# 中国认证认可协会文件

中认协服〔2013〕154号

## 关于对ISO/CD9000《质量管理体系　基础和术语》征求意见的通知

各会员单位：

ISO/TC176/SC1（国际标准化组织/质量管理和质量保证技术委员会/基础和术语分委员会）负责起草的ISO 9000《质量管理体系 基础和术语（Quality management systems – Fundamentals and vocabulary）》已经进入CD阶段，现在开始在各成员国中征求意见。现将有关资料发给各会员单位参考（详见附件）。

各会员单位可组织相关人员根据中国实施质量管理体系标准的情况和审核实践，对该国际标准草案提出意见，填写征求意见表（请用中英文描述），并于2013年8月14日前用电子邮件发送至我会。

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附件：1．关于对ISO/CD9000《质量管理体系 基础和术语》征求意见的通知；

2.Quality management systems—Fundamentals and vocabulary(英文稿)

3.Template for comments(征求意见表)。

中国认证认可协会

2013年7月5日

# 全国质量管理和质量保证标准化技术委员会

质标委文[2013] 14号

## 关于对 ISO/CD 9000《质量管理体系 基础和术语》征求意见的通知

各委员单位:

ISO/TC176/SC1(国际标准化组织/质量管理和质量保证技术委员会/基础和术语分委员会)负责起草的 ISO 9000《质量管理体系 基础和术语（Quality management systems—Fundamentals and vocabulary）》已经进入 CD 阶段，现在开始在各成员国中征求意见。

请各委员单位组织相关人员根据 ISO 9000：2005 在中国实施的情况和审核实践，对该国际标准草案提出意见，填写征求意见表（请用中英文描述），并于 2013 年 8 月 20 日前用电子邮件发至 SAC/TC151 秘书处。

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此致

敬礼！

二〇一三年七月二日

全国质量管理和质量保证标准化技术委员会 业务专用

附件 1: ISO/CD 9000 Quality management systems—Fundamentals and vocabulary（英文稿）;

附件 2: Template for comments （征求意见表）

**ISO/TC 176/SC 1 N 432**

Date: 2013-06-21

**ISO/CD 9000**

ISO/TC 176/SC 1/WG 1

Secretariat: AFNOR

# Quality management systems — Fundamentals and vocabulary

*Systèmes de management de la qualité — Principes essentiels et vocabulaire*

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# Contents

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# Foreword

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

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

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

ISO 9000 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

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

This third edition cancels and replaces the second edition

To be completed

# Introduction

## 0.1 General

ISO 9000 provides the fundamentals and terminology of quality management systems. It is the foundation of other ISO quality management system standards and serves as the normative reference for many of them. It will help the user to understand the principles, systems model and terminology of quality management in order to more effectively and efficiently implement a quality management system and realize value from other ISO quality management system standards.

## 0.2 Quality management, fundamental concepts, principles, terminology and framework

This management standard for quality makes the case for a well-defined quality management system is based on a framework that integrates established quality fundamental concepts, principles, processes and resources to help organizations realize their goals Its aim is to make top management aware of their duties and commitment in achieving their customers and stakeholders needs, expectations and satisfaction with their products and services.

The terminology used within all ISO quality management system standards is provided within ISO 9000.

# Quality management systems — Fundamentals and vocabulary

## 1 Scope

This International Standard describes the fundamental concepts, principles and vocabulary of quality management, and defines related terms. It makes the compelling case to management for adoption of quality management. The concepts are universally applicable to the following:

— organizations seeking sustainable success through the implementation of a quality management system;

— customers seeking confidence in organization's ability to provide satisfactory products;

— organizations seeking confidence in their supply chain that their product requirements will be met;

— stakeholders seeking to improve communication through a common understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);

— organizations performing conformity assessment against the requirements of ISO 9001;

— those providing training on the quality management;

— developers of related standards.

## 2 Fundamental Concepts and Quality Management Principles

### 2.1 Concepts

#### 2.1.1 The concept of organization purpose

Organizations are formed to fulfil a specific purpose and that purpose drives everything an organization does. For an organization to survive in the long term its purpose needs to be outwardly looking towards the external environment (2.1.2) in which it operates. No longer is business performance measured solely in terms of economic performance. Organizations of any type need to take into account ecological and social performance in addition to financial performance. In all organizations economics is a restraint to what the organization and its managers can do.

Profit or surplus is important as a resource, a measure of success and must be sufficient to cover the risks but when perceived as a primary purpose of an organization it encourages managers to look inwardly at financial returns instead of outwardly at the contribution an organization makes to society which is the ultimate judge of its performance. It is therefore vital that the true purpose of the organization is clearly communicated to all those with whom it is involved. Typically this may involve the development of a long term purpose (e.g. Vision and Mission, policies, and improvement objectives) as well as short term performance objectives.

#### 2.1.2 The concept of external environment

An organization is bounded by its external environment and can adapt to that environment or seek to shape it to survive and achieve its aims. It may deliberately influence but cannot control all parts of that external environment or simply react to changes but must understand their influence on itself for the organisation to survive and can choose which parts it works with and how it responds to change.

Note ISO 9004 defines the organization's environment as:

> **3.2**
> **organization's environment**
> combination of internal and external factors and conditions that can affect the achievement of an organization's objectives and its behaviour towards its interested parties

### 2.1.3 The concept of interested parties

Organizations need to attract, capture and retain the support of those organizations and individuals they depend upon for their success. These are an organization’s interested parties and include customers, investors, employees, suppliers and society. Each has a distinct role in influencing the manner in which an organization fulfils its mission so that managing the expectations of these groups of interested parties becomes a critical success factor in any organization. The organisation has no control or choice over some interested parties, such as society and its political impacts but does have a choice over who its employees, customers and suppliers are and what outcomes are delivered to them.

Customers impose the primary demands on the organization's goods and services. The needs of the other interested parties place constraints upon an organization’s strategy for meeting those demands.

Without customers there is no revenue and without revenue there is no business or community to serve. Customers are therefore the most important interested party but in meeting their demands, organizations are obligated to operate in such a manner that satisfies the legitimate needs and expectations of the other interested parties although they do have a choice as to which customers to work with. Consequently interested party management is a key aspect in defining objectives.

### 2.1.4 The concept of quality

Quality is defined as the "degree to which a set of inherent characteristics fulfils requirements" where requirements are stated, implied or obligatory needs and expectations. The degree to which interested party expectations are met defines the quality of an organization’s outputs which include e.g. goods and services, dividends, information and employee satisfaction. Consequently in the ISO 9000 family of standards quality is a variable used to express the gap between a need and its achievement. Therefore on examination, goods and services may be deemed to be of superior, acceptable or inferior quality,

In this sense quality is perceived in several ways:

a) satisfying interested party needs and expectations where the gap is the degree of satisfaction regardless of the stipulated requirements. Higher quality in this sense generally costs more as better features are provided;

b) conformity with customer requirements where the gap is the degree of conformity regardless of the significance of any nonconformities; Higher quality in this sense generally costs less as mistakes and waste is eliminated;

c) freedom from deficiencies where the gap is the level of deficiency regardless of significance. Higher quality in this sense generally costs less as mistakes are eliminated.

Note 1 The term quality is also commonly used as an absolute where a quality product would be one that fully satisfies the needs and requirements and is free from deficiencies.

There are many reasons for paying attention to quality, including:

a) maintaining competitiveness;

b) maintaining reputation and brand equity;

c) managing innovation;

d) minimising waste and reducing internal costs;

e) achieving sustained success

The quality of an organization's goods and services is judged by the ability of their inherent characteristics to not only satisfy particular customers but also to capture a sustainable market.

### 2.1.5 The concept of quality management

For an organization to fulfil its purpose (2.1) and achieve its strategic objectives its activities have to be managed towards these objectives if its purpose is to be fulfilled effectively.

An organization's strategic objectives are derived from understanding and prioritising the mix of interested party needs relative to its purpose and these will include objectives for marketing, innovation, human, financial and physical resources together with financial, social and ecological performance including ethics. Among these objectives has to be the objective of delivering outputs of a quality that satisfy interested party's expectations as economically as is practical whatever the chosen market, product and associated resources. The purpose of quality management is therefore to provide an organization with the capability of delivering the required outputs and managing that capability in a way that produces the desired outcomes for all the interested parties.

#### 2.1.5.1 Quality as the priority

Quality needs to be the first priority in any organization. Companies that put 'profits first' have found themselves losing market position because of the inferior quality and price competitiveness of their goods and services. When quality is the first priority there are no boundaries. With every product there is a service e.g. delivery or after sales, and with every service there is product e.g. information or materials and a process of delivering it. It would be inequitable to pursue a quality first approach with products and a different approach with services and processes, e.g. putting quality first in the supply of electricity but not in its generation, putting quality first in the supply of automobiles but not in their production, delivery and servicing.

It has to be recognised that putting customers first is not the same as putting quality first because organizations can control the quality of its outputs but not its customers. Customers often think short term, don't know what they need and often don't care about the impact of their demands on other interested parties.

Organizations that have made quality their priority have demonstrated a significant improvement in the quality of their goods and services and as a result improved their safety and reliability. This has led over time to a substantial increase in productivity and price competitiveness leading to increase profit and market share. Quality management is therefore of strategic importance in every organization seeking to produce high quality goods and services, at low cost and high productivity which benefit society and the ecology thus seeking sustained success.

#### 2.1.5.2 Quality planning

For quality to be the first priority of an organization it follows that this needs to be translated into objectives and plans for achieving those objectives. Organizations therefore need to set strategic quality objectives that are derived from the needs and expectations of its interested parties and develop strategies and structures for achieving those objectives This has evolved as the concept of quality planning which is carried out at both the strategic level and the operational level. At the operational level effort is focussed on understanding customer needs, developing and validating product features that respond to those needs and developing and validating processes capable of producing those product features. At the strategic level effort is focussed on understanding the needs of all interested parties and developing a system that produces satisfactory outcomes for each of the interested parties.

#### 2.1.5.3 Quality control

To consistently achieve objectives it is necessary to apply appropriate controls to minimise uncertainty in the achievement of desired outputs. As variation can be detrimental to an organization's performance the concept of quality control has evolved to set standards of performance and detect and remove undesirable variation in order to prevent change in accepted standards. If performance becomes predictable, organizations can plan the future with confidence that the plans will be carried out.

Control of quality is accomplished through the following series of steps:

a) determine the quality objectives for the characteristics to be controlled in terms of the units of measure and target values;

b) establish sensing devices to measure the characteristics in terms of the unit of measure;

c) conduct measurement and compare actual performance with the objectives;

d) act on the difference.

This sequence of steps can be applied at any level at which objectives are specified.

The detection and removal of variation may be effected:

a) before an output is produced by such means that anticipates potential problems and institutes techniques that eliminate particular modes of variation through product and process design;

b) during the production of an output by such means that detects and removes variation as it occurs so that subsequent processing may continue;

c) after an output has been produced by such means that rectify problems before release of the output and prevents their recurrence.

This results in there being four types of costs;

a) costs of producing an output assuming variation in performance is not possible;

b) additional costs of detecting and removing variation before its occurrence (prevention cost);

c) additional costs of detecting and removing variation either during of after its occurrence (appraisal cost);

d) additional costs of failing to detect and remove variation before release of product to customers (failure cost).

Awareness of these costs enables management to prioritize action in order to create equilibrium and optimise utilization of resources.

#### 2.1.5.4 Quality improvement

Organizations not only need to maintain standards of performance but also look for better ways of achieving their objectives and raising standards of performance beyond what is currently achievable in order to sustain success as new threats and opportunities emerge in their operating environment.

The concept of quality improvement has evolved for improving performance by better control of quality, by better utilization of resources and better alignment of objectives with those of the organization's interested parties.

When undertaking improvement, the performance of each variable can be improved independently until the slack among them is used up. Then the perceived set of independent variables changes to a formidable set of interdependent variables. Improvement in one variable would come only at the expense of the others. It is therefore necessary to take an approach whereby the quality of a part is not improved unless by doing so the quality of system of which it forms a part is improved.

NOTE 1 Corrective action is not improvement, it is part of quality control and it simply restores performance to where it should have been.

NOTE 2 Quality improvement differs from quality planning in that quality improvement is directed at chronic problems whereas quality planning is directed at meeting stakeholder oriented objectives

#### 2.1.5.5 Quality assurance

To be able to buy with confidence customers need to have trust in a particular product from a particular organization. This trust can only be obtained through an organization developing its reputation for its capability to control the quality of its goods and services and when necessary being prepared to demonstrate this capability to others.

In addition, top management need safeguards against inadvertent deterioration in standards that may arise through changes in personnel, reorganizations and the unforeseen consequences of planned changes and localised initiatives.

For top management to have confidence in the integrity of the management system, and for customers to have trust in the products of an organization, there needs to be a degree of independent verification of performance that is proportional to the significance of failure and which generates documentary evidence of performance.

The concept of quality assurance has evolved to provide to those concerned, when necessary, the evidence needed to establish confidence that quality is being managed effectively and desired standards of performance maintained at all levels in the organization.

Assurance of quality is gained through the following series of steps:

a) determine how objectives have been derived and their achievement planned;

b) review the plans to verify that, if followed, they will result in the satisfaction of interested parties;

c) plan and conduct audits to verify the plans are being followed and the objectives met

d) provision of documentary evidence of the results of assurance activities.

### 2.1.6 People, Processes and Resources

Achieving the desired level of quality depends upon an organization possessing competent people, capable processes, adequate resources and managing them systemically. Quality cannot be inspected into goods and services, it has to be built-in through robust product and process design, and faithful implementation of those designs by people possessing the necessary competences.

#### 2.1.6.1 People

An organization’s performance emerges from how people behave, rather than what people document or say they do and this depends upon the degree to which they are involved in decisions that affect their work. All people are different and the performance of anyone is largely governed by the system in which they work. Empowerment can create conditions in which people are motivated because it offers a way of obtaining higher level of performance without strict supervision.

Work is accomplished more effectively when people are in a state of self-control. Before a person can be in a state of self-control they need to be clear about their responsibilities and authority and are in possession of knowledge of what they are required to achieve, have the freedom, when appropriate, to determine how to achieve the required results, have knowledge of what they are doing either from their own senses or from elsewhere and have a means and the authority of regulating their own performance either by varying their own conduct or the process under their control.

The more complex an organization the more numerous the interrelationships and more resilient the organization will be to fluctuations in the performance of individuals. Consequently when individuals fail to do their job, there will be others who will step in to support them and fill the void. However, sustained success will only be assured if harmonious relationships have been nurtured and this depends on continual good leadership.

It is also important for sustained success in an organization not only that its people are competent and understand their role in the achievement of quality but that its people understand how the organization works and in particular possess

a) an appreciation of systems thinking: understanding the nature and properties of systems and how the organization's outcomes are a product of the interaction between the parts and not of the individual parts themselves;

b) knowledge of variation: the range and causes of variation in quality, and use of statistical sampling in measurements;

c) theory of knowledge: the concepts explaining knowledge and the limits of what can be known:

d) knowledge of psychology: concepts of human nature.

Note also 2.2.2 on leadership.

#### 2.1.6.2 Processes

All work is accomplished by a process and a process can be designed to produce outputs with any desired features or characteristics by altering the variables of inputs, activities, resources, influences and controls. It follows therefore that by designing and managing processes effectively they will consistently and continually produce outputs of the desired quality.

Strategic objectives are generally achieved through a network of processes that span several functions or departments within an organization. These processes can be classified into three groups:

a) those which create and satisfy customer demands e.g. marketing, product development, production, service delivery, sales and after sales service;

b) those which manage the enterprise e.g. strategic planning, organization development, management system design, performance evaluation and improvement;

c) those which supply all processes with resources e.g. human resources, materials, facilities management, IT, finance and maintenance.

Tactical objectives are derived from the strategic objectives and achieved through processes executed primarily by a single function with a low level of support from other functions. These have a narrow scope often limited to a single task or few steps e.g. producing a plan, assigning tasks, making a component, checking conformity, correcting errors and producing a report but they are connected with other micro-processes to form a network of processes that constitute a macro-process serving a specific strategic objective.

Effectively managed processes are those which are designed to achieve specific objectives, are subject to continual monitoring, review and improvement consistent with those objectives as illustrated in Figure 1.

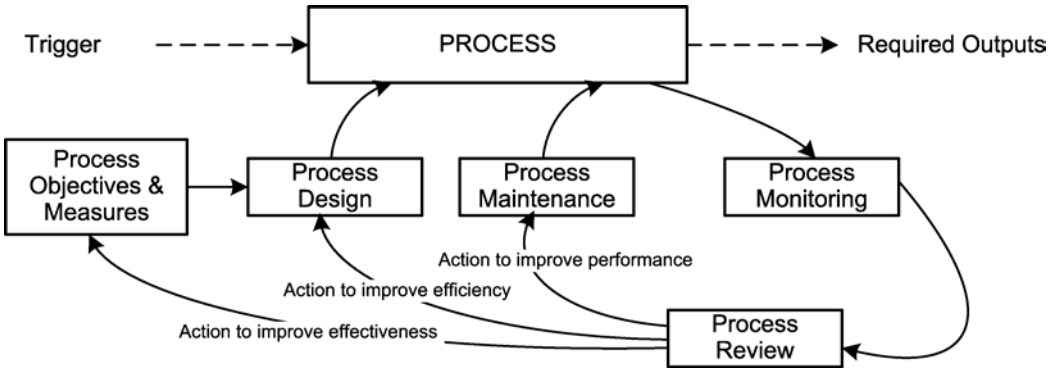



**Figure 1 — A managed process (How consistent results are achieved)**

**Process objectives** relate to the outputs the process is designed to produce e.g. an order that the organization is capable of fulfilling, a design that reflects customer needs, a product that conforms to the specification or a delivery that exceeds customer expectations.

**Process measures** are characteristics by which achievement of the process objectives is judged e.g. on time delivery, yield, injuries, emissions and downtime. These measures are used in process monitoring to determine the behaviour, performance and efficiency of the process.

**Process design** models the sequence or series of actions, decisions and feedback loops necessary to plan or prepare, produce, check, validate and deliver satisfactory process outputs together with assigned responsibilities, the nature, validity and source of inputs (product and information) the provisions made to mitigate risk and rectify errors and deal with changes, the controls to be exercised over product and information that is used and produced to maintain integrity, the constraints such as policies, regulations, codes of practice and conduct and other conditions that govern the manner in which the activities are to be carried out and the records to be maintained both as proof of action and decision and to facilitate enquiry in the event of problems arising subsequently.

**Process reviews** assess the results of process monitoring to determine whether the process needs to be adjusted to improve its performance through better control, improve its efficiency through better utilization of resources or improve its effectiveness through better alignment of the process objectives and measures with the needs and expectations of the organization's interested parties.

**Process maintenance** plans and carries out the agreed process changes to bring about better control.

The **relationship** amongst the key elements that need to be managed to produce outputs of the required quality is illustrated in Figure 2.

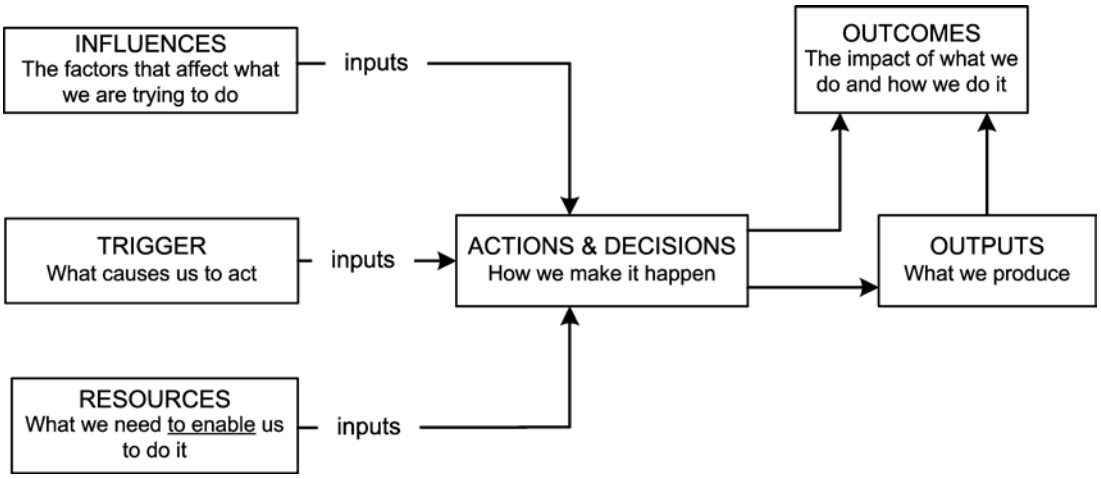



**Figure 2 — An operating process (How work gets done)**

Although it is customary to think of a process as transforming inputs into outputs as illustrated in Figure 1, not all inputs will be transformed by the process.

The effectiveness and capability of, and the risks within, an organization can best be determined by (i) measuring the results of past activities and (ii) analysing indicators that help to predict future performance.

Continuing success depends on achieving an appropriate balance between conformity and the reduction of variation on the one hand, and innovation, responsiveness and improvement on the other.

#### 2.1.6.3 Resources

For a process to deliver the desired outputs it has to be resourced and the requirement for these resources built into the process design. When the process is triggered the necessary resources have to be available for the process to maintain its capability. Consequently, the planning, acquisition, deployment and maintenance of resources of the requisite quality and quantity are essential for processes to maintain their capability. It is also essential that obsolete or redundant resources and resources of unsatisfactory quality are disposed of in ways that satisfy the expectations of all interested parties.

### 2.1.7 The concept of quality management systems

An organization is a complex and dynamic entity that uses a system of management for accomplishing its purpose (2.1.1) and delivering its desired outcomes. This management system covers the whole organisation and everything it does. It comprises the structure, processes and resources needed to establish an organization’s policies and objectives and to implement the policies and achieve those objectives.

An organization’s capability to deliver desired outcomes depends on its leadership’s ability to align its mission, vision, values and culture with the strategies, policies, processes and resources it employs to achieve them.

Organizations that sustain their capability:

a) are adaptive to their external environment;

b) continually enhance their capability to change/adapt;

c) develop collective as well as individual learning;

d) use the results of learning to achieve better results.

An organization’s outcomes can be intended or unintended, and anticipating their possible impact is an essential element in managing performance. Desired outcomes for all of the organisation's interested parties are more likely to be achieved if its objectives and priorities are consistent with those desired outcomes.

Successful performance depends on identifying and managing risks to an organization’s capability to deliver planned outcomes consistently. This system can be examined from the perspective of particular objectives such as financial, quality, social responsibility, environment, health and safety etc. This can result in these different perspectives being labelled financial management system, quality management system, environmental management system etc. In reality these subsystems are parts of the whole system each of which can affect its behaviour or its properties but which cannot operate independently.

Although critical components need to be documented for effective communication, every aspect of the management system can never be fully documented. Any description of a system is at best a model or a particular perspective of reality and in some respects will always be wrong but will often be useful.

### 2.1.8 The role of standards in quality management

Customers need confidence that their suppliers can meet their quality, cost and delivery requirements and have a choice as to how they acquire this confidence. They can select their suppliers:

a) purely on the basis of past performance, reputation or recommendation;

b) by believing the self assessment statement of capability made by a supplier;

c) by assessing the capability of potential suppliers themselves;

d) on the basis of an assessment of capability performed by a third party.

National and International standards have been developed to assist customers translate their needs into common product and process quality requirements that will ensure uniform acceptance criteria are used in designing, producing and delivering those goods and services. These may be used to supplement a customer's own technical requirements and national and international statutory and regulatory requirements.

ISO 9001 has been developed to enable customers to acquire the level of confidence they need (i.e. quality assurance) by being used as the basis of assessment in modes (b), (c) or (d) above (ISO 9001 specifies requirements for a quality management system and does not establish requirements for goods and services). ISO 19011 has been developed to assist customers in assessing the capability of potential suppliers and to assist those suppliers to assess the capability of their own management system.

Organizations may need to achieve sustained success in what can be a complex, demanding and ever changing environment. This depends on their capability to:

a) identify the needs and expectations of their customers and other interested parties;

b) convert customer needs and expectations into goods and services and services that will satisfy them;

c) attract customers to the organization;

d) supply the goods and services that meet customer requirements and deliver the expected benefits;

e) operate in a manner that satisfies the needs of the other interested parties.

ISO 9000 and ISO 9004 have been developed to assist organizations develop, operate and maintain effective management systems that deliver conforming goods and services in a manner that satisfies the expectations of all interested parties.

## 2.2 Fundamental Principles

### 2.2.1 Customer focus

Providing value to the customer is the first principle of quality management. The intent of customer focus is to delight the customer with available and affordable resources. The organization should listen to the voice of the customer by collecting and analysing the customer's wants, needs, expectations and requirements. The customer carries the strongest voice in specifying what quality means. Interested parties such as employees, suppliers, regulators, shareholders, community and society at large contribute to the effectiveness of satisfying the customer. Creating value for the customer leads to customer satisfaction and ensures customer retention.

A customer can be external or internal to the organization. The output of each internal process is the input of the next process. Customer focus provides everyone in the organization the opportunity to see their job work as added value from the perspective of the customer.

Customer focus continually provides information to the customer and listens carefully to the “Voice of the Customer,” transforming their input and feedback to changes that add value. A customer focused leader ensures that the customer is the only person qualified to specify what quality means. Customer focused improvements are possible and worthwhile and sustained operationally and culturally.

It is essential to:

— identify internal and external customers along the supply chain;

— identify customer needs, expectations and feedback;

— establish an effective process to manage customer communication;

— link the organization’s objectives with customer needs and expectations;

— manage relationships with customers through strategic planning, measurement, analysis and improvement;

— rapidly and effectively respond to customer concerns and complaints;

— provide information on new product development, continual improvement and benefits to customers;

— develop, instil and sustain a customer focused culture throughout the organization with a sense of urgency;

— demonstrate total commitment to the customer;

— train everyone in the organization on the importance and application of customer focus.

Examples of techniques and processes that support customer focus include:

— market research and competitive analysis;

— quality function deployment;

— customer satisfaction surveys;

— customer perception audits;

— field data analysis;

— customer relationship management;

— customer satisfaction codes of conduct (See ISO 10001);

— complaint-handling processes (See ISO 10002);

— dispute-resolution processes (See ISO 10003);

— customer satisfaction measuring and monitoring processes (See ISO 10004);

— business to consumer electronic commerce transaction processes (See ISO 10008).

Key benefits include:

— improved understanding of dynamic customer needs and expectations;

— superior product quality;

— increased revenue and market share;

— increased effectiveness in the use of resources;

— increased value within every process;

— improved customer loyalty, retention and repeat business;

— increased awareness of all employees regarding their contribution to customer satisfaction;

— improved confidence in measurement and monitoring of customer satisfaction;

— increased balance between customer needs, product portfolio, and the needs of interested parties;

— improved alignment of processes with customer focus and feedback;

— improved customer satisfaction throughout the product life-cycle.

### 2.2.2 Leadership

An organization’s leadership has a duty to provide a clear vision of company values, direction and purpose. This may be defined in a formal mission statement, developed by senior management, taking into consideration the views, beliefs, aspirations, culture, market positions and experience of the organization. The mission creates the environment in which people become fully involved in achieving the organization's objectives. Leadership depends on personal attributes such as expertise, charisma and the ability to inspire others. Leadership builds organizational competence through assessment, organizational management and business planning to maximize assets in order to ensure successful management of resources.

Effective leadership requires an understanding of fundamentals, methods and application of quality management. These fundamentals must be shared with employees at all levels of the organization.

For the system under their leadership, it is essential for leaders at all levels to:

— establish or contribute to development and deployment of a clear vision and mission;

— create, practice and sustain shared values;

— promote fairness and ethical behaviour;

— devise a strategy and translate it into operational terms through goals and action plans;

— align the system to the strategy;

— deploy quality management policies;

— adapt the system to change;

— consider the needs of all interested parties;

— set challenging goals;

— establish trust and drive out fear;

— provide people with the required resources, training and freedom to act with responsibility and accountability.

— inspire, encourage and recognize people's contributions.

— promote factual decision making.

Examples of techniques for leadership include:

— strategic quality planning;

— quality policy deployment;

— participative management;

— employee involvement;

— employment empowerment;

— autonomous leadership;

— succession planning;

— system thinking;

— statistical thinking;

— balanced scorecard;

— risk analysis;

— self assessment;

— authority matrix;

— business continuity planning and management;

— incentive and recognition programs;

— electronic communications;

— acquisition management;

— resource management.

Key benefits include:

— improved budgetary performance;

— increased competitiveness;

— improved customer retention and loyalty;

— improved effectiveness of decision making;

— optimized use of available resources;

— heightened employee motivation and accountability;

— improved intellectual capital;

— optimized effective and efficient processes;

— improved supply chain performance;

— improved communication among all levels of the organization;

— enhanced organizational performance, credibility and sustainability;

— enhanced alignment of the planning, development, implementation, maintenance and improvement activities;

— improved agility.

### 2.2.3 Engagement of People

Maximizing and harnessing people's capabilities are fundamental for organizational performance, improvement, sustainability, and employee retention. Competent people perform better when they understand the importance of their contribution and role in the organization. Awareness of the significance of peoples' roles and responsibilities is the first step in involving people within the organization. Acceptance and ownership of problems and responsibility for solving them is also fundamental.

Management is responsible for:

— developing, deploying and living by core values;

— developing a culture of transparency and continuous learning;

— maintaining effective communications with all employees;

— empowerment of employees to contribute to decision making process;

— developing a common problem solving approach;

— providing appropriate facilities, equipment, and tools for employee successful performance and fulfilment;

— management by objectives;

— succession planning;

— on the job training;

— team building;

— professional development;

— suggestion programs;

— responsibility matrix;

— communication: bulletin boards, focus groups, internet and intranet;

— incentive and recognition programs;

— a 5S work environment.

The role of management relative to the human resource function may include:

— organizational and personal development;

— job design;

— career planning;

— mentoring;

— employee satisfaction;

— facilitate workers councils;

— human resource planning;

— authority matrix;

— competence matrix;

— knowledge management.

The responsibility of people within the system may include:

— learning, understanding, and following relevant management system policy, codes of conduct, and standards;

— identifying constraints to their performance;

— evaluating their performance against their personal goals and objectives;

— actively seeking opportunities to enhance their competence, knowledge and experience;

— freely sharing knowledge and experience;

— openly discussing problems and issues.

Benefits of competence and engagement of people may include:

— improved customer satisfaction, retention and loyalty;

— heightened employee responsibility and accountability;

— improved intellectual capital;

— enhanced organizational performance;

— optimized effective and efficient processes;

— improved value chain performance;

— reduced costs;

— credibility and sustainability.

NOTE For further guidance on people involvement and competence, see ISO 10018.

### 2.2.4 Process Approach

All work is accomplished through a process which may consist of people, methods, materials, tools and measurement. Outputs of consistent quality will be achieved only when a level of stability and process capability are demonstrated. Each process needs both a set of defined characteristics that are critical to quality and information necessary to achieve process objectives.

It is essential to understand and manage:

— variability of each process;

— validation of processes;

— design based on process capability;

— resources, controls, process parameters, inputs and outputs;

— continual improvement;

— activities necessary to obtain a desired result and the interrelationships of these activities;

— responsibility and accountability for managing key activities;

— indicators for key activities;

— capability of key activities.

Examples of techniques that can be used to manage processes include:

— flowcharting and process mapping;

— lean;

— six sigma;

— value management;

— statistical process control;

— process audits;

NOTE See ISO 10017 for more information on statistical techniques.

For management the good thing about focussing on processes is that it ensures repeatability and predictability, a caution, however, over focus can discourage creativity, experimentation and new solutions.

Understanding and managing the inter-relationships of processes is fundamental to quality management. This can be accomplished by:

— deriving process objectives from the organization’s goals and expressing them in measurable terms;

— establishing measures of success - the factors that will indicate whether the objective has been achieved;

— defining the key stages or activities required for producing outputs that satisfy the process objective;

— defining and supplying the resources, information and competences required to deliver the required outputs;

— identifying the risks and putting in place measures that eliminate, reduce or control these risks;

— determining how performance will be measured against the objectives and variation reduced;

— operating the process as planned, measuring performance and adjusting the process parameters objectively to deliver outputs of consistent quality and regulating the conditions thereafter;

— finding better ways of achieving the process objectives and improving process efficiency;

— periodically determining whether the process objectives remain relevant the needs of the stakeholders parties and if necessary changing them and repeating the sequence;

— identifying the interfaces of key processes within and between the functions of the organization;

— focusing on the resources that will improve key processes of the organization;

— evaluating and managing risks, consequences and impacts of processes on customers, suppliers and other interested parties.

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives. Use of a systems approach enables an organization to operate in an effective and efficient manner to produce quality products.

It is essential to understand and manage:

— the cumulative effect of individual process capability on overall system performance;

— management responsibility for the system;

— the effectiveness and efficiency in achieving system objectives;

— elements and structure of the system to achieve the organization's objectives;

— strengths and weaknesses of interdependencies of processes within the system;

— a structured approach that integrates processes;

— complexity of the system;

— roles and responsibilities necessary for reducing cross-functional barriers;

— organizational capabilities and resource constraints prior to action;

— operation of specific processes within the system;

— continual improvement of the system through measurement and evaluation.

Examples of techniques that can be used to manage systems include:

— strategic quality planning;

— advanced product quality planning;

— contingency planning;

— risk analysis;

— business excellence models;

— self-assessment;

— balanced scorecard;

— preventive actions;

— system audits;

— management reviews;

— value management;

— performance appraisal.

Expected benefits of the process approach can include:

— reduced costs;

— increased competitiveness;

— optimized use of available resources;

— increased employee accountability;

— effective and efficient processes;

— supply chain performance;

— reduced time to market;

— improved organizational performance;

— enhanced credibility and sustainability.

### 2.2.5 Improvement

Improvement is an important objective of every organization, and applies to management and every individual in the organization, leading to sustainable success. The use of quality management provides the opportunity to introduce the concept of continual improvement of products, processes and systems, for the benefit of product quality, innovation, productivity, and competitiveness. This can be accomplished as incremental, break-through and transformational improvements, using many different strategies.

Examples of strategies deployed by management include:

— making improvement an overall objective;

— establishing goals to guide, and measures to track, performance;

— employing a consistent organization-wide approach to improve the organization's performance;

— communicating improvement goals and achievements;

— maximizing work force participation;

— managing by walking around;

— training in the methods and tools of improvement;

— quality improvement teams;

— recognizing and acknowledging improvements;

— responding to external factors such as regulatory changes, emerging technologies, changes in the marketplace, environmental and social pressures.

Examples of techniques, which should be based on factual data, include:

— data collection and analysis;

— voice of Customer and customer feedback;

— employee suggestion systems;

— observing the process in relation to the standard;

— improvement of work environment by use of the 5S technique;

— quality function deployment;

— lean;

— six sigma;

— balanced scorecard;

— re-engineering.

Outcomes of improvement can include:

— benchmarking outputs;

— brainstorming outputs;

— recommendations for improvements;

— self-assessment results;

— audit results;

— results of assessments against excellence models;

— system Changes from benchmarking outputs;

— financial performance improvement;

— results of assessment and implementation using business excellence model;

— management report on the results of balanced scorecard activities;

— results of management reviews;

— results of statistical process control on characteristics critical to quality.

Expected benefits of improvement can include:

— sustainable performance;

— Increased customer satisfaction;

— Increased employee morale, engagement and satisfaction;

— greater supply chain involvement;

— Improved efficiency and effectiveness;

— Improved profitability;

— increased revenues;

— improved budgetary performance;

— reduced costs;

— improved cash flow;

— improved return on investment.

### 2.2.6 Evidence-based decision making

Organizations collect and analyze data relevant to their objectives. This enables management to make factual decisions that are accurate and reliable, balanced with experience. Factual decision making increases confidence and reduces the risk of poor decisions.

It is essential to understand and manage:

— the needs of customers, owners, employees, suppliers, financiers, local communities and society;

— organizational development;

— accuracy and timeliness of data;

— a measurement system in support of decision making;

— planning, collection, evaluation, analysis and reporting of data;

— data monitoring, measurement and record retention;

— corrective and preventive action;

— validation of data for accuracy and consistency;

— statistical thinking;

— accessibility of data to those who need it;

— empowerment and authorization to resolve concerns;

— supplier performance evaluation and remedial actions.

Factual decision making requires the use of data, which could be analyzed using methods, such as following:

— quality engineering and management tools;

— balanced scorecard;

— risk analysis;

— self-assessment;

— business continuity planning;

— succession planning;

— competence management;

— management by objectives;

— knowledge management;

— employee satisfaction/perception survey;

— market survey analysis;

— customer satisfaction survey and feedback;

— statistical methods

Expected benefits of factual decision making can include:

— improved cash flow;

— improved return on investment;

— improved effectiveness of decision making;

— optimized use of available resources;

— optimized effective and efficient processes;

— enhanced organizational performance;

— credibility and sustainability.

NOTE See ISO 10014 for further information regarding economic and financial benefits.

### 2.2.7 Relationship Management

In order to achieve sustained success, an organization should effectively and efficiently engage its interested parties in its management system. An organization and its interested parties are interdependent. Managed effectively, these interdependencies can create value for the organization.

It is essential to:

— align organizational philosophies between the organization and its interested parties;

— understand and respond to needs and expectations of interested parties, including society at large;

— consider integrating quality and other management systems;

— establish partnerships and build trust through clear and transparent communications

— establish long term customer-supplier relationships based on common vision and mission;

— coordinate continual improvement with suppliers and customers;

— assist suppliers with process improvements;

— support technical capability building of suppliers;

— establish a recognition system for suppliers, customers and other interested parties;

— establish relationships that balance short-term gains with long-term considerations;

— pool expertise and resources with partners when possible;

— identify and select key suppliers based on process capability and not simply cost;

— share information and future plans with interested parties as appropriate;

— establish joint development and improvement activities;

— meet statutory and regulatory requirements and influence future policies;

— support, participate and contribute to professional organizations.

Examples of techniques that can be used to support relationship management include:

— supply chain management;

— joint strategic planning with key suppliers and other interested parties;

— electronic data interchange;

— business information systems;

— online communication;

— open book management;

— self-directed work teams;

— autonomous management;

— community involvement programs.

Expected benefits of relationship management can include:

— improved quality, credibility, productivity and profitability;

— optimized use of available resources;

— improved supply chain performance;

— reduced time to market;

— enhanced organizational performance;

— improved brand image;

— committed workforce;

— employee retention;

— creativity and innovation;

— sustainable success.

NOTE 1 For further guidance on people involvement and competence, see ISO 10018.

NOTE 2 For further guidance on customer satisfaction, see ISO 10001, ISO 10002, ISO 10003 and ISO 10004.

NOTE 3 For further guidance on integration, see ISO handbook “Integrated Use of Management System Standards”.

## 2.3 Development of Fundamentals into a QMS

### 2.3.1 PDCA approach

The Plan Do Check Act cycle is an efficient and effective tool for planning, implementing and improving quality management systems. The ‘Plan Do Check Act’ cycle enables the leadership of an organization to transform the fundamentals and the quality principles into a quality management system by providing a systematic method of implementing policy, systems and processes for the realization and improvement of products. However, PDCA is not indicative of a rigid sequence of actions. The first action to take is to check current performance.

#### 2.3.1.1 Check

Before developing a QMS or changing an existing system it is prudent to measure current performance to create a baseline against which performance can be compared after the planned changes have been implemented. An example of some of the parameters that may provide a useful baseline are:

— time to market (time it takes to get a new product into the market);

— customer satisfaction (customer perception of your organization and its products);

— conformity (measure of conformity e.g. ratio of the number of products returned to those shipped or system availability if you are a service provider such as phone company, energy supplier etc.);

— supplier relationships (supplier perception of your organization and the way you deal with them);

— on-time delivery;

— processing delays (the impact of shortages, bottlenecks, down time);

— employee satisfaction (employee perception of your organization and the way you attend to their needs);

— external failure costs (costs of correcting failures after product delivery;

— internal failure costs (costs of correcting errors detected before product delivery;

— appraisal costs (costs of detecting errors);

ISO 9001 should be used as the criteria for an effective QMS rather than a prescription for creating a system that is separate from the way the organization functions. Look at the organisation as a system of processes and look for alignment with the requirements and recommendations of the various standards. Only change the organisation's processes in order to bring about an improvement in its performance, utilisation of resources or alignment with stakeholder needs and expectations. Where there is no alignment: with a particular requirement of ISO 9001.

— verify that the requirement is really applicable to the organization's circumstances;

— plan to change the organisation's processes only if it will yield an economic benefit.

Changing a process simply to meet the requirements of a standard is absurd, there has to be a real benefit to the organisation.

#### 2.3.1.2 Plan

The 'Plan' stage is to plan the development of the QMS. What follows is an outline of the key activities in the sequence in which they should be carried out as each stage generates information needed by subsequent stages:

a) determine the organization's purpose.

b) determine the organization's Stakeholders;

c) determine what the stakeholder's needs and expectations are relative to the organization's purpose

d) determine will the stakeholders look for to assess if their needs and expectations have been met and in response present the Stakeholder success measures or KPIs);

e) determine what outputs will deliver successful outcomes and in response present the key outputs;

f) determine which processes deliver these key outputs;

g) determine what limits the ability of the organization now or in the future to deliver these outputs and in response present the risks and opportunities and thereby define the quality objectives;

h) determine what measures will reveal whether the process objectives and quality objectives have been met and present the process measures and critical to quality characteristics;

i) determine what provisions have been built into the process design to prevent these processes failing to deliver the required outputs and in response present the preventive action plans;

j) design the processes that will deliver the key outputs, mitigate the risks and exploit the opportunities.

#### 2.3.1.3 Do

The “Do” stage requires the authorization of the plan, communication and general understanding of its objectives throughout the organization and supply chain. Training is vital during this stage. The plans are implemented and the new processes or changes to processes installed and reported with metrics. Interfaces with other aspects of the organization are vital to ensure common objectives are achieved. Parallel operations in the supply chain require equal attention to achieve success and continuity to internal operations.

#### 2.3.1.4 Act

The “Act” stage includes assessment of process capability, actions on concerns, and improvement activities. Assessments should also include quality, cost targets and validation results. Management communication is crucial at this stage to ensure customer timing commitments and resource utilization are achieves and issues are resolved.

Where system performance is below that required to satisfy the stakeholders, action should be taken to establish the cause and remove it by System redesign. Note changing parts of the system in isolation may not result in improved system performance.

### 2.3.2 Process approach to QMS development

### 2.3.3 Correlation of fundamental concepts with QMS model

Table 1 correlates the concepts described in 2.1 with the a model of a QMS as represented by the requirements of ISO 9001.

**Table 1 — Correlation between the fundamental concepts and the requirements of ISO 9001** (1 of 4)

| Concepts | ISO 9001 Clause |
|---|---|
| The concept of organization purpose | 4.1 Understanding the organization and its context |
| | 6.1 Actions to address risks and opportunities |
| The concept of external environment | 4.1 Understanding the organization and its context |
| | 6.3 Planning of changes |
| The concept of interested parties | 4.2 Understanding the needs and expectations of interested parties |
| | 5.1.2 Leadership and commitment with respect to the needs and expectations of customers |
| | 6.2 Quality objectives and planning to achieve them |
| The concept of quality | |

**Table 1 — Correlation between the fundamental concepts and the requirements of ISO 9001** (2 of 4)

| Concepts | ISO 9001 Clause |
|---|---|
| The concept of quality management | 5.2 Quality policy |
| | 6.2 Quality objectives and planning to achieve them |
| Quality as the priority | |
| Quality planning | |
| (quality objectives) | 6.2 Quality objectives and planning to achieve them |
| (Strategic level planning) | 6.2 Quality objectives and planning to achieve them |
| (understand customer needs) | 7.3 Awareness |
| (developing processes) | 8.1 Operational planning and control |
| (customer needs) | 8.2 Determination of market needs and interactions with customers (General) |
| (operational level planning) | 8.3 Operational planning process |
| (customer needs) | 8.2.2 Determination of requirements related to the goods and services |
| (developing product features) | 8.5.1 Development processes |
| (validating process capability) | 8.6.1 Control of production of goods and provision of services |
| Quality control | |
| (quality objectives) | 6.2 Quality objectives and planning to achieve them |
| (measuring devices) | 7.1.4 Monitoring and measuring devices |
| (cost of variation) | 7.3 Awareness |
| (units of measure and targets) | 8.1 Operational planning and control |
| (control before output is produced) | 8.2.3 Review of requirements related to the goods and services |
| (control before output is produced) | 8.4 Control of external provision of goods and services |
| (control before output is produced) | 8.5.1 Development processes |
| (control during output production) | 8.5.2 Development controls |
| (control after output production) | 8.5.2 Development controls |
| (control after output production) | 8.5.3 Development transfer |
| (control before, during and after output production) | 8.6.1 Control of production of goods and provision of services |
| (control before, during and after output production) | 8.8 Nonconforming goods and services |
| (control before output is produced) | 9.1 Monitoring, measurement, analysis and evaluation |
| (control after output is produced) | 10.1 Nonconformity and corrective action |
| Quality improvement | |
| (looking for better ways) | 9.1.3 Analysis and evaluation of data |
| (better control, better ways, better alignment) | 10.2 Improvement |

**Table 1 — Correlation between the fundamental concepts and the requirements of ISO 9001** (3 of 4)

| Concepts | ISO 9001 Clause |
|---|---|
| Quality assurance | |
| (reviewing plans) | 6.3 Planning of changes |
| (Documentary evidence) | 8.7 Release of goods and services |
| (review and audit plans) | 9.2 Internal Audit |
| People | |
| (Empowerment) | 5.1.1 Leadership and commitment with respect to the quality management system |
| (Psychological) | 7.1.3 Process environment |
| (Awareness) | 5.1.1 Leadership and commitment with respect to the quality management system |
| (knowledge) | 7.1.5 Knowledge |
| (competent) | 7.2 Competence |
| (understand their role) | 7.3 Awareness |
| (self-control) | 5.3 Organizational roles, responsibilities and authorities |
| Processes | 4.4.2 Process approach |
| (process design) | 6.1 Actions to address risks and opportunities |
| (objectives and measures) | 6.2 Quality objectives and planning to achieve them |
| (tactical level) | 6.3 Planning of changes |
| (strategic level) | 6.3 Planning of changes |
| (process design) | 8.1 Operational planning and control |
| (process for creating and satisfying customers) | 8.2 Determination of market needs and interactions with customers (General) |
| (measuring results) | 9.1.2 Customer satisfaction |
| (reviewing results) | 9.1.3 Analysis and evaluation of data |
| (reviewing results) | 9.2 Internal Audit |
| (reviewing results) | 9.3 Management review |
| (process design) | 7.5.2 Documented information (Creating and updating) |
| (process design) | 7.5.3 Control of documented Information |
| (process design) | 7.5.1 Documented information (General) |
| (process design) | 8.4.3 Documented information for external providers |
| (process design) | 8.6.3 Property belonging to customers or external providers. |
| (process design) | 8.6.4 Preservation of goods and services |
| (process design) | 8.6.2 Identification and traceability |
| (process design) | 8.6.5 Post delivery activities |
| (process design) | 8.6.6 Control of changes |

**Table 1 — Correlation between the fundamental concepts and the requirements of ISO 9001** (4 of 4)

| Concepts | ISO 9001 Clause |
|---|---|
| Resources | |
| (Availability) | 7.1.1 Resources (General) |
| (Maintain capability) | 7.1.2 Infrastructure |
| (Requisite quality) | 7.1.4 Monitoring and measuring devices |
| (Planning and acquisition) | 8.4 Control of external provision of goods and services |
| The concept of quality management systems | |
| (scope) | 4.3 Determining the scope of the quality management system |
| (QMS perspective) | 4.4.1 General Quality management system requirements |
| (Risk identification) | 5.1.1 Leadership and commitment with respect to the quality management system |
| (Risk identification) | 6.1 Actions to address risks and opportunities |
| (Objectives) | 6.2 Quality objectives and planning to achieve them |
| (Change) | 6.3 Planning of changes |
| (Resources) | 7.1.1 Resources (General) |
| (Resources) | 7.1.2 Infrastructure |
| (capability to adapt and change) | 7.1.5 Knowledge |
| (develop learning) | 7.1.5 Knowledge |
| (documentation) | 7.5.1 Documented information (General) |
| The role of standards in quality management | |

## 2.4 QMS model

### 2.4.1 General

As stated in 2.1.7 the organization's management system comprises the structure, processes and resources needed to establish an organization's policies and objectives and to implement the policies and achieve those objectives. By examining this system from a quality perspective a conceptual model can be constructed showing the interacting processes within a typical quality management system and the primary interfaces it has with the organization's stakeholders that sit in the external environment. The model illustrated in Figure 3 displays several important features:

a) the stakeholders sit outside the management system boundary because they are not controlled by this system but the wider system of which they are a part. The stakeholders are those parties that contribute to the organizations wealth creating capacity and in return accrue certain benefits and share the risks. These parties can be categorised as customers, investors, employees, suppliers and society;

b) success depends on understanding stakeholder needs and expectations, responding to their concerns and adapting to changes in the external environment. and thus there is a need for a Manage Organization Process;

c) organizations satisfy customers by fulfilling their demands and thus there is a "Fulfil Demand Process";

d) for demands to be fulfilled they have firstly to be created and therefore there is a "Create Demand Process";

e) both these processes need resources and therefore there is a "Resource Management Process" which feeds the Demand Creation and Fulfilment Processes with capable resources when needed. The resources come from the other stakeholders and are provided by suppliers, employees and investors;

f) these three processes need to be designed and managed in such a way as to enable the organization to consistently fulfil its purpose and this is another role of the Manage Organization process;

g) intelligence and feedback is also gathered by the Manage Organization process promptly analysed and improvements made to all processes to sustain success.

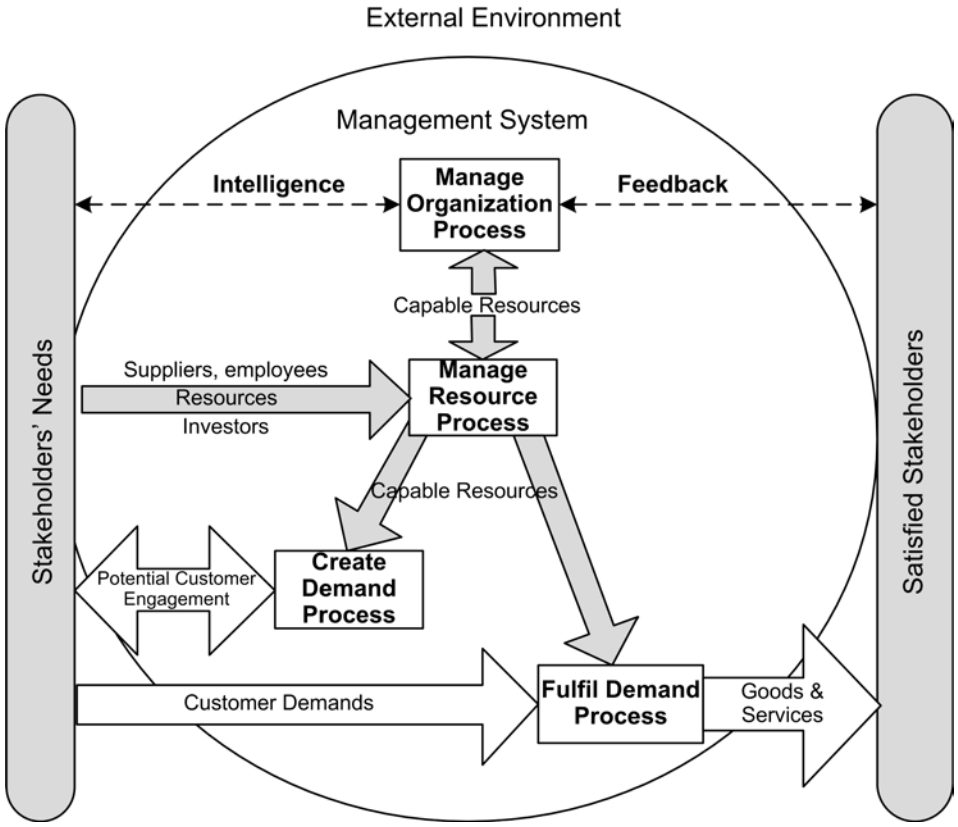



**Figure 3 — Model of a process-based management system**

### 2.4.2 Requirement for QMS and its product

### 2.4.3 Plan Do Check Act in the development of an organization's Quality Management System

#### 2.4.3.1 Planning and design of processes and systems

An approach to planning, designing, developing, implementing, maintaining and improving a quality management system consists of the following actions organized according to Plan Do Check Act (PDCA) cycle:

— determining the needs and expectations of customers and other interested parties;

— establishing the quality policy and quality objectives of the organization;

— determining the processes and responsibilities necessary to attain the quality objectives;

— determining and providing the resources necessary to attain the quality objectives;

— establishing methods to measure the effectiveness and efficiency of each process;

— applying these measures to determine the effectiveness and efficiency of each process;

— determining means of preventing nonconformities and eliminating their causes;

— establishing and applying a process for continual improvement of the quality management system.

An organization that deploys a quality management system creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement leading to increased satisfaction of customers and other interested parties and the success of the organization.

#### 2.4.3.2 Activities in Quality Management Systems

##### 2.4.3.2.1 General

A quality management system is a set of interrelated and/or interacting processes developed in accordance with established policy and objectives with appropriate resources to achieve quality. Key elements consist of a quality policy, objectives, processes and resources. Systems can be established at different levels (subsystems), each interrelated to one another. E.g.: measurement, auditing, complaint handling and dispute resolution.

All systems and subsystems are interrelated and interdependent, to achieve a desired outcome. A quality management system as an element, can organize a subsystem, for example,

##### 2.4.3.2.2 Establishing Quality policy and quality objectives

Quality policy and quality objectives are established to provide an internal and external focus to direct the organization strategy. Both determine the desired results and assist the organization to apply its resources to achieve these results. The quality policy provides a framework for establishing and reviewing quality objectives. The quality objectives need to be consistent with the quality policy and the commitment to continual improvement, and their achievement needs to be measurable by management metrics. The achievement of quality objectives can have a positive impact on product quality, operational effectiveness and financial performance and thus on the satisfaction and confidence of interested parties.

##### 2.4.3.2.3 Continual improvement

The management objectives in continual improvement are twofold, firstly in the quality management system is to establish reliable, understandable and repeatable systems and capable processes to increase the probability of predictable outcomes and enhancing the satisfaction of customers and other interested parties by delivering on time, on cost and quality products and services. Secondly, the continual improvement of products, processes and services. Actions for improvement may include the following:

— analysing and evaluating the existing situation to identify areas for improvement;

— establishing the objectives for improvement;

— determining the process capability on Critical to Quality products and processes and assigning management responsibilities for non capable processes;

— searching for possible solutions to achieve the objectives;

— evaluating these solutions and making a selection;

— implementing the selected solution;

— measuring, verifying, analysing and evaluating results of the implementation to determine that the

— objectives have been met;

— formalizing changes.

Results are reviewed from both product quality and improvement benefit cost saving. In this way, improvement is seen as a vital continual activity that management maintains for survival and sustainability. Feedback from customers and other interested parties, audits and review of the quality management system can also be used to identify opportunities for improvement.

#### 2.4.3.2.4 The management role in understanding statistical thinking and the application of statistical techniques

The use of statistical techniques and other problem solving tools can help in understanding process variability and thereby can help management make decisions based on reliable facts. The policy and operating process of implementing the use of statistical methods therefore should be built into the quality management system and provided with adequate resources and management involvement.

The use of statistical techniques have five important objectives:

— they are a proven technique for improving productivity;

— they provide the means of preventing defects;

— they prevent unnecessary process adjustment;

— they provide diagnostic data;

— they provide management with vital data on process capability.

This builds an environment in which all individual s in an organization can seek continual improvement and productivity. These techniques also facilitate better use of available data to assist in decision making. Variability can be observed in the behaviour and outcome of all processes and activities, even under conditions of apparent stability. Such variability can be observed in measurable characteristics of products and processes, and may be seen to exist at various stages over the life cycle of products from market research to customer service and final disposal.

Statistical techniques can help to measure, describe, analyse, interpret and model such variability, even with a relatively limited amount of data. Statistical analysis of such data can help to provide a better understanding of the nature, extent and causes of variability, thus helping to solve and even prevent problems that may result from such variability, and to promote continual improvement.

Guidance on statistical techniques in a quality management system is given in ISO/TR 10017.and ISOTC69 series of standards.

### 2.4.3.3 Evaluation and improvement of Quality Management System

When evaluating quality management systems, there are four basic questions that should be asked in relation to every process being evaluated.

— Is the process identified and appropriately defined?

— Are responsibilities assigned?

— Are the procedures implemented and maintained?

— Is the process capable of achieving the required specification?

The collective answers to the above questions can determine the result of the evaluation. Evaluation of a quality management system can vary in scope and encompass a range of activities, such as auditing and reviewing the quality management system, and self-assessments.

#### 2.4.3.3.1 Auditing the quality management system

Management audits are carried out to provide management with the data on the performance of the QMS. The data is used to analyse whether the quality objectives are being achieved and to determine the extent to which the quality management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the quality management system, deficiencies, weaknesses and to identify remedial action and opportunities for continual improvement.

First-party audits are conducted by, or on behalf of, the organization itself for internal purposes and can form the basis for an organization's self-declaration of conformity.

Second-party audits are conducted by customers of the organization or by other persons on behalf of the customer.

Third-party audits are conducted by external independent organizations. Such organizations, usually accredited, provide certification or registration of conformity with requirements such as those of ISO 9001.

Data from the audit and management review are essential to the organization strategic quality planning and its essential for top management.

ISO 19011 provides guidance on auditing.

#### 2.4.3.3.2 Reviewing the quality management system

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy, quality objectives and deployment. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties. The review includes determination of the need for actions.

Amongst other sources of information, audit reports are used for review of the quality management system.

#### 2.4.3.3.3 Self-assessment

An organization's self-assessment is a comprehensive and systematic review of the organization's activities and results referenced against the quality management system or a model of excellence. Self-assessment can provide an overall view of the performance of the organization and the degree of maturity of the quality management system. It can also help to identify areas requiring improvement in the organization and to determine priorities.

### 2.4.3.4 Leadership

Through leadership and actions, top management can create an environment where people are fully involved and in which a quality management system can operate effectively. The quality management principles (see 0.2) can be used by top management as the basis of its role, which is as follows:

— to establish and maintain the quality policy and quality objectives of the organization;

— to promote the quality policy and quality objectives throughout the organization to increase awareness, motivation and involvement;

— to ensure focus on customer requirements throughout the organization;

— to ensure that appropriate processes are implemented to enable requirements of customers and other interested parties to be fulfilled and quality objectives to be achieved;

— to ensure that an effective and efficient quality management system is established, implemented and maintained to achieve these quality objectives;

— to ensure the availability of necessary resources;

— to review the quality management system periodically;

— to decide on actions regarding the quality policy and quality objectives;

— to decide on actions for improvement of the quality management system.

## 2.5 Beyond QMS

### 2.5.1 ISO 9001 model

Provides the basic quality management requirements needed to conduct business in the global world. It is supported by a series of standards supporting the application of the requirements.

**ISO 9004 model**

Provides a progressive role for management to pursue in the quest for Continual Improvement

#### 2.5.1.1 Relationship of a quality management system and the ISO 9000 family of standards

The ISO 9000 family of standards provides a comprehensive set of requirements and guidelines for quality management systems.

ISO 9001 specifies requirements for a quality management system. ISO 9004 provides guidance on a wide range of objectives of a quality management system for sustainable success and improved performance.

As part of the ISO 9000 family, the following standards provide guidelines for components of the quality management system and can also be used to establish independent systems:

— ISO 10001 for customer satisfaction code of conduct;

— ISO 10002 for complaint handling;

— ISO 10003 for dispute resolution;

— ISO 10004 for measuring and monitoring customer satisfaction;

— ISO 10008 for electronic commerce transactions;

— ISO 10012 for measurement management;

— ISO 19011 for auditing.

The following standards provide guidelines for technical subjects in support of quality management systems:

— ISO 10005 for quality plans;

— ISO 10006 for project management;

— ISO 10007 for configuration management;

— ISO 10014 for financial and economic benefits;

— ISO 10015 for training;

— ISO 10018 for people involvement and competence;

— ISO 10019 for quality consultants.

The ISO 9000 family also includes the following technical reports in support of quality management systems:

— ISO/TR 10013 for documentation;

— ISO/TR 10017 for statistical techniques

NOTE See also sector specific standards such as ISO/TS 16949 for automotive suppliers.

### 1.1.1 QMS model and excellence model

The approaches of quality management systems given in the ISO 9000 family of standards and in organizational excellence models are based on common principles. Both approaches

— enable an organization to identify its strengths and weaknesses;

— contain provision for evaluation against generic models;

— provide a basis for continual improvement; and

— contain provision for external recognition.

The difference between the approaches of the quality management systems in the ISO 9000 family and the excellence models lies in their scope of application. The ISO 9000 family of standards provides requirements and guidelines for quality management systems. Evaluation of quality management systems determines fulfillment of those requirements and guidelines. The excellence models contain criteria that are applicable to all activities and all interested parties of an organization. Assessment criteria in excellence models provide a basis for an organization to compare its performance with the performance of other organizations.

### 2.5.2 Integration of QMS and other management systems

The quality management system is that part of the organization's management system that focuses on the achievement of results in relation to the quality objectives. The quality objectives complement other objectives of the organization such as those related to growth, funding, profitability, the environment and occupational health and safety. The various parts of an organization's management system, including its quality management system, should be integrated into a single management system. This can facilitate planning, allocation of resources, definition of complementary objectives and evaluation of the overall effectiveness of the organization. The organization’s management system can be audited against the requirements of International Standards such as ISO 9001 and ISO 14001. These management system audits can be carried out separately or in combination.

NOTE See ISO Handbook “Integrated Use of Management System Standards”.

# 3 Terms and definitions

A term in a definition or note which is defined elsewhere in this clause is indicated by italic font followed by its entry number in parentheses in regular font. These terms should be replaceable by their definition without major change to the sense of the definition.

For example:

**product** (3.5.4) is defined as “result of a *process* (3.5.1)”;

**process** is defined as “set of interrelated or interacting activities which transforms inputs into outputs”.

If the term “**process**” is replaced by its definition, as follows:

**product** then becomes “result of a set of interrelated or interacting activities which transforms inputs into outputs”.

A concept limited to a special meaning in a particular context is indicated by designating the subject field in angle brackets, < >, before the definition.

EXAMPLE In the context of an audit, the term entry for technical expert is:

**3.15**
**technical expert**
<audit> person who provides specific *knowledge* (3.8.11) or expertise to the *audit team* (3.9)

## 3.1 Terms related to quality

**3.1.1**
**object**
**entity**
anything perceivable or conceivable

[ISO 1087-1:2000]

EXAMPLES Product, process, person, organization, system.

Note 1 to entry: Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn).

**3.1.2**
**quality**
degree to which a set of inherent *characteristics* (3.6.1) of an *object* (3.1.1) fulfils *requirements* (3.1.3)

Note 1 to entry: The term “quality” can be used with adjectives such as poor, good or excellent.

Note 2 to entry: “Inherent”, as opposed to “assigned”, means existing in the *object* (3.1.1), especially as a permanent *characteristic* (3.6.1).

**3.1.3**
**requirement**
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: “Generally implied” means that it is custom or common practice for the *organization* (3.4.1) and other *interested parties* (3.4.5) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.8.7). [Annex SL Appendix 3, 3.03 of the ISO/IEC Directives Part 2:2012]

Note 3 to entry: A qualifier can be used to denote a specific type of requirement e.g. product requirement, quality management requirement, customer requirement, *quality requirement* ().

Note 4 to entry: Requirements can be generated by different *interested parties* (3.4.5).

Note 5 to entry: It can be necessary for reaching high *customer satisfaction* (3.1.7) to fulfil an expectation of a *customer* (3.4.6) even if it is neither stated nor generally implied or obligatory.

**3.1.4**
**quality requirement**
*requirement* (3.1.3) related to *quality* (3.1.2)

**3.1.5**
**statutory requirement**
obligatory *requirement* (3.1.3) specified by a legislative body

**3.1.6**
**regulatory requirement**
obligatory *requirement* (3.1.3) specified by an authority mandated by a legislative body

**3.1.7**
**grade**
category or rank given to different *quality requirements* (3.1.4) for an *object* (3.1.1) having the same functional use

EXAMPLE Class of airline ticket and category of hotel in a hotel guide.

Note 1 to entry: When establishing a *quality requirement* (3.1.4), the grade is generally specified.

**3.1.8**
**customer satisfaction**
*customer*'s (3.4.6) perception of the degree to which the *customer*'s (3.4.6) expectations have been fulfilled

Note 1 to entry: It can be that the *customer's* (3.4.6) expectation is not known to the *organization* (3.4.1), or even to himself until the *product* (3.5.4) is delivered. It can be necessary for reaching high customer satisfaction to fulfil an expectation of a *customer* () even if it is neither stated nor generally implied or obligatory.

Note 2 to entry: *Complaints* () are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

Note 3 to entry: Even when customer requirements have been agreed with the *customer* (3.4.6) and fulfilled, this does not necessarily ensure high customer satisfaction .

Note 4 to entry: See ISO 10004, *Quality Management — Customer satisfaction — Guidance for monitoring and measuring*.

**3.1.9**
**capability**
ability of an *object* (3.1.1) to realize a *product* (3.5.4) that will fulfil the *requirements* (3.1.3) for that *product* (3.5.4)

Note 1 to entry: Process capability terms in the field of statistics are defined in ISO 3534-2.

**3.1.10**
**competence**
ability to apply *knowledge* (3.8.11) and skills to achieve intended results

**3.1.11**
**performance**
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the *management* (3.2.9) of activities, *processes* (3.5.1), *products (3.5.4)* (including *services* (3.5.11), *systems* (3.2.8) or *organizations* (3.4.1).

**3.1.12**
**human factors**
physical or cognitive characteristics, or social behaviour, of a person

Note 1 to entry: Human factors can have a significant influence on the interaction within, and the functioning of, management systems (3.2.10).

[ISO 10018:2012]

**3.1.13**
**competence acquisition**
*process* (3.5.1) to ensure that *competence* (3,1.10) is attained by a person, a group of people, or an *organization* (3.4.1)

[ISO 10018:2012]

**3.1.14**
**competence development**
process (3.5.1) to increase the *competence* (3.1.10) of a person, a group of people, or an *organization* (3.4.1)

[ISO 10018:2012]

## 3.2 Terms related to management

**3.2.1**
**top management**
person or group of people who directs and controls an *organization* (3.4.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.4.1).

Note 2 to entry: If the scope of the *management system* (3.2.10) covers only part of an *organization* (3.4.1) then top management refers to those who direct and control that part of the *organization* (3.4.1).

**3.2.2**
**vision**
<organization's own future> that which an *organization* (3.4.1) aims to become as formally expressed by *top management* (3.2.1)

**3.2.3**
**mission**
<organization> *organization's* (3.4.1) purpose for existing as formally expressed by *top management* (3.2.1)

**3.2.4**
**policy**
<organization> intentions and direction of an *organization* (3.4.1) as formally expressed by its *top management* (3.2.1)

**3.2.5**
**risk**
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of *information* (3.8.1) related to, understanding or *knowledge* (3.8.11) of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential *events* (ISO Guide 73, 3.5.1.3) and *consequences* (ISO Guide 73, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated *likelihood* (ISO Guide 73, 3.6.1.1) of occurrence.

Note 5 to entry: The term “risk” is sometimes used only when there is the possibility of negative consequences

**3.2.6**
**objective**
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, *organization* (3.4.1)-wide, *project* (3.14.1), *product* (3.5.4) and *process* (3.5.1).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a *quality* (3.1.2) *objective* (3.2.6) or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *quality management systems* (3.3.3) *quality* (3.1.2) *objectives* (3.2.6) are set by the *organization* (3.4.1), consistent with the *quality* (3.1.2) *policy* (3.2.4), to achieve specific results.

**3.2.7**
**strategy**
planned activities to reach an *objective* (3.2.6)

**3.2.8**
**system**
set of interrelated or interacting elements

**3.2.9**
**management**
coordinated activities to direct and control an *organization* (3.4.1)

Note 1 to entry: Management can include establishing *policies* (3.2.4) and *objectives* (3.2.6) and *processes* (3.5.1) to achieve these *objectives* (3.2.6)

Note 2 to entry: In English, the term “management” sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an *organization* (3.4.1). When “management” is used in this sense, it should always be used with some form of qualifier to avoid confusion with the concept “management” defined above. For example, “management shall…” is deprecated whereas “*top management* (3.2.1) shall…” is acceptable. Otherwise different words should be adopted to convey the concept when related to people e.g. managerial or managers.

**3.2.10**
**management system**
set of interrelated or interacting elements of an *organization* (3.4.1) to establish *policies* (3.2.4) and *objectives* (3.2.6) and *processes* (3.5.1) to achieve those *objectives* (3.2.6)

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the *organization's* (3.4.1) structure, roles and responsibilities, planning, operation, etc.

Note 3 to entry: The scope of a management system may include the whole of the *organization* (3.4.1), specific and identified functions of the *organization* (3.4.1), specific and identified sections of the *organization* (3.4.1), or one or more functions across a group of *organizations* (3.4.1).

**3.2.11**
**continual improvement**
recurring activity to enhance *performance* (3.1.9)

Note 1 to entry: The *process* (3.5.1) of establishing *objectives* (3.2.6) and finding opportunities for improvement is a continual process through the use of *audit findings* (3.10.7) and *audit conclusions* (3.10.8), analysis of data, *management* (3.2.9) *reviews* (3.9.2) or other means and generally leads to *corrective action* (3.7.5) or *preventive action* (3.7.4).

**3.2.12**
**outsource**
make an arrangement where an external *organization* (3.4.1) performs part of an *organization's* (3.4.1) function or *process* (3.5.1)

Note 1 to entry: An external *organization* (3.4.1) is outside the scope of the *management system* (3.2.10), although the outsourced function or *process* (3.5.1) is within the scope.

**3.2.13**
**success**
<organization> reaching an *objective* (3.2.6)

Note 1 to entry: The success of an *organization* (3.4.1) emphasizes the need for a balance between its economic or financial interests and the needs of its *interested parties* (3.4.5), such as *customers* (3.4.6), users, investors / shareholders (owners), people in the *organization* (3.4.1), *suppliers* (3.4.7), partners, interest groups and communities.

**3.2.14**
**sustainable success**
<organization> success (3.2.13) over a period of time

Note 1 to entry: Sustainable success emphasizes the need for a balance between economic-financial interests of an *organization* (3.1.4) and those of the social and ecological environment.

Note 2 to entry: Sustainable success relates to the *interested parties* (3.4.5) of an *organization* (3.4.1) such as *customers* (3.4.6), owners, people in an *organization* (3.4.1), *suppliers* (3.4.7), bankers, unions, partners or society.

## 3.3 Terms related to quality management system

**3.3.1**
**quality objective**
objective (3.2.6) related to quality (3.1.2)

Note 1 to entry: Quality objectives are generally based on the *organization*'s (3.4.1) *quality policy* (3.3.2).

Note 2 to entry: Quality objectives are generally specified for relevant functions and levels in the *organization* (3.4.1).

**3.3.2**
**quality policy**
*policy* (3.2.4) related to *quality* (3.1.2)

Note 1 to entry: Generally the quality policy is consistent with the overall *policy* (3.2.4) of the *organization* (3.4.1), can be aligned with the organization's *vision* (3.2.3) and *mission* (3.2.5) and provides a framework for the setting of *quality objectives* (3.3.1).

Note 2 to entry: *Quality management* (3.3.6) principles presented in this International Standard can form a basis for the establishment of a quality policy (See 0.2.)

**3.3.3**
**quality management system**
*management system* (3.2.10) with regard to *quality* (3.1.2)

**3.3.4**
**quality management system consultant**
person who assists the *organization* (3.4.1) on *quality management system realization* (3.3.5), giving advice or *information* (3.8.1)

NOTE 1 to entry: The consultant can also assist in realizing parts of a *quality management system*(3.3.3).

NOTE 2 This International Standard provides guidance on how to distinguish a competent quality management system consultant from one who is not competent.

[ISO 10019]

**3.3.5**
**quality management system realization**
*process* (3.5.1) of establishing, documenting, implementing, maintaining and continually improving a *quality management system* (3.3.3)

**proposed action: delete this entry**

NOTE 1 to entry: Quality management system realization can include the following:

a) identifying the *processes* (3.5.1) needed for a *quality management system* (3.3.3) and their application throughout the *organization* (3.4.1);

b) determining the sequence and interaction of the identified *processes* (3.5.1);

c) determining criteria and methods needed to ensure that both the operation and control of the identified *processes* (3.5.1) are effective;

d) ensuring the availability of resources and information (3.8.1.1) necessary to support the operation and *monitoring* (3.9.3) of the identified *processes* (3.5.1);

e) *monitoring*, (3.9.3) measuring and analysing the identified *processes* (3.5.1);

f) implementing actions necessary to achieve planned results and *continual improvement* (3.2.11) of the identified *processes* (3.4.1)

[ISO 10019]

**3.3.6**
**quality management**
*management* (3.2.9) with regard to *quality* (3.1.2)

Note 1 to entry: Direction and control with regard to *quality* (3.1.2) generally includes establishment of the *quality policy* (3.3.2) and *quality objectives* (3.3.1), *quality planning* (3.3.7), *quality control* (3.3.8), *quality assurance* (3.3.9) and *quality improvement* (3.3.10)

**3.3.7**
**quality planning**
part of *quality management* (3.3.6) focused on setting *quality objectives* (3.3.1) and specifying necessary operational *processes* (3.4.1) and related resources to fulfil the *quality objectives* (3.3.1)

Note 1 to entry: Establishing *quality plans* (3.8.5) can be part of quality planning.

**3.3.8**
**quality control**
part of *quality management* (3.3.6) focused on fulfilling *quality requirements* (3.1.4)

**3.3.9**
**quality assurance**
part of *quality management* (3.3.6) focused on providing confidence that *quality requirements* (3.1.4) will be fulfilled

**3.3.10**
**quality improvement**
part of *quality management* (3.3.6) focused on increasing the ability to fulfil *quality requirement*s (3.1.4)

Note 1 to entry: The *quality requirements* (3.1.4) can be related to any aspect such as *effectiveness* (3.3.12), *efficiency* (3.3.11) or *traceability* (3.6.5).

**3.3.11**
**effectiveness**
extent to which planned activities are realized and planned results achieved

**3.3.12**
**efficiency**
relationship between the result achieved and the resources used

## 3.4 Terms related to organization

**3.4.1**
**organization**
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.2.6)

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

**3.4.2**
**association**
<customer satisfaction> *organization* (3.4.1) consisting of member *organizations* (3.4.1) or persons

[10003:2007]

**3.4.3**
**organizational structure**
arrangement of responsibilities, authorities and relationships between people

Note 1 to entry: A formal expression of the organizational structure is often provided in a *quality manual* (3.8.4) or a *quality plan* (3.8.5) for a *project* (3.14.1).

Note 2 to entry: The scope of an organizational structure can include relevant interfaces to external *organizations* (3.4.1).

**3.4.4**
**infrastructure**
<organization> *system* (3.2.8) of facilities, equipment and *services* (3.5.11) needed for the operation of an *organization* (3.4.1)

**3.4.5**
**interested party (preferred term)**
stakeholder (admitted term)
person or *organization* (3.4.1) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

EXAMPLE *Customers* (3.4.6), owners, people in an *organization* (3.4.1), *suppliers* (3.4.7), bankers, unions, partners or society that may include competitors or opposing pressure groups.

**3.4.6**
**customer**
person or *organization* (3.4.1) that receives a *product* (3.5.4)

EXAMPLES Consumer, client, end-user, retailer, beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the *organization* (3.4.1)

**3.4.7**
**supplier**
person or *organization* (3.4.1) that provides a *product* (3.5.4)

EXAMPLE Producer, distributor, retailer or vendor of a *product* (3.5.4), or provider of a *service* (3.5.11) or *information* (3.8.1).

Note 1 to entry: A supplier can be internal or external to the *organization* (3.4.1).

Note 2 to entry: In a contractual situation, a supplier is sometimes called “contractor”.

**3.4.8**
**contract**
binding agreement

**3.4.9**
**involvement**
engagement in, and contribution to, shared objectives

[ISO 10018: 2012]

**3.4.10**
**people involvement**
*involvement* (3.4.9) of people through the provision of responsibility and authority to achieve desired results

**3.4.11**
**business environment**
combination of internal and external factors and conditions that can have an effect on an *organization*'s (3.4.1) approach to its *products* (3.5.4) and investments, and its behaviour towards *interested parties* (3.4.5)

Note 1 to entry: The concept of a business environment is equally applicable to not-for-profit or public service *organizations* (3.4.1) as it is to those seeking profits.

**3.4.12**
**work environment**
set of conditions under which work is performed

Note1 to entry; Conditions can include physical, social, psychological and environmental factors (such as temperature, recognition schemes, occupational stress, ergonomics and atmospheric composition).

## 3.5 Terms related to process and product

**3.5.1**
**process**
set of interrelated or interacting activities which transforms inputs into outputs

Note 1 to definition: Inputs to a process are generally outputs of other processes.

Note 1 to entry: Processes in an *organization* (3.4.1) are generally planned and carried out under controlled conditions to add value.

Note 2 to entry: A process where the *conformity* (3.7.1) of the resulting output cannot be readily or economically validated is frequently referred to as a “special process”.

**3.5.2**
**procedure**
specified way to carry out an activity or a *process* (3.5.1)

NOTE 1 Procedures can be documented or not.

NOTE 2 When a procedure is documented, the term “written procedure” or “documented procedure” is frequently used. The *document* (3.8.2) that contains a procedure can be called a “procedure document” or a “process specification”.

**3.5.3**
**design and development**
design
development
set of *processes* (3.5.1) that transforms *requirements* (3.1.3) for an *object* (3.1.1) into more detailed *requirements* (3.1.3)

Note 1 to entry: The *requirements* (3.1.3) forming input to design and development can be expressed in a broader, more general sense than the requirements (3.1.3) forming the output of design and development. In a *project* (3.14.1) there can be several design and development stages.

Note 2 to entry: In English the words “design” and “development” and the term “design and development” are sometimes used synonymously and sometimes used to define different stages of the overall design and development. In French the words “conception” and “developpement” and the term “conception et developpement” are sometimes used synonymously and sometimes used to define different stages of the overall design and development.

Note 3 to entry: A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. *product* (3.5.4) design and development or *process* (3.5.1) design and development).

**3.5.4**
**product**
result of a *process* (3.5.1)

NOTE 1 to entry: There are four generic product categories, as follows:

— services (3.5.5);

— software (3.5.6);

— hardware (3.5.7);

— processed material (3.5.8).

Many *offered products* (3.5.9) comprise elements belonging to different generic product categories. Whether the *offered product* (3.5.9) is then called *hardware* (3.5.7), *processed material* (3.5.8), *software* (3.5.6) or *service* (3.5.5), depends on the dominant element). For example, the *offered product* (3.5.9) "automobile" consists of *hardware* (3.5.7) (e.g. tyres), *processed material* (3.5.8) (e.g. fuel, cooling liquid), *software* (3.5.6) (e.g. copyright of the engine control software, driver's manual), and *service* (3.5.5) (e.g. operating explanations given by the salesman. If it is bought from a retailer it is predominantly *hardware* (3.5.7) but if custom built it is bespoke and predominantly a *service* (3.5.5).

NOTE 2 to entry: A product can be intended (e.g. *offered product* (), internal *service* ()) or unintended (e.g. pollutant or unwanted effect).

**3.5.5**
**service**
intangible *product* (3.5.4) that is the result of at least one activity necessarily performed at the interface between the *supplier* (3.4.7) and the *customer* (3.4.6)

EXAMPLES

— an activity performed on a customer-supplied tangible *product* (3.5.4) (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible *product* (3.5.4) (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible *product* (3.5.4) (e.g. the delivery of *information* (3.8.1) in the context of *knowledge* (3.8.11) transmission);

— the creation of ambience for the *customer* (3.4.6) (e.g. in hotels and restaurants)

Note 1 to entry: Many services (3.5.5) provided comprise a higher or lower amount of elements belonging to other generic product categories.

**3.5.6**
**software**
intangible *product* (3.5.4) that is intellectual creation providing *information* (3.8.1)

EXAMPLE computer program, dictionary, procedure, rule, or a combination or part of it

NOTE 1 to entry: The concept software is not limited for use only in the context an information processing system or computer system.

NOTE 2 to entry: Software is often subject of patents, trademarks or copyright.

**3.5.7**
**hardware**
tangible *product* (3.5.4), the amount of which is a countable characteristic

EXAMPLE engine mechanical part, automobile tyre, glass bottle, computer hardware, CD-ROM (containing *software* (3.5.6) or not)

NOTE 1 to entry: In a commercial context hardware and *processed material* (3.5.8) often are referred to as goods.

**3.5.8**
**processed material**
tangible *product* (3.5.4), the amount of which is a continuous characteristic

EXAMPLE lubricant, tomato juice, steel sheet on a coil, polycarbonate granule

Note 1 to entry: In a commercial context processed material and *hardware* (3.5.7) often are referred to as goods.

**3.5.9**
**offered product**
*product* (3.5.4) that is intended for or required by a *customer* (3.4.6) and realized by the *organization* (3.4.1)

Note 1 to entry: Offered products can be intended for or required by one or more specific *customers* (3.4.6) or a target group of *customers* (3.4.6) in a market.

## 3.6 Terms related to characteristics

**3.6.1**
**characteristic**
distinguishing feature

Note 1 to entry: A characteristic can be inherent or assigned.

Note 2 to entry: A characteristic can be qualitative or quantitative.

Note 3 to entry: There are various classes of characteristic, such as the following:

a) physical (e.g. mechanical, electrical, chemical or biological characteristics);

b) sensory (e.g. related to smell, touch, taste, sight, hearing);

c) behavioural (e.g. courtesy, honesty, veracity); temporal (e.g. punctuality, reliability, availability);ergonomic (e.g. physiological characteristic, or related to human safety);

d) ergonomic (e.g. physiological characteristic, or related to human safety);

e) functional (e.g. maximum speed of an aircraft)

**3.6.2**
**quality characteristic**
inherent *characteristic* (3.6.1) of an *object* (3.1.1) related to a *requirement* (3.1.2)

Note 1 to definition: Inherent means existing in something, especially as a permanent characteristic.

Note 2 to entry: A characteristic assigned to an *object* (3.1.1) (e.g. the price of an *object* (3.1.1)) is not a quality characteristic of that *object* (3.1.1).

**3.6.3**
**performance metric**
**performance indicator**
*characteristic* (3.6.1) having significant impact on realization of the *product* (3.5.4) and *customer satisfaction* (3.1.7)

EXAMPLE *nonconformities* (3.7.2) per million opportunities, first time *capability* (3.1.8), *nonconformities* (3.7.2) per unit

**3.6.4**
**dependability**
availability *performance* (3.1.9) of an *object* (3.1.1) under specified conditions

**3.6.5**
**traceability**
ability to trace the history, application or location of an *object* (3.1.1)

Note 1 to definition: When considering *product* (3.5.4), traceability can relate to:

— the origin of materials and parts;

— the processing history; and

— the distribution and location of the *product* (3.5.4) after delivery

Note 2 to entry: In the field of metrology the definition in VIM:1993, 6.10, is the accepted definition.

## 3.7 Terms related to conformity

**3.7.1**
**conformity**
fulfilment of a *requirement* (3.1.3)

Note 1 to term: In English the word “conformance” is synonymous but deprecated. In French the word “compliance” is synonymous but deprecated.

**3.7.2**
**nonconformity**
non-fulfilment of a *requirement* (3.1.3)

**3.7.3**
**defect**
nonconformity (3.7.1) related to an intended or specified use

Note 1 to entry: The distinction between the concepts defect and *nonconformity* (3.7.2) is important as it has legal connotations, particularly those associated with *product* (3.5.4) liability issues.

Note 2 to entry: The intended use as intended by the *customer* (3.4.6) can be affected by the nature of the *information* (3.8.1), such as operating or maintenance instructions, provided by the *supplier* (3.4.7).

**3.7.4**
**preventive action**
action to eliminate the cause of a potential *nonconformity* (3.7.2) or other undesirable potential situation

Note 1 to definition: There can be more than one cause for a potential *nonconformity* (3.7.2).

Note 2 to entry: Preventive action is taken to prevent occurrence whereas *corrective action* (3.7.5) is taken to prevent recurrence.

**3.7.5**
**corrective action**
action to eliminate the cause of a *nonconformity* (3.7.2) and to prevent recurrence

Note 1 to definition: There can be more than one cause for a nonconformity (3.7.2).

Note 2 to entry: Corrective action is taken to prevent recurrence whereas *preventive action* (3.7.4) is taken to prevent occurrence.

**3.7.6**
**correction**
action to eliminate a detected *nonconformity* (3.7.2)

Note 1 to entry: A correction can be made in conjunction with a *corrective action* (3.7.5).

Note 2 to entry: A correction can be, for example, *rework* (3.7.7) or *regrade* (3.7.8).

**3.7.7**
**rework**
action on a *nonconforming* (3.7.2) *product* (3.5.4) to make it *conform* (3.7.1) to the *requirements* (3.1.3)

Note 1 to entry: Unlike rework *repair* (3.7.9) can affect or change parts of the *nonconforming* (3.7.2) *product* (3.5.4).

**3.7.8**
**regrade**
alteration of the *grade* (3.1.7) of a *nonconforming* (3.7.2) *product* (3.5.4) in order to make it conform to *requirements* (3.1.3) differing from the initial *requirements* (3.1.3)

**3.7.9**
**repair**
action on a *nonconforming* (3.7.2) *product* (3.5.4) to make it acceptable for the intended use

Note 1 to entry: A successful repair of a nonconforming *product* () does not necessarily make the *product* conform to the *requirements* (). It can be that in conjunction with a repair a *concession* () is required.

Note 2 to entry: Repair includes remedial action taken on a previously *conforming* (3.7.1) *product* (3.5.4) to restore it for use, for example as part of maintenance.

Note 3 to entry: Unlike *rework* (3.7.7), repair can affect or change parts of the *nonconforming* (3.7.2) *product* (3.5.4).

**3.7.10**
**scrap**
action on a nonconforming *product* (3.5.4) to preclude its originally intended use

EXAMPLE Recycling, destruction

Note 1 to entry: In a nonconforming *service* (3.5.5) situation, use is precluded by discontinuing the *service* (3.5.5).

**3.7.11**
**concession**
permission to use or release a product (3.5.4) that does not conform to specified *requirements* (3.1.3)

Note 1 to entry: A concession is generally limited to the delivery of a *product* (3.5.4) that has *nonconforming* (3.7.2) *characteristics* (3.6.1) within specified limits and is generally given for a limited quantity of *product* (3.5.4) or period of time, and for a specific use.

**3.7.12**
**deviation permit**
permission to depart from the originally specified *requirements* (3.1.3) of a *product* (3.5.4) prior to realization

Note 1 to entry: A deviation permit is generally given for a limited quantity of *product* (3.5.4) or period of time, and for a specific use.

**3.7.13**
**release**
permission to proceed to the next stage of a *process* (3.5.1)

Note 1 to entry: In English, in the context of *software* (3.5.7) and *documents* (3.8.2), the word “release” is frequently used to refer to a version of the *software* (3.5.7) or the *document* (3.8.2) itself.

## 3.8 Terms related to documentation

**3.8.1**
**information**
meaningful data

**3.8.2**
**document**
*information* (3.8.2) and its supporting medium

EXAMPLE *Record* (3.8.6), *specification* (3.8.3), procedure document, drawing, report, standard.

Note 1 to entry: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or combination thereof.

Note 2 to entry: A set of documents, for example *specifications* (3.8.3) and *records* (3.8.6), is frequently called “documentation”.

Note 3 to entry: Some *requirements* (3.1.3) (e.g. the *requirement* (3.1.3) to be readable) relate to all types of documents, however there can be different *requirements* (3.1.3) for specifications (3.8.3) (e.g. the *requirement* (3.1.3) to be revision controlled) and for *records* (3.8.6) (e.g. the *requirement* (3.1.3) to be retrievable).

**3.8.3**
**specification**
*document* (3.8.2) stating *requirements* (3.1.3)

EXAMPLE *Quality manual* (3.8.4), *quality plan* (3.8.5), technical drawing, procedure document, work instruction

Note 1 to entry: A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (3.5.4) (e.g. product specification, performance specification and drawing).

Note 2 to entry: It can be, that by stating *requirements* () a specification additionally is stating results achieved by *design and development* () and thus in some cases can be used as a *record* ().

**3.8.4**
**quality manual**
specification (3.8.3) for and of the quality management system (3.3.3) of an organization (3.4.1)

Note 1 to entry: Quality manuals can vary in detail and format to suit the size and complexity of an individual *organization* (3.4.1).

**3.8.5**
**quality plan**
*specification (3.8.3)* of the *procedures* (3.5.2) and associated resources that shall be applied by when and by whom to a specific *object* (3.1.1)

Note 1 to definition: These *procedures* (3.5.2) generally include those referring to quality management processes and to product realization processes.

Note 2 to entry: A quality plan often makes reference to parts of the *quality manual* (3.8.4) or to procedure documents.

Note 3 to entry: A quality plan is generally one of the results of *quality planning* (3.3.7).

**3.8.6**
**record**
*document* (3.8.1) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalise *traceability* (3.6.5) and to provide evidence of *verification* (3.9.7), *preventive action* (3.7.4) and *corrective action* (3.7.5).

Note 2 to entry: Generally records need not be under revision control.

**3.8.7**
**documented information**
*information* (3.8.1) required to be controlled and maintained by an *organization* (3.4.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

a) the *management system* (3.2.10), including related *processes* (3.5.1);

b) *information* (3.8.1) created in order for the *organization (3.4.1)* to operate (documentation);

c) evidence of results achieved (*records* (3.8.6)

**3.8.8**
**objective evidence**
data supporting the existence or verity of something

Note 1 to entry: Objective evidence may be obtained through observation, *measurement* (3.9.6), *test* (3.9.5), or other means.

**3.8.9**
**information system**
<QMS> network of communication channels used within an organization

**3.8.10**
**specific case**
subject of the *quality plan* (3.8.5)

NOTE This term is used to avoid repetition of "*process* (3.5.1), *product* (3.5.4), *project* (3.14.1) or *contract* (3.4.8)" within this International Standard.

**proposed action: delete entry**

[ISO 10005 quality plans]

**3.8.11**
**knowledge**
available collection of *information* (3.8.1) being a justified belief and having a high certainty to be true

Note 1 to entry: Knowledge can be implicit (as with practical skill or expertise) or explicit (as with the theoretical understanding of an object), can be more or less formal or systematic and can be true or false.

Note 2 to entry: The collection of *information* () can consist of facts, theories, rules, descriptions

## 3.9 Terms related to determination

**3.9.1**
**determination**
activity to find out something

Note 1 to entry: Something in this definition means one or more characteristics and their characteristic values

**3.9.2**
**review**
*determination* (3.9.1) of the suitability, adequacy and *effectiveness* () of an *object* (3.1.1) to achieve established *objectives* (3.2.6)

EXAMPLE Management review, design and development review, review of customer requirements, nonconformity review and peer review.

Note to 1 entry: Review can also include the *determination* () of *efficiency* (3.3.12).

**3.9.3**
**monitoring (v)**
*determining* (3.9.1) the status of a *system* (3.2.8), a *process* (3.5.1) or an activity

Note 1 to entry: To determine the status there may be a need to check, supervise or critically observe.

Note 2 to entry: Monitoring is generally a *determination* (3.9.1) of the *object* (3.1.1) being monitored, carried out at different stages or at different times

**3.9.4**
**inspection**
*determination* (3.9.1) of *conformity* (3.7.1) to specified *requirements* (3.1.3)

Note 1 to entry: If the result of an inspection shows *conformity* (3.7.1), it can be used for purposes of *verification* (3.9.7).

Note 2 to entry: The result of an inspection can show *conformity* (3.7.1) or *nonconformity* (3.7.2) or a degree of *conformity* (3.7.1)

**3.9.5**
**test**
*determination* (3.9.1) according to *requirements* (3.1.3) for a specific intended use or application

Note 1 to entry: If the result of a test shows *conformity* (3.7.1), it can be used for purposes of *validation* (3.9.8).

**3.9.6**
**measurement**
*process* (3.5.1) to determine a value

Note 1 to entry: According to ISO 3534-2:2006 the value determined is generally the value of a quantity.

**3.9.7**
**verification**
confirmation, through the provision of *objective evidence* (3.8.8), that specified *requirements* (3.1.3) have been fulfilled

Note 1 to entry: The *objective evidence* (3.8.8) needed for a verification can be the result of an *inspection* (3.9.4) or of other forms of *determination* (3.9.1) such as performing alternative calculations or reviewing *documents* (3.8.2)

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process

Note 3 to entry: The word “verified” is used to designate the corresponding status.

**3.9.8**
**validation**
confirmation, through the provision of *objective evidence* (3.8.8), that the *requirements* (3.1.3) for a specific intended use or application have been fulfilled

Note 1 to entry: The *objective evidence* (3.8.8) needed for a validation is the result of a *test* (3.9.5) or other form of *determination* (3.9.1) such as performing alternative calculations or reviewing *documents* (3.8.2)

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

## 3.10 Terms related to audit

**3.10.1**
**audit**
systematic, independent and documented *process* (3.5.1) for obtaining *audit evidence* (3.10.3) and evaluating it objectively to determine the extent to which the *audit criteria* (3.10.2) are fulfilled

Note 1 to entry: The fundamental elements of an audit include the *determination* (3.9.1) of the *conformity* (3.7.1) of an *object* (3.1.1) according to a *procedure* (3.5.2) carried out by personnel not being responsible for the *object* (3.1.1) audited

Note 2 to entry: An audit can be an internal or first party audit, or an external or second party audit or third party audit and it can be a combined audit (combining two or more disciplines).

Note 3 to entry: Internal audits, sometimes called first-party audits are conducted by, or on behalf of, the *organization* (3.4.1) itself for *management* (3.2.9) *review* (3.9.2) and other internal purposes, and may form the basis for an *organization's* (3.4.1) declaration of *conformity* (3.7.1). In many cases, particularly in smaller *organizations* (3.4.1), independence can be demonstrated by the freedom from responsibility for the activity being audited.

Note 4 to entry: External audits include those generally called second and third-party audits*.* Second party audits are conducted by parties having an interest in the *organization* (3.4.1), such as *customers* (3.4.6), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing *organizations* (3.4.1) such as those providing certification/registration of *conformity* (3.7.1) to ISO 9001 or ISO 14001.

Note 5 to entry: When two or more *management systems* (3.2.10) are audited together, this is called a “combined audit”.

Note 6 to entry: When two or more auditing *organizations* (3.4.1) cooperate to audit a single *auditee* (3.10.7), this is called a “joint audit”.

Note to this draft only: With regard to Notes to definition 5 and 6 – these are hidden term entries that should be made full term entries

**3.10.2**
**audit criteria**
set of *policies* (3.2.4), *procedures* (3.5.2) or *requirements* (3.1.3) used as a reference against which *audit evidence* (3.10.3) is compared

Audit criteria are used as a reference against which *audit evidence* (3.10.3) is compared.

**3.10.3**
**audit evidence**
*records* (3.8.6), statements of fact or other *information* (3.8.1) which are relevant to the *audit criteria* (3.10.2) and verifiable

Note 1 to entry: Audit evidence can be qualitative or quantitative.

**3.10.4**
**audit findings**
results of the evaluation of the collected *audit evidence* (3.10.3) against *audit criteria* (3.10.2)

Note 1 to entry: Audit findings indicate *conformity* (3.7.1) or *nonconformity* (3.7.2).

Note 2 to entry: Audit findings can lead to the identification of opportunities for improvement or recording good practices.

Note 3 to entry: If the *audit criteria* (3.10.2) are selected from *statutory requirements* (3.1.5) or *regulatory requirements* (3.1.6), the audit finding can be called compliance or non-compliance.

**3.10.5**
**audit conclusion**
outcome of an *audit* (3.10.1), after consideration of the *audit* (3.10.1) objectives and all *audit findings* (3.10.4)

**3.10.6**
**audit client**
*organization* (3.4.1) or person requesting an audit (3.10.1)

Note 1 to entry: In the case of internal *audit* (3.10.1), the audit client can also be the *auditee* (3.10.7) or the person managing the *audit programme* (3.10.13). Requests for external *audit* (3.10.1) can come from sources such as regulators, contracting parties or potential clients.

**3.10.7**
**auditee**
*organization* (3.4.1) being audited

**3.10.8**
**auditor**
person who conducts an *audit* (3.10.1)

**3.10.9**
**audit team**
one or more *auditors* (3.10.8) conducting an *audit* (3.10.1), supported if needed by *technical experts* (3.10.10)

Note 1 to entry: One *auditor* (3.10.8) of the audit team is appointed as the audit team leader.

Note 2 to entry: The audit team may include auditors-in-training.

**3.10.10**
**technical expert**
<audit> person who provides specific *knowledge* (3.8.11) or expertise to the *audit team* (3.10.9)

Note 1 to entry: Specific *knowledge* (3.8.11) or expertise relates to the *organization* (3.3.1), the *process* (3.5.1) or activity to be audited, or language or culture.

Note 2 to entry: A technical expert does not act as an *auditor* (3.10.8) in the *audit team* (3.10.9).

**3.10.11**
**observer**
<audit> person who accompanies the *audit team* (3.10.9) but does not *audit* (3.10.1)

Note 1 to entry: An observer is not a part of the *audit team* (3.10.9) and does not influence or interfere with the conduct of the *audit* (3.10.1).

Note 2 to entry: An observer can be from the *auditee* (3.10.7), a regulator or other interested party who witnesses the *audit* (3.10.1).

**3.10.12**
**guide**
<audit> person appointed by the *auditee* (3.10.7) to assist the *audit team* (3.10.9)

**3.10.13**
**audit programme**
arrangements for a set of one or more *audits* (3.10.1) planned for a specific time frame and directed towards a specific purpose

**3.10.14**
**audit scope**
extent and boundaries of an *audit* (3.10.1)

Note 1 to entry: The audit scope generally includes a description of the physical locations, organizational units, activities and *processes* (3.5.1), as well as the time period covered.

**3.10.15**
**audit plan**
description of the activities and arrangements for an *audit* (3.10.1)

## 3.11 Terms related to quality management for measurement processes [ISO 10012:2003]

**3.11.1**
**measurement management system**
set of interrelated and interacting elements necessary to achieve *metrological confirmation* (3.11.3) and continual control of *measurement processes* (3.11.2)

**3.11.2**
**measurement process**
set of operations to determine the value of a quantity

**3.11.3**
**metrological confirmation**
set of operations required to ensure that *measuring equipment* (3.11.4) conforms to the *requirements* (3.1.3) for its intended use

Note 1 to entry: Metrological confirmation generally includes calibration or *verification* (3.9.7), any necessary adjustment or *repair* (3.7.9), and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labelling.

Note 2 to entry: Metrological confirmation is not achieved until and unless the fitness of the *measuring equipment* (3.11.4) for the intended use has been demonstrated and documented.

Note 3 to entry: The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

Note to this draft only: These requirements should be named as “metrological requirements” unless they are different from the other references and relate to requirements defined at (3.1.3)

Note 4 to entry: Metrological requirements are usually distinct from, and are not specified in, *product* (3.5.4) *requirements* (3.1.3).

**3.11.4**
**measuring equipment**
measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement process* (3.11.2)

**3.11.5**
**metrological characteristic**
distinguishing feature which can influence the results of *measurement* (3.9.6)

Note 1 to entry: *Measuring equipment* (3.11.4) usually has several metrological characteristics.

Note 2 to entry: Metrological characteristics can be the subject of calibration.

**3.11.6**
**metrological function**
function with administrative and technical responsibility for defining and implementing the *measurement management system* (3.11.1)

Note 1 to entry: The word “defining” has the meaning of “specifying”. It is not used in the terminological sense of “defining a concept” (in some languages, this distinction is not clear from the context alone).

## 3.12 Terms related to customer satisfaction and dispute resolution [ISO 10001:2007, ISO 10002:2004, ISO 10003:2007]

NOTE In the ISO 10001, ISO 10002, ISO 10003 standards there may be differing notes added to these terms and those adopted from ISO 9000.

**3.12.1**
**customer satisfaction code of conduct**
**code**
promises made to *customers* (3.4.6) by an *organization* (3.4.1) concerning its behaviour that are aimed at enhanced *customer satisfaction* (3.1.8), and related provisions

Note 1 to definition: Related provisions can include *objectives* (3.2.6), conditions, limitations, contact *information* (3.8.1), and *complaints* (3.12.3) handling *procedures* (3.5.2).

Note 2 to entry: Hereafter, in this International Standard the term “code” is used instead of “customer satisfaction code of conduct.”

**3.12.2**
**customer service**
interaction of the *organization* (3.4.1) with the *customer* (3.4.6) throughout the life cycle of a *product* (3.5.4)

**3.12.3**
**complaint**
<customer satisfaction> expression of dissatisfaction made to an *organization* (3.4.1), related to its *products* (3.5.4), or the complaints handling *process* (3.5.1) itself, where a response or resolution is explicitly or implicitly expected

**3.12.4**
**dispute**
<customer satisfaction> disagreement, arising from a *complaint* (3.12.3), submitted to a *provider* (3.12.6)

Note to entry: Some *organizations* (3.4.1) allow their *customers* (3.4.6) to express their dissatisfaction to a *provider* (3.12.6) in the first instance. In this situation, the dissatisfaction becomes a *complaint* (3.12.3) when sent to the *organization* (3.4.1) for a response, and becomes a dispute if not resolved by the *organization* (3.4.1) without *provider* (3.12.6) intervention. Many *organizations* (3.4.1) prefer their *customers* (3.4.6) to first express any dissatisfaction to the *organization* (3.4.1) before utilizing dispute resolution external to the *organization* (3.4.1). [ISO 10003]

**3.12.5**
**dispute resolver**
<customer satisfaction> individual assigned by a *provider* (3.12.6) to assist the parties in resolving a *dispute* (3.12.4)

NOTE These may be staff, volunteer or *contract* (3.4.8) individuals.

**3.12.6**
**provider**
<customer satisfaction> person or *organization* (3.4.1) that supplies and operates an external *dispute* (3.12.4) resolution *process* (3.5.1)

Note 1 to entry: Generally, a provider is a legal entity, separate from the *organization* (3.4.1) or person as an individual and the complainant. In this way, the attributes of independence and fairness are emphasized. In some situations, a separate unit is established within the *organization* (3.4.1) to handle unresolved *complaints* (3.12.3). This International Standard {ISO 100xx} is not intended for that situation but it may be useful.

Note 2 to entry: The provider utilizes support, executive and other managerial staff to supply financial resources, clerical support, scheduling assistance, training, meeting rooms, supervision and similar functions. The provider also supplies *dispute resolvers* (3.12.5). The provider *contracts* (3.4.8) with the parties to provide *dispute* (3.12.4) resolution, and is accountable for *performance* (3.1.9).

Note 3 to entry: Providers can take many forms including not-for-profit, for-profit and public entities.

**3.12.7**
**feedback**
<customer satisfaction> opinions, comments and expressions of interest in the products (3.5.4) or the *complaints* (3.12.3)-handling *process* (3.5.1)

## 3.13 Terms related to configuration management [ISO 10007:2003]

**3.13.1**
**dispositioning authority**
<configuration management> person or a group of persons assigned responsibility and authority to make decisions on the *configuration* (3.13.7)

Note 1 to entry: Dispositioning authority can also be called a “configuration control board”.

Note 2 to entry: Relevant *interested parties* (3.4.5) within and outside the *organization* (3.4.1) should be represented on the dispositioning authority.

**3.13.2**
**configuration management**
coordinated activities to direct and control *configuration* (3.13.7)

Note 1 to entry: Configuration management generally concentrates on technical and *organizational* (3.4.1) activities that establish and maintain control of a *product* (3.5.4) and its *product configuration information* (3.13.3) throughout the life cycle of the *product* (3.5.4).

**3.13.3**
**product configuration information**
*requirements* (3.1.3) for *product* (3.5.4) design, realization, *verification* (3.9.7), operation and support

**3.13.4**
**change control**
<configuration management> activities for control of the *product* (3.5.4) after formal approval of its *product configuration information* ( 3.13.3)

**3.13.5**
**configuration baseline**
approved *product configuration information* (3.13.3) that establishes the *characteristics* (3.6.1) of a *product* (3.5.4) at a point in time that serves as reference for activities throughout the life cycle of the *product* (3.5.4)

**3.13.6**
**configuration item**
entity within a *configuration* (3.13.7) that satisfies an end use function

**3.13.7**
**configuration**
interrelated functional and physical *characteristics* (3.6.1) of a *product* (3.5.4) defined in *product configuration information* (3.13.3)

**3.13.8**
**configuration status accounting**
formalized recording and reporting of *product configuration information* (3.13.3), the status of proposed changes and the status of the implementation of approved changes

## 3.14 Terms related to quality in project management [ISO 10006:2003]

**3.14.1**
**project**
unique *process* (3.5.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an *objective* (3.2.6) conforming to specific *requirements* (3.1.3), including the constraints of time, cost and resources

Note 1 to entry: An individual project can form part of a larger project structure.

Note 2 to entry: In some projects the *objectives* (3.2.6) are refined and the *product* (3.5.4) *characteristics* (3.6.1) defined progressively as the project proceeds.

Note 3 to entry: The outcome of a project can be one or several units of *product* (3.5.4).

Note 4 to entry: The project's *organization* (3.4.1) is normally temporary and established for the lifetime of the project.

Note 5 to definition: The complexity of the interactions among project activities is not necessarily related to the project size.

**3.14.2**
**project management**
planning, organizing, *monitoring* (3.9.3), controlling and reporting of all aspects of a *project* (3.14.1) and the motivation of all those involved in it to achieve the *project* (3.14.1) *objectives* (3.2.6)

**3.14.3**
**project management plan**
document specifying what is necessary to meet the *objective(s)* (3.2.6) of the *project* (3.14.1)

Note 1 to entry: A project management plan should include or refer to the *project's* (3.14.1) *quality plan* (3.8.5).

Note 2 to entry: The project management plan also includes or references such other plans as those relating to *organizational structures* (3.4.3), resources, schedule, budget, *risk* (3.2.5) *management* (3.2.9), environmental management, health and safety *management* (3.2.9) and security *management* (3.2.9), as appropriate.

**3.14.4**
**activity**
<project management> smallest identified item of work in a *project* (3.14.1)

**3.14.5**
**progress evaluation**
<project management> assessment of progress made on achievement of the *project* (3.14.1) *objectives* (3.2.6)

Note 1 to definition: This assessment should be carried out at appropriate points in the *projec*t (3.14.1) life cycle across *project* (3.14.1) *processes* (3.5.1), based on criteria for *project* (3.14.1) *processes* (3.5.1) and *product* (3.5.4).

Note 2 to entry: The results of progress evaluations may lead to revision of the *project management plan (*3.14.3).

Note to the draft only: Terms and definitions of the following documents will be added as soon as FDIS approval is given in the order that they reach that stage but currently have the following order.

## 3.15 Terms related to B2C ECT

### 3.16.1 Terms related to electoral management system

### 3.16.2 Terms related to electoral infrastructure and logistics

### 3.16.3 Terms related to vote

## 3.17 Terms related to local government MS

# Annex A
(informative)

# Methodology used in the development of the vocabulary

## A.1 Introduction

The universality of application of the ISO 9000 family of standards requires the use of

— a technical description but without the use of technical language; and

— a coherent and harmonized vocabulary that is easily understandable by all potential users of quality management systems standards.

Concepts are not independent of one another, and an analysis of the relationships between concepts within the field of quality management systems and the arrangement of them into concept systems is a prerequisite of a coherent vocabulary. Such an analysis was used in the development of the vocabulary specified in this document. Since the concept diagrams employed during the development process may be helpful in an informative sense, they are reproduced in A.4.

## A.2 Content of a vocabulary entry and the substitution rule

The concept forms the unit of transfer between languages (including variants within one language, for example American English and British English). For each language, the most appropriate term for the universal transparency of the concept in that language, i.e. not a literal approach to translation, is chosen.

A definition is formed by describing only those characteristics that are essential to identify the concept. Information concerning the concept which is important but which is not essential to its description is put in one or more notes to the definition.

When a term is substituted by its definition, subject to minor syntax changes, there should be no change in the meaning of the text. Such a substitution provides a simple method for checking the accuracy of a definition. However, where the definition is complex in the sense that it contains a number of terms, substitution is best carried out taking one or, at most, two definitions at a time. Complete substitution of the totality of the terms will become difficult to achieve syntactically and unhelpful in conveying meaning.

## A.3 Concept relationships and their graphical representation

### A.3.1 General

In terminology work, the relationships between concepts are based on the hierarchical formation of the characteristics of a species so that the most economical description of a concept is formed by naming its species and describing the characteristics that distinguish it from its parent or sibling concepts.

There are three primary forms of concept relationships indicated in this annex: generic (A.3.2), partitive (A.3.3) and associative (A.3.4).

### A.3.2 Generic relation

Subordinate concepts within the hierarchy inherit all the characteristics of the superordinate concept and contain descriptions of these characteristics which distinguish them from the superordinate (parent) and coordinate (sibling) concepts, e.g. the relation of spring, summer, autumn and winter to season.

Generic relations are depicted by a fan or tree diagram without arrows (see Figure A.1).

Example from ISO 704:2009 (5.5.2.2.1)

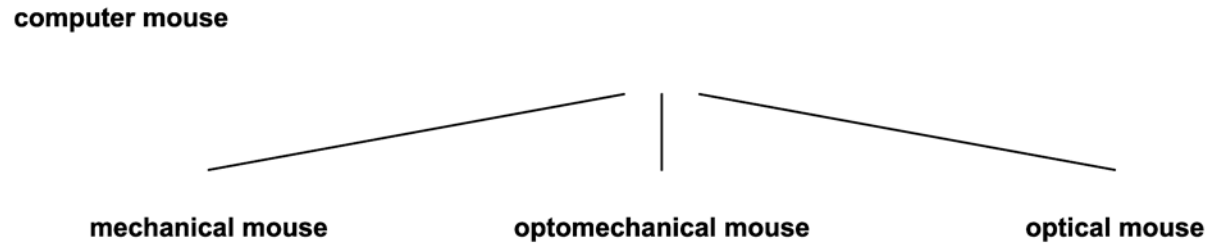



**Figure A.1 — Graphical representation of a generic relation**

### A.3.3 Partitive relation

Subordinate concepts within the hierarchy form constituent parts of the superordinate concept, e.g. spring, summer, autumn and winter may be defined as parts of the concept year. In comparison, it is inappropriate to define sunny weather (one possible characteristic of summer) as part of a year.

Partitive relations are depicted by a rake without arrows (see Figure A.2). Singular parts are depicted by one line, multiple parts by double lines.

Example from ISO 704:2009 (5.5.2.3.1)

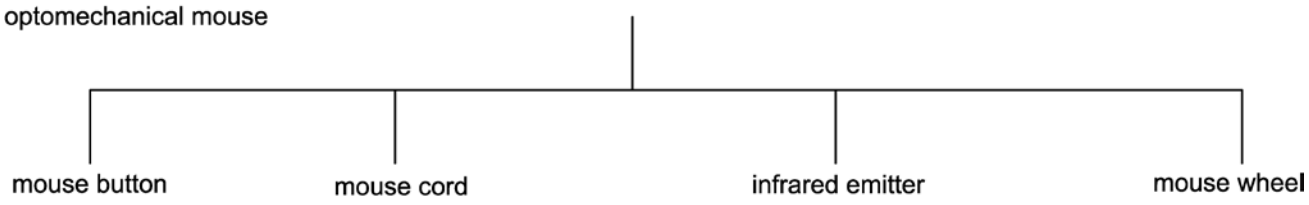



**Figure A.2 — Graphical representation of a partitive relation**

### A.3.4 Associative relation

Associative relations cannot provide the economies in description that are present in generic and partitive relations but are helpful in identifying the nature of the relationship between one concept and another within a concept system, e.g. cause and effect, activity and location, activity and result, tool and function, material and product.

Associative relations are depicted by a line with arrowheads at each end (see Figure A.3).

Example from ISO 704:2009 (5.6.2)

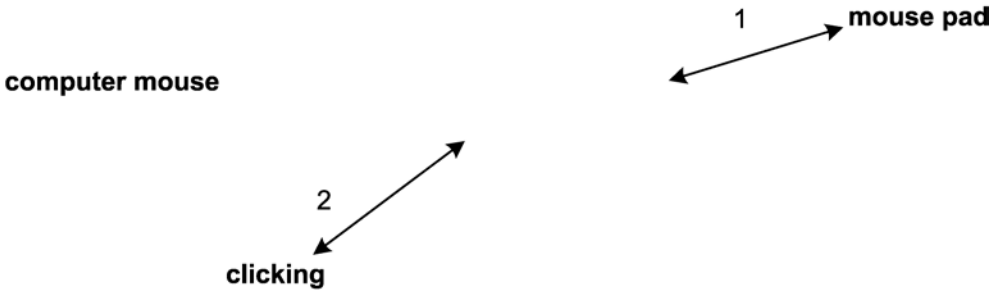
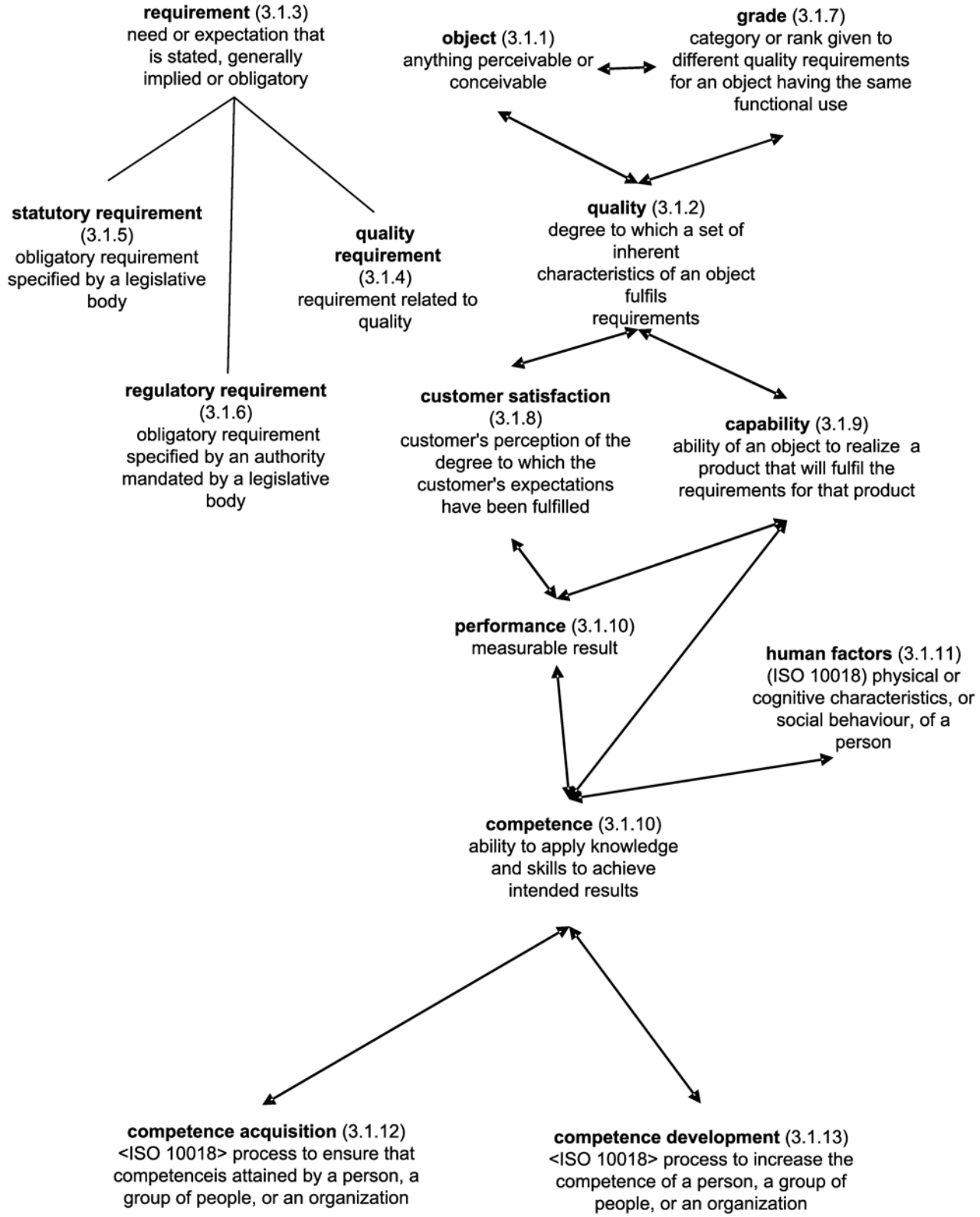


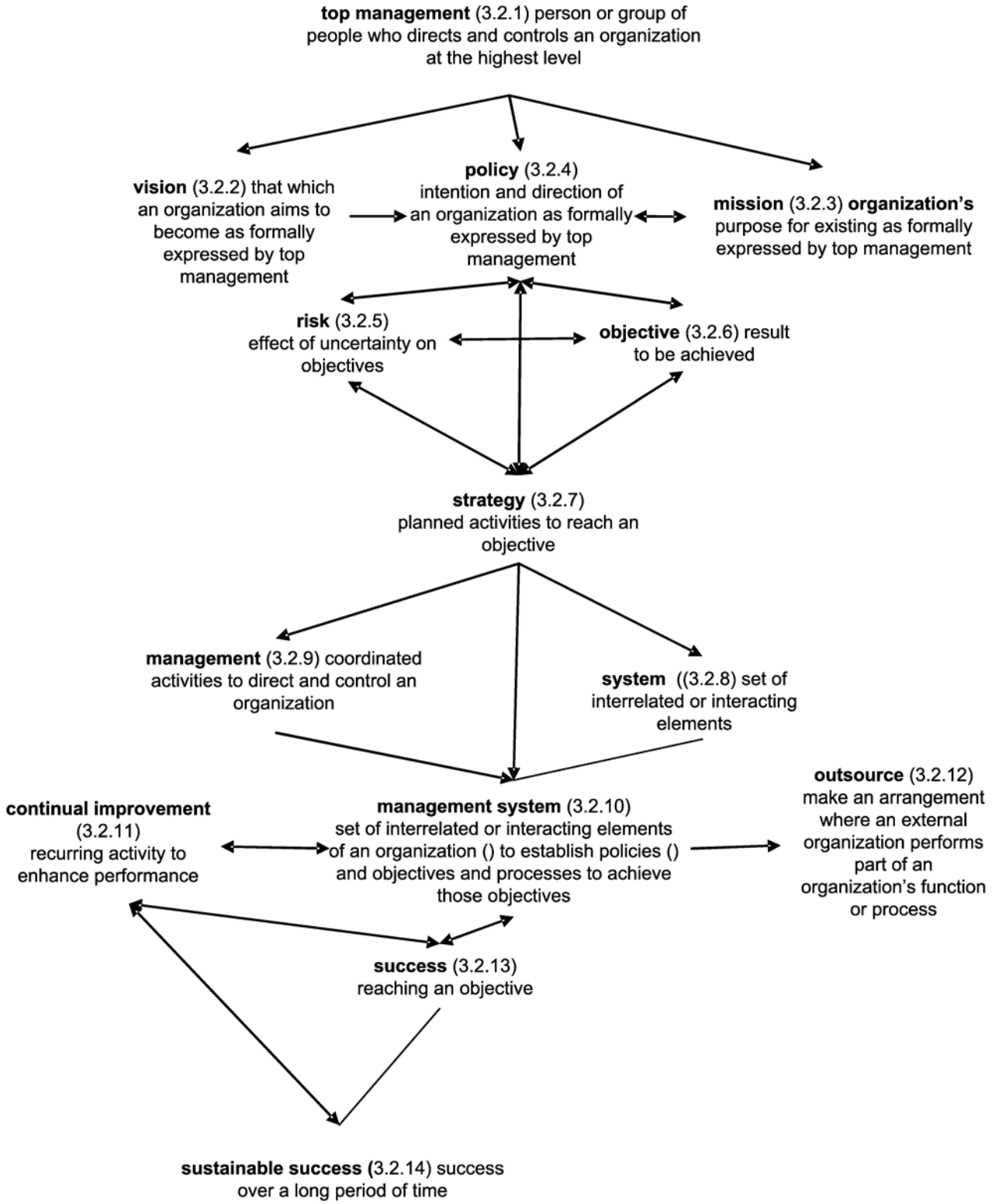

**Figure A.3 — Graphical representation of an associative relation**

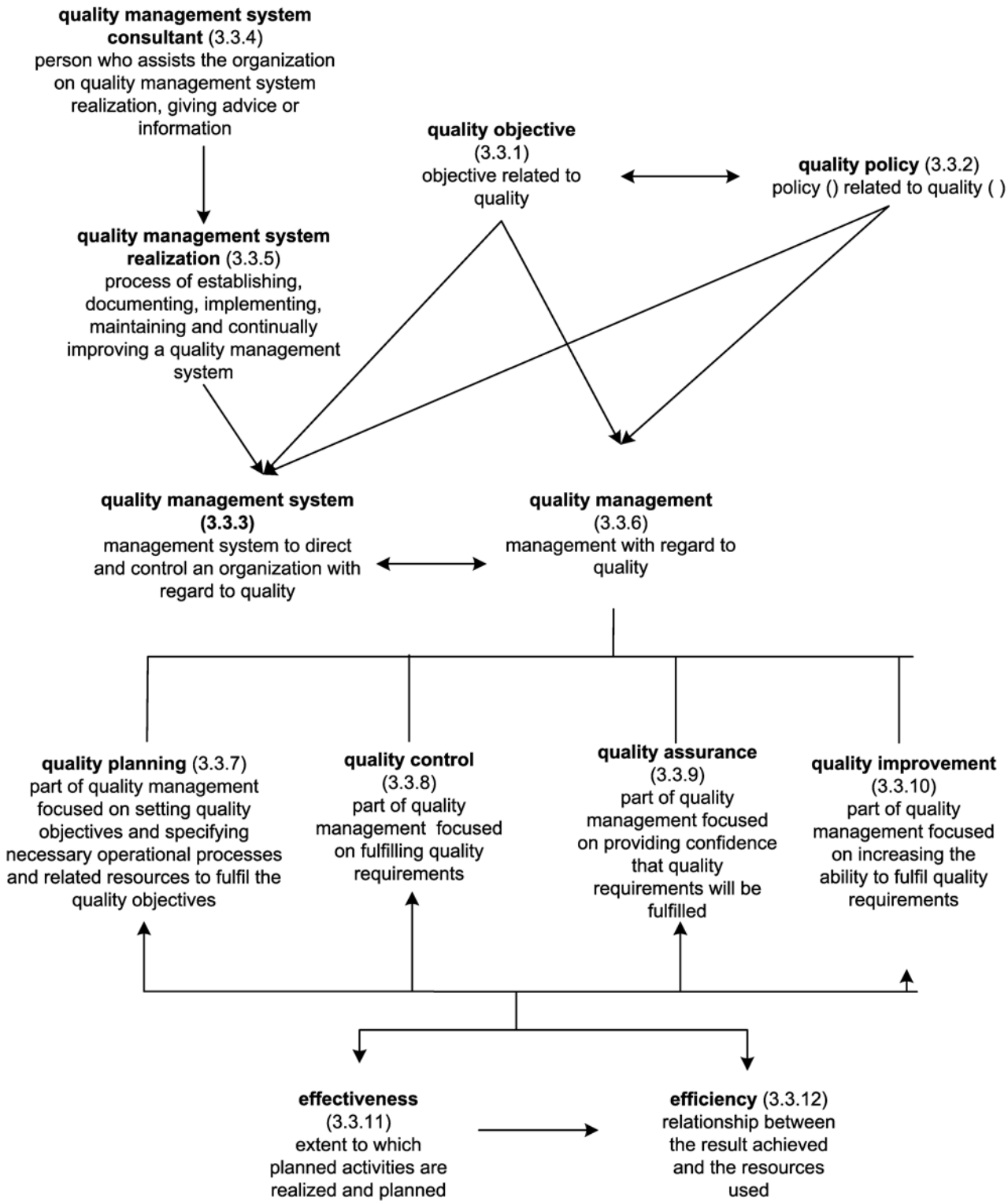
## A.4 Concept diagrams

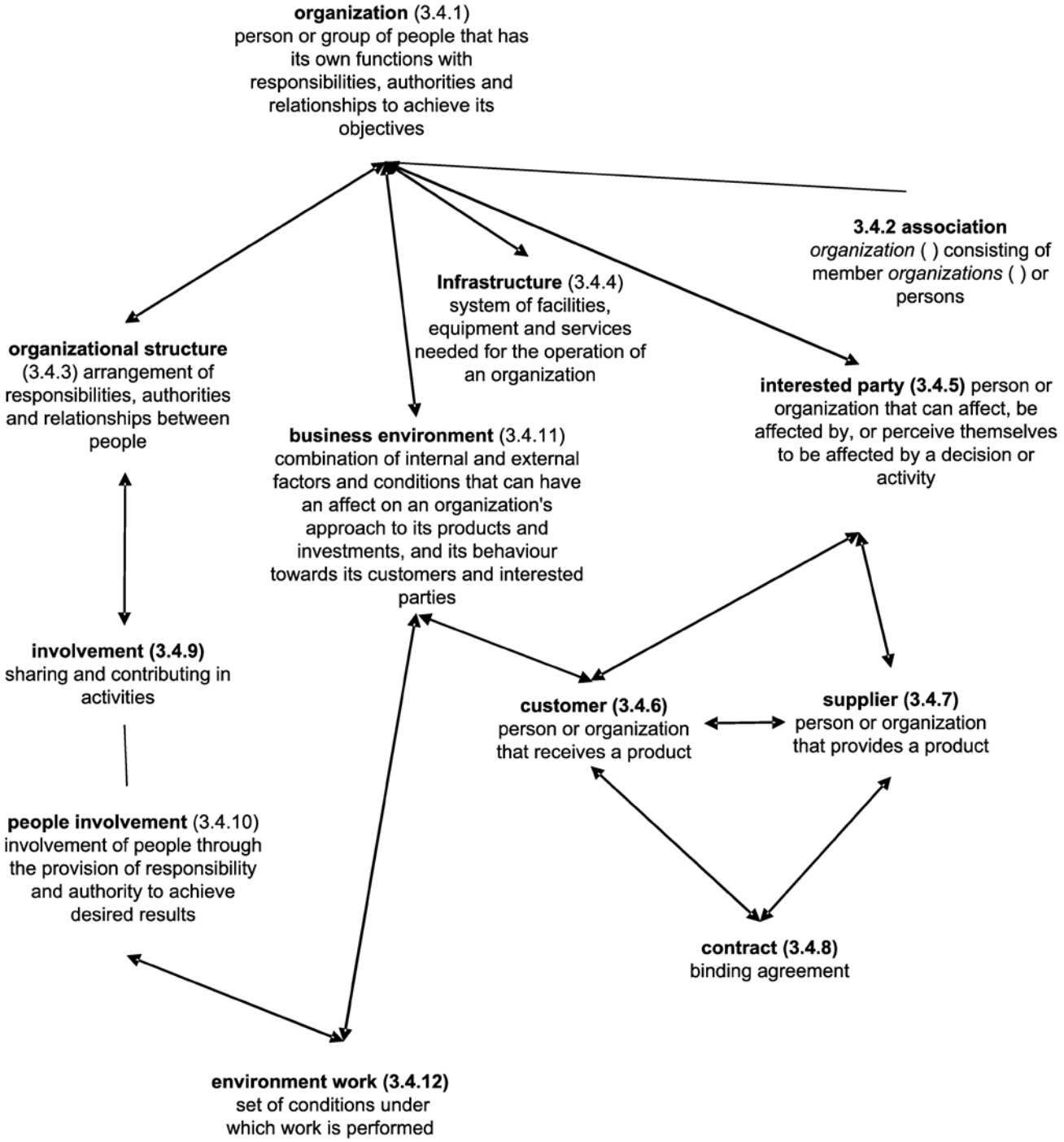
Figures A.4 to A.17 show the concept diagrams on which the thematic groupings of Clause 3 are based.

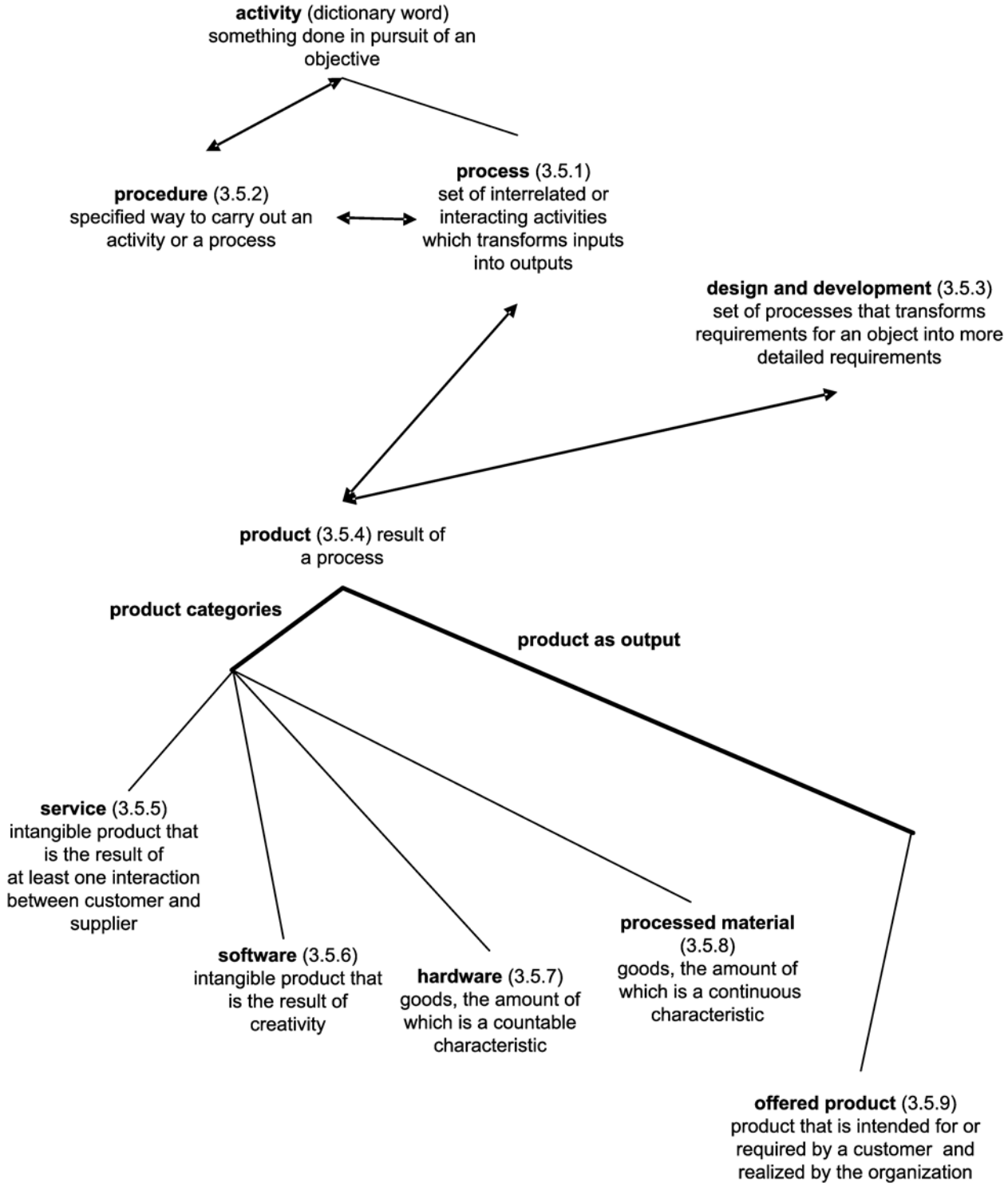
Since the definitions of the terms are repeated without any related notes, it is recommended to refer to Clause 3 to consult any such notes.

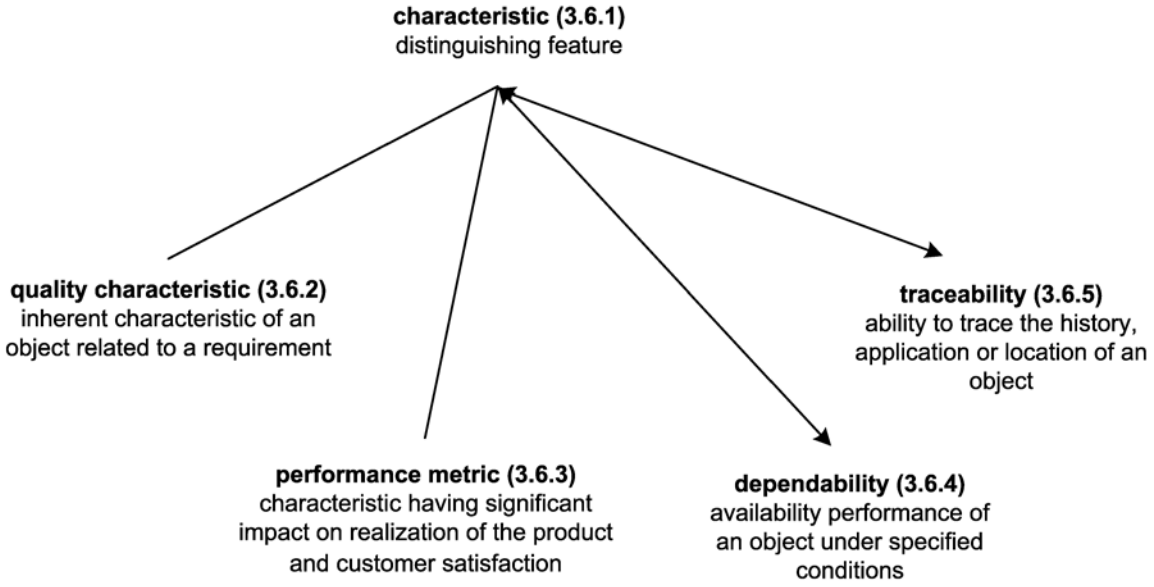


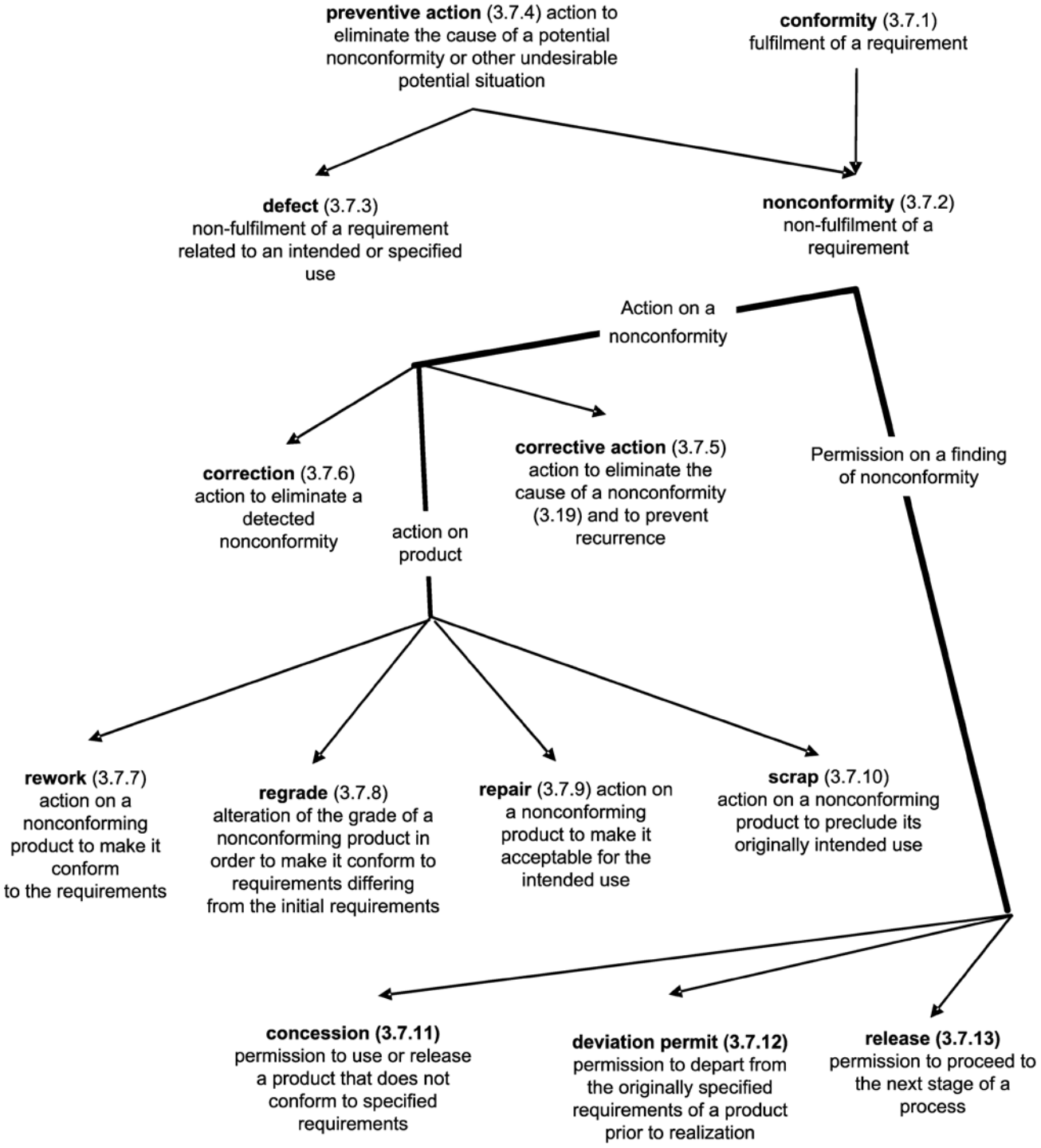












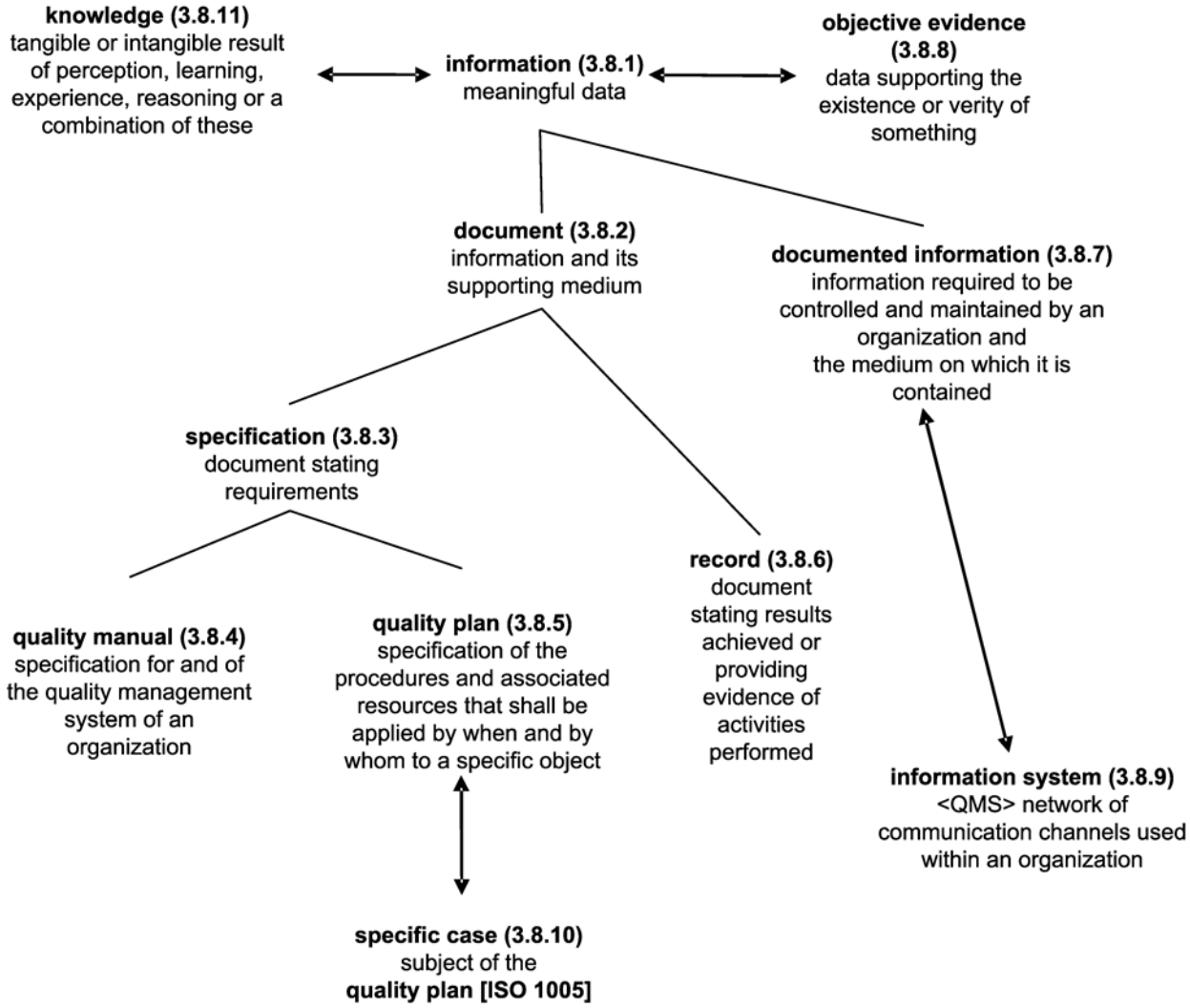



**Figure A.11 — Concepts related to documentation**

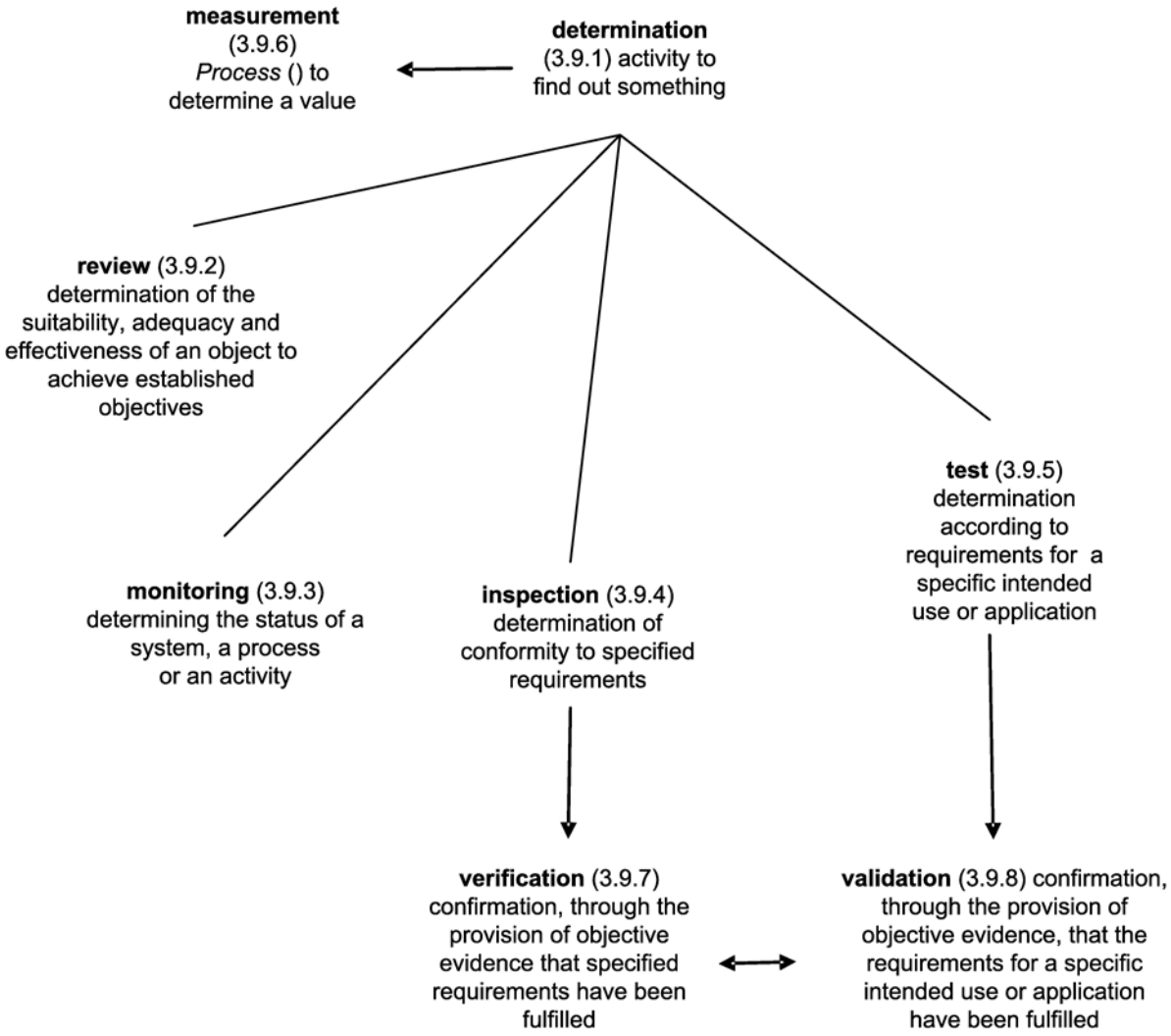
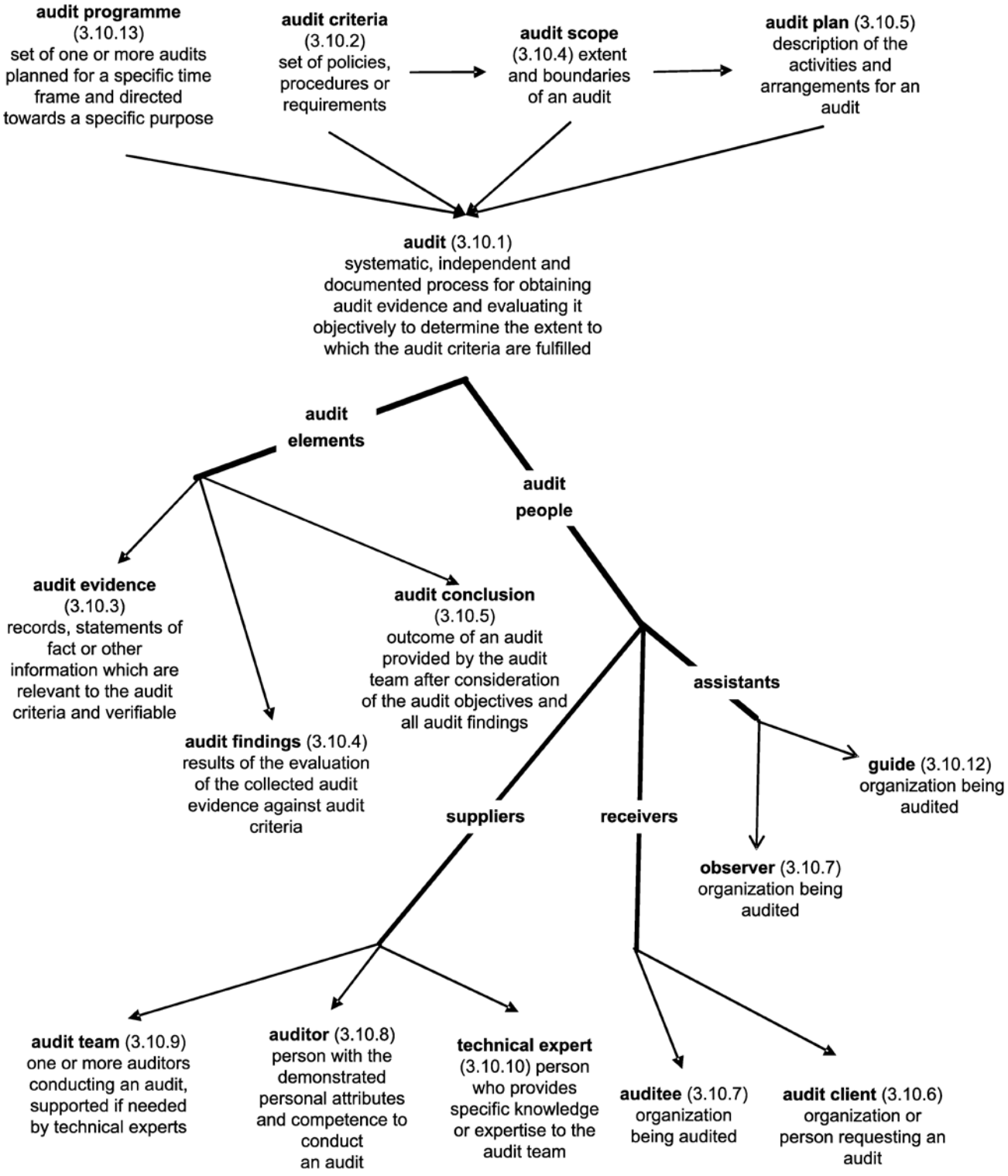
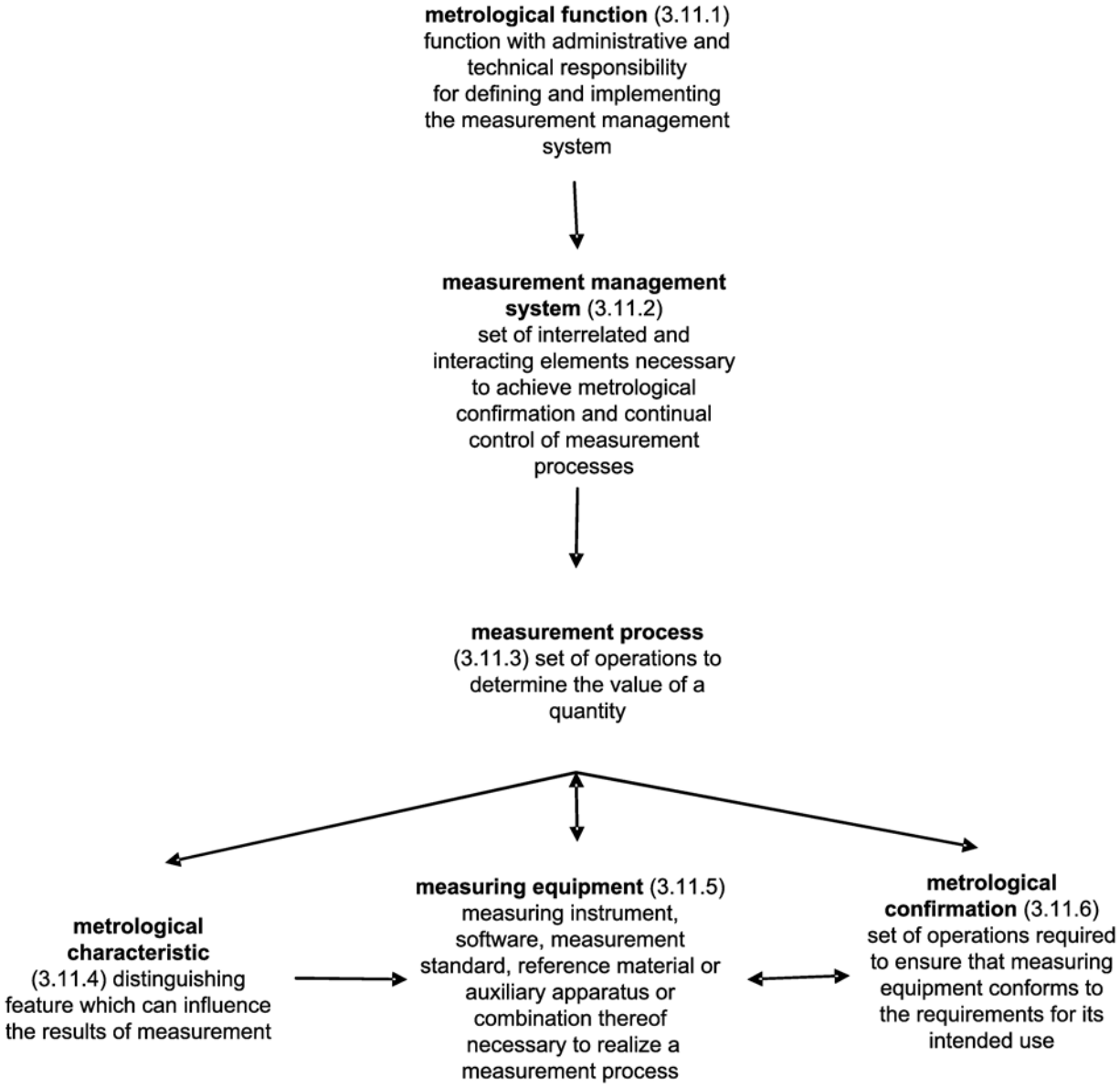
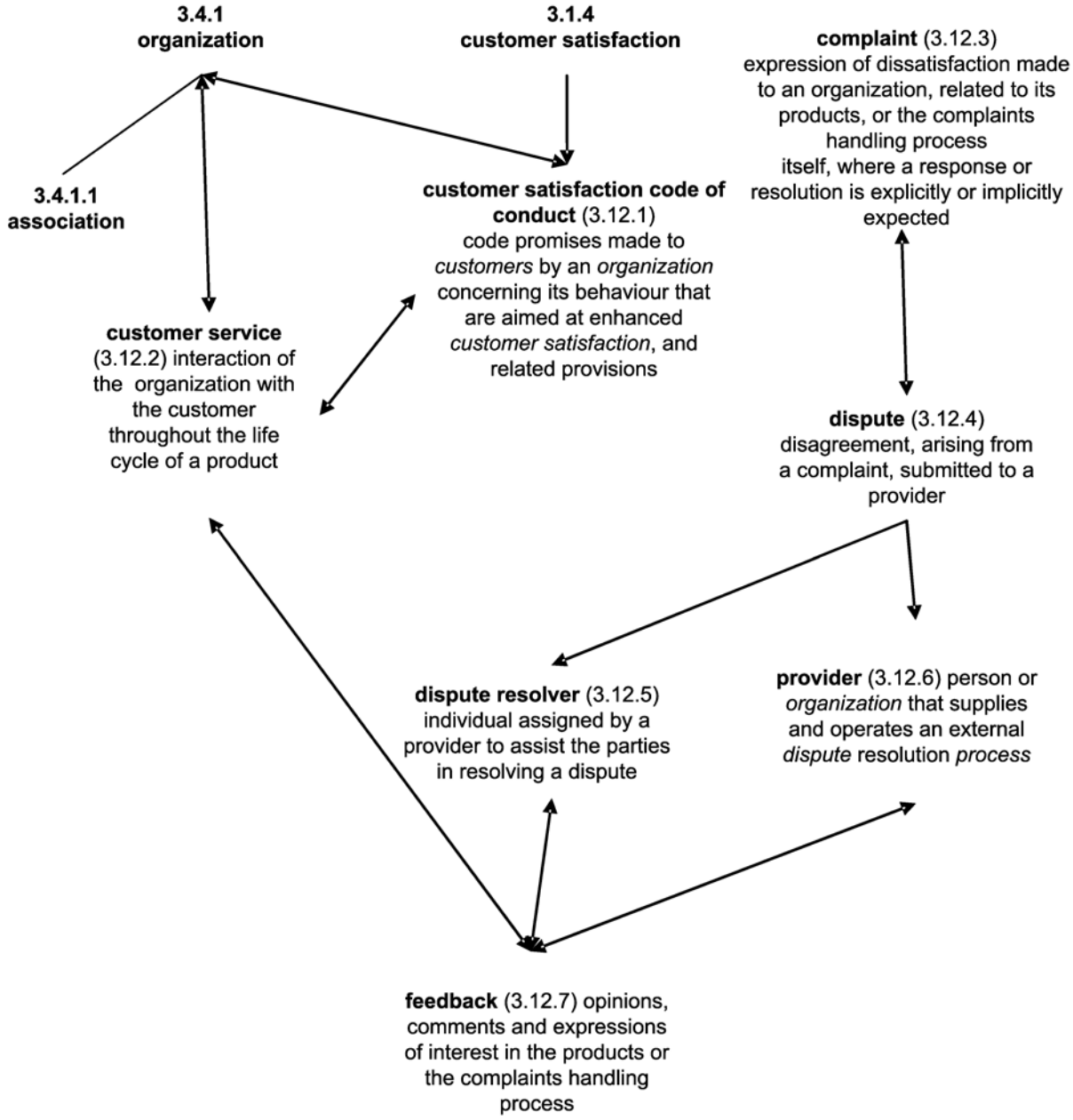


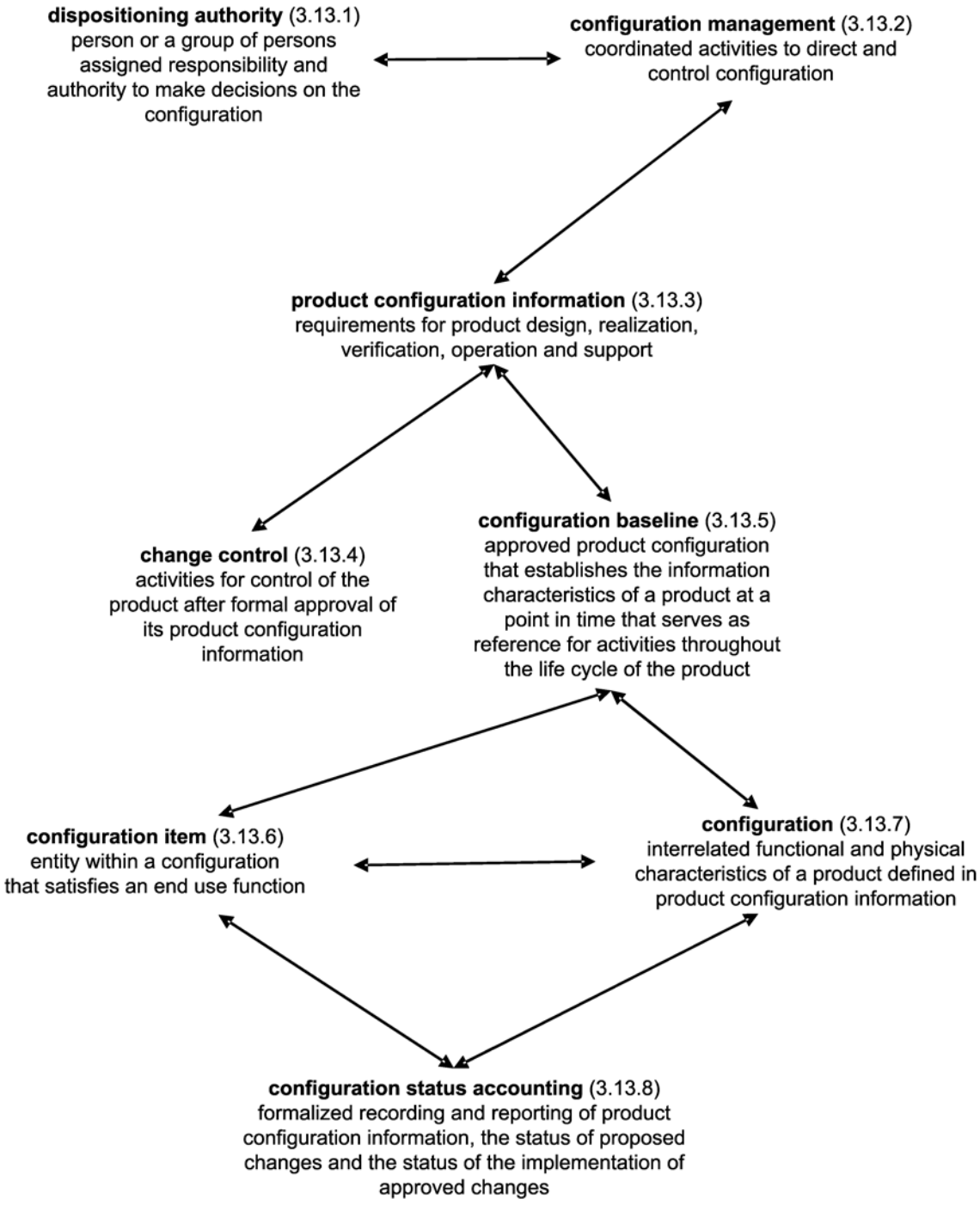

**Figure A.13 — Concepts related to determination**

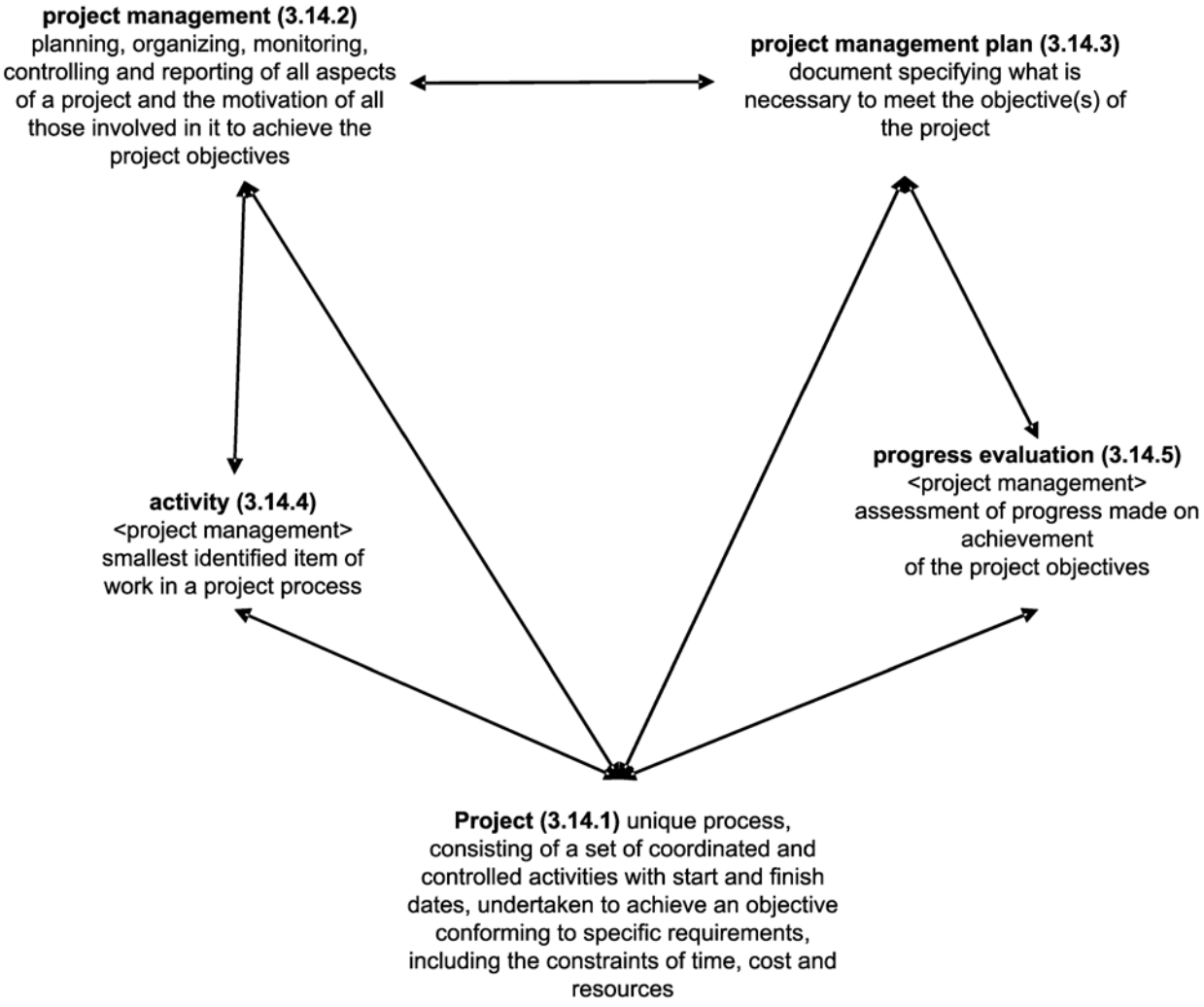






### 3.13 Concepts related configuration management





附件 2

**Comments on ISO/CD 9000 Quality management systems - Fundamentals and vocabulary**

| **Date : 2013-06-24** | **Document: ISO/TC 176/SC 1** |
|---|---|

| MB/ NC[1] | Line number | Clause/ Subclause | Paragraph/ Figure/ Table/ | Type of comment[2] | Comments | Proposed change | Observations of the secretariat |
|---|---|---|---|---|---|---|---|
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