INTERNATIONAL STANDARD

ISO 9000

Third edition
2005-09-15

Quality management systems — Fundamentals and vocabulary

Systèmes de management de la qualité — Principes essentiels et vocabulaire

Reference number
ISO 9000:2005(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

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

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

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

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

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

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

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

This third edition cancels and replaces the second edition (ISO 9000:2000). It includes the changes accepted in the Draft Amendment ISO/DAM 9000:2004.

Annex A includes concept diagrams that provide a graphical representation of the relationships between terms in specific fields relative to quality management systems.

Introduction

0.1 General

The ISO 9000 family of standards listed below has been developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

— ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.

— ISO 9001 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfil customer and applicable regulatory requirements and aims to enhance customer satisfaction.

— ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties.

— ISO 19011 provides guidance on auditing quality and environmental management systems.

Together they form a coherent set of quality management system standards facilitating mutual understanding in national and international trade.

0.2 Quality management principles

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

a) **Customer focus**

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

b) **Leadership**

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

c) **Involvement of people**

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

d) **Process approach**

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

e) **System approach to management**

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

f) **Continual improvement**

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

g) **Factual approach to decision making**

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

h) **Mutually beneficial supplier relationships**

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

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.

This International Standard is applicable to the following:

a) organizations seeking advantage through the implementation of a quality management system;

b) organizations seeking confidence from their suppliers that their product requirements will be satisfied;

c) users of the products;

d) those concerned with a mutual understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);

e) those internal or external to the organization who assess the quality management system or audit it for conformity with the requirements of ISO 9001 (e.g. auditors, regulators, certification/registration bodies);

f) those internal or external to the organization who give advice or training on the quality management system appropriate to that organization;

g) developers of related standards.

2 Fundamentals of quality management systems

2.1 Rationale for quality management systems

Quality management systems can assist organizations in enhancing customer satisfaction.

Customers require products with characteristics that satisfy their needs and expectations. These needs and expectations are expressed in product specifications and collectively referred to as customer requirements. Customer requirements may be specified contractually by the customer or may be determined by the organization itself. In either case, the customer ultimately determines the acceptability of the product. Because customer needs and expectations are changing, and because of competitive pressures and technical advances, organizations are driven to improve continually their products and processes.

The quality management system approach encourages organizations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep these processes under control. A quality management system can provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties. It provides confidence to the organization and its customers that it is able to provide products that consistently fulfil requirements.

2.2 Requirements for quality management systems and requirements for products

The ISO 9000 family distinguishes between requirements for quality management systems and requirements for products.

Requirements for quality management systems are specified in ISO 9001. Requirements for quality management systems are generic and applicable to organizations in any industry or economic sector regardless of the offered product category. ISO 9001 itself does not establish requirements for products.

Requirements for products can be specified by customers or by the organization in anticipation of customer requirements, or by regulation. The requirements for products and in some cases associated processes can be contained in, for example, technical specifications, product standards, process standards, contractual agreements and regulatory requirements.

2.3 Quality management systems approach

An approach to developing and implementing a quality management system consists of several steps including the following:

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

b) establishing the quality policy and quality objectives of the organization;

c) determining the processes and responsibilities necessary to attain the quality objectives;

d) determining and providing the resources necessary to attain the quality objectives;

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

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

g) determining means of preventing nonconformities and eliminating their causes;

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

Such an approach is also applicable to maintaining and improving an existing quality management system.

An organization that adopts the above approach creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement. This can lead to increased satisfaction of customers and other interested parties and to the success of the organization.

2.4 The process approach

Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.

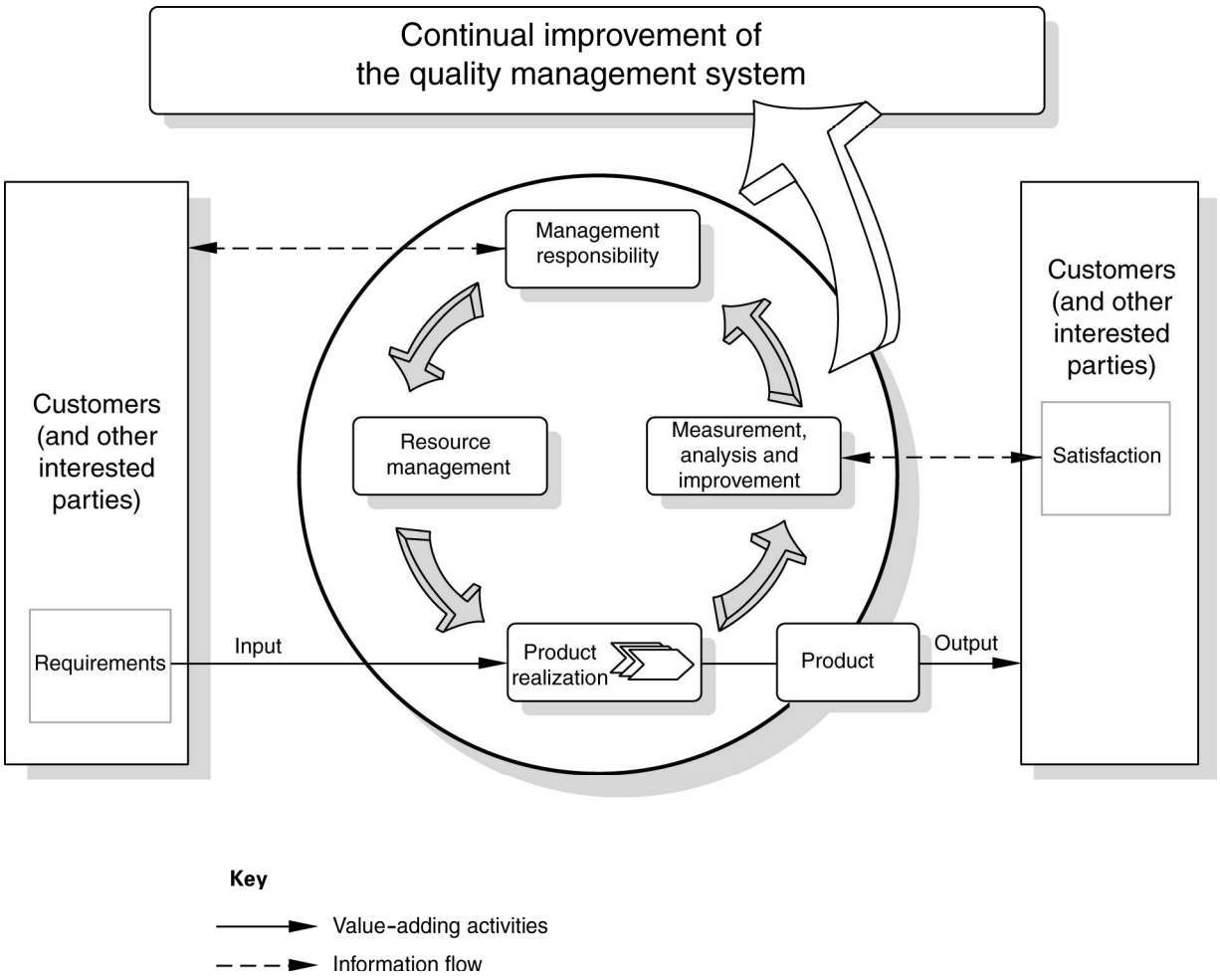
For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes is referred to as the “process approach”.

The intent of this International Standard is to encourage the adoption of the process approach to manage an organization.

Figure 1 illustrates the process-based quality management system described in the ISO 9000 family of standards. This illustration shows that interested parties play a significant role in providing inputs to the organization. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to the extent to which their needs and expectations have been met. The model shown in Figure 1 does not show processes at a detailed level.

2.5 Quality policy and quality objectives

Quality policy and quality objectives are established to provide a focus to direct the organization. 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. 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.



NOTE Statements in parentheses do not apply to ISO 9001.

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

2.6 Role of top management within the quality management system

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:

a) to establish and maintain the quality policy and quality objectives of the organization;

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

c) to ensure focus on customer requirements throughout the organization;

d) 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;

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

f) to ensure the availability of necessary resources;

g) to review the quality management system periodically;

h) to decide on actions regarding the quality policy and quality objectives;

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

2.7 Documentation

2.7.1 Value of documentation

Documentation enables communication of intent and consistency of action. Its use contributes to

a) achievement of conformity to customer requirements and quality improvement,

b) provision of appropriate training,

c) repeatability and traceability,

d) provision of objective evidence, and

e) evaluation of the effectiveness and continuing suitability of the quality management system.

Generation of documentation should not be an end in itself but should be a value-adding activity.

2.7.2 Types of document used in quality management systems

The following types of document are used in quality management systems:

a) documents that provide consistent information, both internally and externally, about the organization's quality management system; such documents are referred to as quality manuals;

b) documents that describe how the quality management system is applied to a specific product, project or contract; such documents are referred to as quality plans;

c) documents stating requirements; such documents are referred to as specifications;

d) documents stating recommendations or suggestions; such documents are referred to as guidelines;

e) documents that provide information about how to perform activities and processes consistently; such documents can include documented procedures, work instructions and drawings;

f) documents that provide objective evidence of activities performed or results achieved; such documents are referred to as records.

Each organization determines the extent of documentation required and the media to be used. This depends on factors such as the type and size of the organization, the complexity and interaction of processes, the complexity of products, customer requirements, the applicable regulatory requirements, the demonstrated ability of personnel, and the extent to which it is necessary to demonstrate fulfilment of quality management system requirements.

2.8 Evaluating quality management systems

2.8.1 Evaluating processes within the quality management system

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

a) Is the process identified and appropriately defined?

b) Are responsibilities assigned?

c) Are the procedures implemented and maintained?

d) Is the process effective in achieving the required results?

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.

2.8.2 Auditing the quality management system

Audits are used 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 and to identify opportunities for 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.

ISO 19011 provides guidance on auditing.

2.8.3 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 and quality objectives. 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.

2.8.4 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.

2.9 Continual improvement

The aim of continual improvement of a quality management system is to increase the probability of enhancing the satisfaction of customers and other interested parties. Actions for improvement include the following:

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

b) establishing the objectives for improvement;

c) searching for possible solutions to achieve the objectives;

d) evaluating these solutions and making a selection;

e) implementing the selected solution;

f) measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met;

g) formalizing changes.

Results are reviewed, as necessary, to determine further opportunities for improvement. In this way, improvement is a continual activity. Feedback from customers and other interested parties, audits and review of the quality management system can also be used to identify opportunities for improvement.

2.10 Role of statistical techniques

The use of statistical techniques can help in understanding variability, and thereby can help organizations to solve problems and improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making.

Variability can be observed in the behaviour and outcome of many 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.

2.11 Quality management systems and other management system focuses

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, to satisfy the needs, expectations and requirements of interested parties, as appropriate. 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 might be integrated, together with the quality management system, into a single management system using common elements. 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 assessed against the organization's management system requirements. The management system can also 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.

2.12 Relationship between quality management systems and excellence models

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

a) enable an organization to identify its strengths and weaknesses,

b) contain provision for evaluation against generic models,

c) provide a basis for continual improvement, and

d) 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 for quality management systems and guidance for performance improvement; evaluation of quality management systems determines fulfilment of those requirements. The excellence models contain criteria that enable comparative evaluation of organizational performance and this is 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.

3 Terms and definitions

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition. For example:

product (3.4.2) is defined as “result of a **process** (3.4.1)”;

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:

3.9.11
technical expert
⟨audit⟩ person who provides specific knowledge or expertise to the **audit team** (3.9.10)

3.1 Terms relating to quality

3.1.1
quality
degree to which a set of inherent **characteristics** (3.5.1) fulfils **requirements** (3.1.2)

NOTE 1 The term “quality” can be used with adjectives such as poor, good or excellent.

NOTE 2 “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

3.1.2
requirement
need or expectation that is stated, generally implied or obligatory

NOTE 1 “Generally implied” means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the need or expectation under consideration is implied.

NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

NOTE 3 A specified requirement is one that is stated, for example in a **document** (3.7.2).

NOTE 4 Requirements can be generated by different **interested parties** (3.3.7).

NOTE 5 This definition differs from that provided in 3.12.1 of ISO/IEC Directives, Part 2:2004.

3.12.1
requirement
expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted

3.1.3
grade
category or rank given to different quality requirements for **products** (3.4.2), **processes** (3.4.1) or **systems** (3.2.1) having the same functional use

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

NOTE When establishing a quality requirement, the grade is generally specified.

3.1.4
customer satisfaction
customer's perception of the degree to which the customer's **requirements** (3.1.2) have been fulfilled

NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

3.1.5
capability
ability of an **organization** (3.3.1), **system** (3.2.1) or **process** (3.4.1) to realize a **product** (3.4.2) that will fulfil the **requirements** (3.1.2) for that product

NOTE Process capability terms in the field of statistics are defined in ISO 3534-2.

3.1.6
competence
demonstrated ability to apply knowledge and skills

NOTE The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.

3.2 Terms relating to management

3.2.1
system
set of interrelated or interacting elements

3.2.2
management system
system (3.2.1) to establish policy and objectives and to achieve those objectives

NOTE A management system of an **organization** (3.3.1) can include different management systems, such as a **quality management system** (3.2.3), a financial management system or an environmental management system.

3.2.3
quality management system
management system (3.2.2) to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1)

3.2.4
quality policy
overall intentions and direction of an **organization** (3.3.1) related to **quality** (3.1.1) as formally expressed by **top management** (3.2.7)

NOTE 1 Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of **quality objectives** (3.2.5).

NOTE 2 Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy. (See 0.2.)

3.2.5
quality objective
something sought, or aimed for, related to **quality** (3.1.1)

NOTE 1 Quality objectives are generally based on the organization's **quality policy** (3.2.4).

NOTE 2 Quality objectives are generally specified for relevant functions and levels in the **organization** (3.3.1).

3.2.6
management
coordinated activities to direct and control an **organization** (3.3.1)

NOTE 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. 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** (3.2.7) shall…” is acceptable.

3.2.7
top management
person or group of people who directs and controls an **organization** (3.3.1) at the highest level

3.2.8
quality management
coordinated activities to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1)

NOTE Direction and control with regard to quality generally includes establishment of the **quality policy** (3.2.4) and **quality objectives** (3.2.5), **quality planning** (3.2.9), **quality control** (3.2.10), **quality assurance** (3.2.11) and **quality improvement** (3.2.12).

3.2.9
quality planning
part of **quality management** (3.2.8) focused on setting **quality objectives** (3.2.5) and specifying necessary operational **processes** (3.4.1) and related resources to fulfil the quality objectives

NOTE Establishing **quality plans** (3.7.5) can be part of quality planning.

3.2.10
quality control
part of **quality management** (3.2.8) focused on fulfilling quality requirements

3.2.11
quality assurance
part of **quality management** (3.2.8) focused on providing confidence that quality requirements will be fulfilled

3.2.12
quality improvement
part of **quality management** (3.2.8) focused on increasing the ability to fulfil quality requirements

NOTE The requirements can be related to any aspect such as **effectiveness** (3.2.14), **efficiency** (3.2.15) or **traceability** (3.5.4).

3.2.13
continual improvement
recurring activity to increase the ability to fulfil **requirements** (3.1.2)

NOTE The **process** (3.4.1) of establishing objectives and finding opportunities for improvement is a continual process through the use of **audit findings** (3.9.5) and **audit conclusions** (3.9.6), analysis of data, management **reviews** (3.8.7) or other means and generally leads to **corrective action** (3.6.5) or **preventive action** (3.6.4).

3.2.14
effectiveness
extent to which planned activities are realized and planned results achieved

3.2.15
efficiency
relationship between the result achieved and the resources used

3.3 Terms relating to organization

3.3.1
organization
group of people and facilities with an arrangement of responsibilities, authorities and relationships

EXAMPLE Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof.

NOTE 1 The arrangement is generally orderly.

NOTE 2 An organization can be public or private.

NOTE 3 This definition is valid for the purposes of **quality management system** (3.2.3) standards. The term "organization" is defined differently in ISO/IEC Guide 2.

3.3.2
organizational structure
arrangement of responsibilities, authorities and relationships between people

NOTE 1 The arrangement is generally orderly.

NOTE 2 A formal expression of the organizational structure is often provided in a **quality manual** (3.7.4) or a **quality plan** (3.7.5) for a **project** (3.4.3).

NOTE 3 The scope of an organizational structure can include relevant interfaces to external **organizations** (3.3.1).

3.3.3
infrastructure
〈organization〉 **system** (3.2.1) of facilities, equipment and services needed for the operation of an **organization** (3.3.1)

3.3.4
work environment
set of conditions under which work is performed

NOTE Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).

3.3.5
customer
organization (3.3.1) or person that receives a **product** (3.4.2)

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

NOTE A customer can be internal or external to the organization.

3.3.6
supplier
organization (3.3.1) or person that provides a **product** (3.4.2)

EXAMPLE Producer, distributor, retailer or vendor of a product, or provider of a service or information.

NOTE 1 A supplier can be internal or external to the organization.

NOTE 2 In a contractual situation, a supplier is sometimes called "contractor".

3.3.7
interested party
person or group having an interest in the performance or success of an **organization** (3.3.1)

EXAMPLE **Customers** (3.3.5), owners, people in an organization, **suppliers** (3.3.6), bankers, unions, partners or society.

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

3.3.8
contract
binding agreement

NOTE The concept of contract is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.

3.4 Terms relating to process and product

3.4.1
process
set of interrelated or interacting activities which transforms inputs into outputs

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Processes in an **organization** (3.3.1) are generally planned and carried out under controlled conditions to add value.

NOTE 3 A process where the **conformity** (3.6.1) of the resulting **product** (3.4.2) cannot be readily or economically verified is frequently referred to as a "special process".

3.4.2
product
result of a **process** (3.4.1)

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

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the **supplier** (3.3.6) and **customer** (3.3.5) and is generally intangible. Provision of a service can involve, for example, the following:

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

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

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

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

Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures** (3.4.5).

Hardware is generally tangible and its amount is a countable **characteristic** (3.5.1). Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

NOTE 3 **Quality assurance** (3.2.11) is mainly focused on intended product.

3.4.3
project
unique **process** (3.4.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific **requirements** (3.1.2), including the constraints of time, cost and resources

NOTE 1 An individual project can form part of a larger project structure.

NOTE 2 In some projects the objectives are refined and the product **characteristics** (3.5.1) defined progressively as the project proceeds.

NOTE 3 The outcome of a project can be one or several units of **product** (3.4.2).

NOTE 4 Adapted from ISO 10006:2003.

3.4.4
design and development
set of **processes** (3.4.1) that transforms **requirements** (3.1.2) into specified **characteristics** (3.5.1) or into the **specification** (3.7.3) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1)

NOTE 1 The terms “design” and “development” are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.

NOTE 2 A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. product design and development or process design and development).

3.4.5
procedure
specified way to carry out an activity or a **process** (3.4.1)

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** (3.7.2) that contains a procedure can be called a “procedure document”.

3.5 Terms relating to characteristics

3.5.1
characteristic
distinguishing feature

NOTE 1 A characteristic can be inherent or assigned.

NOTE 2 A characteristic can be qualitative or quantitative.

NOTE 3 There are various classes of characteristic, such as the following:

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

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

— behavioral (e.g. courtesy, honesty, veracity);

— temporal (e.g. punctuality, reliability, availability);

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

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

3.5.2
quality characteristic
inherent **characteristic** (3.5.1) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1) related to a **requirement** (3.1.2)

NOTE 1 Inherent means existing in something, especially as a permanent characteristic.

NOTE 2 A characteristic assigned to a product, process or system (e.g. the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.

3.5.3
dependability
collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance

NOTE Dependability is used only for general descriptions in non-quantitative terms.

[IEC 60050-191:1990].

3.5.4
traceability
ability to trace the history, application or location of that which is under consideration

NOTE 1 When considering **product** (3.4.2), traceability can relate to

— the origin of materials and parts,

— the processing history, and

— the distribution and location of the product after delivery.

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

3.6 Terms relating to conformity

3.6.1
conformity
fulfilment of a **requirement** (3.1.2)

NOTE The term “conformance” is synonymous but deprecated.

3.6.2
nonconformity
non-fulfilment of a **requirement** (3.1.2)

3.6.3
defect
non-fulfilment of a **requirement** (3.1.2) related to an intended or specified use

NOTE 1 The distinction between the concepts defect and **nonconformity** (3.6.2) is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term “defect” should be used with extreme caution.

NOTE 2 The intended use as intended by the **customer** (3.3.5) can be affected by the nature of the information, such as operating or maintenance instructions, provided by the **supplier** (3.3.6).

3.6.4
preventive action
action to eliminate the cause of a potential **nonconformity** (3.6.2) or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas **corrective action** (3.6.5) is taken to prevent recurrence.

3.6.5
corrective action
action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.6.4) is taken to prevent occurrence.

NOTE 3 There is a distinction between **correction** (3.6.6) and corrective action.

3.6.6
correction
action to eliminate a detected **nonconformity** (3.6.2)

NOTE 1 A correction can be made in conjunction with a **corrective action** (3.6.5).

NOTE 2 A correction can be, for example, **rework** (3.6.7) or **regrade** (3.6.8).

3.6.7
rework
action on a nonconforming **product** (3.4.2) to make it conform to the **requirements** (3.1.2)

NOTE Unlike rework, **repair** (3.6.9) can affect or change parts of the nonconforming product.

3.6.8
regrade
alteration of the **grade** (3.1.3) of a nonconforming **product** (3.4.2) in order to make it conform to **requirements** (3.1.2) differing from the initial ones

3.6.9
repair
action on a nonconforming **product** (3.4.2) to make it acceptable for the intended use

NOTE 1 Repair includes remedial action taken on a previously conforming product to restore it for use, for example as part of maintenance.

NOTE 2 Unlike **rework** (3.6.7), repair can affect or change parts of the nonconforming product.

3.6.10
scrap
action on a nonconforming **product** (3.4.2) to preclude its originally intended use

EXAMPLE Recycling, destruction.

NOTE In a nonconforming service situation, use is precluded by discontinuing the service.

3.6.11
concession
permission to use or release a **product** (3.4.2) that does not conform to specified **requirements** (3.1.2)

NOTE A concession is generally limited to the delivery of a product that has nonconforming **characteristics** (3.5.1) within specified limits for an agreed time or quantity of that product.

3.6.12
deviation permit
permission to depart from the originally specified **requirements** (3.1.2) of a **product** (3.4.2) prior to realization

NOTE A deviation permit is generally given for a limited quantity of product or period of time, and for a specific use.

3.6.13
release
permission to proceed to the next stage of a **process** (3.4.1)

NOTE In English, in the context of computer software, the term “release” is frequently used to refer to a version of the software itself.

3.7 Terms relating to documentation

3.7.1
information
meaningful data

3.7.2
document
information (3.7.1) and its supporting medium

EXAMPLE **Record** (3.7.6), **specification** (3.7.3), procedure document, drawing, report, standard.

NOTE 1 The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.

NOTE 2 A set of documents, for example specifications and records, is frequently called “documentation”.

NOTE 3 Some **requirements** (3.1.2) (e.g. the requirement to be readable) relate to all types of documents, however there can be different requirements for specifications (e.g. the requirement to be revision controlled) and records (e.g. the requirement to be retrievable).

3.7.3
specification
document (3.7.2) stating **requirements** (3.1.2)

NOTE A specification can be related to activities (e.g. procedure document, process specification and test specification), or **products** (3.4.2) (e.g. product specification, performance specification and drawing).

3.7.4
quality manual
document (3.7.2) specifying the **quality management system** (3.2.3) of an **organization** (3.3.1)

NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

3.7.5
quality plan
document (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract

NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes.

NOTE 2 A quality plan often makes reference to parts of the **quality manual** (3.7.4) or to procedure documents.

NOTE 3 A quality plan is generally one of the results of **quality planning** (3.2.9).

3.7.6
record
document (3.7.2) stating results achieved or providing evidence of activities performed

NOTE 1 Records can be used, for example, to document **traceability** (3.5.4) and to provide evidence of **verification** (3.8.4), **preventive action** (3.6.4) and **corrective action** (3.6.5).

NOTE 2 Generally records need not be under revision control.

3.8 Terms relating to examination

3.8.1
objective evidence
data supporting the existence or verity of something

NOTE Objective evidence may be obtained through observation, measurement, **test** (3.8.3), or other means.

3.8.2
inspection
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging

[ISO/IEC Guide 2]

3.8.3
test
determination of one or more **characteristics** (3.5.1) according to a **procedure** (3.4.5)

3.8.4
verification
confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design **specification** (3.7.3) with a similar proven design specification,

— undertaking **tests** (3.8.3) and demonstrations, and

— reviewing documents prior to issue.

3.8.5
validation
confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The use conditions for validation can be real or simulated.

3.8.6
qualification process
process (3.4.1) to demonstrate the ability to fulfil specified **requirements** (3.1.2)

NOTE 1 The term “qualified” is used to designate the corresponding status.

NOTE 2 Qualification can concern persons, **products** (3.4.2), processes or **systems** (3.2.1).

EXAMPLE Auditor qualification process, material qualification process.

3.8.7
review
activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives

NOTE Review can also include the determination of **efficiency** (3.2.15).

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

3.9 Terms relating to audit

3.9.1
audit
systematic, independent and documented **process** (3.4.1) for obtaining **audit evidence** (3.9.4) and evaluating it objectively to determine the extent to which **audit criteria** (3.9.3) are fulfilled

NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the **organization** (3.3.1) itself for management review and other internal purposes, and may form the basis for an organization’s declaration of **conformity** (3.6.1). In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as **customers** (3.3.5), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing certification/registration of conformity to ISO 9001 or ISO 14001.

NOTE 3 When two or more **management systems** (3.2.2) are audited together, this is termed a combined audit.

NOTE 4 When two or more auditing organizations cooperate to audit a single **auditee** (3.9.8), this is termed a joint audit.

3.9.2
audit programme
set of one or more **audits** (3.9.1) planned for a specific time frame and directed towards a specific purpose

NOTE An audit programme includes all activities necessary for planning, organizing and conducting the audits.

3.9.3
audit criteria
set of policies, **procedures** (3.4.5) or **requirements** (3.1.2)

NOTE Audit criteria are used as a reference against which **audit evidence** (3.9.4) is compared.

3.9.4
audit evidence
records (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable

NOTE Audit evidence can be qualitative or quantitative.

3.9.5
audit findings
results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3)

NOTE Audit findings can indicate either **conformity** (3.6.1) or **nonconformity** (3.6.2) with audit criteria or opportunities for improvement.

3.9.6
audit conclusion
outcome of an **audit** (3.9.1) provided by the **audit team** (3.9.10) after consideration of the audit objectives and all **audit findings** (3.9.5)

3.9.7
audit client
organization (3.3.1) or person requesting an **audit** (3.9.1)

NOTE The audit client may be the **auditee** (3.9.8) or any other **organization** (3.3.1) that has the regulatory or contractual right to request an audit.

3.9.8
auditee
organization (3.3.1) being audited

3.9.9
auditor
person with the demonstrated personal attributes and **competence** (3.1.6 and 3.9.14) to conduct an **audit** (3.9.1)

NOTE The relevant personal attributes for an auditor are described in ISO 19011.

3.9.10
audit team
one or more **auditors** (3.9.9) conducting an **audit** (3.9.1), supported if needed by **technical experts** (3.9.11)

NOTE 1 One auditor of the audit team is appointed as the audit team leader.

NOTE 2 The audit team may include auditors-in-training.

3.9.11
technical expert
⟨audit⟩ person who provides specific knowledge or expertise to the **audit team** (3.9.10)

NOTE 1 Specific knowledge or expertise relates to the **organization** (3.3.1), the **process** (3.4.1) or activity to be audited, or language or culture.

NOTE 2 A technical expert does not act as an **auditor** (3.9.9) in the audit team.

3.9.12

audit plan

description of the activities and arrangements for an **audit** (3.9.1)

3.9.13

audit scope

extent and boundaries of an **audit** (3.9.1)

NOTE The audit scope generally includes a description of the physical locations, organizational units, activities and **processes** (3.4.1), as well as the time period covered.

3.9.14

competence

〈audit〉 demonstrated personal attributes and demonstrated ability to apply knowledge and skills

3.10 Terms related to quality management for measurement processes

3.10.1

measurement management system

set of interrelated and interacting elements necessary to achieve **metrological confirmation** (3.10.3) and continual control of **measurement processes** (3.10.2)

3.10.2

measurement process

set of operations to determine the value of a quantity

3.10.3

metrological confirmation

set of operations required to ensure that **measuring equipment** (3.10.4) conforms to the **requirements** (3.1.2) for its intended use

NOTE 1 Metrological confirmation generally includes calibration or **verification** (3.8.4), any necessary adjustment or **repair** (3.6.9), 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 Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented.

NOTE 3 The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

NOTE 4 Metrological requirements are usually distinct from, and are not specified in, product requirements.

3.10.4

measuring equipment

measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a **measurement process** (3.10.2)

3.10.5

metrological characteristic

distinguishing feature which can influence the results of measurement

NOTE 1 **Measuring equipment** (3.10.4) usually has several metrological characteristics.

NOTE 2 Metrological characteristics can be the subject of calibration.

3.10.6
metrological function
function with administrative and technical responsibility for defining and implementing the **measurement management system** (3.10.1)

NOTE 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).

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).

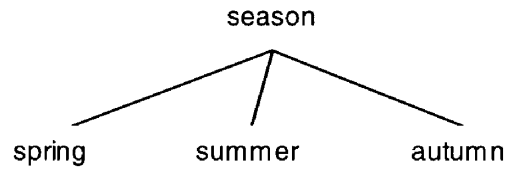


Figure A.1 — Graphical representation of a generic relation

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.

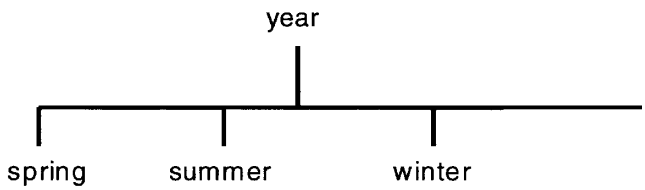


Figure A.2 — Graphical representation of a partitive relation

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).

Figure A.3 — Graphical representation of an associative relation

A.4 Concept diagrams

Figures A.4 to A.13 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.

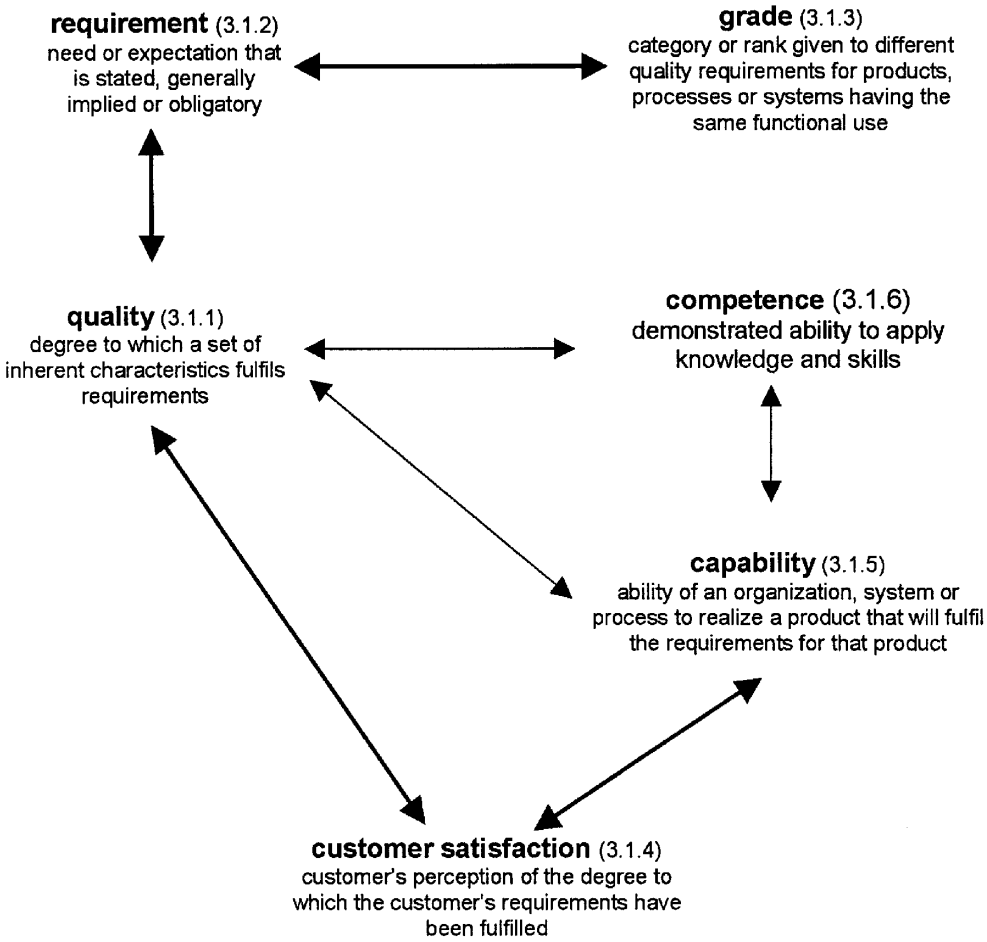


Figure A.4 — Concepts relating to quality (3.1)

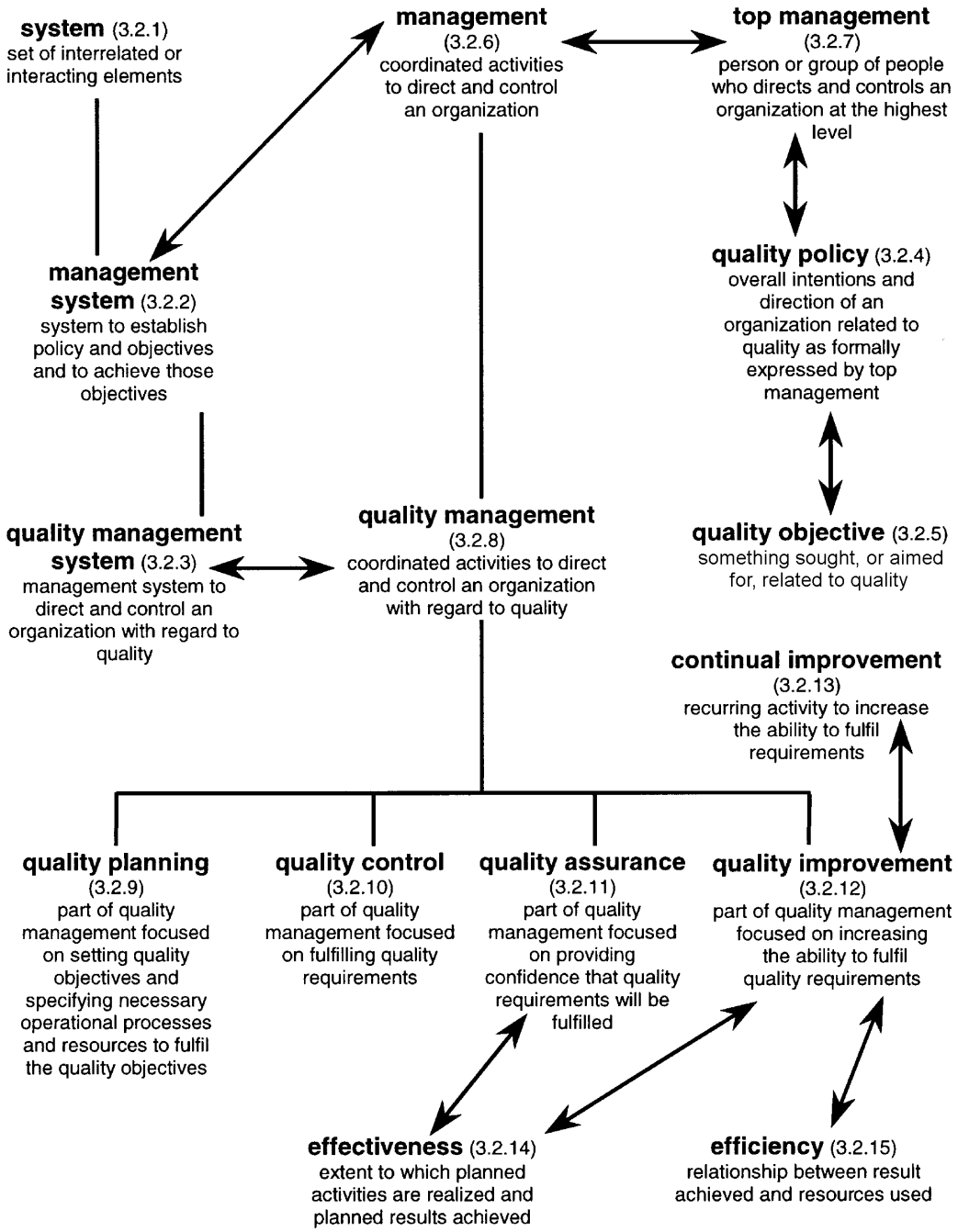


Figure A.5 — Concepts relating to management (3.2)

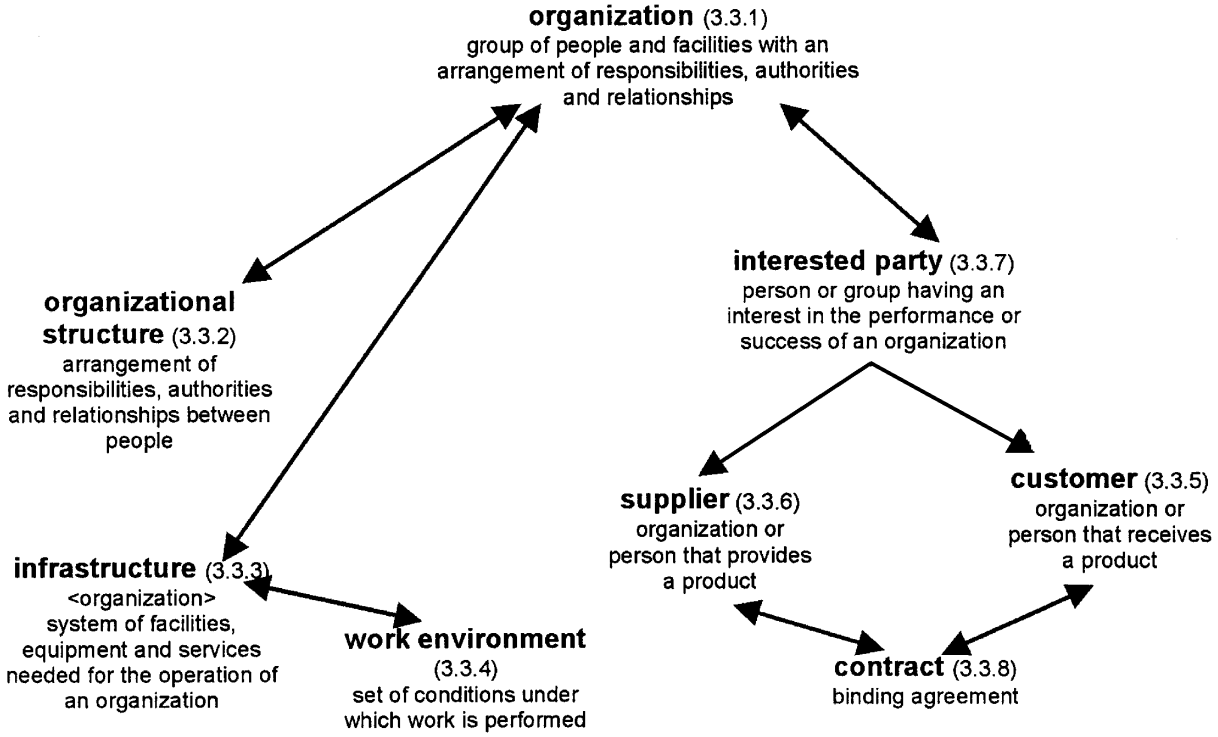


Figure A.6 — Concepts relating to organization (3.3)

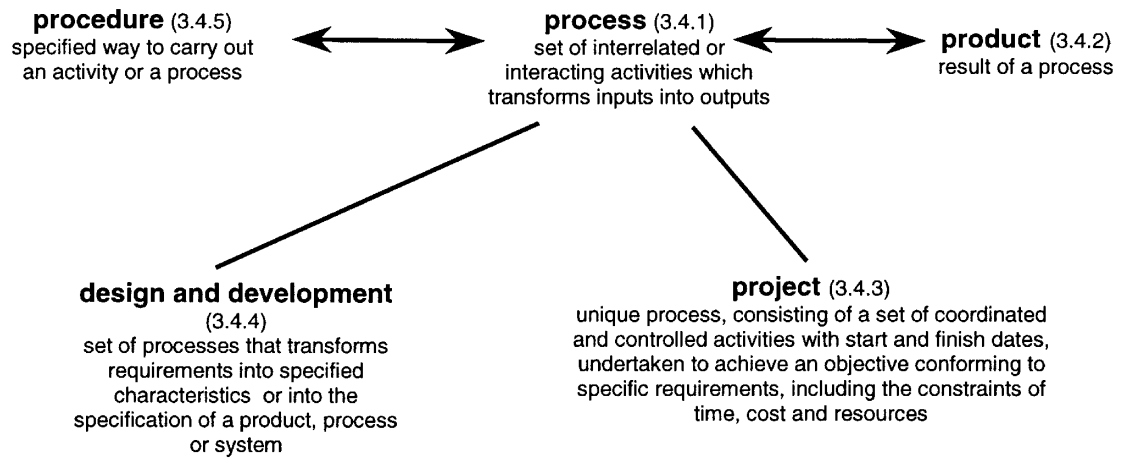


Figure A.7 — Concepts relating to process and product (3.4)

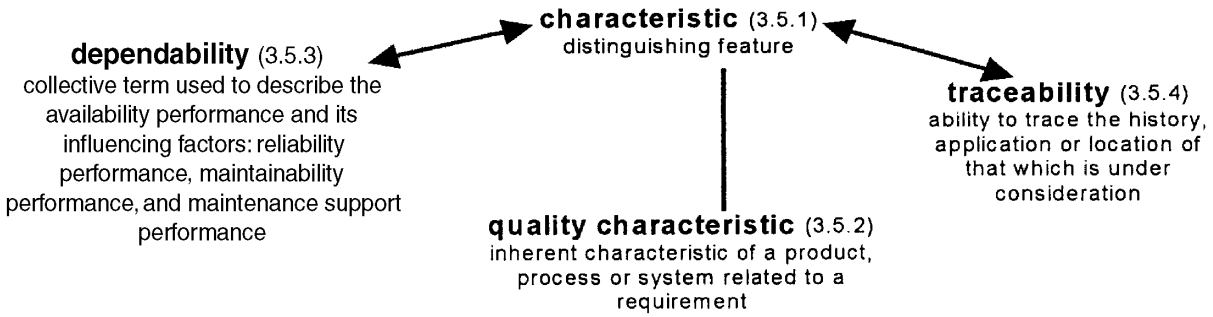


Figure A.8 — Concepts relating to characteristics (3.5)

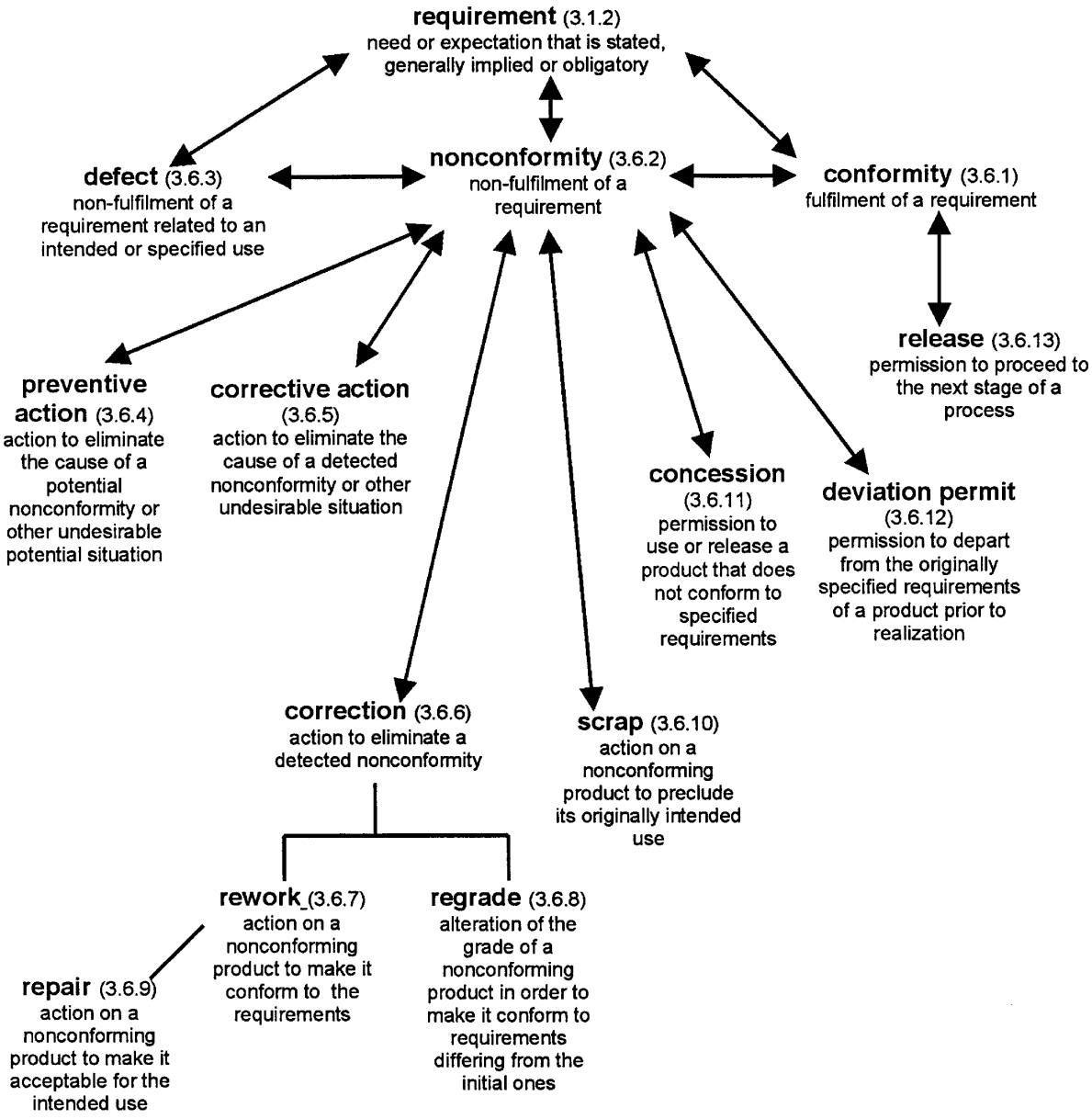


Figure A.9 — Concepts relating to conformity (3.6)

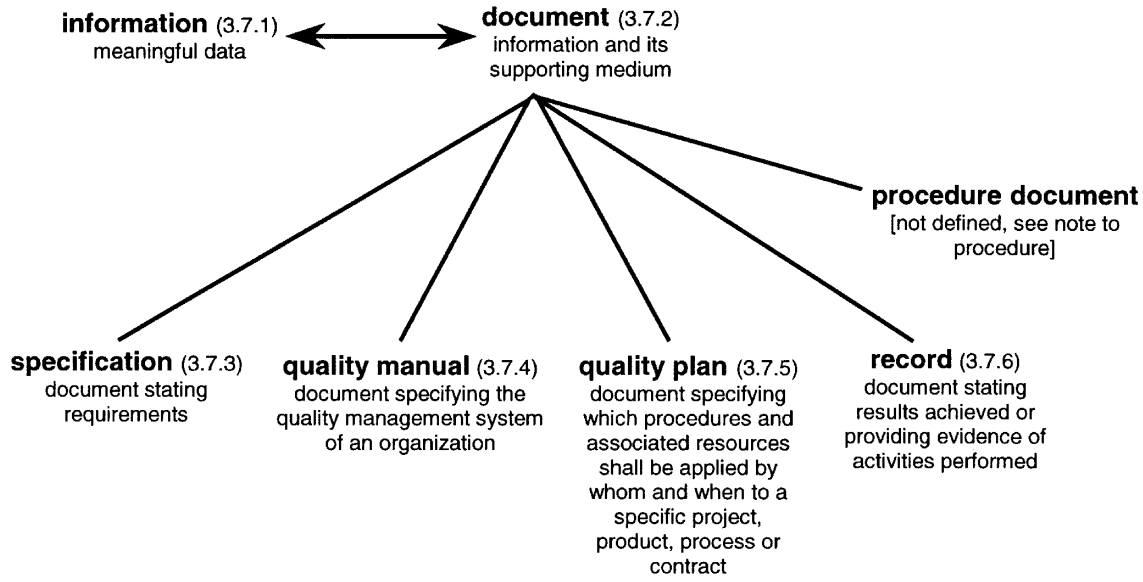


Figure A.10 — Concepts relating to documentation (3.7)

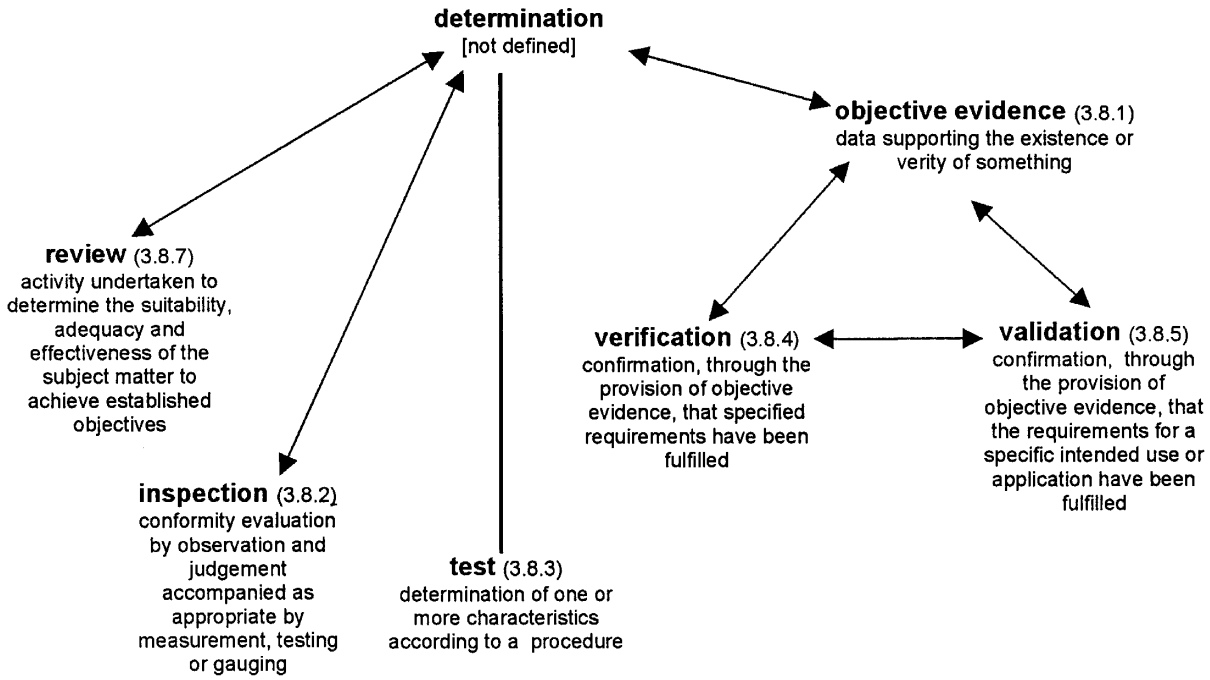


Figure A.11 — Concepts relating to examination (3.8)

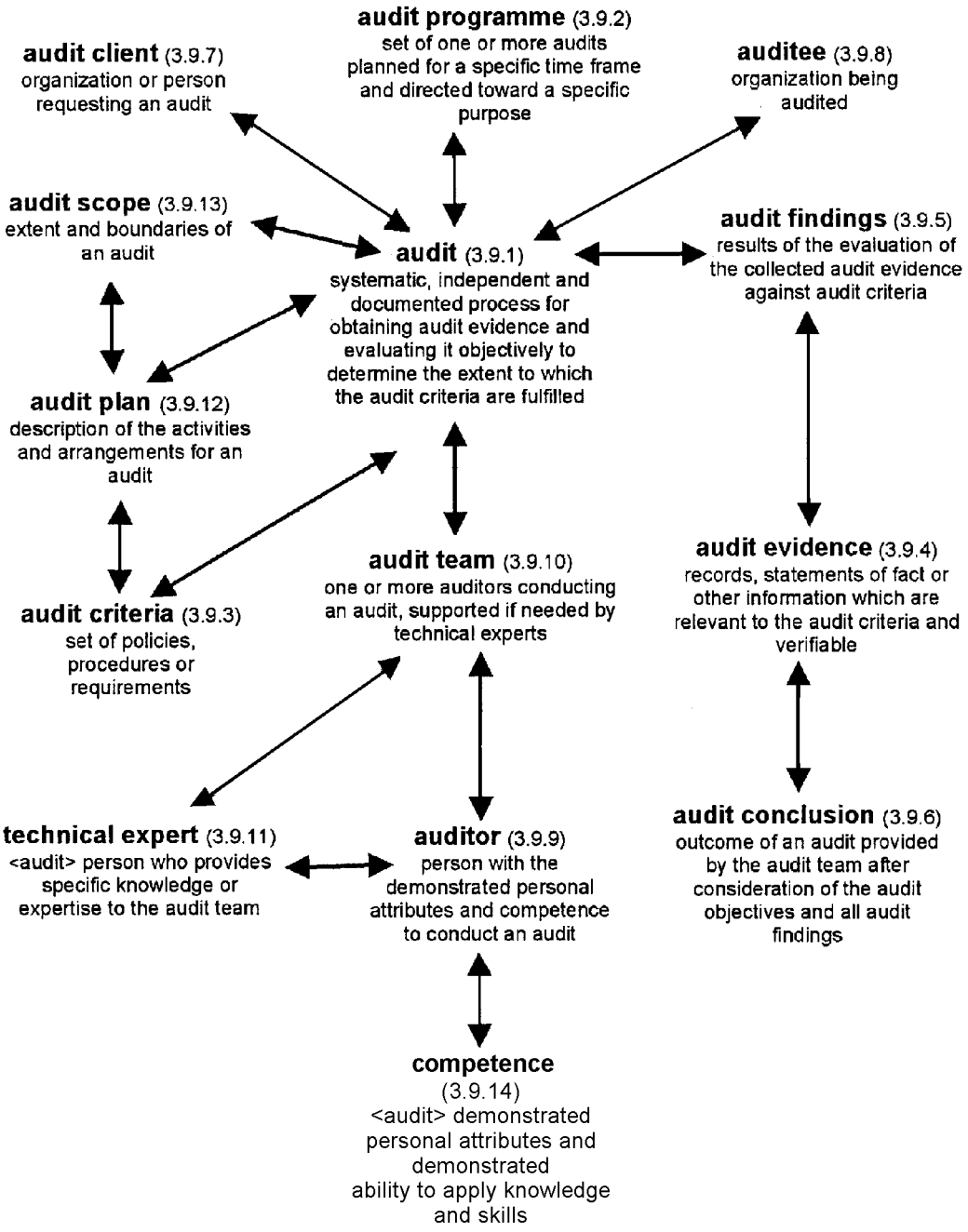


Figure A.12 — Concepts relating to audit (3.9)

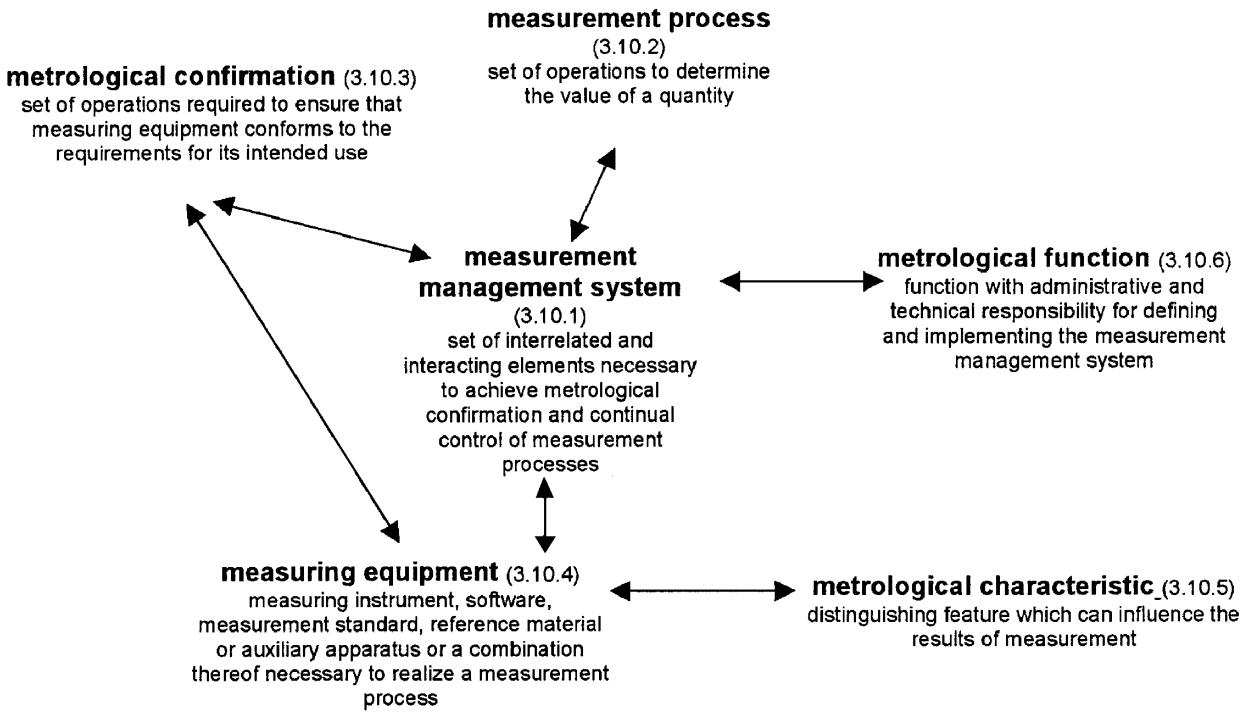


Figure A.13 — Concepts relating to quality management for measurement processes (3.10)

Bibliography

[1] ISO 704, *Terminology work — Principles and methods*

[2] ISO 1087-1, *Terminology work — Vocabulary — Part 1: Theory and application*

[3] ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*[1)]

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

[5] ISO 9004:2000, *Quality management systems — Guidelines for performance improvements*

[6] ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

[7] ISO/TR 10013, *Guidelines for quality management system documentation*

[8] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:2000*

[9] ISO 10019, *Guidelines for the selection of quality management system consultants and use of their services*

[10] ISO 10241, *International terminology standards — Preparation and layout*

[11] ISO/TR 13425, *Guidelines for the selection of statistical methods in standardization and specification*

[12] ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

[13] ISO 19011, *Guidelines for quality and/or environmental management systems auditing*

[14] ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*

[15] IEC 60050-191, *International Electrotechnical Vocabulary — Chapter 191: Dependability and quality of service*

[16] IEC 60050-191/A2:2002, *International Electrotechnical Vocabulary — Chapter 191: Dependability and quality of service:* Amendment 2

[17] VIM:1993, *International vocabulary of basic and general terms in metrology*, BIPM/IEC/ IFCC/ISO/OIML/IUPAC/IUPAP

[18] *Quality Management Principles Brochure* [2)]

[19] *ISO 9000 + ISO 14000 News* (a bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world) [3)]

[20] ISO/IEC Directives, Part 1, Part 2:2004 and Supplement

1) To be published.

2) Available from website: http://www.iso.org

3) Available from ISO Central Secretariat (sales@iso.org).

Alphabetical index

ICS 01.040.03; 03.120.10

Price based on 30 pages