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**International Workshop Agreement 2 — Quality Management Systems — Guidelines for the application of ISO 9001:2000 on education**

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## 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to decide whether it will be confirmed for a further three years, transferred to an ISO technical body for revision, or withdrawn.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again after a further three years, at which time it must be either revised by the relevant ISO technical body or withdrawn.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.

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

## International Workshop Agreement 2 — Quality Management Systems — Guidelines for the application of ISO 9001:2000 on education

### Introduction

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

Note 1: The text of ISO 9004:2000 Quality management systems – Guidelines to performance improvement 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 or training organisation.

### 0.1 General

The adoption of a quality management system should be a strategic decision by the top management of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization.

This International Standard is based on eight quality management principles. However, it is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The purpose of an organization is:

- to identify and meet the needs and expectations of its customers and other interested parties (people in the organization, suppliers, owners, society), to achieve competitive advantage, and to do this in an effective and efficient manner, and
- to achieve, maintain, and improve overall organizational performance and capabilities.

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

- customer loyalty,
- repeat business and referral,
- operational results such as revenue and market share,
- flexible and fast responses to market opportunities,
- costs and cycle times through effective and efficient use of resources,
- alignment of processes which will best achieve desired results,
- competitive advantage through improved organizational capabilities,
- understanding and motivation of people towards the organization's goals and objectives, as well as participation in continual improvement,
- confidence of interested parties in the effectiveness and efficiency of the organization, as demonstrated by the financial and social benefits from the organization's performance, product life cycle, and reputation,
- ability to create value for both the organization and its suppliers by optimization of costs and resources as well as flexibility and speed of joint responses to changing markets.

### 0.1 General

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

Each quality management system is influenced by different educational and training objectives, by different instructional methods, and by different administrative practices specific to the organization. Therefore, quality systems can be expected to vary from one organization to another.

The quality management system should be the simplest one that works well. It need be only 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.

## 0.2 Process Approach

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

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

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

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

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

- a) understanding and fulfilling the requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

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

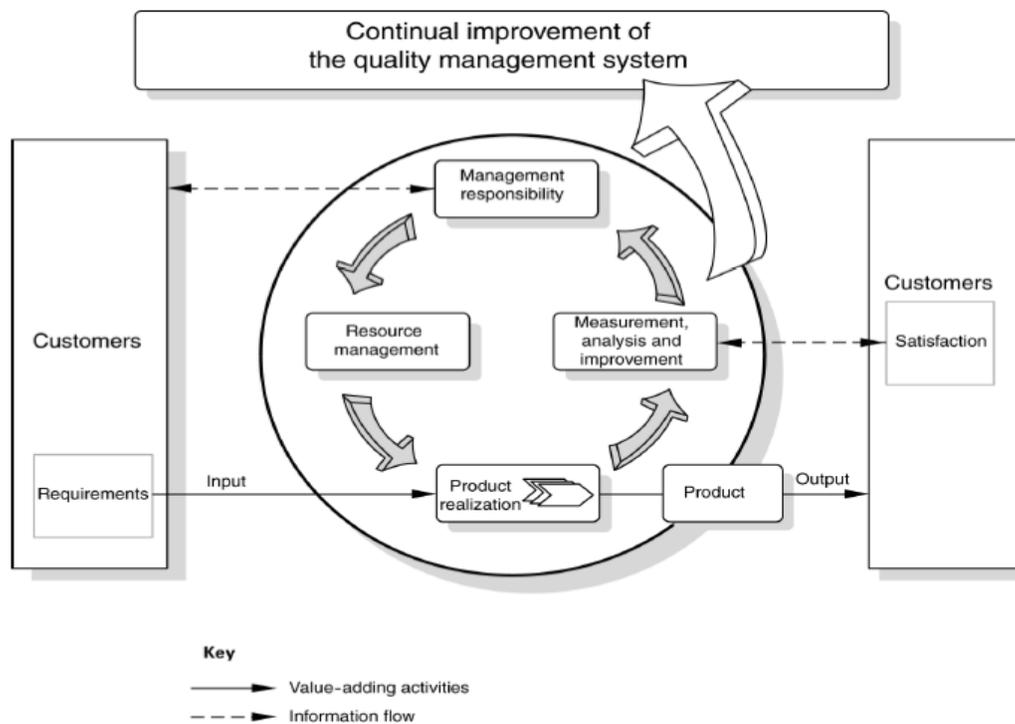


Figure 1 — Model of a process-based quality management system

*Educational organizations which 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 social-economic environment*
- b) provision of the pedagogical capability of the learning providers*
- c) maintenance of the working environment*
- d) developing, reviewing and updating study plans and curricula.*
- e) admission and selection of applicants,*
- f) student's education follow-up and assessment,*
- g) 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.*
- h) 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.*

- i) *Internal and external communication*
- j) *Measurement of educational processes*

### 0.3 Relationship with ISO 9001

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

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

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

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

### 0.4 Compatibility with other management systems

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

#### 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 System – 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**

#### **1.1 For educational organizations**

*To provide guidelines for the application of ISO 9001:2000 in educational organizations providing educational products at all levels*

*These guidelines do not add to, change or modify the requirements of ISO 9001:2000 and are not intended for use in contracts, neither for compliance assessments, nor for certification.*

*Each clause of ISO 9001:2000, framed with continuous solid line, will appear with its corresponding text of IWA 2, framed with discontinuous line. The whole text of ISO 9004:2000 is used to provide a complete vision of the continual and performance improvement of organizations.*

## **2 Normative reference**

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to

agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

### **3 Terms and definitions**

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

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

Supplier  $\longrightarrow$  organization  $\longrightarrow$  customer (interested parties)

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

## **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**  $\longrightarrow$  **organizations**  $\longrightarrow$  **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 the education sector***

*For the purposes of IWA 2, the terms and definitions given in ISO 9000 and the following apply*

#### ***3.1***

***customer [ISO 9000:2000]***

***organization (3.3.2) or person that receives a product (3.4.2)***

*EXAMPLE for IWA 2 clauses: A customer can be a **consumer**, in education or training, generally a learner, a **client** or **purchaser**, in education or training, generally a person or body funding the learner who may also be the learner, an **end-user**, in education or training, generally the person or organization that benefits from the learning achieved by the learner.*

### 3.2

#### **interested party [ISO 9000:2000]**

*person or group having an interest in the performance or success of an organization*

*EXAMPLE for IWA 2 clauses: 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)*

*NOTE: educational process covers different kinds of learning activity such as training, adult education, university, secondary and primary education.*

### 3.4

#### **educational product**

*product concerned with education*

*NOTE : An educational product generally involves the provision of a service that includes the 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 **educational product** (3.4)*

### 3.6

#### **education provider**

*person who delivers **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*

## 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.

#### 4.1 General requirements

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

The organization shall:

- a) identify the processes needed for the quality management system and their application throughout the organization,
- b) determine the sequence and interaction of these processes,

- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyze 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.

#### **4.1 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 the ISO9001, the guidelines are limited to:*

*1. 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.*

*2. The conditions for the acceptance of the education at the time of delivery.*

*3. Continual improvement of these processes and provision of resources are also included.*

*The educational organization should establish very clearly what exactly the intended "organization" is to be to which the intended quality management system is to apply. Eg is it to be a department or school within a larger education institution, an entire educational institution or all the education institutions in a given government or local government division.*

*Answers to this question will help the educational organization to identify who "Top management" are and the nature of the systems and processes that have to be understood if continual improvement and customer satisfaction are to be achieved.*

It will also help in identification of what services are delivered which is essential in identification and separation of customers and other interested parties.4.2.

## 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.

## **4.2 Documentation requirements**

### **4.2.1 General**

The quality management system documentation shall include:

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by this International Standard,
- d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard.

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

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

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

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

### **4.2.2 Quality manual**

The organization shall establish and maintain a quality manual that includes:

- a) the scope of the quality management system, including details of and justification for any exclusions,
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

### **4.2.3 Control of documents**

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

A documented procedure shall be established to define the controls needed:

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

#### **4.2.4 Control of records**

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

### **4.2 Documentation Requirements**

#### **4.2.1 General**

*When planning a quality management system, educational organizations developing their quality manual could include or make reference to other issues, apart from the ones established by ISO 9001:2000 standard, (see ISO/TR 10013 Guidelines for the development of quality management system documentation) such as but not limited to:*

- a) the terms and definitions required by the organization*
- b) regulatory and organizational policies*
- c) applicable laws and regulations*
- d) the teaching staff/professor's competencies*
- e) accreditation and certification programs.*

- f) *study plans and curricula*
- g) *competence programs, awareness, education, training and updating; and*
- h) *support services.*

## **4.2 Documentation in the educational organization**

### **4.2.2 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 system is based.*

*When planning a quality management system, educational organizations developing their quality manual could include or make reference to other issues, apart from the ones established by ISO 9001:2000 standard,*

### **4.2.3 Control of documents in the educational organization**

*The purpose of document control is ensuring that documents from the quality management system are continually updated and be available for their use. For that, the educational organization should establish a documented procedure describing:*

- *the mechanisms for editing, reviewing and approving the internal documents, including their identification and its revision status.*
- *the mechanism for document control, including the external documents, mainly the relevant regulations that should be permanently updated.*
- *the mechanism allowing that documents are available for the organization staff.*
- *the mechanisms for managing and controlling the students 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 compliance.*

*Information about the textbook or learning edition, 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 documents. (for example, but not limited to, Legislation, Rules, Government Circulars, Accreditation Regulations, etc.)

#### **4.2.4 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.

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.

The following types of records are examples that may be a part of the quality management system:

- 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 is defined in clause 5 to 8 by reference to 4.2.4.

### 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.

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.

## 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 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.

### **5.1 Management commitment in the education sector**

*Top management, a person or a group of people who directs and controls an educational organization at the highest level, shall identify which are the satisfying factors for the needs and expectations of the customer.*

*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 institutions are:*

- organization quality policies;*
- diffusion of the quality management system plan;*
- diffusion plan reviewing and follow-up.*
- Reviewing and follow-up of the diffusion plan.*

*Among other means to establish a diffusion plan enabling the visibility of the commitment and values of top management, to create the proper environment for:*

- -establishing a quality policy that allows to let all the members of the institution 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 the whole educational organization, through its formal structure the importance of meeting the students/customer requirements, as well as the legal an regulatory requirements for the educational service provided.*
- -publication of organization bulletins for communicating the relevant quality- related matters as quality objectives performance, giving feedback to students/ customers.*
- -measuring the organization performance in order to monitor the fulfillment of the established policies and objectives.*

*Top- management should ensure that educational program and processes comply with the legal and regulatory requirements, for their certification or accreditation.*

*Top management (superintendents, principals, directors, faculty senates, deans, vice-presidents, presidents) in cooperation 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.*

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### 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 analyze 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.

## **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 Customer focus**

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

#### **5.2 Customer focus in the educational organization**

*The educational organization top management should identify the needs and expectations of the customers and all interested parties in order to strive for their fulfillment.*

*Needs and expectations should be identified by taking into account that an educational organization has very concrete needs and expectations therefore customers needs and expectations should be defined by the specific educational organization.*

*Stakeholders' requirements are often implied. They should be defined and documented as curriculum requirements that include well-defined learning outcomes and performance standards. Instructional designs that should be reviewed at the proposal stage and, at a minimum, annually thereafter to assure that all requirements are met and are aligned with institutional objectives.*

#### **5.2.3 Statutory and regulatory requirements**

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

- the promotion of ethical, effective and efficient compliance with current and prospective requirements,
- the benefits to interested parties from exceeding compliance, and
- the role of the organization in the protection of community interests.

### **5.3 Quality policy**

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

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

In establishing the quality policy, top management should consider:

- the level and type of future improvement needed for the organization to be successful,
- the expected or desired degree of customer satisfaction,

- the development of people in the organization,
- the needs and expectations of other interested parties,
- the resources needed to go beyond ISO 9001 requirements, and
- the potential contributions of suppliers and partners.

The quality policy can be used for improvement provided that:

- it is consistent with top management's vision and strategy for the organization's future,
- it permits quality objectives to be understood and pursued throughout the organization,
- it demonstrates top management's commitment to quality and the provision of adequate resources for achievement of objectives,
- it aids in promoting a commitment to quality throughout the organization, with clear leadership by top management,
- it includes continual improvement as related to satisfaction of the needs and expectations of customers and other interested parties, and
- it is effectively formulated and efficiently communicated.

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

### **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 education organizational**

*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. Management 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 staff involved on the educational process continuous improvement*

## **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.

## **5.2 Planning**

### **5.4.1 Quality objectives**

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

#### **5.4.1 Quality objectives in the educational organization**

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

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

#### **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, an
- needs for documentation, including records.

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

#### **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 education organization**

*The quality management system planning should consist of the activities and the resources needed to achieve the educational organizational objectives. For examples refer to ISO 9004.*

### **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.

#### **5.5.1 Responsibility and authority in the education sector**

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

*An instructional quality 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 instructional organizations' employees or appropriate suppliers. Processes should be documented and reviewed on an annual basis to facilitate continuous improvement.*

*Control of instruction may be exercised during the Add following processes:*

- a) *instructional needs analysis;*
- b) *instructional design;*
- c) *instructional development;*
- d) *delivery of instruction;*
- e) *instructional evaluation;*
- f) *faculty development; and*
- g) *operation of libraries, workshops, and laboratories.*

### 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.

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

### **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.

#### **5.5.3 Internal communication**

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

### **5.5.3 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, thorough different areas and departments, in order to share the information related to the effectiveness of the quality management system.*

## 5.6 Management review

### 5.6.1 General

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

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

## 5.6 Management review

### 5.6.1 General

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

Records from management reviews shall be maintained.

## **5.6 Management review in the educational organization**

### 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**

*Entry information to assess the quality management system effectiveness should consider the students/ customers, and could also include for example:*

- comparative studies with other organizations, eg. benchmarking*
- status of graduates' follow-up actions,*
- proposals for improvement/changes.*

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

### **5.6.2 Review input**

The input to management review shall include information on:

- a) results of audits
- b) customer feedback
- c) process performance and product conformity
- d) status of preventive and corrective actions
- e) follow-up actions from previous management reviews
- f) changes that could affect the quality management system, and
- g) recommendations for improvement

### **5.6.3 Review output**

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

Additional outputs to enhance efficiency include, for example:

- performance objectives for products and processes,

- performance improvement objectives for the organization,
- appraisal of the suitability of the organization's structure and resources,
- strategies and initiatives for marketing, products, and satisfaction of customers and other interested parties,
- loss prevention and mitigation plans for identified risks, and
- information for strategic planning for future needs of the organization.

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

### **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.*
- .When a textbook or interactive learning program is changed, the design review should be revised or the review re-performed.*

*NOTE: Move to chapter 7*

*Top management (superintendents, principals, directors, faculty senates, deans, vice-presidents, presidents) in cooperation 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.*

*Note refer to 7.1: Educational organizations should plan as a minimum, the different stages of instructional design, development, delivery and evaluation and support services activities, resource allocation, evaluation criteria, and improvement procedures to achieve the desired result*

*Note include in section 8.3: Waivers for special programs should be recorded and viewed annually.*

*Note refer to 7.5.1: An instructional quality 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 instructional organizations' 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) faculty development; and*
- g) operation of libraries, workshops, and laboratories*

*Note move to 6.x: The educational organization top- management should provide the resources to effectively communicate to the staff, the administrative staff, employees and customers.*

## 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.

## 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.

## **6.1 Provision of resources in the education sector**

*The organization providing educational services at its different levels and modes should establish mechanisms for identifying resource needs for the teaching- learning processes performance and ensure their availability for an effective functioning of the quality management system, as well as providing with resources for enhance customer satisfaction by meeting customer requirements:*

- a) establishing information inputs for detecting the needs for resources;*
- b) performing resource planning at a short, medium and long term; and*
- c) carrying out the follow- up of verification and assessment tasks.*

## **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.

## 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 education sector*

### 6.2.1 *General*

*The educational organization should plan a personnel system to maintain and improve the teacher and the supporting staff competence.*

*Competence may include elements such as:*

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

*Interested parties need to be assured that the educational organization has the qualified instructional personnel 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.*

## 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.

### **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
- e) to the achievement of the quality objectives, and
- f) maintain appropriate records of education, training, skills and experience.

### 6.2.2 *Competence, awareness and training in the education sector.*

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

*The educational organization should:*

- carry out systematic actions for detecting competence needs by comparing curricula requirements with current staff competencies,*
- determine the need for training, or other activities to close any competence gaps;*
- ensure that teachers operate with up to date and harmonized evaluation criteria;*
- keep records of academic and administrative staff competencies.(see 4.2.4 of ISO 9001:2000).*

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

### 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.

### 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 education sector

*The educational organization should establish mechanisms to identify specific needs regarding infrastructure and equipment, needed to achieve conformity to product requirements.*

*Defining responsibilities and authorities for carrying out bidding, purchase, reception, storage, safeguarding, installation, usage and maintenance activities.*

*The educational organization should determine programs 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: fuels and for instrumental usage.*
  - *health services.*
- c) *equipment for the teaching- learning process, according to the educational level and mode: this includes accessories, supplies and consumables;*
- 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 mechanics of all the materials and facilities used for instruction.*

#### 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.

#### 6.4 Work environment

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

#### 6.4 *Work environment in the education sector*

*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. Instructional organizations should consider learning environment and conditions for off campus learning environments.*

#### 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:

- optimising the number of suppliers and partners,
- establishing two-way communication at appropriate levels in both organizations to facilitate the rapid solution of problems, and to avoid costly delays or disputes,
- cooperating with suppliers in validation of the capability of their processes,
- monitoring the ability of suppliers to deliver conforming products with the aim of eliminating redundant verifications,
- encouraging suppliers to implement programmes for continual improvement of performance and to participate in other joint improvement initiatives,
- involving suppliers in the organization's design and development activities to share knowledge and effectively and efficiently improve the realization and delivery processes for conforming products,
- involving partners in identification of purchasing needs and joint strategy development, and
- evaluating, recognizing and rewarding efforts and achievements by suppliers and partners.

### **6.7 Natural resources**

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

### **6.8 Financial resources**

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

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

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

- a) internally, by reducing process and product failures, or waste in material and time, or
- b) externally, by reducing product failures, costs of compensation under guarantees and warranties, and costs of lost customers and markets.

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

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

## **7 Product realization**

### **7.1 General guidance**

#### **7.1.1 Introduction**

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

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

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

#### **7.1.2 Issues to be considered**

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

Results from verification and validation of processes and outputs should also be considered as inputs to a process, to achieve continual improvement of performance and the promotion of excellence throughout the organization.

Continual improvement of the organization's processes will improve the effectiveness and efficiency of the quality management system and the organization's performance. Annex B describes a "Process for continual improvement" that can be used to assist in the identification of actions needed for continual improvement of the effectiveness and efficiency of processes.

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

Documentation related to processes should support:

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

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

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

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

### **7.1.3 Managing processes**

#### **7.1.3.1 General**

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

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

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

Examples of support processes include:

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

### **7.1.3.2 Process inputs, outputs and review**

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

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

Examples of input issues to consider include:

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

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

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

- reliability and repeatability of the process,
- identification and prevention of potential nonconformities,
- adequacy of design and development inputs and outputs,
- consistency of inputs and outputs with planned objectives,
- potential for improvements, and
- unresolved issues.

## **7 Product realization**

### **7.1 Planning of product realization**

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

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

- a) quality objectives and requirements for the product;

- b) the need to establish processes, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria
- d) for product acceptance;
- e) records needed to provide evidence that the realization processes and resulting product meet requirements.

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

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

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

### **7.1 Planning of product realization in the education sector**

*The organization should plan the necessary resources for all processes.*

*In educational organizations, some processes for the 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 staff,*
- f) *acquiring materials and other resources,*
- g) *admitting of candidates - students.*
- h) *Controlling design and development changes in curricula, course calendars, timetables and pre requisites.*
- i) *Securing accreditation of programs, professional degrees, and post-graduate studies*
- j) *Providing library, audio- visual equipment, computers, and other services.*
- k) *Providing security, safety and civil protection services.*

l) *Allocating classrooms, laboratories, workshops, auditorium, classroom for ceremonies, multi-use room and other similar spaces.*

m) *Maintaining facilities*

### **7.1.1 Introduction**

*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 institutions 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.*

### **7.1.3.3 Product and process validation and changes**

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

Issues to consider should include:

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

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

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

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

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

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

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

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

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

## **7.2 Processes related to interested parties**

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

identification and review of relevant information and should actively involve customers and other interested parties. Examples of relevant process information include:

- requirements of the customer or other interested parties,
- market research, including sector and end-user data,
- contract requirements,
- competitor analysis,
- benchmarking, and
- processes due to statutory or regulatory requirements.

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

## **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 any additional requirements determined by the organization.

### **7.2.2 Review of requirements related to the product**

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

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organization has the ability to meet the defined requirements.

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

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

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

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

### **7.2.3 Customer communication**

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

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

## **7.2 Processes related to interested parties**

*For the most part, education institutions provide a service that is intangible, not storable, and consumed during delivery. Education institutions provide the opportunity for students to study existing knowledge and to practice its application. These institutions also have administrative support systems that help to ensure quality instruction.*

*Generic independent interested parties requirements may include (but not restricted to):*

- a) *safe, clean, facilities with someone in charge;*
- b) *two-way communication procedures between individuals and the instructional organization should be responsive;*
- c) *all the organizations' personnel treat interested parties with respect;*
- d) *appropriate activities conducted by qualified personnel.*

### **7.2.1 Determination of product-related requirements in the education institution**

*The education requirements are expressed as behaviour needed to meet academic professional and societies expectations*

### 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.

### 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.

### **7.3.1 Design and development planning in the education institution**

*In designing and developing the curriculum plan, the institution should consider entrance for the next grade to be the exit level of the present grade or competence level.*

*Top management should consider the design and development of education for the benefits of students and other interested parties.*

*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 assessment 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 intervention to improve performance;*
- state any differences between required and acquired performance gaps, which 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 unstated in a contract, instruction specification, or curriculum.*

### **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.

**7.3.2 Design and development inputs**

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

These shall include:

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

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

**7.3.3 Design and development outputs**

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

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and for service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

***7.3.2 Design and development inputs in the education institution***

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

*It should include:*

- results on effectiveness of instructional materials;*
- certification, licenses or occupational requirements,*
- data on research of student learning capacity;*
- the required competency of teachers;*
- pre requisite for courses;*
- difficult 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,*
- *reliable delivery media*

### **7.3.4 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.

#### **7.3.4 Design and development review**

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

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems and propose necessary actions.

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

#### **7.3.5 Design and development verification**

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

#### **7.3.6 Design and development validation**

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

#### **7.3.7 Control of design and development changes**

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

#### ***7.3.4 Design and development review in the education sector.***

*Depending on its complexity, the design and development review could be done in one or several stages, or should 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 meeting reviews.*

*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 stakeholders, 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 project by-project experience and information from the succeeding 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; try out of both the instruction and the criterion-referenced assessments with students from the target population, and revisions made based upon the experience of students;

At least one of the tryouts 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.

Implementation phase. Organizations should describe how the development process should be reviewed and revised based upon project-by-project experience with the process, including any stakeholder complaints which become available during the process.

### **7.3.5 Design and development verification in the education sector**

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

### **7.3.6 Design and development validation in the education sector**

*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 accreditation are accepted validation methods*

### **7.3.7 Control of design and development changes in the education sector**

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

*The up dating of any subject should include the evaluation of its effect in the entire curriculum, and records maintained.*

## **7.4 Purchasing**

### **7.4.1 Purchasing Process**

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

Use of electronic linkage with suppliers should be considered in order to optimise 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.

## **7.4 Purchasing**

### **7.4.1 Purchasing process**

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

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

### **7.4.2 Purchasing information**

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

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

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

### **7.4.3 Verification of purchased product**

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

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

## **7.5 Production and service operations**

### **7.5.1 Operation and realization**

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

- reducing waste,
- training of people,

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

## **7.5 Production and service provision**

### **7.5.1 Control of production and service provision**

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

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

### **7.5.2 Validation of processes for production and service provision**

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

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

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

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,

- d) requirements for records, and
- e) revalidation.

## **7.5 Production and service provision.**

### **7.5.1 Control of production and service provision in the education sector**

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

- *selecting and enrolling students*
- *designing curricula on different subjects.*
- *developing course catalogs.*
- *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.*
- *tutoring and consulting on vocational opportunities.*

*If a contract agreement requires on going 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 each entering student 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 class 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 education sector**

*This clause should be applied when monitoring and measurement of educational services cannot be carried out, as described in clause 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 qualification*
- *course notes and examination papers*
- *records data, and*
- *revalidation frequency.*

### **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.

### **7.5.3 Identification and traceability**

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

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

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

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

### **7.5.3 Identification and traceability in the education sector**

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

- *curricula, course, content unit codes*
- *student identification records*
- *class schedule*
- *text books/notes*
- *laboratories equipment*
- *research contracts.*

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

### **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.

#### **7.5.4 Customer property**

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

NOTE Customer property can include intellectual property.

#### **7.5.4 Customer property in the education sector**

*In educational organizations, the properties provided by customers/students are those provided in the moment of the 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*

– *facilities for courses provided at customer's premises.*

#### 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.

#### 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 education sector

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

*Also could be included supplies for education and/or training processes, i.e. chemicals for laboratories, raw or processed materials for pilot plants, limited shelf life products for teaching purposes or research & 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, which should be provided such as health, counselling, personal safety, lodgings, food services, etc.*

*Customer property includes items such as textbooks, workbooks, case studies, special education provision, 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*

## 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.

### 7.6 Control of monitoring and measuring devices

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

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

Where necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable calibration status to be determined;
- d) be safeguarded from adjustments that would invalidate the measurement result;}
- e) be protected from damage and deterioration during handling, maintenance and storage.

Furthermore, the organization shall evaluate and register the validity of the previous measurement results when it is detected that the equipment is not accord with the requirements. The organization should take proper actions on the equipment and on any other affected product. Register results of calibration and validation shall be maintained by the organization.

The organization shall confirm the capacity of the software to satisfy its application when this are used at the monitoring and measuring activities of the specific requirements. These shall be done before its utilization and to be confirmed whenever its necessary.

### **7.6. Control of monitoring and measuring devices in the education sector**

*To ensure that the 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 the instruction to assure compliance with the instructional plan. This may include student performance profiles, assessments of staffing records, written course assessments, observations which note whether instructors are following the plan, and final examinations.*

*If follow-up of graduates identifies omitted or incorrect instruction, the instructional organization may wish to recall the materials and/or provide students with the missing or corrected instruction.*

## **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).

## 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.

### 8.1 *General guidance in educational organizations*

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

#### 8.1.1 *Introduction*

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

- ~~a)~~ *deciding which measurements will be of value to monitor;*
- ~~b)~~ *observing and making qualitative and/or quantitative measures; and*
- converting information into knowledge*

## **8.2 Measurement and monitoring**

### **8.2.1 Measurement and monitoring of system performance**

#### **8.2.1.1 General**

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

- satisfaction surveys for customers and other interested parties,
- internal audits,
- financial measurements, and
- self-assessment.

#### **8.2.1.2 Measurement and monitoring of customer satisfaction**

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

Examples of customer-related information include:

- customer and user surveys,
- feedback on aspects of product,
- customer requirements and contract information,
- market needs,
- service delivery data, and
- information relating to competition.

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

The organization should establish and use sources of customer satisfaction information and should cooperate with its customers in order to anticipate future needs. The organization should plan and establish processes to listen effectively and efficiently to the "voice of the customer". Planning for these processes should define and implement data-

collection methods, including information sources, frequency of collection, and data-analysis review. Examples of sources of information on customer satisfaction include:

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

## **8.2 Monitoring and measurement**

### **8.2.1 Customer satisfaction**

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

#### **8.2.1 Customer satisfaction in educational organizations**

*Educational organizations should have reliable methods for monitoring and measuring customer satisfaction. Trend indicators of customer satisfaction should be documented and supported by objective evidence. They should communicate the results of customer satisfaction with the appropriate frequency to interested parties.*

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

#### **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.

### **8.2.2 Internal audit**

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

- a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

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

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

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

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

## **8.2.2 Internal audit in educational organizations**

*Educational organizations should carry out internal audits considering aspects related to educational product, accreditation and certification, failures in the teaching/ learning process, the effectiveness of teaching methods, educational processes and the quality management system performance, and to 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;*
- all quality records as stated in the quality management system;*
- all activities of the organization staff that affects quality; and*
- ensuring that ISO 9001 requirements are known, implemented, and maintained.*

### **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 judgment of the effectiveness and efficiency of the organization and the maturity of the quality management system. It can be used by the organization to benchmark its performance against that of external organizations and world-class performance. Self-assessment also aids in evaluating the performance improvement of the organization, whereas the internal audit process of an organization is an independent audit used to obtain objective evidence that existing policies, procedures or requirements have been met, as it evaluates the effectiveness and efficiency of the quality management system.

The range and depth of self-assessment should be planned in relation to the organization's objectives and priorities.

The self-assessment approach described in annex A focuses on determining the degree of the effectiveness and efficiency of the implementation of the organization's quality management system. Some of the advantages of using the self-assessment approach given in annex A are that:

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

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

### **8.2.2 Measurement and monitoring of processes**

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

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

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

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

### **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 educational organizations**

*Educational organizations 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 to include, but not limited to:*

- *administrations of enrolments and assessments*
- *records management*
- *educational programs*

*The organization should document methods used in order to measure the processes. Examples of methods include, but not limited to comparative analysis, statistical methods, cycle time, etc.*

### 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 Monitoring and measurement of product**

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

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

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

#### ***8.2.4 Monitoring and measurement of product in educational organizations***

*Educational organizations 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 for 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.*

#### 8.2.4 Monitoring and measurement the satisfaction of interested parties

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

- a) For people in the organization, the organization should:
  - survey the opinions of its people regarding how well the organization satisfies their needs and expectations, and
  - assess individual and collective performances and their contribution to organizational results.
- b) For owners and investors, the organization should:
  - assess its capacity to attain defined objectives,
  - assess its financial performance,
  - evaluate the impact of external factors on its results, and
  - identify the value contributed by the actions taken.
- c) For suppliers and partners, the organization should:
  - survey the opinions of suppliers and partners on their satisfaction with the purchasing processes of the organization,
  - monitor and supply feedback on the performance of suppliers and partners and their compliance with the organization's purchasing policy, and
  - assess the quality of product purchased, contributions from suppliers and partners, and mutual benefits derived from the relationship.
- d) For society, the organization should:
  - define and track suitable data relative to its objectives, in order to achieve satisfactory interaction with society, and
  - periodically assess the effectiveness and efficiency of its actions and the perceptions of its performance by relevant parts of society.

### 8.3 Control of nonconformity

#### 8.3.1 General

Top management should empower people in the organization with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities.

Authority for response to nonconformities should be defined to maintain achievement of process and product requirements. The organization should effectively and efficiently control nonconforming product identification, segregation and disposition in order to prevent misuse. Where practical, nonconformities should be recorded, together with their disposition, to assist learning and to provide data for analysis and improvement activities. The organization may also decide that nonconformities to both product realization and support processes should be recorded and controlled.

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

#### 8.3.2 Nonconformity review and disposition

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

People carrying out the review should have the competence to evaluate the total effects of the nonconformity and should have the authority and resources to disposition the nonconformity and to define appropriate corrective action.

Acceptance of nonconformity disposition may be a contractual requirement of the customer, or a requirement of other interested parties.

#### 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 non-conforming product in educational organizations**

#### **8.3.1 General**

*Areas in which non conformance may be found include, but are not limited to, training plan, teaching staff and student performance, materials, and services provided for educational organizations.*

#### **8.3.2 Non conformity review and disposition**

*Where a nonconformity involving student participation in the education process and, where permitted, students may be:*

- a) provided with additional training and permitted to be reassessed;*
- b) permitted to continue in the educational program in accordance to defined procedures;*
- c) transferred to another study program*

*Non conforming product may include educational programs, training plans, support materials, or tools.*

### **8.4 Analysis of data**

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

Decisions based on facts require effective and efficient actions such as:

- valid analysis methods,

- appropriate statistical techniques, and
- making decisions and taking actions based on results of logical analyses, as balanced with experience and intuition.

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

For an effective evaluation by management of the total performance of the organization, data and information from all parts of the organization should be integrated and analysed. The organization's overall performance should be presented in a format that is suitable for different levels of the organization. The results of this analysis can be used by the organization to determine:

- trends,
- customer satisfaction,
- satisfaction of other interested parties,
- effectiveness and efficiency of its processes,
- supplier contribution,
- success of its performance improvement objectives,
- economics of quality, financial and market-related performance,
- benchmarking of its performance, and
- competitiveness.

#### **8.4 Analysis of data**

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

The analysis of data shall provide information relating to:

- a) customer satisfaction,
- b) conformity to product requirements,

- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

#### **8.4 Analysis of data in educational organizations**

*Educational organizations should collect data for analysis about the performance of the requirements of the quality management system and educational processes. Data should be collected from:*

- *management review.*
- *teaching and administrative staff, as well as students competence.*
- *product requirement review.*
- *educational program and training plan design and development*
- *educational products performance*
- *supplier evaluation.*
- *customer and other identified interested parties satisfaction surveys.*
- *outputs from audits.*
- *monitoring and measurement at the beginning, during and at the end of the process.*
- *product identification.*
- *customer's goods and properties.*
- *verification and validation of methods used for monitoring and measurement.*
- *non-conforming product.*

*Educational organizations should analyse collected data and information making use, but not limited to, of the accepted methods of analysis and solution of problems, such as:*

- *process conceptual diagram.*
- *process diagram.*
- *flow chart.*
- *statistical control graph.*

- *pareto diagram.*
- *cause and effect diagram,*
- *outputs from internal audit*
- *failure Mode and Effect Analysis (FMEA), among others.*

*Once the analysis is done, it should be used to support continuous improvement or corrective or preventive actions, as it may be the case.*

*Statistical techniques may be applied to any aspect of the quality system. Evidence of statistical analysis of the variability for such measures as performance indicators, dropout rates, achievement records, student satisfaction, and trend analysis can help assure students that effective process control is a part of the quality system.*

*Instructional processes often have quantitative as well as qualitative characteristics. Many quantifiable factors outside the “classroom” setting also influence the effectiveness of instruction. Data for some of these factors such as the degree of parental or employer interaction with the institution and frequency and severity of violent incidents and accidents should be gathered as part of the improvement process.*

*Examples of quantitative instruction characteristics include: instruction time, waiting time, student performance, dropout rates, costs, reliability and validity of examinations, number of student places available, course transfer rates, retraining time by local businesses, number of textbooks, instruction support resources, degrees, and advanced degrees granted.*

*Examples of qualitative instruction characteristics include: credibility, accessibility, security, responsiveness, courtesy, comfort, competence, dependability, esteem, usefulness, aesthetics of environment, and hygiene.*

*Measurement and evaluation should be continual and direct during the instruction. Effectiveness is not always known until the enhanced skills and knowledge are applied, but the student needs to be assured that predictions of successful application are made with appropriate statistical precision.*

*Educational organizations should analyse data from various sources to assess performance against plans and goals and to identify areas for improvement. They should consider the use of statistical methodologies for data analysis, which can help in assessing, controlling, and improving performance of processes.*

## **8.5 Improvement**

### **8.5.1 General**

Management should continually seek to improve the effectiveness and efficiency of the processes of the organization, rather than wait for a problem to reveal opportunities for improvement. Improvements can range from small-step ongoing continual improvement to strategic breakthrough improvement projects. The organization should have a process in

place to identify and manage improvement activities. These improvements may result in change to the product or processes and even to the quality management system or to the organization.

## **8.5 Improvement**

### **8.5.1 Continual improvement**

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

#### **8.5.1 Continual improvement in educational organizations**

*Educational organizations should continuously aim to improve the effectiveness of their quality management system and educational processes by allowing all staff to constantly identify and establish improvement projects within their scope.*

*Appropriate methods used to identify potential improvement are based, but not limited to, on quality analysis methods by using information gathered from sources such as:*

- internal evaluations on quality policy understanding by the organization staff*
- achievement of quality objectives.*
- performance outcomes*
- inputs from customers and other identified interested parties: Parents, industry, government and society*

*The improvement process should address customers and other identified interested parties complaints and comments, outputs of quality audits, retention and success rates.*

- inputs from customers and other identified interested parties: Parents, industry, government and society*

*The improvement process should address customers and other identified interested parties complaints and comments, outputs of quality audits, retention and success rates.*

### **8.5.2 Corrective action**

Top management should ensure that corrective action is used as a tool for improvement. Corrective action planning should include evaluation of the significance of problems, and should be in terms of the potential impact on such aspects as operating costs, costs of nonconformity, product performance, dependability and the safety and satisfaction of customers and other interested parties. People from appropriate disciplines should

participate in the corrective action process. Also, the effectiveness and efficiency of processes should be emphasized when actions are taken and the actions should be monitored to ensure that desired goals are met. Corrective actions should be considered for inclusion in management review.

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

- customer complaints,
- nonconformity reports,
- internal audit reports,
- outputs from management review,
- outputs from data analysis,
- outputs from satisfaction measurements,
- relevant quality management system records,
- the organization's people,
- process measurements, and
- results of self-assessment.

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

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

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

### **8.5.2 Corrective action in educational organizations**

*Educational organizations should implement corrective actions that are identified from the cause analysis of non-conformities and improvement opportunities. Corrective actions should be taken to eliminate non-conformities occurring during educational processes performance, such as:*

- *non-conforming educational product.*
- *non achievement of educational objectives.*
- *deviations from educational programs and training plans.*

- *output data from design review, verification, validation and modification of educational product design and development.*
- *high rates of dropout.*
- *customer and other identified interested parties complaints .*
- *outputs from audits.*
- *non-conformities identified in monitoring and measurement of educational processes and products.*

*These corrective actions should be established and be appropriate for eliminating the causes of non conformities identified in the performed analysis and identified level of risk.*

*Corrective actions should be recorded to ensuring their implementation.*

*There should be a monitoring procedure for corrective actions including analysis to ensure their effectiveness in order to avoid the recurrence of the non-conformity, related to root causes. Evaluation should be designed to identify root causes before corrective action is taken.*

### **8.5.3 Loss prevention**

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

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

- use of risk analysis tools such as fault mode and effects analysis,
- review of customer needs and expectations,
- market analysis,
- management review output,
- outputs from data analysis,
- satisfaction measurements,
- process measurements,
- systems that consolidate sources of information from interested parties,

- relevant quality management system records,
- lessons learned from past experience,
- results of self-assessment, and
- processes that provide early warning of approaching out-of-control operating conditions.

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

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

### **8.5.3 Preventive action**

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

A documented procedure shall be established to define requirements for:

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken, and
- e) reviewing preventive action taken.

### **8.5.3 Preventive action in educational organizations**

Educational organizations should implement preventive actions that result from the cause analysis of potential non-conformities and improvement opportunities of the quality management system and educational processes, from data such as:

- *information coming from trends, indicators of teaching and administrative staff performance,*
- *achievement of quality objectives*
- *cost analysis related to the achievement of quality objectives*
- *satisfaction surveys from customers and other identified interested parties*

– *outputs from audits and management review*

Preventive actions should be recorded for ensuring their implementation. Actions resulting from the preventive action process should be documented and communicated to the appropriate areas of the organization.

The learnings resulting from the preventive action process should be reviewed and communicated to the whole organization.

#### **8.5.4 Continual improvement of the organization**

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

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

This can be achieved by activities such as:

- setting of objectives for people, projects and the organization,
- benchmarking competitor performance and best practice,
- recognition and reward for achievement of improvement, and
- suggestion schemes including timely reaction by management.

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

- effectiveness (such as outputs meeting requirements),
- efficiency (such as resources per unit in terms of time and money),
- external effects (such as statutory and regulatory change),
- potential weakness (such as lack of capability and consistency),
- the opportunity to employ better methods,
- control of planned and unplanned change, and
- measurement of planned benefits.

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

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

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

- validation data,
- process yield data
- test data,
- data from self-assessment,
- stated requirements and feedback from interested parties,
- experience of people in the organization,
- financial data,
- product performance data, and
- service delivery data.

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

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

**ANNEX A - (INFORMATIVE) GUIDELINES FOR SELF ASSESSMENT**

**ANNEX B - (INFORMATIVE) CONTINUOUS IMPROVEMENT PROCESS**