2000, Quality management systems — Guidelines for performance improvements

4.2 Documentation

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

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

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

- contractual requirements from the customer and other interested parties,
- acceptance of international, national, regional and industry sector standards,
- relevant statutory and regulatory requirements,
- decisions by the organization,
- sources of external information relevant for the development of the organization's competencies, and
- information about the needs and expectations of interested parties.

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

- functionality (such as speed of processing),
- user friendliness,
- resources needed,
- policies and objectives,

— current and future requirements related to managing knowledge,

— benchmarking of documentation systems, and

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

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

4.3 Use of quality management principles

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

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

a) **Customer focus**

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

b) **Leadership**

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

c) **Involvement of people**

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

d) **Process approach**

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

e) **System approach to management**

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

f) **Continual improvement**

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

g) **Factual approach to decision making**

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

h) **Mutually beneficial supplier relationships**

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

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

ISO 9001:2000, Quality management systems — Requirements

5 Management responsibility

5.1 Management commitment

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

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

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5 Management responsibility

5.1 Management commitment in the educational organization

Top management (a person or a group of people who direct and control an educational organization at the highest level) should identify the factors which satisfy the needs and expectations of the customer.

Top management should ensure that educational programmes and processes comply with legal and regulatory requirements for their certification or accreditation.

The main requirement of this clause is that top management identifies and shows their commitment to achieve the development and continual improvement of the quality management system.

Some strategies that could be used in educational organizations are:

— *organization quality policies;*

— *communicating the quality management system plan throughout the organization; and*

— *communication plan reviewing and follow-up.*

Among other means, establishing a communication plan and ensuring its review and follow-up ensures the visibility of the commitment and values of top management which creates the proper environment for:

— *establishing a quality policy that allows all the members of the organization to know the vision and mission with which top management has decided to manage the quality-related processes;*

— *establishing quality objectives in order to realize aims and intentions, expressed in the quality policy, in operating actions;*

— *ensuring availability, as far as possible, of human and material resources, necessary for achieving the objectives;*

— *communicating to the whole educational organization, through its formal structure, the importance of meeting the students/customer requirements, as well as the legal and regulatory requirements for the educational service provided;*

— *publication of organization bulletins for communicating the relevant quality-related matters as performance quality objectives, giving feedback to students/customers; and*

— *measuring the organization performance in order to monitor the fulfilment of the established policies and objectives.*

ISO 9004:2000, Quality management systems — Guidelines for performance improvements

5 Management responsibility

5.1 General guidance

5.1.1 Introduction

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

- establishing a vision, policies and strategic objectives consistent with the purpose of the organization,
- leading the organization by example, in order to develop trust within its people,
- communicating organizational direction and values regarding quality and the quality management system,
- participating in improvement projects, searching for new methods, solutions and products,
- obtaining feedback directly on the effectiveness and efficiency of the quality management system,
- identifying the product realization processes that provide added value to the organization,
- identifying the support processes that influence the effectiveness and efficiency of the realization processes,
- creating an environment that encourages the involvement and development of people, and
- provision of the structure and resources that are necessary to support the organization's strategic plans.

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

Methods include

- financial measurement,
- measurement of process performance throughout the organization,
- external measurement, such as benchmarking and third-party evaluation,
- assessment of the satisfaction of customers, people in the organization and other interested parties,
- assessment of the perceptions of customers and other interested parties of performance of products provided, and
- measurement of other success factors identified by management.

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

5.1.2 Issues to be considered

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

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

- understanding current and future customer needs and expectations, in addition to requirements;
- promoting policies and objectives to increase awareness, motivation and involvement of people in the organization;
- establishing continual improvement as an objective for processes of the organization;
- planning for the future of the organization and managing change;
- setting and communicating a framework for achieving the satisfaction of interested parties.

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

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

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

Consideration should be given to

— ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively and efficiently,
— ensuring process inputs, activities and outputs are clearly defined and controlled,
— monitoring inputs and outputs to verify that individual processes are linked and operate effectively and efficiently,
— identifying and managing risks, and exploiting performance improvement opportunities,
— conducting data analysis to facilitate continual improvement of processes,
— identifying process owners and giving them full responsibility and authority,
— managing each process to achieve the process objectives, and
— the needs and expectations of interested parties.

ISO 9001:2000, Quality management systems — Requirements

5.2 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).

5.2 Customer focus in the educational organization

The educational organization top management should identify the needs and expectations of its customers to fulfil them in order to strive for their satisfaction.

Needs and expectations should be identified by taking into account that an educational organization has very specific needs and expectations. Therefore, customers' needs and expectations should be defined by the particular educational organization.

Customers' requirements are often implied. They should be defined and documented as curriculum requirements that include well-defined learning outcomes and specified performance indicators, instructional designs that should be reviewed at the proposal stage and, as a minimum, annually thereafter to assure that all requirements are met and are aligned with the organization's objectives.

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5.2 Needs and expectations of interested parties

5.2.1 General

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

— customers and end-users,

— people in the organization,

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

— suppliers and partners, and

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

5.2.2 Needs and expectations

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

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

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

— translate identified needs and expectations into requirements,

— communicate the requirements throughout the organization, and

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

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

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

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

— identify and assess competition in its market, and

— identify market opportunities, weaknesses and future competitive advantage.

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

— conformity,

— dependability,

— availability,

— delivery,

— post-realization activities,

— price and life-cycle costs,

— product safety,

— product liability, and

— environmental impact.

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

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

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

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

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

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

— set goals to secure opportunities for continuing partnerships.

In considering its relationships with society, the organization should

— demonstrate responsibility for health and safety,

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

— identify applicable statutory and regulatory requirements, and

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

5.2.3 Statutory and regulatory requirements

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

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

— the benefits to interested parties from exceeding compliance, and

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

ISO 9001:2000, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

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

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

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.3 Quality policy in the educational organization

Quality policy should be documented.

The quality policy should be consistent with professional standards, government rules and regulations, and other policies of the educational organization. Managers should ensure that the quality policy is understood, implemented, and maintained by the organization.

The educational organization top management should use the quality policy for guiding and leading the decision-making of the personnel involved in the continual improvement of the educational process.

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5.3 Quality policy

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

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

In establishing the quality policy, top management should consider

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

— the expected or desired degree of customer satisfaction,

— the development of people in the organization,

— the needs and expectations of other interested parties,

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

— the potential contributions of suppliers and partners.

The quality policy can be used for improvement provided that

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

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

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

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

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

— it is effectively formulated and efficiently communicated.

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

ISO 9001:2000, Quality management systems — Requirements

5.4 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 Planning

5.4.1 Quality objectives in the educational organization

Objectives should be measurable and pertinent to the activities and processes of the quality management system, besides being aligned with the organization's quality policy.

Quality objectives should be integrated in the educational organizations' overall objectives, support service specifications, and include performance measures or indicators.

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5.4 Planning

5.4.1 Quality objectives

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

— current and future needs of the organization and the markets served,
— relevant findings from management reviews,
— current product and process performance,
— levels of satisfaction of interested parties,
— self-assessment results,
— benchmarking, competitor analysis, opportunities for improvement, and
— resources needed to meet the objectives.

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

ISO 9001:2000, Quality management systems — Requirements

5.4.2 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.

5.4.2 Quality management system planning in the educational organization

Quality management system planning should consist of the activities and resources needed to achieve the educational organization's objectives. For examples refer to ISO 9004.

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5.4.2 Quality planning

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

Inputs for effective and efficient planning include

— strategies of the organization,
— defined organizational objectives,
— defined needs and expectations of the customers and other interested parties,
— evaluation of statutory and regulatory requirements,
— evaluation of performance data of the products,
— evaluation of performance data of processes,
— lessons learned from previous experience,
— indicated opportunities for improvement, and
— related risk assessment and mitigation data.

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

— skills and knowledge needed by the organization,
— responsibility and authority for implementation of process improvement plans,
— resources needed, such as financial and infrastructure,
— metrics for evaluating the achievement of the organization's performance improvement
— needs for improvement including methods and tools, and
— needs for documentation, including records.

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

ISO 9001:2000, Quality management systems — Requirements

5.5 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 Responsibility, authority and communication

5.5.1 Responsibility and authority in the educational organization

The educational organization top management should clearly describe the organizational structure, with a focus on processes which support the development and deployment of the quality management system. This should include responsibility and authority delegation per functional area of the personnel involved in the quality management system processes.

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5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

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

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

ISO 9001:2000, Quality management systems — Requirements

5.5.2 Management representative

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

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

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

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

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

5.5.2 Management representative in the educational organization

The educational organization should assign a person(s) the responsibility for ensuring that the requirements of ISO 9001:2000 are met on an on-going basis and that the guidance provided in this IWA is being implemented. This person should know the contents of these standards and be available for advice on their implementation.

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5.5.2 Management representative

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

ISO 9001:2000, Quality management systems — Requirements

5.5.3 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.

5.5.3 Internal communication in the educational organization

The educational organization top management should ensure that there are communication processes vertically, at the different organization levels, as well as horizontally, through different areas and departments, in order to share information related to the effectiveness of the quality management system.

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5.5.3 Internal communication

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

Activities for communicating include, for example

— management-led communication in work areas,

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

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

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

— employee surveys and suggestion schemes.

ISO 9001:2000, Quality management systems — Requirements

5.6 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 Management review in the education sector

5.6.1 General

The educational organization top management should carry out the quality management system review periodically, according to the organization's needs, in order to assess the effectiveness in the fulfilment of requirements and indicators of the quality management system, and should establish preventive and corrective actions for identified or potential nonconformities.

A review of the quality management system should include the scheduled periodic review of the instructional and support systems, customer satisfaction, assessment criteria, evaluation results, and documented improvements. This list is neither exhaustive nor prescriptive. Records of these reviews should be kept.

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5.6 Management review

5.6.1 General

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

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

ISO 9001:2000, Quality management systems — Requirements

5.6.2 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.

5.6.2 Review input in the educational organization

Input information to assess the quality management system effectiveness should consider the students and/or customers, and also for example:

- *comparative studies with other organizations, e.g. benchmarking;*
- *status of follow-up actions on graduates; and*
- *proposals for improvement/changes.*

A review of the quality management system should include the scheduled periodic review of the educational and support processes, customer satisfaction, assessment criteria, evaluation results, and documented improvements. This list is neither exhaustive nor prescriptive.

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5.6.2 Review input

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

- status and results of quality objectives and improvement activities,
- status of management review action items,
- results of audits and self-assessment of the organization,
- feedback on the satisfaction of interested parties, perhaps even to the point of their participation,
- market-related factors such as technology, research and development, and competitor performance,
- results from benchmarking activities,
- performance of suppliers,
- new opportunities for improvement,
- control of process and product nonconformities,
- marketplace evaluation and strategies,
- status of strategic partnership activities,
- financial effects of quality related activities, and
- other factors which may impact the organization, such as financial, social or environmental conditions, and relevant statutory and regulatory changes.

ISO 9001:2000, Quality management systems — Requirements

5.6.3 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.

5.6.3 Review output in the educational organization

The educational organization top management, as a result of reviewing the quality management system, should:

— *establish improvement parameters for the processes of the educational organization, for example teaching-learning; and*

— *revise or perform again the design review when a textbook or interactive learning programme is changed.*

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5.6.3 Review output

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

Additional outputs to enhance efficiency include, for example

— performance objectives for products and processes,

— performance improvement objectives for the organization,

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

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

— loss prevention and mitigation plans for identified risks, and

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

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

ISO 9001:2000, Quality management systems — Requirements

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 Resource management

6.1 Provision of resources in the educational organization

The organization providing educational services should establish arrangements for identifying resource needs for the performance of the teaching-learning processes. The organization should also ensure resource availability for effective functioning of the quality management system, as well as providing resources for enhancing customer satisfaction by meeting customer requirements. The organization should:

a) establish information inputs for detecting the needs for resources;

b) perform resource planning at a short, medium and long term;

c) carry out the follow-up of verification and assessment tasks; and

d) provide the resources to communicate effectively to the instruction staff, the administrative staff, employees and customers.

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6 Resource management

6.1 General guidance

6.1.1 Introduction

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

6.1.2 Issues to be considered

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

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

— tangible resources such as improved realization and support facilities,

— intangible resources such as intellectual property,

— resources and mechanisms to encourage innovative continual improvement,

— organization structures, including project and matrix management needs,

— information management and technology,

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

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

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

— planning for future resource needs.

ISO 9001:2000, Quality management systems — Requirements

6.2 Human resources

6.2.1 General

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

6.2 Human resources in the educational organization

6.2.1 General

The educational organization should plan a personnel system to maintain and improve the competence of teaching and supporting personnel.

Competence may include elements such as:

- *adaptation of curricula to accommodate scientific and technological changes;*
- *assessment of student achievement and organization effectiveness based on fulfilment of educational goals; and*
- *ensuring staff competence for carrying out their functions.*

Customers need to be assured that the educational organization has the qualified instructional personnel needed to meet students' instructional requirements. Qualification may include academic degrees held by instructors, employment history, special courses or certificates, and in-service training, which should be a part of the quality records.

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6.2 People

6.2.1 Involvement of people

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

- by providing ongoing training and career planning,
- by defining their responsibilities and authorities,
- by establishing individual and team objectives, managing process performance and evaluating results,
- by facilitating involvement in objective setting and decision making,
- by recognizing and rewarding,
- by facilitating the open, two-way communication of information,
- by continually reviewing the needs of its people,
- by creating conditions to encourage innovation,
- by ensuring effective teamwork,
- by communicating suggestions and opinions,
- by using measurements of its people's satisfaction, and
- by investigating the reasons why people join and leave the organization.

ISO 9001:2000, Quality management systems — Requirements

6.2.2 Competence, awareness and training

The organization shall

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

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

c) evaluate the effectiveness of the actions taken,

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

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

6.2.2 Competence, awareness, and training in the educational organization

Top management should provide teaching and supporting staff with information on how their competence, awareness, and training are aligned with their responsibilities, authorities, and academic-administrative activities.

The educational organization should:

— *carry out systematic actions for detecting competence needs by comparing curricula requirements with current personnel competencies;*

— *determine the need for training, or other activities to close any competence gaps;*

— *ensure that teachers operate with current and harmonised evaluation criteria; and*

— *keep records of academic and administrative staff competence. (See 4.2.4 of ISO 9001:2000.)*

Records should show a periodic review of training needs and their outcome.

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6.2.2 Competence, awareness and training

6.2.2.1 Competence

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

Consideration of the need for competence includes sources such as

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

— anticipated management and workforce succession needs,

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

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

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

6.2.2.2 Awareness and training

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

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

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

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

— experience of people,
— tacit and explicit knowledge,
— leadership and management skills,
— planning and improvement tools,
— teambuilding,
— problem solving,
— communication skills,
— culture and social behaviour,
— knowledge of markets and the needs and expectations of customers and other interested parties, and
— creativity and innovation.

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

— the vision for the future of the organization,
— the organization's policies and objectives,
— organizational change and development,
— the initiation and implementation of improvement processes,
— benefits from creativity and innovation,
— the organization's impact on society,
— introductory programmes for new people, and
— periodic refresher programmes for people already trained.

Training plans should include

— objectives,
— programmes and methods,
— resources needed,
— identification of necessary internal support,
— evaluation in terms of enhanced competence of people, and
— measurement of the effectiveness and the impact on the organization.

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

ISO 9001:2000, Quality management systems — Requirements

6.3 Infrastructure

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

a) buildings, workspace and associated utilities,

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

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

6.3 Infrastructure in the educational organization

The educational organization should establish arrangements to identify the specific infrastructure and equipment needed to achieve conformity to product requirements.

The organization should define responsibilities and authorities for carrying out bidding, purchase, reception, storage, safeguarding, installation, usage, and maintenance activities.

The educational organization should determine programmes for planning, providing and maintaining the necessary infrastructure, and for analysing the associated risks regarding people security and hygiene.

Infrastructure includes, when applicable:

a) buildings, working spaces: classrooms, laboratories, workshops, libraries, green areas;

b) associated services, such as
- *water,*
- *electric current with the proper installations,*
- *gases and fuels including those needed for instrumental usage,*
- *health services;*

c) equipment for the teaching-learning process: this includes accessories, supplies and consumables; and

d) support services, such as transport, bookstore, school items, cafeterias, refectories and crèches, as necessary.

If the materials and facilities to be used in instruction have not been developed according to this guideline, then resources should be available which describe the prerequisites, objectives, standards for assessments, instructional strategies, necessary controls, and arrangements for all the materials and facilities used for instruction.

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6.3 Infrastructure

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

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

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

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

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

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

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

ISO 9001:2000, Quality management systems — Requirements

6.4 Work environment

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

6.4 Work environment in the educational organization

An instruction plan should require that conditions for learning include safe classrooms, offices, laboratories, dormitories, and common spaces, free of health hazards and physical distractions. Supporting services should reinforce learning and not interfere with the learning process. Educational organizations should consider the learning environment and conditions for-off campus learning environments.

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6.4 Work environment

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

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

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

— ergonomics,

— workplace location,

— social interaction,

— facilities for people in the organization,

— heat, humidity, light, airflow, and

— hygiene, cleanliness, noise, vibration and pollution.

6.5 Information

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

— identify its information needs,

— identify and access internal and external sources of information,

— convert information to knowledge of use to the organization,

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

— ensure appropriate security and confidentiality, and

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

6.6 Suppliers and partnerships

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

— optimizing the number of suppliers and partners,

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

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

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

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

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

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

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

6.7 Natural resources

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

6.8 Financial resources

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

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

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

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

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

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

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

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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, 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 Product realization

7.1 Planning of product realization in the educational organization

Educational organizations should plan, as a minimum, the different stages of instructional design, development, delivery, evaluation and support services activities, resource allocation, evaluation criteria, and improvement procedures to achieve the desired results.

The organization should plan the necessary resources for all processes.

In educational organizations, some processes for product realization are:

a) teaching-learning activities;

b) designing and developing curricula;

c) formulation or establishment of research areas or projects;

d) training or other activities;

e) hiring personnel;

f) acquiring materials and other resources;

g) admitting of candidates (students);

h) controlling design and development changes in curricula, course calendars, timetables and prerequisites;

i) securing accreditation of programs, professional degrees, and post-graduate studies;

j) providing library, audiovisual equipment, computers, and other services;

k) providing security, safety and civil protection services;

l) allocating classrooms, laboratories, workshops, auditorium, classroom for ceremonies; and

m) maintaining facilities.

The major instructional processes that should be controlled may include needs assessment, instructional design, development and delivery, and outcome measurement. The major support processes described in ISO 9001 should also be controlled. For organizations selecting ISO 9001, control methods developed by instructors or a control committee may be established. The control method should be part of the management review to assure that instructional specifications are met and that the control methods are consistent with

accepted quality practices. Changes in the control method of these major processes should be documented and the instruction should be evaluated after any change has taken place.

Observations should be made to verify that control methods are effective. Ineffective control methods should be modified.

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7 Product realization

7.1 General guidance

7.1.1 Introduction

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

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

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

7.1.2 Issues to be considered

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

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

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

— identifying and communicating the significant features of the processes,
— training in the operation of processes,
— sharing knowledge and experience in teams and work groups,
— measurement and audit of processes, and
— analysis, review and improvement of processes.

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

— to ensure the health and safety of people,
— to ensure that the necessary skills exist,
— to support coordination of processes,
— to provide for input from people in process analysis, and
— to promote innovation from people.

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

7.1.3 Managing processes

7.1.3.1 General

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

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

— input and output requirements (for example specifications and resources),
— activities within the processes,
— verification and validation of processes and products,
— analysis of the process including dependability,
— identification, assessment and mitigation of risk,
— corrective and preventive actions,
— opportunities and actions for process improvement, and
— control of changes to processes and products.

Examples of support processes include

— managing information,
— training of people,
— finance-related activities,
— infrastructure and service maintenance,
— application of industrial safety/protective equipment, and
— marketing.

7.1.3.2 Process inputs, outputs and review

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

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

Examples of input issues to consider include

— competence of people,
— documentation,
— equipment capability and monitoring, and
— health, safety and work environment.

Process outputs that have been verified against process input requirements, including acceptance criteria, should consider the needs and expectations of customers and other interested parties. For verification purposes, the outputs should be recorded and evaluated against input requirements and acceptance criteria. This evaluation should identify necessary corrective actions, preventive actions or potential improvements in the effectiveness and efficiency of the process. Verification of the product can be carried out in the process in order to identify variation.

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

— reliability and repeatability of the process,
— identification and prevention of potential nonconformities,
— adequacy of design and development inputs and outputs,
— consistency of inputs and outputs with planned objectives,

— potential for improvements, and
— unresolved issues.

7.1.3.3 Product and process validation and changes

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

Issues to consider should include

— quality policy and objectives,
— capability or qualification of equipment,
— operating conditions for the product,
— use or application of the product,
— disposal of the product,
— product life cycle,
— environmental impact of the product, and
— impact of the use of natural resources including materials and energy.

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

— for high value and safety critical products,
— where deficiency in product will only be apparent in use,
— which cannot be repeated, and
— where verification of product is not possible.

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

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

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

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

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

— fault modes and effects analysis,
— fault tree analysis,
— relationship diagrams,
— simulation techniques, and
— reliability prediction.

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7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

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

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

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

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

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

a) product requirements are defined,

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

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

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

7.2 Customer-related processes

For the most part, educational organizations provide a service that is intangible, not storable, and consumed during delivery. Educational organizations provide the opportunity for students to study existing knowledge and to practice its application. These organizations also have administrative support systems that help to ensure high-grade instruction. Generic independent customer requirements may include (but are not restricted to) the following:

a) providing safe, clean facilities with someone in charge;

b) ensuring that two-way communication procedures between individuals and the educational organization are responsive;

c) ensuring that all the organizations' personnel treat interested parties with respect; and

d) providing appropriate activities conducted by qualified personnel.

7.2.1 Determination of product-related requirements in the educational organization

The education requirements are expressed as behaviour needed to meet academic, professional and society's expectations.

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7.2 Processes related to interested parties

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

— requirements of the customer or other interested parties,

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

— contract requirements,

— competitor analysis,

— benchmarking, and

— processes due to statutory or regulatory requirements.

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

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7.3 Design and development

7.3.1 Design and development planning

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

During the design and development planning, the organization shall determine

a) the design and development stages,

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

c) the responsibilities and authorities for design and development.

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

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

7.3 Design and development

7.3.1 Design and development planning in the educational organization

In designing and developing the curriculum plan, the organization should consider entrance to the next grade to be the exit level from the present grade or competence level.

Top management should consider the design and development of education for the benefits of students and other customers.

Design control activities should be appropriate to the purpose and duration of the education.

Procedures should ensure that appropriate instruction materials match the instruction requirements.

Calibrated equipment may be needed for some instructional purposes.

Since needs assessments include student achievement and organization effectiveness, these assessments should include potential or actual performance requirements to determine:

- *how instruction can help students to become competent;*
- *how new requirements can be met;*
- *specific measures of instructional effectiveness; and*
- *if skills to be taught match curricular requirements.*

These assessments should provide information that can be used in the instruction review process. Where experimental validation of instruction is not permitted, a peer review process could be adopted.

A needs analysis report should provide input to the instructional design process, describe the results of the needs assessment and state the goals for design.

Typically a report should:

- *state why training was chosen as the means to improve performance;*
- *state any differences between required and acquired performance gaps that the instruction was designed to meet;*
- *state how the gaps are to be met in performance terms and state the rationale;*
- *identify the target student population;*
- *identify preventive action;*

— *specify any changes in instruction activities; and*

— *state that all relevant safety and legislative regulations are observed even when not stated in a contract, instruction specification, or curriculum.*

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7.3 Design and development

7.3.1 General guidance

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

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

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

— design fault modes and effects analysis,

— fault tree analysis,

— reliability prediction,

— relationship diagrams,

— ranking techniques, and

— simulation techniques.

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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 verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

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

c) contain or reference product acceptance criteria, and

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

7.3.2 Design and development inputs in the educational organization

The educational organization should identify the inputs to the design of curricula.

They should include:

- *results on effectiveness of instructional materials;*
- *certification, licenses or occupational requirements;*
- *data on research of student learning capacity;*
- *the required competence of teachers;*
- *prerequisites for courses; and*
- *difficulty level of objectives.*

7.3.3 Design and development outputs

Design and development outputs should, at least, include the following:

- *skills and knowledge to be acquired;*
- *assessment of performance;*
- *appropriate instruction strategies; and*
- *reliable delivery media.*

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7.3.2 Design and development input and output

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

Examples are as follows:

a) external inputs such as
   - customer or marketplace needs and expectations,
   - needs and expectation of other interested parties,
   - supplier's contributions,
   - user input to achieve robust design and development,
   - changes in relevant statutory and regulatory requirements,
   - international or national standards, and
   - industry codes of practice;

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

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

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

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

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

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

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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 (see 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 (see 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 (see 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).

7.3.4 Design and development review in the educational organization

Depending on its complexity, the design and development review could be done in one or several stages, or could be planned as per 7.3.1. Participants from relevant activities in each stage should review the design and development results versus the corresponding requirements (i.e. professional profiles, competence certification). Records for complex matters could be minutes of formal meetings.

A design report review (assessment and evaluation) process should be used for all instructional designs. The review should be accomplished by a team of people including those who are responsible for the design, some interested parties, and some not responsible for the design. These people review the design reports and should be responsible for judging the adequacy of the design to meet the requirements.

The design process should be evaluated and revised in terms of the instructional outcome desired. This review should be based upon experience of successful projects and information from the subsequent development and implementation phases.

A development process should be documented and used by developers. There may be a specific process statement for each delivery medium, or a generic process for all media. These processes include the sequence of steps in the development process, the personnel involved, the review processes, and associated criteria.

A development report or checklist should be generated to document the procedures used and how they ensured that the instruction meets the design specifications.

An instruction review process should be used for all instruction. Personnel who participate in the review and who are responsible for its revisions should be identified. Criteria for acceptance, in terms of readiness for use in instruction, should be specified and may include the following:

a) approval of content accuracy by one or more subject-matter specialists who did not participate in the development of the instruction;

b) approval of the prose, illustrations, and appearance by editorial and graphics specialists;

c) approval, if appropriate, of the technological soundness by a technology specialist; tryout trial of both the instruction and the criterion-referenced assessments with students from the target population, and revisions made based upon the experience of students; and

d) at least one of the tryouts trials should be in an environment similar to that in which the instruction will be conducted, including the support materials for students as well as procedures and support materials for preparing instructors.

In the implementation phase, organizations should describe how the development process should be reviewed and revised based upon successive project-by-project experience with the process, including any customers complaints that become available during the process.

7.3.5 Design and development verification in the educational organization

Design verification should be performed in one or several stages according to the design and development plan. This activity could be performed either internally, by any specialist who has not participated in the design and development verification, or externally. The design and development output stage should match the design development input specifications.

7.3.6 Design and development validation in the educational organization

This process is carried out to ensure that planned product characteristics are met by the resulting curriculum or syllabus design.

Validation should be performed generally on the final design stages. Among others, piloting and certification are accepted validation methods.

7.3.7 Control of design and development changes in the educational organization

In the education environment the rapid evolution of knowledge leads to periodic curricula and syllabus review, and resulting revision. These changes should be identified, documented, authorised and communicated.

The revision of any subject should include the evaluation of its effect on the entire curriculum, and records should be maintained.

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7.3.3 Design and development review

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

Examples of topics for such reviews include

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

— progress of the planned design and development process,

— meeting verification and validation goals,

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

— life-cycle data on performance of the product,

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

— identification and correction of problems,

— opportunities for design and development process improvement, and

— potential impact of the product on the environment.

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

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

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

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

— evaluation against similar products,

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

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

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

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

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

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

— validation of services prior to widespread introduction.

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

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

— process and product improvement,

— usability of output,

— adequacy of process and review records,

— failure investigation activities, and

— future design and development process needs.

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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.

7.4 Purchasing

No guidance is considered necessary.

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7.4 Purchasing

7.4.1 Purchasing process

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

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

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

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

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

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

— unique supplier processes;

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

— warranty replacement for nonconforming purchased products;
— logistic requirements;
— product identification and traceability;
— preservation of product;
— documentation, including records;
— control of purchased product which deviates from requirements;
— access to suppliers' premises;
— product delivery, installation or application history;
— supplier development;
— identification and mitigation of risks associated with the purchased product.

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

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

7.4.2 Supplier control process

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

Examples of inputs to the supplier control process include

— evaluation of relevant experience,
— performance of suppliers against competitors,
— review of purchased product quality, price, delivery performance and response to problems,
— audits of supplier management systems and evaluation of their potential capability to provide the required products effectively and efficiently and within schedule,
— checking supplier references and available data on customer satisfaction,
— financial assessment to assure the viability of the supplier throughout the intended period of supply and cooperation,
— supplier response to inquiries, quotations and tendering,
— supplier service, installation and support capability and history of performance to requirements,
— supplier awareness of and compliance with relevant statutory and regulatory requirements,
— the supplier's logistic capability including locations and resources, and
— the supplier's standing and role in the community, as well as perception in society.

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

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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.

7.5 Production and service provision

7.5.1 Control of production and service provision in the educational organization

Top management (superintendents, principals, directors, faculty senates, deans, vice-presidents, presidents) in co-operation with the instructors, should identify overall topics and themes of the subject matter to be taught, the generally accepted methods of instruction, and establish various accepted measures for determining compliance with the learning objectives.

The educational organization should ensure the control of processes. For this, an educational organization should consider the following processes, as appropriate:

— *selecting and enrolling students;*

— *designing curricula on different subjects;*

— *developing course catalogues;*

— *allocating teaching loads;*

— *providing practice manuals for laboratories and workshops;*

— *allocating the resources necessary to carry out off-campus instruction;*

— *developing course material;*

— *establishing methods to verify academic performance;*

— *allocating spaces for classrooms, laboratories, workshops, libraries, and other similar spaces; and*

— *tutoring and consulting on vocational opportunities.*

If a contract agreement requires further support of students after completion of their program of studies, the organization should indicate how such support will be given and monitored.

The aptitude, knowledge, skills and ability of new students should be assessed to ensure that the instruction can be provided at an appropriate level and at an appropriate pace. Advertising, course brochures, and other items produced by the instructional organization should state clearly how prior education, training, and experience are related to the learning needs of students. The absence of specific entrance requirements need not negate an assessment of individual student needs that may be then used to adjust the instruction to those individual needs.

A database should be established to identify the actual instruction provided, which may include:

a) student course records;

b) the course syllabus;

c) the learner group schedule;

d) textbook and edition;

e) list of instructors' names;

f) instruction materials; and

g) relevant pre-requisite knowledge or experience.

7.5.2 Validation of processes for production and service provision in the educational organization

This clause should be applied when monitoring and measurement of educational services cannot be carried out as described in 8.2.3.

The validation of learning processes should include, as necessary:

- *design and development validation results of curricula or syllabus;*
- *equipment approval and teachers' qualifications;*
- *course notes and examination papers;*
- *records data; and*
- *revalidation frequency.*

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7.5 Production and service operations

7.5.1 Operation and realization

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

- reducing waste,
- training of people,
- communicating and recording information,
- developing supplier capability,
- improving infrastructure,
- preventing problems,
- processing methods and process yield, and
- methods of monitoring.

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7.5.3 Identification and traceability

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

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

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

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

7.5.3 Identification and traceability in the educational organization

Identification and traceability of relevant information should include, as necessary:

- *curricula, course, content unit codes;*
- *student identification records;*
- *learner group schedules;*
- *text books/notes;*
- *laboratory equipment; and*
- *research contracts.*

The ongoing monitoring and performance status of students/groups should be identified and recorded.

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7.5.2 Identification and traceability

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

The need for identification and traceability may arise from

- status of products, including component parts,
- status and capability of processes,
- benchmarking performance data, such as marketing,
- contract requirements, such as product recall capability,
- relevant statutory and regulatory requirements,
- intended use or application,
- hazardous materials, and
- mitigation of identified risks.

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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 (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.4 Customer property in the educational organization

In the educational organization, property provided by customers/students is that provided at the moment of admission for registration or registration renewal purposes and during the service provision. Among other documents, there are:

- *documents given by students, such as certificates, diplomas of previous scholar levels, personal ID documents (birth certificate, identifications) and other similar ones;*
- *intellectual property agreements;*
- *medical exams, studies or certificates of the student;*
- *exams, tests or paperwork performed by the student;*
- *final works, prototypes developed and others;*
- *applications, records or documents given by the student for his registration or registration renewal;*
- *records and documents of the student's academic history;*
- *student/customer owned equipment; and*
- *facilities for courses provided at the customer's premises.*

Customer property includes items such as textbooks, workbooks, case studies, special education provisions, computers, software, art supplies, or facilities supplied by companies that purchase instruction for employees. As appropriate, standards and specifications may be established for supplied materials to ensure suitability for use in instruction.

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7.5.3 Customer property

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

- ingredients or components supplied for inclusion in a product,
- product supplied for repair, maintenance or upgrading,
- packaging materials supplied directly by the customer,
- customer materials handled by service operations such as storage,
- services supplied on behalf of the customer, such as transport of customer property to a third party, and
- customer intellectual property, including specifications, drawings and proprietary information.

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7.5.5 Preservation of product

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

7.5.5 Preservation of product in the educational organization

The educational organization should consider preserving academic documents such as syllabus, curricula and printed or electronic materials (books, course notes, magnetic or optical disks, computer programs, files, etc.).

Supplies for education and/or training processes, could also be included, e.g., chemicals for laboratories, raw or processed materials for pilot plants, limited shelf-life products for teaching purposes or research and development work.

There may be some limited applications of this element in ISO 9001 which include the method of delivery, how materials should be presented to the student, equipment that needs to be available (e.g., video tapes), etc. For resident students there may also be services that should be provided such as health, counselling, personal safety, lodgings, food services, etc.

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7.5.4 Preservation of product

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

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

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

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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;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the 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 See ISO 10012-1 and ISO 10012-2 for guidance.

7.6 Control of monitoring and measuring devices in the educational organization

To ensure that measurement capability is consistent with the measurement requirements, measurement systems should be validated for their reliability and utility.

Monitoring and measurement should be carried out during instruction to assure conformity with the instructional plan. This may include student performance profiles, assessments of personnel records, written course assessments, observations which note whether instructors are following the plan, and final examinations.

If follow-ups of graduates identify omitted or incorrect instruction, the educational organization may wish to recall the materials and/or provide students with the missing or corrected instruction.

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7.6 Control of measuring and monitoring devices

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

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

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

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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 Measurement, analysis and improvement

8.1 General guidance in the educational organizations

The educational organization should establish a process for collecting the appropriate information, including the identification of information sources. Data should be used to ensure the effectiveness of the teaching/learning process. Examples include control graphs, histograms, Pareto charts, satisfaction surveys of customer and other identified interested parties, teaching methods, organizational-administrative measurements, measurements of variables related to students, teaching staff, support staff, and other relevant indicators such as failures, expenses, dropout and students' performance.

The measurement process for education and supporting processes should be divided into the following steps:

— *deciding which measurements will be of value to monitor;*

— *observing and making qualitative and/or quantitative measures; and*

— *converting information into knowledge.*

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8 Measurement, analysis and improvement

8.1 General guidance

8.1.1 Introduction

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

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

— measurement and evaluation of its products,

— capability of processes,

— achievement of project objectives, and

— satisfaction of customer and other interested parties.

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

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

8.1.2 Issues to be considered

Measurement, analysis and improvement include the following considerations:

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

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

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

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

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

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

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

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

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

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

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

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8.2 Monitoring and measurement

8.2.1 Customer satisfaction

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

8.2 Monitoring and measurement

8.2.1 Customer satisfaction in the educational organization

The educational organization should have reliable methods for monitoring and measuring customer satisfaction. Trend indicators of customer satisfaction should be documented and supported by objective evidence. The organization should communicate the results of customer satisfaction at appropriate frequencies to interested parties.

Examples of monitoring and measurement of customer satisfaction include timely answers to complaints, satisfaction surveys regarding the courtesy of administrative and teaching staff.

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8.2 Measuring and monitoring

8.2.1 Measurement and monitoring of system performance

8.2.1.1 General

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

— satisfaction surveys for customers and other interested parties,

— internal audits,

— financial measurements, and

— self-assessment.

8.2.1.2 Measurement and monitoring of customer satisfaction

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

— customer and user surveys,

— feedback on aspects of product,

— customer requirements and contract information,

— market needs,

— service delivery data, and

— information relating to competition.

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

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

— customer complaints,
— communicating directly with customers,
— questionnaires and surveys,
— subcontracted collection and analysis of data,
— focus groups,
— reports from consumer organizations,
— reports in various media, and
— sector and industry studies.

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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.

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.

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

8.2.2 Internal audit in the educational organization

The educational organization should carry out internal audits considering aspects related to the educational product, accreditation and certification, failures in the teaching/learning process, the effectiveness of teaching methods, educational processes and performance of the quality management system. The organization should document the final report of the internal audit.

Examples of aspects to be evaluated are:

- *verifying that the procedures for the achievement of educational objectives have been fully implemented;*
- *verifying that quality management system requirements have been achieved;*
- *verifying that sufficient resources have been provided to achieve quality objectives;*
- *quality records as stated in the quality management system;*
- *activities of the organization personnel that affect quality; and*
- *ensuring that ISO 9001 requirements are known, implemented, and maintained.*

NOTE See ISO 19011:2002.

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8.2.1.3 Internal audit

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

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

Examples of subjects for consideration by internal auditing include

— effective and efficient implementation of processes,
— opportunities for continual improvement,
— capability of processes,
— effective and efficient use of statistical techniques,
— use of information technology,
— analysis of quality cost data,
— effective and efficient use of resources,
— process and product performance results and expectations,
— adequacy and accuracy of performance measurement,
— improvement activities, and
— relationships with interested parties.

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

8.2.1.4 Financial measures

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

— prevention and appraisal costs analysis,
— nonconformity cost analysis,
— internal and external failure cost analysis, and
— life-cycle cost analysis.

8.2.1.5 Self-assessment

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

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

— it is simple to understand,
— it is easy to use,
— it has minimal impact on the use of management resources, and
— it provides input for enhancing the performance of the organization's quality management system.

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

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8.2.3 Monitoring and measurement of processes

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

8.2.3 Monitoring and measurement of processes in the educational organization

The educational organization should measure and monitor the processes used to manage and deliver the educational products. Measurement should be done at appropriate periods.

Examples of the processes that should be monitored include, but are not limited to:

- *administration of enrolments and assessments;*
- *record management; and*
- *educational programmes.*

The educational organization should document methods used in order to measure the processes. Examples of methods include comparative analysis, statistical methods, cycle time, etc.

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8.2.2 Measurement and monitoring of processes

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

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

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

- capability,
- reaction time,
- cycle time or throughput,
- measurable aspects of dependability,
- yield,
- the effectiveness and efficiency of the organization's people,
- utilization of technologies,
- waste reduction, and
- cost allocation and reduction.

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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. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery 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.

8.2.4 Monitoring and measurement of product in the educational organization

The educational organization should establish and use methods for monitoring educational product outcomes in order to maintain established educational processes.

For all types of education, specific evaluation processes, such as assessments, tests or examinations, should be used to measure the progress toward fulfilling the curriculum requirements.

A range of measures from observation of performance to a full set of examinations may be used.

The results of this evaluation process should be recorded and used to demonstrate that the educational products achieved the planned objectives.

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8.2.3 Measurement and monitoring of product

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

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

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

b) equipment, software and tools required;

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

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

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

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

g) where, when and how the organization intends, or is required by the customer or statutory and regulatory authorities, to engage qualified third parties to perform
   - type testing,
   - in-process inspections or testing,
   - product verification,
   - product validation, and
   - product qualification;

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

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

j) recording the results of product measurements.

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

— inspection and test reports,
— material release notices,
— product acceptance forms, and
— certificates of conformity as required.

8.2.4 Measurement and monitoring the satisfaction of interested parties

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

a) For people in the organization, the organization should
   — survey the opinions of its people regarding how well the organization satisfies their needs and expectations, and
   — assess individual and collective performances and their contribution to organizational results.

b) For owners and investors, the organization should
   — assess its capacity to attain defined objectives,
   — assess its financial performance,
   — evaluate the impact of external factors on its results, and
   — identify the value contributed by the actions taken.

c) For suppliers and partners, the organization should
   — survey the opinions of suppliers and partners on their satisfaction with the purchasing processes of the organization,
   — monitor and supply feedback on the performance of suppliers and partners and their compliance with the organization's purchasing policy, and
   — assess the quality of product purchased, contributions from suppliers and partners, and mutual benefits derived from the relationship.

d) For society, the organization should
   — define and track suitable data relative to its objectives, in order to achieve satisfactory interaction with society, and
   — periodically assess the effectiveness and efficiency of its actions and the perceptions of its performance by relevant parts of society.

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8.3 Control of nonconforming product

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

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

a) by taking action to eliminate the detected nonconformity;

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

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

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

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

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

8.3 Control of nonconforming products in the educational organization

Areas in which nonconformities can may be found include, but are not limited to, training plans, teaching staff and student performance, materials, and services provided for educational organizations.

Where a nonconformity exists, involving student participation in the educational process, students may be, where permitted:

a) provided with additional training and permitted to be reassessed;

b) to continue in the educational programme in accordance to defined procedures; and

c) transferred to another study programme;

Nonconforming products may include educational programmes, training plans, support materials, or tools.

Waivers for special programs should be recorded and reviewed annually.

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8.3 Control of nonconformity

8.3.1 General

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

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

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