

INTERNATIONAL STANDARD

ISO 9000

Fourth edition
2015-09-15

Quality management systems — Fundamentals and vocabulary

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



Reference number
ISO 9000:2015(E)

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Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

This fourth edition cancels and replaces the third edition (ISO 9000:2005), which has been technically revised.

Introduction

This International Standard provides the fundamental concepts, principles and vocabulary for quality management systems (QMS) and provides the foundation for other QMS standards. This International Standard is intended to help the user to understand the fundamental concepts, principles and vocabulary of quality management, in order to be able to effectively and efficiently implement a QMS and realize value from other QMS standards.

This International Standard proposes a well-defined QMS, based on a framework that integrates established fundamental concepts, principles, processes and resources related to quality, in order to help organizations realize their objectives. It is applicable to all organizations, regardless of size, complexity or business model. Its aim is to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and interested parties, and in achieving satisfaction with its products and services.

This International Standard contains seven quality management principles supporting the fundamental concepts described in 2.2. In 2.3, for each quality management principle, there is a "statement" describing each principle, a "rationale" explaining why the organization would address the principle, "key benefits" that are attributed to the principles, and "possible actions" that an organization can take in applying the principle.

This International Standard contains the terms and definitions that apply to all quality management and QMS standards developed by ISO/TC 176, and other sector-specific QMS standards based on those standards, at the time of publication. The terms and definitions are arranged in conceptual order, with an alphabetical index provided at the end of the document. Annex A includes a set of diagrams of the concept systems that form the concept ordering.

NOTE Guidance on some additional frequently-used words in the QMS standards developed by ISO/TC 176, and which have an identified dictionary meaning, is provided in a glossary available at: http://www.iso.org/iso/03_terminology_used_in_iso_9000_family.pdf

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes the fundamental concepts and principles of quality management which are universally applicable to the following:

- organizations seeking sustained success through the implementation of a quality management system;
- customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements;
- organizations seeking confidence in their supply chain that product and service requirements will be met;
- organizations and interested parties seeking to improve communication through a common understanding of the vocabulary used in quality management;
- organizations performing conformity assessments against the requirements of ISO 9001;
- providers of training, assessment or advice in quality management;
- developers of related standards.

This International Standard specifies the terms and definitions that apply to all quality management and quality management system standards developed by ISO/TC 176.

2 Fundamental concepts and quality management principles

2.1 General

The quality management concepts and principles described in this International Standard give the organization the capacity to meet challenges presented by an environment that is profoundly different from recent decades. The context in which an organization works today is characterized by accelerated change, globalization of markets and the emergence of knowledge as a principal resource. The impact of quality extends beyond customer satisfaction: it can also have a direct impact on the organization's reputation.

Society has become better educated and more demanding, making interested parties increasingly more influential. By providing fundamental concepts and principles to be used in the development of a quality management system (QMS), this International Standard provides a way of thinking about the organization more broadly.

All concepts, principles and their interrelationships should be seen as a whole and not in isolation of each other. No individual concept or principle is more important than another. At any one time, finding the right balance in application is critical.

2.2 Fundamental concepts

2.2.1 Quality

An organization focused on quality promotes a culture that results in the behaviour, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties.

The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties.

The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer.

2.2.2 Quality management system

A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results.

The QMS manages the interacting processes and resources required to provide value and realize results for relevant interested parties.

The QMS enables top management to optimize the use of resources considering the long and short term consequences of their decision.

A QMS provides the means to identify actions to address intended and unintended consequences in providing products and services.

2.2.3 Context of an organization

Understanding the context of the organization is a process. This process determines factors which influence the organization's purpose, objectives and sustainability. It considers internal factors such as values, culture, knowledge and performance of the organization. It also considers external factors such as legal, technological, competitive, market, cultural, social and economic environments.

Examples of the ways in which an organization's purpose can be expressed include its vision, mission, policies and objectives.

2.2.4 Interested parties

The concept of interested parties extends beyond a focus solely on the customer. It is important to consider all relevant interested parties.

Part of the process for understanding the context of the organization is to identify its interested parties. The relevant interested parties are those that provide significant risk to organizational sustainability if their needs and expectations are not met. Organizations define what results are necessary to deliver to those relevant interested parties to reduce that risk.

Organizations attract, capture and retain the support of the relevant interested parties they depend upon for their success.

2.2.5 Support

2.2.5.1 General

Top management support of the QMS and engagement of people enables:

- provision of adequate human and other resources;
- monitoring processes and results;

- determining and evaluating of risks and opportunities;
- implementing appropriate actions.

Responsible acquisition, deployment, maintenance, enhancement and disposal of resources support the organization in achieving its objectives.

2.2.5.2 People

People are essential resources within the organization. The performance of the organization is dependent upon how people behave within the system in which they work.

Within an organization, people become engaged and aligned through a common understanding of the quality policy and the organization's desired results.

2.2.5.3 Competence

A QMS is most effective when all employees understand and apply the skills, training, education and experience needed to perform their roles and responsibilities. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies.

2.2.5.4 Awareness

Awareness is attained when people understand their responsibilities and how their actions contribute to the achievement of the organization's objectives.

2.2.5.5 Communication

Planned and effective internal (i.e. throughout the organization) and external (i.e. with relevant interested parties) communication enhances people's engagement and increased understanding of:

- the context of the organization;
- the needs and expectations of customers and other relevant interested parties;
- the QMS.

2.3 Quality management principles

2.3.1 Customer focus

2.3.1.1 Statement

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

2.3.1.2 Rationale

Sustained success is achieved when an organization attracts and retains the confidence of customers and other relevant interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to the sustained success of the organization.

2.3.1.3 Key benefits

Some potential key benefits are:

- increased customer value;

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- increased customer satisfaction;
- improved customer loyalty;
- enhanced repeat business;
- enhanced reputation of the organization;
- expanded customer base;
- increased revenue and market share.

2.3.1.4 Possible actions

Possible actions include:

- recognize direct and indirect customers as those who receive value from the organization;
- understand customers' current and future needs and expectations;
- link the organization's objectives to customer needs and expectations;
- communicate customer needs and expectations throughout the organization;
- plan, design, develop, produce, deliver and support products and services to meet customer needs and expectations;
- measure and monitor customer satisfaction and take appropriate actions;
- determine and take action on relevant interested parties' needs and appropriate expectations that can affect customer satisfaction;
- actively manage relationships with customers to achieve sustained success.

2.3.2 Leadership

2.3.2.1 Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

2.3.2.2 Rationale

Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

2.3.2.3 Key benefits

Some potential key benefits are:

- increased effectiveness and efficiency in meeting the organization's quality objectives;
- better coordination of the organization's processes;
- improved communication between levels and functions of the organization;
- development and improvement of the capability of the organization and its people to deliver desired results.

2.3.2.4 Possible actions

Possible actions include:

- communicate the organization's mission, vision, strategy, policies and processes throughout the organization;
- create and sustain shared values, fairness and ethical models for behaviour at all levels of the organization;
- establish a culture of trust and integrity;
- encourage an organization-wide commitment to quality;
- ensure that leaders at all levels are positive examples to people in the organization;
- provide people with the required resources, training and authority to act with accountability;
- inspire, encourage and recognize the contribution of people.

2.3.3 Engagement of people

2.3.3.1 Statement

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.

2.3.3.2 Rationale

In order to manage an organization effectively and efficiently, it is important to respect and involve all people at all levels. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.

2.3.3.3 Key benefits

Some potential key benefits are:

- improved understanding of the organization's quality objectives by people in the organization and increased motivation to achieve them;
- enhanced involvement of people in improvement activities;
- enhanced personal development, initiatives and creativity;
- enhanced people satisfaction;
- enhanced trust and collaboration throughout the organization;
- increased attention to shared values and culture throughout the organization.

2.3.3.4 Possible actions

Possible actions include:

- communicate with people to promote understanding of the importance of their individual contribution;
- promote collaboration throughout the organization;
- facilitate open discussion and sharing of knowledge and experience;
- empower people to determine constraints to performance and to take initiatives without fear;

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- recognize and acknowledge people's contribution, learning and improvement;
- enable self-evaluation of performance against personal objectives;
- conduct surveys to assess people's satisfaction, communicate the results and take appropriate actions.

2.3.4 Process approach

2.3.4.1 Statement

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

2.3.4.2 Rationale

The QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

2.3.4.3 Key benefits

Some potential key benefits are:

- enhanced ability to focus effort on key processes and opportunities for improvement;
- consistent and predictable outcomes through a system of aligned processes;
- optimized performance through effective process management, efficient use of resources and reduced cross-functional barriers;
- enabling the organization to provide confidence to interested parties related to its consistency, effectiveness and efficiency.

2.3.4.4 Possible actions

Possible actions include:

- define objectives of the system and processes necessary to achieve them;
- establish authority, responsibility and accountability for managing processes;
- understand the organization's capabilities and determine resource constraints prior to action;
- determine process interdependencies and analyse the effect of modifications to individual processes on the system as a whole;
- manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently;
- ensure the necessary information is available to operate and improve the processes and to monitor, analyse and evaluate the performance of the overall system;
- manage risks which can affect outputs of the processes and overall outcomes of the QMS.

2.3.5 Improvement

2.3.5.1 Statement

Successful organizations have an ongoing focus on improvement.

2.3.5.2 Rationale

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

2.3.5.3 Key benefits

Some potential key benefits are:

- improved process performance, organizational capability and customer satisfaction;
- enhanced focus on root cause investigation and determination, followed by prevention and corrective actions;
- enhanced ability to anticipate and react to internal and external risks and opportunities;
- enhanced consideration of both incremental and breakthrough improvement;
- improved use of learning for improvement;
- enhanced drive for innovation.

2.3.5.4 Possible actions

Possible actions include:

- promote establishment of improvement objectives at all levels of the organization;
- educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives;
- ensure people are competent to successfully promote and complete improvement projects;
- develop and deploy processes to implement improvement projects throughout the organization;
- track, review and audit the planning, implementation, completion and results of improvement projects;
- integrate improvement consideration into development of new or modified products and services and processes;
- recognize and acknowledge improvement.

2.3.6 Evidence-based decision making

2.3.6.1 Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

2.3.6.2 Rationale

Decision-making can be a complex process and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.

2.3.6.3 Key benefits

Some potential key benefits are:

- improved decision making processes;

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- improved assessment of process performance and ability to achieve objectives;
- improved operational effectiveness and efficiency;
- increased ability to review, challenge and change opinions and decisions;
- increased ability to demonstrate the effectiveness of past decisions.

2.3.6.4 Possible actions

Possible actions include:

- determine, measure and monitor key indicators to demonstrate the organization's performance;
- make all data needed available to the relevant people;
- ensure that data and information are sufficiently accurate, reliable and secure;
- analyse and evaluate data and information using suitable methods;
- ensure people are competent to analyse and evaluate data as needed;
- make decisions and take actions based on evidence, balanced with experience and intuition.

2.3.7 Relationship management

2.3.7.1 Statement

For sustained success, organizations manage their relationships with relevant interested parties, such as providers.

2.3.7.2 Rationale

Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its provider and partner networks is of particular importance.

2.3.7.3 Key benefits

Some potential key benefits are:

- enhanced performance of the organization and its relevant interested parties through responding to the opportunities and constraints related to each interested party;
- common understanding of objectives and values among interested parties;
- increased capability to create value for interested parties by sharing resources and competence and managing quality related risks;
- a well-managed supply chain that provides a stable flow of products and services.

2.3.7.4 Possible actions

Possible actions include:

- determine relevant interested parties (such as providers, partners, customers, investors, employees or society as a whole) and their relationship with the organization;
- determine and prioritize interested party relationships that need to be managed;

- establish relationships that balance short-term gains with long-term considerations;
- gather and share information, expertise and resources with relevant interested parties;
- measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives;
- establish collaborative development and improvement activities with providers, partners and other interested parties;
- encourage and recognize improvements and achievements by providers and partners.

2.4 Developing the QMS using fundamental concepts and principles

2.4.1 QMS model

2.4.1.1 General

Organizations share many characteristics with humans as a living and learning social organism. Both are adaptive and comprise interacting systems, processes and activities. In order to adapt to their varying context, each needs the ability to change. Organizations often innovate to achieve breakthrough improvements. An organization's QMS model recognizes that not all systems, processes and activities can be predetermined; therefore it needs to be flexible and adaptable within the complexities of the organizational context.

2.4.1.2 System

Organizations seek to understand the internal and external context to identify the needs and expectations of relevant interested parties. This information is used in the development of the QMS to achieve organizational sustainability. The outputs from one process can be the inputs into other processes and are interlinked into the overall network. Although often appearing to be comprised of similar processes, each organization and its QMS is unique.

2.4.1.3 Processes

The organization has processes that can be defined, measured and improved. These processes interact to deliver results consistent with the organization's objectives and cross functional boundaries. Some processes can be critical while others are not. Processes have interrelated activities with inputs to deliver outputs.

2.4.1.4 Activity

People collaborate within a process to carry out their daily activities. Some activities are prescribed and depend on an understanding of the objectives of the organization, while others are not and react to external stimuli to determine their nature and execution.

2.4.2 Development of a QMS

A QMS is a dynamic system that evolves over time through periods of improvement. Every organization has quality management activities, whether they have been formally planned or not. This International Standard provides guidance on how to develop a formal system to manage these activities. It is necessary to determine activities which already exist in the organization and their suitability regarding the context of the organization. This International Standard, along with ISO 9004 and ISO 9001, can then be used to assist the organization to develop a cohesive QMS.

A formal QMS provides a framework for planning, executing, monitoring and improving the performance of quality management activities. The QMS does not need to be complicated; rather it needs to accurately

reflect the needs of the organization. In developing the QMS, the fundamental concepts and principles given in this International Standard can provide valuable guidance.

QMS planning is not a singular event, rather it is an ongoing process. Plans evolve as the organization learns and circumstances change. A plan takes into account all quality activities of the organization and ensures that it covers all guidance of this International Standard and requirements of ISO 9001. The plan is implemented upon approval.

It is important for an organization to regularly monitor and evaluate both the implementation of the plan and the performance of the QMS. Carefully considered indicators facilitate these monitoring and evaluation activities.

Auditing is a means of evaluating the effectiveness of the QMS, in order to identify risks and to determine the fulfilment of requirements. In order for audits to be effective, tangible and intangible evidence needs to be collected. Actions are taken for correction and improvement based upon analysis of the evidence gathered. The knowledge gained could lead to innovation, taking QMS performance to higher levels.

2.4.3 QMS standards, other management systems and excellence models

The approaches to a QMS described in QMS standards developed by ISO/TC 176, in other management system standards and in organizational excellence models are based on common principles. They all enable an organization to identify risks and opportunities and contain guidance for improvement. In the current context, many issues such as innovation, ethics, trust and reputation could be regarded as parameters within the QMS. Standards related to quality management (e.g. ISO 9001), environmental management (e.g. ISO 14001) and energy management (e.g. ISO 50001), as well as other management standards and organizational excellence models, have addressed this.

The QMS standards developed by ISO/TC 176 provide a comprehensive set of requirements and guidelines for a QMS. ISO 9001 specifies requirements for a QMS. ISO 9004 provides guidance on a wide range of objectives of a QMS for sustainable success and improved performance. Guidelines for components of a QMS include ISO 10001, ISO 10002, ISO 10003, ISO 10004, ISO 10008, ISO 10012 and ISO 19011. Guidelines for technical subjects in support of a QMS include ISO 10005, ISO 10006, ISO 10007, ISO 10014, ISO 10015, ISO 10018 and ISO 10019. Technical reports in support of a QMS include ISO/TR 10013 and ISO/TR 10017. Requirements for a QMS are also provided in sector-specific standards, such as ISO/TS 16949.

The various parts of an organization's management system, including its QMS, can be integrated as a single management system. The objectives, processes and resources related to quality, growth, funding, profitability, environment, occupational health and safety, energy, security and other aspects of the organization can be more effectively and efficiently achieved and used when the QMS is integrated with other management systems. The organization can perform an integrated audit of its management system against the requirements of multiple International Standards, such as ISO 9001, ISO 14001, ISO/IEC 27001 and ISO 50001.

NOTE The ISO handbook "The integrated use of management system standards" can provide useful guidance.

3 Terms and definitions

3.1 Terms related to person or people

3.1.1

top management

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

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

Note 2 to entry: If the scope of the *management system* (3.5.3) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.1.2

quality management system consultant

person who assists the *organization* (3.2.1) on *quality management system realization* (3.4.3), giving advice or *information* (3.8.2)

Note 1 to entry: The quality management system consultant can also assist in realizing parts of a *quality management system* (3.5.4).

Note 2 to entry: ISO 10019:2005 provides guidance on how to distinguish a competent quality management system consultant from one who is not competent.

[SOURCE: ISO 10019:2005, 3.2, modified]

3.1.3

involvement

taking part in an activity, event or situation

3.1.4

engagement

involvement (3.1.3) in, and contribution to, activities to achieve shared *objectives* (3.7.1)

3.1.5

configuration authority

configuration control board

dispositioning authority

person or a group of persons with assigned responsibility and authority to make decisions on the *configuration* (3.10.6)

Note 1 to entry: Relevant *interested parties* (3.2.3) within and outside the *organization* (3.2.1) should be represented on the configuration authority.

[SOURCE: ISO 10007:2003, 3.8, modified]

3.1.6

dispute resolver

<customer satisfaction> individual person assigned by a *DRP-provider* (3.2.7) to assist the parties in resolving a *dispute* (3.9.6)

EXAMPLE Staff, volunteer, *contract* (3.4.7) personnel.

[SOURCE: ISO 10003:2007, 3.7, modified]

3.2 Terms related to organization

3.2.1

organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.7.1)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, *association* (3.2.8), charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 1 to entry.

3.2.2

context of the organization

combination of internal and external issues that can have an effect on an *organization's* (3.2.1) approach to developing and achieving its *objectives* (3.7.1)

Note 1 to entry: The organization's objectives can be related to its *products* (3.7.6) and *services* (3.7.7), investments and behaviour towards its *interested parties* (3.2.3).

Note 2 to entry: The concept of context of the organization is equally applicable to not-for-profit or public service organizations as it is to those seeking profits.

Note 3 to entry: In English, this concept is often referred to by other terms such as "business environment", "organizational environment" or "ecosystem of an organization".

Note 4 to entry: Understanding the *infrastructure* (3.5.2) can help to define the context of the organization.

3.2.3

interested party

stakeholder

person or *organization* (3.2.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE *Customers* (3.2.4), owners, people in an organization, *providers* (3.2.5), bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding the Example.

3.2.4

customer

person or *organization* (3.2.1) that could or does receive a *product* (3.7.6) or a *service* (3.7.7) that is intended for or required by this person or organization

EXAMPLE Consumer, client, end-user, retailer, receiver of product or service from an internal *process* (3.4.1), beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the organization.

3.2.5

provider

supplier

organization (3.2.1) that provides a *product* (3.7.6) or a *service* (3.7.7)

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

Note 1 to entry: A provider can be internal or external to the organization.

Note 2 to entry: In a contractual situation, a provider is sometimes called "contractor".

3.2.6

external provider

external supplier

provider (3.2.5) that is not part of the *organization* (3.2.1)

EXAMPLE Producer, distributor, retailer or vendor of a *product* (3.7.6) or a *service* (3.7.7)

3.2.7**DRP-provider**

dispute resolution process provider

person or *organization* (3.2.1) that supplies and operates an external *dispute* (3.9.6) resolution *process* (3.4.1)

Note 1 to entry: Generally, a DRP-provider is a legal entity, separate from the organization 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 to handle unresolved *complaints* (3.9.3).

Note 2 to entry: The DRP-provider *contracts* (3.4.7) with the parties to provide dispute resolution, and is accountable for *performance* (3.7.8). The DRP-provider supplies *dispute resolvers* (3.1.6). The DRP-provider also utilizes support, executive and other managerial staff to supply financial resources, clerical support, scheduling assistance, training, meeting rooms, supervision and similar functions.

Note 3 to entry: DRP-providers can take many forms including not-for-profit, for-profit and public entities. An *association* (3.2.8) can also be a DRP-provider.

Note 4 to entry: In ISO 10003:2007 instead of the term DRP-provider, the term “provider” is used.

[SOURCE: ISO 10003:2007, 3.9, modified]

3.2.8**association**

<customer satisfaction> *organization* (3.2.1) consisting of member organizations or persons

[SOURCE: ISO 10003:2007, 3.1]

3.2.9**metrological function**

functional unit with administrative and technical responsibility for defining and implementing the *measurement management system* (3.5.7)

[SOURCE: ISO 10012:2003, 3.6, modified]

3.3 Terms related to activity**3.3.1****improvement**

activity to enhance *performance* (3.7.8)

Note 1 to entry: The activity can be recurring or singular.

3.3.2**continual improvement**

recurring activity to enhance *performance* (3.7.8)

Note 1 to entry: The *process* (3.4.1) of establishing *objectives* (3.7.1) and finding opportunities for *improvement* (3.3.1) is a continual process through the use of *audit findings* (3.13.9) and *audit conclusions* (3.13.10), analysis of *data* (3.8.1), *management* (3.3.3) *reviews* (3.11.2) or other means and generally leads to *corrective action* (3.12.2) or *preventive action* (3.12.1).

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.3.3**management**

coordinated activities to direct and control an *organization* (3.2.1)

Note 1 to entry: Management can include establishing *policies* (3.5.8) and *objectives* (3.7.1), and *processes* (3.4.1) to achieve these objectives.

Note 2 to entry: The word “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 of “management” as a set of activities defined above. For example, “management shall...” is deprecated whereas “*top management* (3.1.1) shall...” is acceptable. Otherwise different words should be adopted to convey the concept when related to people, e.g. managerial or managers.

3.3.4 quality management

management (3.3.3) with regard to *quality* (3.6.2)

Note 1 to entry: Quality management can include establishing *quality policies* (3.5.9) and *quality objectives* (3.7.2), and *processes* (3.4.1) to achieve these quality objectives through *quality planning* (3.3.5), *quality assurance* (3.3.6), *quality control* (3.3.7), and *quality improvement* (3.3.8).

3.3.5 quality planning

part of *quality management* (3.3.4) focused on setting *quality objectives* (3.7.2) and specifying necessary operational *processes* (3.4.1), and related resources to achieve the quality objectives

Note 1 to entry: Establishing *quality plans* (3.8.9) can be part of quality planning.

3.3.6 quality assurance

part of *quality management* (3.3.4) focused on providing confidence that *quality requirements* (3.6.5) will be fulfilled

3.3.7 quality control

part of *quality management* (3.3.4) focused on fulfilling *quality requirements* (3.6.5)

3.3.8 quality improvement

part of *quality management* (3.3.4) focused on increasing the ability to fulfil *quality requirements* (3.6.5)

Note 1 to entry: The quality requirements can be related to any aspect such as *effectiveness* (3.7.11), *efficiency* (3.7.10) or *traceability* (3.6.13).

3.3.9 configuration management

coordinated activities to direct and control *configuration* (3.10.6)

Note 1 to entry: Configuration management generally concentrates on technical and organizational activities that establish and maintain control of a *product* (3.7.6) or *service* (3.7.7) and its *product configuration information* (3.6.8) throughout the life cycle of the product.

[SOURCE: ISO 10007:2003, 3.6, modified — Note 1 to entry has been modified]

3.3.10 change control

<configuration management> activities for control of the *output* (3.7.5) after formal approval of its *product configuration information* (3.6.8)

[SOURCE: ISO 10007:2003, 3.1, modified]

3.3.11 activity

<project management> smallest identified object of work in a *project* (3.4.2)

[SOURCE: ISO 10006:2003, 3.1, modified]

3.3.12**project management**

planning, organizing, *monitoring* (3.11.3), controlling and reporting of all aspects of a *project* (3.4.2), and the motivation of all those involved in it to achieve the project objectives

[SOURCE: ISO 10006:2003, 3.6]

3.3.13**configuration object**

object (3.6.1) within a *configuration* (3.10.6) that satisfies an end-use function

[SOURCE: ISO 10007:2003, 3.5, modified]

3.4 Terms related to process**3.4.1****process**

set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the “intended result” of a process is called *output* (3.7.5), *product* (3.7.6) or *service* (3.7.7) depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

Note 4 to entry: Processes in an *organization* (3.2.1) are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the *conformity* (3.6.11) of the resulting output cannot be readily or economically validated is frequently referred to as a “special process”.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified to prevent circularity between process and output, and Notes 1 to 5 to entry have been added.

3.4.2**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* (3.7.1) conforming to specific *requirements* (3.6.4), including the constraints of time, cost and resources

Note 1 to entry: An individual project can form part of a larger project structure and generally has a defined start and finish date.

Note 2 to entry: In some projects the objectives and scope are updated and the *product* (3.7.6) or *service* (3.7.7) *characteristics* (3.10.1) defined progressively as the project proceeds.

Note 3 to entry: The *output* (3.7.5) of a project can be one or several units of product or service.

Note 4 to entry: The project’s *organization* (3.2.1) is normally temporary and established for the lifetime of the project.

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

[SOURCE: ISO 10006:2003, 3.5, modified — Notes 1 to 3 have been modified]

3.4.3

quality management system realization

process (3.4.1) of establishing, documenting, implementing, maintaining and continually improving a *quality management system* (3.5.4)

[SOURCE: ISO 10019:2005, 3.1, modified — Notes have been deleted]

3.4.4

competence acquisition

process (3.4.1) of attaining *competence* (3.10.4)

[SOURCE: ISO 10018:2012, 3.2, modified]

3.4.5

procedure

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

Note 1 to entry: Procedures can be documented or not.

3.4.6

outsource (verb)

make an arrangement where an external *organization* (3.2.1) performs part of an organization's function or *process* (3.4.1)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.5.3), although the outsourced function or process is within the scope.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.4.7

contract

binding agreement

3.4.8

design and development

set of *processes* (3.4.1) that transform *requirements* (3.6.4) for an *object* (3.6.1) into more detailed requirements for that object

Note 1 to entry: The requirements forming input to design and development are often the result of research and can be expressed in a broader, more general sense than the requirements forming the *output* (3.7.5) of design and development. The requirements are generally defined in terms of *characteristics* (3.10.1). In a *project* (3.4.2) 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 "développement" and the term "conception et développement" 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* (3.7.6) design and development, *service* (3.7.7) design and development or process design and development).

3.5 Terms related to system

3.5.1

system

set of interrelated or interacting elements

3.5.2**infrastructure**

<organization> *system* (3.5.1) of facilities, equipment and *services* (3.7.7) needed for the operation of an *organization* (3.2.1)

3.5.3**management system**

set of interrelated or interacting elements of an *organization* (3.2.1) to establish *policies* (3.5.8) and *objectives* (3.7.1), and *processes* (3.4.1) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines, e.g. *quality management* (3.3.4), financial management or environmental management.

Note 2 to entry: The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

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

Note 4 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Notes 1 to 3 to entry.

3.5.4**quality management system**

part of a *management system* (3.5.3) with regard to *quality* (3.6.2)

3.5.5**work environment**

set of conditions under which work is performed

Note 1 to entry: Conditions can include physical, social, psychological and environmental factors (such as temperature, lighting, recognition schemes, occupational stress, ergonomics and atmospheric composition).

3.5.6**metrological confirmation**

set of operations required to ensure that *measuring equipment* (3.11.6) conforms to the *requirements* (3.6.4) for its intended use

Note 1 to entry: Metrological confirmation generally includes calibration or *verification* (3.8.12), any necessary adjustment or *repair* (3.12.9), 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 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 4 to entry: Metrological requirements are usually distinct from, and are not specified in, *product* (3.7.6) requirements.

[SOURCE: ISO 10012:2003, 3.5, modified — Note 1 to entry has been modified]

3.5.7**measurement management system**

set of interrelated or interacting elements necessary to achieve *metrological confirmation* (3.5.6) and control of *measurement processes* (3.11.5)

[SOURCE: ISO 10012:2003, 3.1, modified]

3.5.8 policy

<organization> intentions and direction of an *organization* (3.2.1) as formally expressed by its *top management* (3.1.1)

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.5.9 quality policy

policy (3.5.8) related to *quality* (3.6.2)

Note 1 to entry: Generally the quality policy is consistent with the overall policy of the *organization* (3.2.1), can be aligned with the organization's *vision* (3.5.10) and *mission* (3.5.11) and provides a framework for the setting of *quality objectives* (3.7.2).

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

3.5.10 vision

<organization> aspiration of what an *organization* (3.2.1) would like to become as expressed by *top management* (3.1.1)

3.5.11 mission

<organization> *organization's* (3.2.1) purpose for existing as expressed by *top management* (3.1.1)

3.5.12 strategy

plan to achieve a long-term or overall *objective* (3.7.1)

3.6 Terms related to requirement

3.6.1 object

entity
item
anything perceivable or conceivable

EXAMPLE *Product* (3.7.6), *service* (3.7.7), *process* (3.4.1), person, *organization* (3.2.1), *system* (3.5.1), resource.

Note 1 to entry: Objects can be material (e.g. an engine, a sheet of paper, a diamond), non-material (e.g. conversion ratio, a project plan) or imagined (e.g. the future state of the organization).

[SOURCE: ISO 1087-1:2000, 3.1.1, modified]

3.6.2 quality

degree to which a set of inherent *characteristics* (3.10.1) of an *object* (3.6.1) fulfils *requirements* (3.6.4)

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* (3.6.1).

3.6.3 grade

category or rank given to different *requirements* (3.6.4) for an *object* (3.6.1) having the same functional use

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

Note 1 to entry: When establishing a *quality requirement* (3.6.5), the grade is generally specified.

3.6.4 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* (3.2.1) and *interested parties* (3.2.3) 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* (3.8.6).

Note 3 to entry: A qualifier can be used to denote a specific type of requirement, e.g. *product* (3.7.6) requirement, *quality management* (3.3.4) requirement, *customer* (3.2.4) requirement, *quality requirement* (3.6.5).

Note 4 to entry: Requirements can be generated by different interested parties or by the organization itself.

Note 5 to entry: It can be necessary for achieving high *customer satisfaction* (3.9.2) to fulfil an expectation of a customer even if it is neither stated nor generally implied or obligatory.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Notes 3 to 5 to entry.

3.6.5 quality requirement

requirement (3.6.4) related to *quality* (3.6.2)

3.6.6 statutory requirement

obligatory *requirement* (3.6.4) specified by a legislative body

3.6.7 regulatory requirement

obligatory *requirement* (3.6.4) specified by an authority mandated by a legislative body

3.6.8 product configuration information

requirement (3.6.4) or other information for *product* (3.7.6) design, realization, *verification* (3.8.12), operation and support

[SOURCE: ISO 10007:2003, 3.9, modified]

3.6.9 nonconformity

non-fulfilment of a *requirement* (3.6.4)

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.6.10 defect

nonconformity (3.6.9) related to an intended or specified use

Note 1 to entry: The distinction between the concepts defect and nonconformity is important as it has legal connotations, particularly those associated with *product* (3.7.6) and *service* (3.7.7) liability issues.

Note 2 to entry: The intended use as intended by the *customer* (3.2.4) can be affected by the nature of the *information* (3.8.2), such as operating or maintenance instructions, provided by the *provider* (3.2.5).

3.6.11 conformity

fulfilment of a *requirement* (3.6.4)

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

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.6.12 capability

ability of an *object* (3.6.1) to realize an *output* (3.7.5) that will fulfil the *requirements* (3.6.4) for that output

Note 1 to entry: *Process* (3.4.1) capability terms in the field of statistics are defined in ISO 3534-2.

3.6.13 traceability

ability to trace the history, application or location of an *object* (3.6.1)

Note 1 to entry: When considering a *product* (3.7.6) or a *service* (3.7.7), traceability can relate to:

- the origin of materials and parts;
- the processing history;
- the distribution and location of the product or service after delivery.

Note 2 to entry: In the field of metrology, the definition in ISO/IEC Guide 99 is the accepted definition.

3.6.14 dependability

ability to perform as and when required

[SOURCE: IEC 60050-192, modified — Notes have been deleted]

3.6.15 innovation

new or changed *object* (3.6.1) realizing or redistributing value

Note 1 to entry: Activities resulting in innovation are generally managed.

Note 2 to entry: Innovation is generally significant in its effect.

3.7 Terms related to result

3.7.1 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 objectives) and can apply at different levels (such as strategic, *organization* (3.2.1)-wide, *project* (3.4.2), *product* (3.7.6) and *process* (3.4.1)).

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 objective* (3.7.2) 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* (3.5.4) *quality objectives* (3.7.2) are set by the *organization* (3.2.1), consistent with the *quality policy* (3.5.9), to achieve specific results.

Note 5 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 2 to entry.

3.7.2 quality objective

objective (3.7.1) related to *quality* (3.6.2)

Note 1 to entry: Quality objectives are generally based on the *organization's* (3.2.1) *quality policy* (3.5.9).

Note 2 to entry: Quality objectives are generally specified for relevant functions, levels and *processes* (3.4.1) in the *organization* (3.2.1).

3.7.3 success

<organization> achievement of an *objective* (3.7.1)

Note 1 to entry: The success of an *organization* (3.2.1) emphasizes the need for a balance between its economic or financial interests and the needs of its *interested parties* (3.2.3), such as *customers* (3.2.4), users, investors/shareholders (owners), people in the organization, *providers* (3.2.5), partners, interest groups and communities.

3.7.4 sustained success

<organization> *success* (3.7.3) over a period of time

Note 1 to entry: Sustained success emphasizes the need for a balance between economic-financial interests of an *organization* (3.2.1) and those of the social and ecological environment.

Note 2 to entry: Sustained success relates to the *interested parties* (3.2.3) of an organization, such as *customers* (3.2.4), owners, people in an organization, *providers* (3.2.5), bankers, unions, partners or society.

3.7.5 output

result of a *process* (3.4.1)

Note 1 to entry: Whether an output of the *organization* (3.2.1) is a *product* (3.7.6) or a *service* (3.7.7) depends on the preponderance of the *characteristics* (3.10.1) involved, e.g. a painting for sale in a gallery is a product whereas supply of a commissioned painting is a service, a hamburger bought in a retail store is a product whereas receiving an order and serving a hamburger ordered in a restaurant is part of a service.

3.7.6 product

output (3.7.5) of an *organization* (3.2.1) that can be produced without any transaction taking place between the organization and the *customer* (3.2.4)

Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between *provider* (3.2.5) and customer, but can often involve this *service* (3.7.7) element upon its delivery to the customer.

Note 2 to entry: The dominant element of a product is that it is generally tangible.

Note 3 to entry: Hardware is tangible and its amount is a countable *characteristic* (3.10.1) (e.g. tyres). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of *information* (3.8.2) regardless of delivery medium (e.g. computer programme, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license).

3.7.7 service

output (3.7.5) of an *organization* (3.2.1) with at least one activity necessarily performed between the organization and the *customer* (3.2.4)

Note 1 to entry: The dominant elements of a service are generally intangible.

Note 2 to entry: Service often involves activities at the interface with the customer to establish customer *requirements* (3.6.4) as well as upon delivery of the service and can involve a continuing relationship such as banks, accountancies or public organizations, e.g. schools or hospitals.

ISO 9000:2015(E)

Note 3 to entry: Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible *product* (3.7.6) (e.g. a car 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* (3.8.2) in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants);

Note 4 to entry: A service is generally experienced by the customer.

3.7.8 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* (3.3.3) of *activities* (3.3.11), *processes* (3.4.1), *products* (3.7.6), *services* (3.7.7), *systems* (3.5.1) or *organizations* (3.2.1).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 2 to entry.

3.7.9 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* (3.8.2) related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73:2009, 3.5.1.3) and consequences (as defined in ISO Guide 73:2009, 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 (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

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

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 5 to entry.

3.7.10 efficiency relationship between the result achieved and the resources used

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

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding “are” before “achieved”.

3.8 Terms related to data, information and document

3.8.1

data

facts about an *object* (3.6.1)

3.8.2

information

meaningful *data* (3.8.1)

3.8.3

objective evidence

data (3.8.1) supporting the existence or verity of something

Note 1 to entry: Objective evidence can be obtained through observation, *measurement* (3.11.4), *test* (3.11.8), or by other means.

Note 2 to entry: Objective evidence for the purpose of *audit* (3.13.1) generally consists of *records* (3.8.10), statements of fact or other *information* (3.8.2) which are relevant to the *audit criteria* (3.13.7) and verifiable.

3.8.4

information system

<quality management system> network of communication channels used within an *organization* (3.2.1)

3.8.5

document

information (3.8.2) and the medium on which it is contained

EXAMPLE *Record* (3.8.10), *specification* (3.8.7), 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 and records, is frequently called “documentation”.

Note 3 to entry: Some *requirements* (3.6.4) (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 for records (e.g. the requirement to be retrievable).

3.8.6

documented information

information (3.8.2) required to be controlled and maintained by an *organization* (3.2.1) 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:

- the *management system* (3.5.3), including related *processes* (3.4.1);
- information created in order for the organization to operate (documentation);
- evidence of results achieved (*records* (3.8.10)).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.8.7

specification

document (3.8.5) stating *requirements* (3.6.4)

EXAMPLE *Quality manual* (3.8.8), *quality plan* (3.8.9), technical drawing, procedure document, work instruction.

ISO 9000:2015(E)

Note 1 to entry: A specification can be related to activities (e.g. procedure document, *process* (3.4.1) specification and *test* (3.11.8) specification), or *products* (3.7.6) (e.g. product specification, *performance* (3.7.8) 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* (3.4.8) and thus in some cases can be used as a *record* (3.8.10).

3.8.8 quality manual

specification (3.8.7) for the *quality management system* (3.5.4) of an *organization* (3.2.1)

Note 1 to entry: Quality manuals can vary in detail and format to suit the size and complexity of an individual *organization* (3.2.1).

3.8.9 quality plan

specification (3.8.7) of the *procedures* (3.4.5) and associated resources to be applied when and by whom to a specific *object* (3.6.1)

Note 1 to entry: These procedures generally include those referring to *quality management* (3.3.4) *processes* (3.4.1) and to *product* (3.7.6) and *service* (3.7.7) realization processes.

Note 2 to entry: A quality plan often makes reference to parts of the *quality manual* (3.8.8) or to procedure *documents* (3.8.5).

Note 3 to entry: A quality plan is generally one of the results of *quality planning* (3.3.5).

3.8.10 record

document (3.8.5) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize *traceability* (3.6.13) and to provide evidence of *verification* (3.8.12), *preventive action* (3.12.1) and *corrective action* (3.12.2).

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

3.8.11 project management plan

document (3.8.5) specifying what is necessary to meet the *objective(s)* (3.7.1) of the *project* (3.4.2)

Note 1 to entry: A project management plan should include or refer to the project's *quality plan* (3.8.9).

Note 2 to entry: The project management plan also includes or references such other plans as those relating to organizational structures, resources, schedule, budget, *risk* (3.7.9) *management* (3.3.3), environmental management, health and safety management, and security management, as appropriate.

[SOURCE: ISO 10006:2003, 3.7]

3.8.12 verification

confirmation, through the provision of *objective evidence* (3.8.3), that specified *requirements* (3.6.4) have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an *inspection* (3.11.7) or of other forms of *determination* (3.11.1) such as performing alternative calculations or reviewing *documents* (3.8.5).

Note 2 to entry: The activities carried out for verification are sometimes called a qualification *process* (3.4.1).

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

3.8.13 validation

confirmation, through the provision of *objective evidence* (3.8.3), that the *requirements* (3.6.4) for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a *test* (3.11.8) or other form of *determination* (3.11.1) such as performing alternative calculations or reviewing *documents* (3.8.5).

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.

3.8.14 configuration status accounting

formalized recording and reporting of *product configuration information* (3.6.8), the status of proposed changes and the status of the implementation of approved changes

[SOURCE: ISO 10007:2003, 3.7]

3.8.15 specific case

<quality plan> subject of the *quality plan* (3.8.9)

Note 1 to entry: This term is used to avoid repetition of “*process* (3.4.1), *product* (3.7.6), *project* (3.4.2) or *contract* (3.4.7)” within ISO 10005.

[SOURCE: ISO 10005:2005, 3.10, modified — Note 1 to entry has been modified]

3.9 Terms related to customer

3.9.1 feedback

<customer satisfaction> opinions, comments and expressions of interest in a *product* (3.7.6), a *service* (3.7.7) or a complaints-handling *process* (3.4.1)

[SOURCE: ISO 10002:2014, 3.6, modified — The term “service” has been included in the definition]

3.9.2 customer satisfaction

customer's (3.2.4) perception of the degree to which the customer's expectations have been fulfilled

Note 1 to entry: It can be that the customer's expectation is not known to the *organization* (3.2.1), or even to the customer in question, until the *product* (3.7.6) or *service* (3.7.7) is delivered. It can be necessary for achieving 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* (3.9.3) 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* (3.6.4) have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

[SOURCE: ISO 10004:2012, 3.3, modified — Notes have been modified]

3.9.3 complaint

<customer satisfaction> expression of dissatisfaction made to an *organization* (3.2.1), related to its *product* (3.7.6) or *service* (3.7.7), or the complaints-handling *process* (3.4.1) itself, where a response or resolution is explicitly or implicitly expected

[SOURCE: ISO 10002:2014, 3.2, modified — The term “service” has been included in the definition]

3.9.4

customer service

interaction of the *organization* (3.2.1) with the *customer* (3.2.4) throughout the life cycle of a *product* (3.7.6) or a *service* (3.7.7)

[SOURCE: ISO 10002:2014, 3.5, modified — The term “service” has been included in the definition]

3.9.5

customer satisfaction code of conduct

promises, made to *customers* (3.2.4) by an *organization* (3.2.1) concerning its behaviour, that are aimed at enhanced *customer satisfaction* (3.9.2) and related provisions

Note 1 to entry: Related provisions can include *objectives* (3.7.1), conditions, limitations, contact *information* (3.8.2), and *complaints* (3.9.3) handling *procedures* (3.4.5).

Note 2 to entry: In ISO 10001:2007, the term “code” is used instead of “customer satisfaction code of conduct”.

[SOURCE: ISO 10001:2007, 3.1, modified — The term “code” has been removed as an admitted term, and Note 2 to entry has been modified]

3.9.6

dispute

<customer satisfaction> disagreement, arising from a *complaint* (3.9.3), submitted to a *DRP-provider* (3.2.7)

Note 1 to entry: Some *organizations* (3.2.1) allow their *customers* (3.2.4) to express their dissatisfaction to a DRP-provider in the first instance. In this situation, the expression of dissatisfaction becomes a complaint when sent to the organization for a response, and becomes a dispute if not resolved by the organization without DRP-provider intervention. Many organizations prefer their customers to first express any dissatisfaction to the organization before utilizing dispute resolution external to the organization.

[SOURCE: ISO 10003:2007, 3.6, modified]

3.10 Terms related to characteristic

3.10.1

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);
- d) temporal (e.g. punctuality, reliability, availability, continuity);
- e) ergonomic (e.g. physiological characteristic, or related to human safety);
- f) functional (e.g. maximum speed of an aircraft).

3.10.2

quality characteristic

inherent *characteristic* (3.10.1) of an *object* (3.6.1) related to a *requirement* (3.6.4)

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

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

3.10.3

human factor

characteristic (3.10.1) of a person having an impact on an *object* (3.6.1) under consideration

Note 1 to entry: Characteristics can be physical, cognitive or social.

Note 2 to entry: Human factors can have a significant impact on a *management system* (3.5.3).

3.10.4

competence

ability to apply knowledge and skills to achieve intended results

Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.10.5

metrological characteristic

characteristic (3.10.1) which can influence the results of *measurement* (3.11.4)

Note 1 to entry: *Measuring equipment* (3.11.6) usually has several metrological characteristics.

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

3.10.6

configuration

interrelated functional and physical *characteristics* (3.10.1) of a *product* (3.7.6) or *service* (3.7.7) defined in *product configuration information* (3.6.8)

[SOURCE: ISO 10007:2003, 3.3, modified — The term “service” has been included in the definition]

3.10.7

configuration baseline

approved *product configuration information* (3.6.8) that establishes the *characteristics* (3.10.1) of a *product* (3.7.6) or *service* (3.7.7) at a point in time that serves as reference for activities throughout the life cycle of the product or service

[SOURCE: ISO 10007:2003, 3.4, modified — The term “service” has been included in the definition]

3.11 Terms related to determination

3.11.1

determination

activity to find out one or more *characteristics* (3.10.1) and their characteristic values

3.11.2

review

determination (3.11.1) of the suitability, adequacy or *effectiveness* (3.7.11) of an *object* (3.6.1) to achieve established *objectives* (3.7.1)

EXAMPLE Management review, *design and development* (3.4.8) review, review of *customer* (3.2.4) *requirements* (3.6.4), review of *corrective action* (3.12.2) and peer review.

Note 1 to entry: Review can also include the determination of *efficiency* (3.7.10).

3.11.3

monitoring

determining (3.11.1) the status of a *system* (3.5.1), a *process* (3.4.1), a *product* (3.7.6), a *service* (3.7.7), or an activity

Note 1 to entry: For the determination of the status there can be a need to check, supervise or critically observe.

Note 2 to entry: Monitoring is generally a determination of the status of an *object* (3.6.1), carried out at different stages or at different times.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition and Note 1 to entry have been modified, and Note 2 to entry has been added.

3.11.4

measurement

process (3.4.1) to determine a value

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

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

3.11.5

measurement process

set of operations to determine the value of a quantity

3.11.6

measuring equipment

measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement process* (3.11.5)

3.11.7

inspection

determination (3.11.1) of *conformity* (3.6.11) to specified *requirements* (3.6.4)

Note 1 to entry: If the result of an inspection shows conformity, it can be used for purposes of *verification* (3.8.12).

Note 2 to entry: The result of an inspection can show conformity or *nonconformity* (3.6.9) or a degree of conformity.

3.11.8

test

determination (3.11.1) according to *requirements* (3.6.4) for a specific intended use or application

Note 1 to entry: If the result of a test shows *conformity* (3.6.11), it can be used for purposes of *validation* (3.8.13).

3.11.9

progress evaluation

<project management> assessment of progress made on achievement of the *project* (3.4.2) *objectives* (3.7.1)

Note 1 to entry: This assessment should be carried out at appropriate points in the project life cycle across project *processes* (3.4.1), based on criteria for project processes and *product* (3.7.6) or *service* (3.7.7).

Note 2 to entry: The results of progress evaluations can lead to revision of the *project management plan* (3.8.11).

[SOURCE: ISO 10006:2003, 3.4, modified — Notes to entry have been modified]

3.12 Terms related to action

3.12.1

preventive action

action to eliminate the cause of a potential *nonconformity* (3.6.9) or other potential undesirable situation

Note 1 to entry: There can be more than one cause for a potential nonconformity.

Note 2 to entry: Preventive action is taken to prevent occurrence whereas *corrective action* (3.12.2) is taken to prevent recurrence.

3.12.2

corrective action

action to eliminate the cause of a *nonconformity* (3.6.9) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas *preventive action* (3.12.1) is taken to prevent occurrence.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Notes 1 and 2 to entry.

3.12.3

correction

action to eliminate a detected *nonconformity* (3.6.9)

Note 1 to entry: A correction can be made in advance of, in conjunction with or after a *corrective action* (3.12.2).

Note 2 to entry: A correction can be, for example, *rework* (3.12.8) or *regrade* (3.12.4).

3.12.4

regrade

alteration of the *grade* (3.6.3) of a *nonconforming* (3.6.9) *product* (3.7.6) or *service* (3.7.7) in order to make it conform to *requirements* (3.6.4) differing from the initial requirements

3.12.5

concession

permission to use or *release* (3.12.7) a *product* (3.7.6) or *service* (3.7.7) that does not conform to specified *requirements* (3.6.4)

Note 1 to entry: A concession is generally limited to the delivery of products and services that have *nonconforming* (3.6.9) *characteristics* (3.10.1) within specified limits and is generally given for a limited quantity of products and services or period of time, and for a specific use.

3.12.6

deviation permit

permission to depart from the originally specified *requirements* (3.6.4) of a *product* (3.7.6) or *service* (3.7.7) prior to its realization

Note 1 to entry: A deviation permit is generally given for a limited quantity of products and services or period of time, and for a specific use.

3.12.7

release

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

Note 1 to entry: In English, in the context of software and *documents* (3.8.5), the word “release” is frequently used to refer to a version of the software or the document itself.

3.12.8 rework

action on a *nonconforming* (3.6.9) *product* (3.7.6) or *service* (3.7.7) to make it conform to the *requirements* (3.6.4)

Note 1 to entry: Rework can affect or change parts of the nonconforming product or service.

3.12.9 repair

action on a *nonconforming* (3.6.9) *product* (3.7.6) or *service* (3.7.7) to make it acceptable for the intended use

Note 1 to entry: A successful repair of a nonconforming product or service does not necessarily make the product or service conform to the *requirements* (3.6.4). It can be that in conjunction with a repair a *concession* (3.12.5) is required.

Note 2 to entry: Repair includes remedial action taken on a previously conforming product or service to restore it for use, for example as part of maintenance.

Note 3 to entry: Repair can affect or change parts of the nonconforming product or service.

3.12.10 scrap

action on a *nonconforming* (3.6.9) *product* (3.7.6) or *service* (3.7.7) to preclude its originally intended use

EXAMPLE Recycling, destruction.

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

3.13 Terms related to audit

3.13.1 audit

systematic, independent and documented *process* (3.4.1) for obtaining *objective evidence* (3.8.3) and evaluating it objectively to determine the extent to which the *audit criteria* (3.13.7) are fulfilled

Note 1 to entry: The fundamental elements of an audit include the *determination* (3.11.1) of the *conformity* (3.6.11) of an *object* (3.6.1) according to a *procedure* (3.4.5) carried out by personnel not being responsible for the object audited.

Note 2 to entry: An audit can be an internal audit (first party), or an external audit (second party or third party), and it can be a *combined audit* (3.13.2) or a *joint audit* (3.13.3).

Note 3 to entry: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the *organization* (3.2.1) itself for *management* (3.3.3) *review* (3.11.2) and other internal purposes, and can form the basis for an organization's declaration of conformity. 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, such as *customers* (3.2.4), 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 or governmental agencies.

Note 5 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition and Notes to entry have been modified to remove effect of circularity between audit criteria and audit evidence term entries, and Notes 3 and 4 to entry have been added.

3.13.2**combined audit**

audit (3.13.1) carried out together at a single *auditee* (3.13.12) on two or more *management systems* (3.5.3)

Note 1 to entry: The parts of a management system that can be involved in a combined audit can be identified by the relevant management system standards, product standards, service standards or process standards being applied by the *organization* (3.2.1).

3.13.3**joint audit**

audit (3.13.1) carried out at a single *auditee* (3.13.12) by two or more auditing *organizations* (3.2.1)

3.13.4**audit programme**

set of one or more *audits* (3.13.1) planned for a specific time frame and directed towards a specific purpose

[SOURCE: ISO 19011:2011, 3.13, modified]

3.13.5**audit scope**

extent and boundaries of an *audit* (3.13.1)

Note 1 to entry: The audit scope generally includes a description of the physical locations, organizational units, activities and *processes* (3.4.1).

[SOURCE: ISO 19011:2011, 3.14, modified — Note to entry has been modified]

3.13.6**audit plan**

description of the activities and arrangements for an *audit* (3.13.1)

[SOURCE: ISO 19011:2011, 3.15]

3.13.7**audit criteria**

set of *policies* (3.5.8), *procedures* (3.4.5) or *requirements* (3.6.4) used as a reference against which *objective evidence* (3.8.3) is compared

[SOURCE: ISO 19011:2011, 3.2, modified — The term “audit evidence” has been replaced by “objective evidence”]

3.13.8**audit evidence**

records, statements of fact or other information, which are relevant to the *audit criteria* (3.13.7) and verifiable

[SOURCE: ISO 19011:2011, 3.3, modified — Note to entry has been deleted]

3.13.9**audit findings**

results of the evaluation of the collected *audit evidence* (3.13.8) against *audit criteria* (3.13.7)

Note 1 to entry: Audit findings indicate *conformity* (3.6.11) or *nonconformity* (3.6.9).

Note 2 to entry: Audit findings can lead to the identification of opportunities for *improvement* (3.3.1) or recording good practices.

Note 3 to entry: In English, if the *audit criteria* (3.13.7) are selected from *statutory requirements* (3.6.6) or *regulatory requirements* (3.6.7), the audit finding can be called compliance or non-compliance.

[SOURCE: ISO 19011:2011, 3.4, modified — Note 3 to entry has been modified]

3.13.10

audit conclusion

outcome of an *audit* (3.13.1), after consideration of the audit objectives and all *audit findings* (3.13.9)

[SOURCE: ISO 19011:2011, 3.5]

3.13.11

audit client

organization (3.2.1) or person requesting an *audit* (3.13.1)

[SOURCE: ISO 19011:2011, 3.6, modified — Note to entry has been deleted]

3.13.12

auditee

organization (3.2.1) being audited

[SOURCE: ISO 19011:2011, 3.7]

3.13.13

guide

<audit> person appointed by the *auditee* (3.13.12) to assist the *audit team* (3.13.14)

[SOURCE: ISO 19011:2011, 3.12]

3.13.14

audit team

one or more persons conducting an *audit* (3.13.1), supported if needed by *technical experts* (3.13.16)

Note 1 to entry: One *auditor* (3.13.15) of the audit team is appointed as the audit team leader.

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

[SOURCE: ISO 19011:2011, 3.9, modified]

3.13.15

auditor

person who conducts an *audit* (3.13.1)

[SOURCE: ISO 19011:2011, 3.8]

3.13.16

technical expert

<audit> person who provides specific knowledge or expertise to the *audit team* (3.13.14)

Note 1 to entry: Specific knowledge or expertise relates to the *organization* (3.2.1), the *process* (3.4.1) or activity to be audited, or language or culture.

Note 2 to entry: A technical expert does not act as an *auditor* (3.13.15) in the *audit team* (3.13.14).

[SOURCE: ISO 19011:2011, 3.10, modified — Note 1 to entry has been modified]

3.13.17

observer

<audit> person who accompanies the *audit team* (3.13.14) but does not act as an *auditor* (3.13.15)

Note 1 to entry: An observer can be a member of the *auditee* (3.13.12), a regulator or other *interested party* (3.2.3) who witnesses the *audit* (3.13.1).

[SOURCE: ISO 19011:2011, 3.11, modified — The verb “audit” has been removed from the definition; Note to entry has been modified]

Annex A (informative)

Concept relationships and their graphical representation

A.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 (see [Clause A.2](#)), partitive (see [Clause A.3](#)) and associative (see [Clause A.4](#)).

A.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 adapted from ISO 704:2009, (5.5.2.2.1)

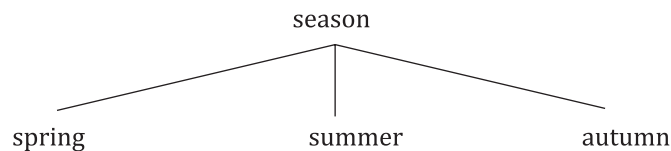


Figure A.1 — Graphical representation of a generic relation

A.3 Partitive relation

Subordinate concepts within the hierarchy form constituent parts of the superordinate concept, e.g. spring, summer, autumn and winter can 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](#)).

Example adapted from ISO 704:2009, (5.5.2.3.1)

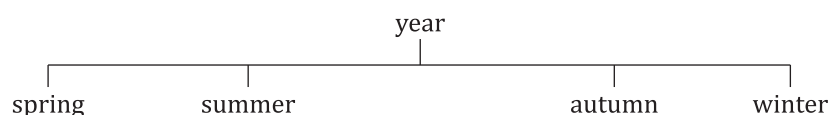


Figure A.2 — Graphical representation of a partitive relation

A.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 adapted from ISO 704:2009, (5.6.2)

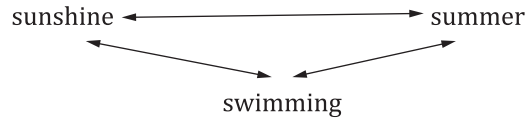


Figure A.3 — Graphical representation of an associative relation

A.5 Concept diagrams

[Figures A.4](#) to [A.16](#) 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.

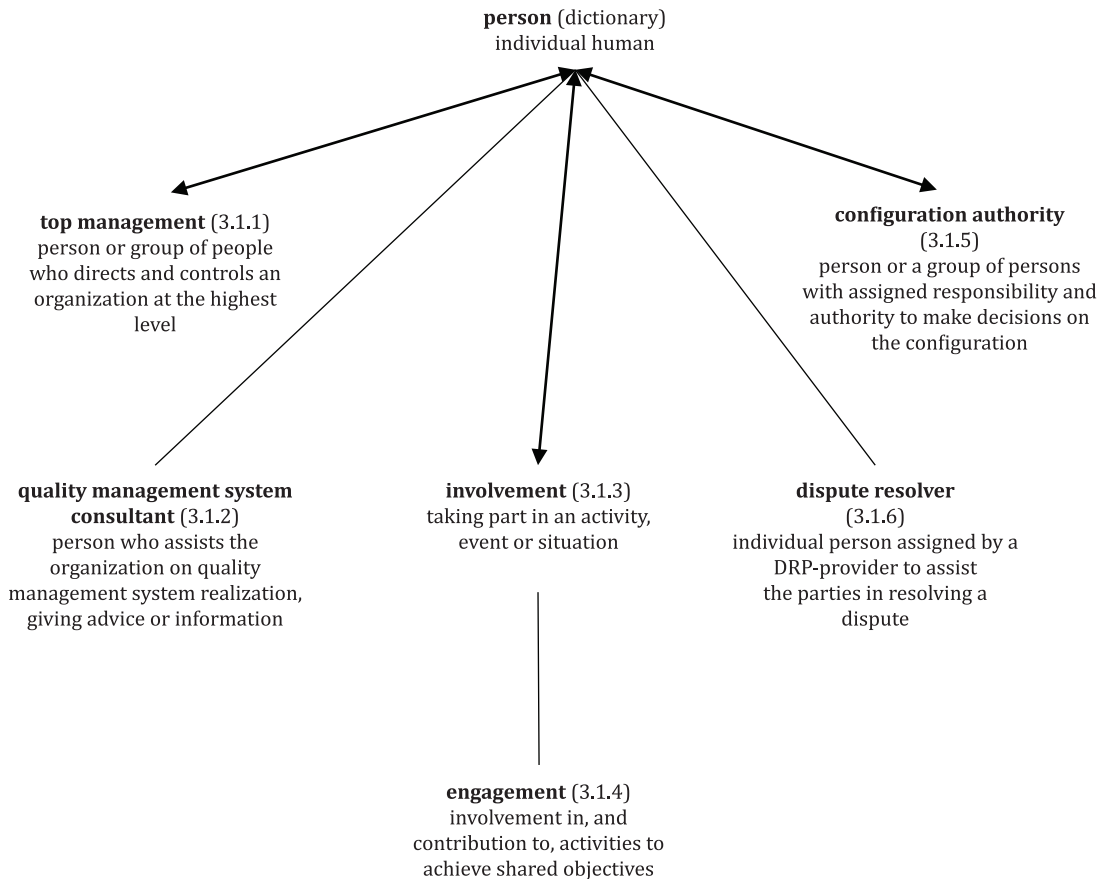


Figure A.4 — 3.1 Concepts of the class “person or people” and related concepts

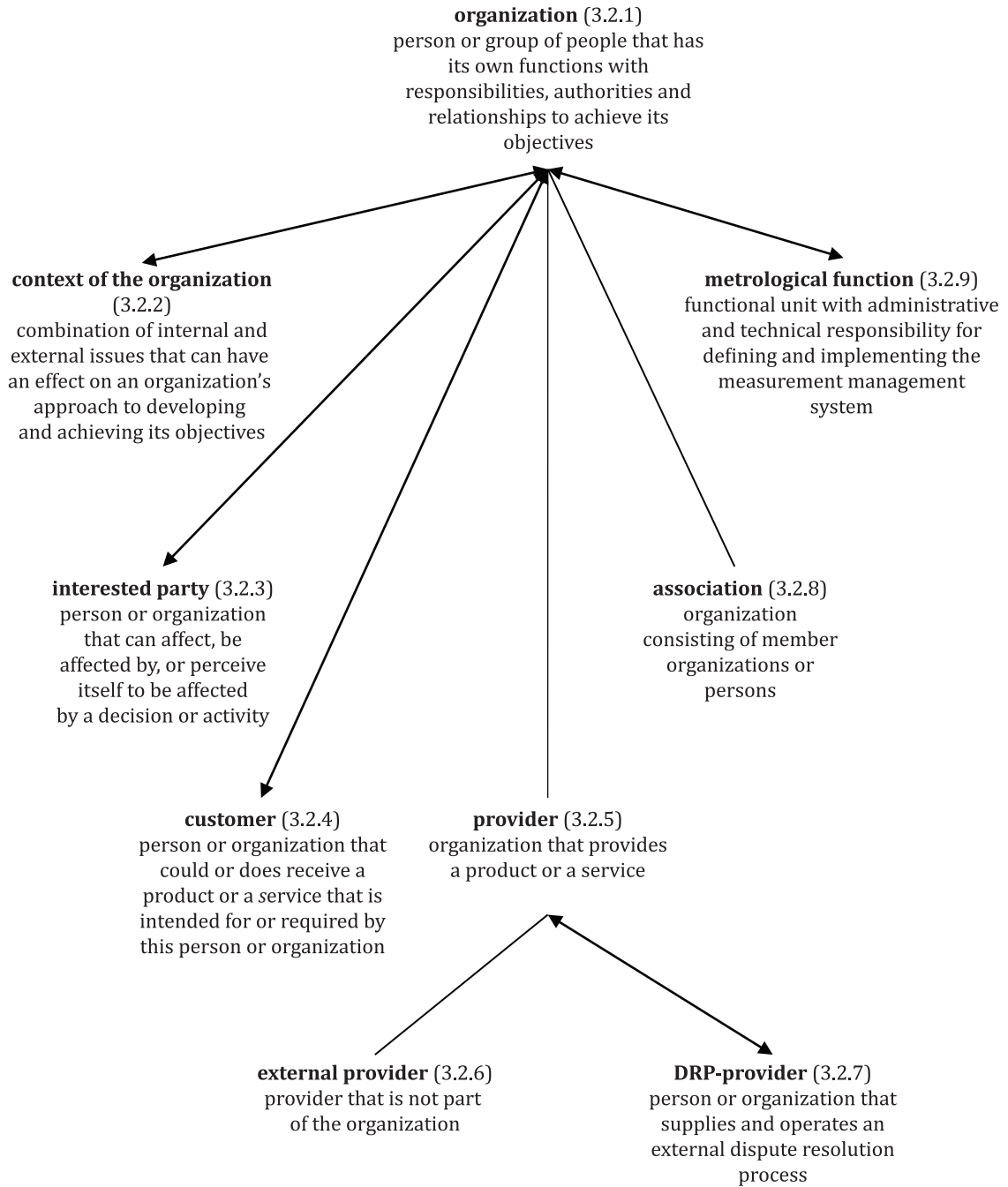


Figure A.5 — 3.2 Concepts of the class “organization” and related concepts

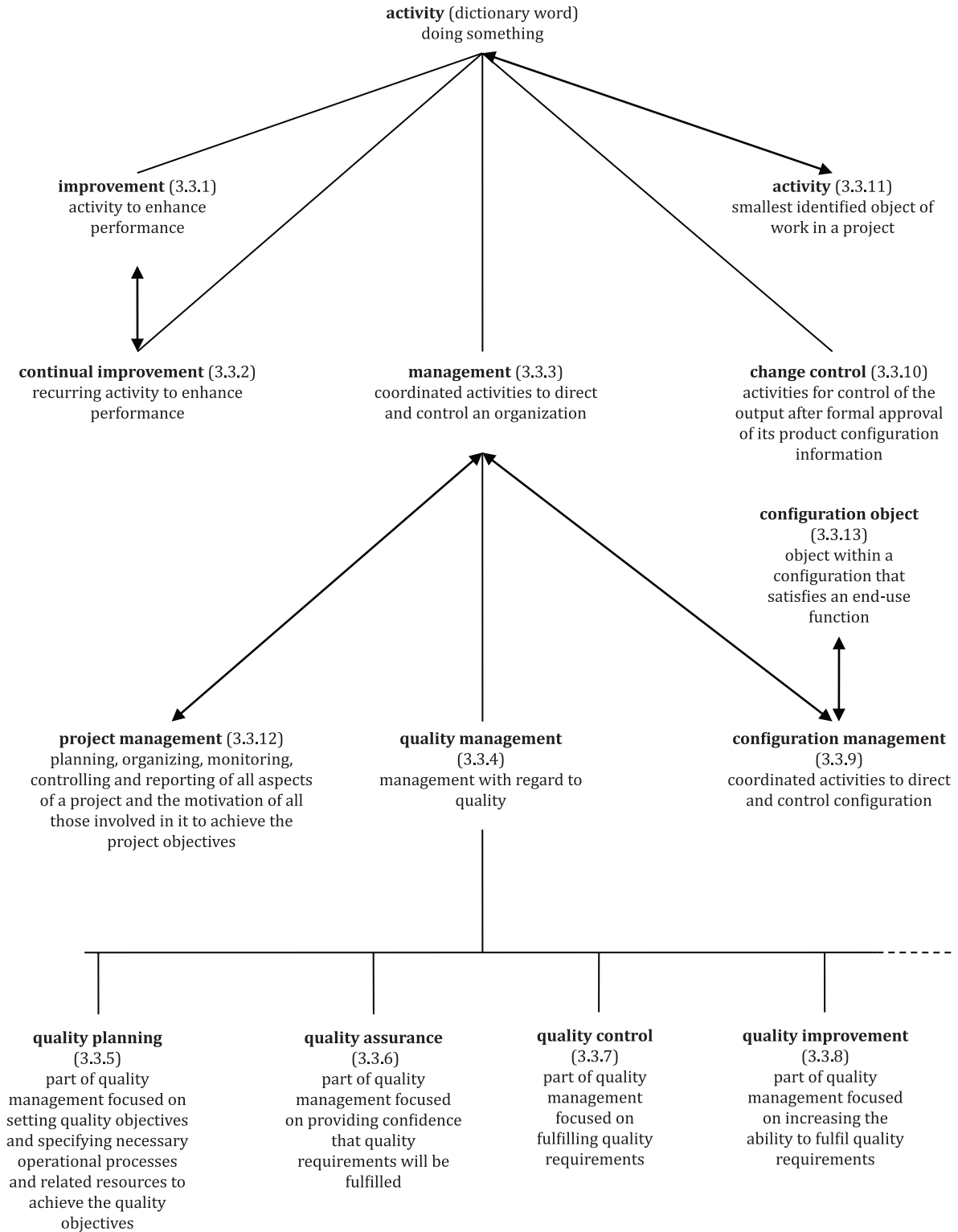


Figure A.6 — 3.3 Concepts of the class “activity” and related concepts

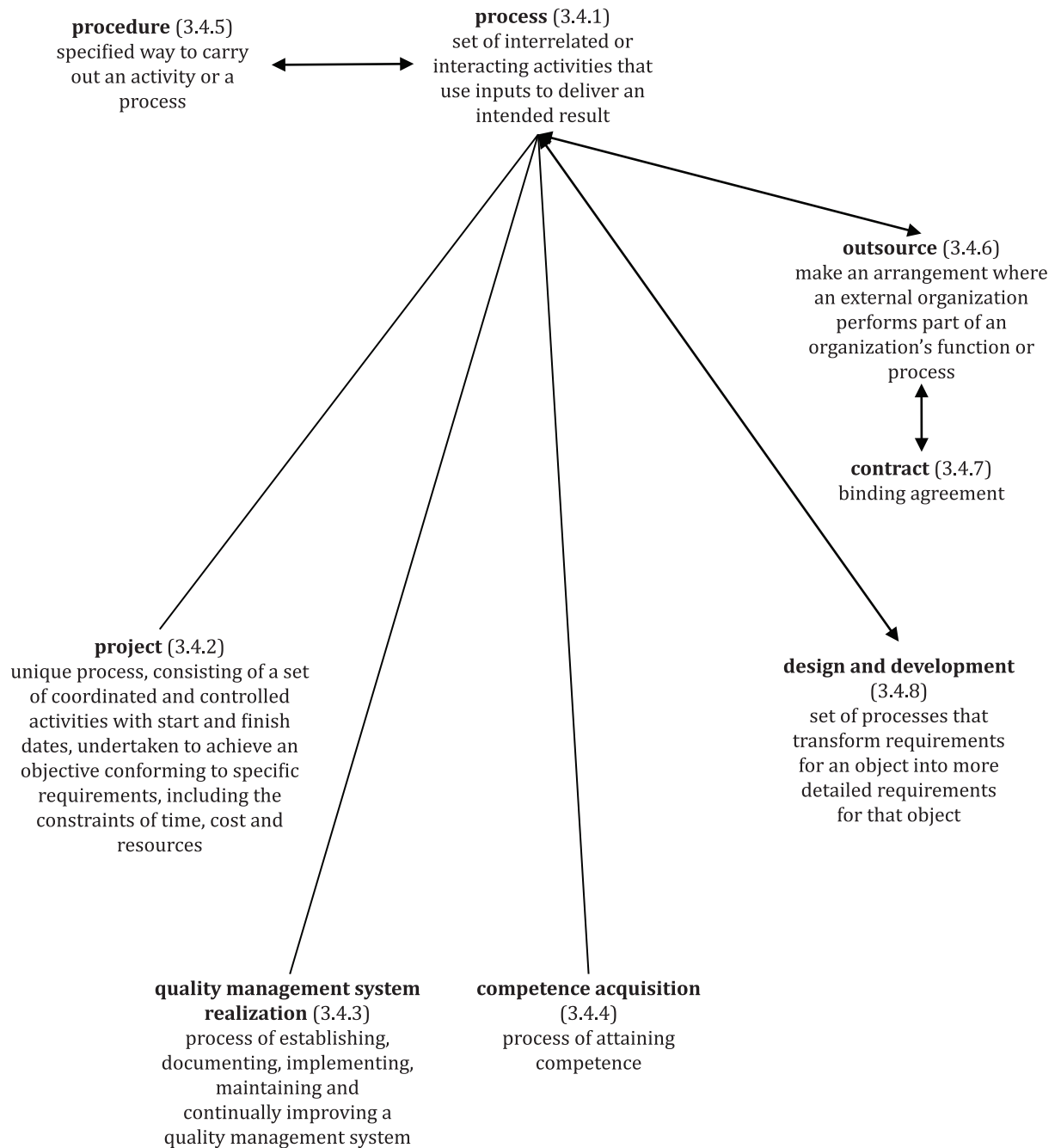


Figure A.7 — 3.4 Concepts of the class “process” and related concepts

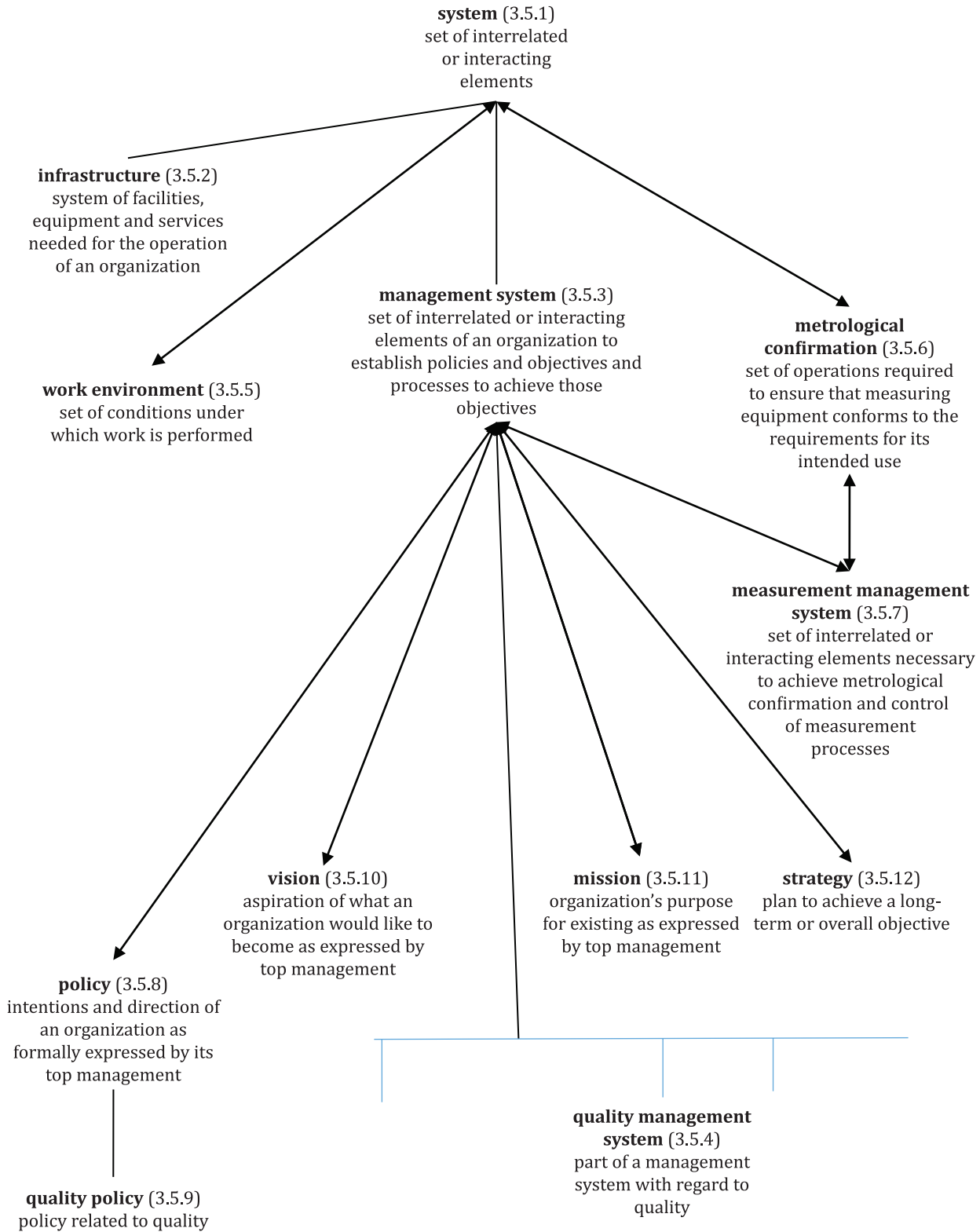


Figure A.8 — 3.5 Concepts of the class “system” and related concepts

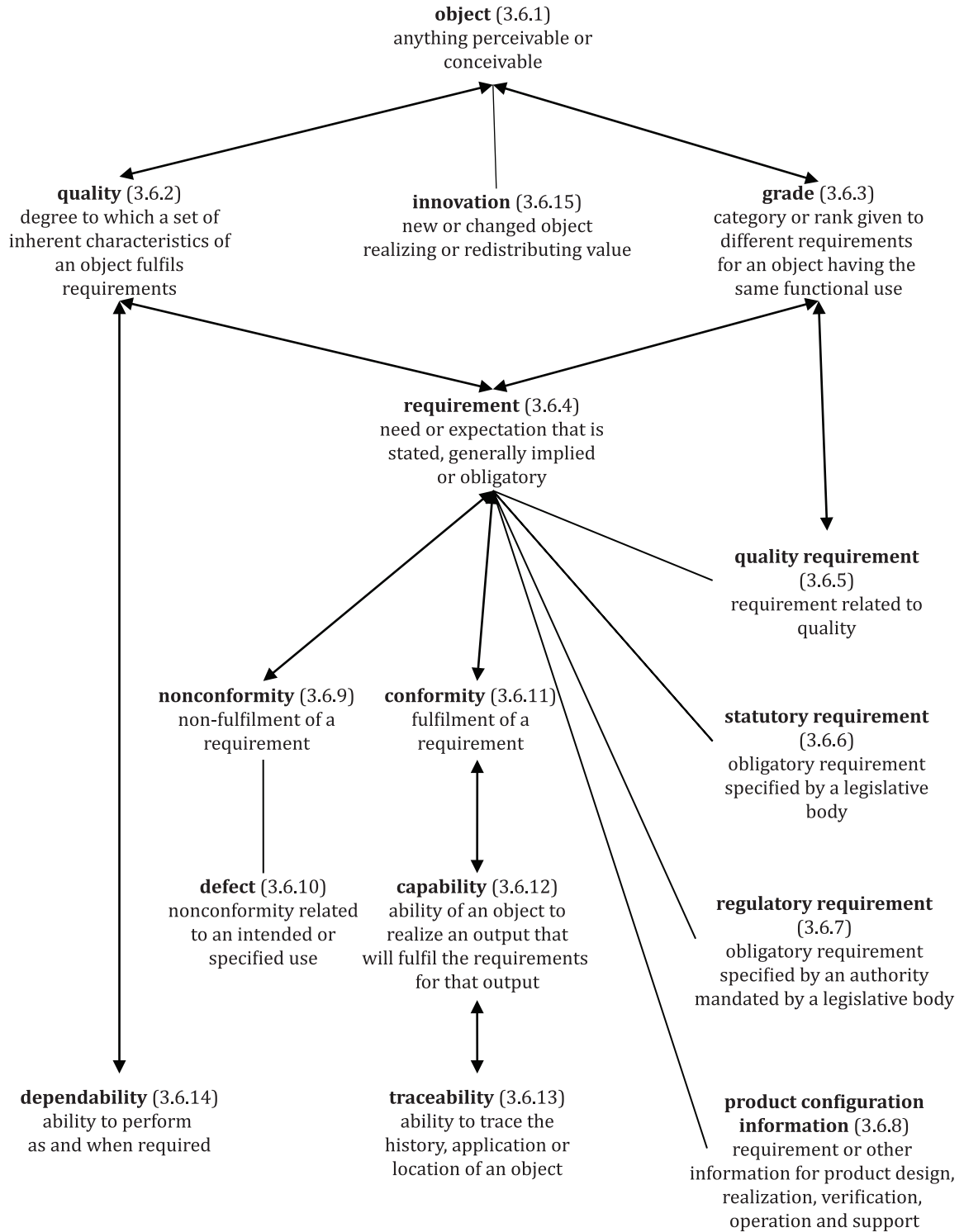


Figure A.9 — 3.6 Concepts of the class “requirement” and related concepts

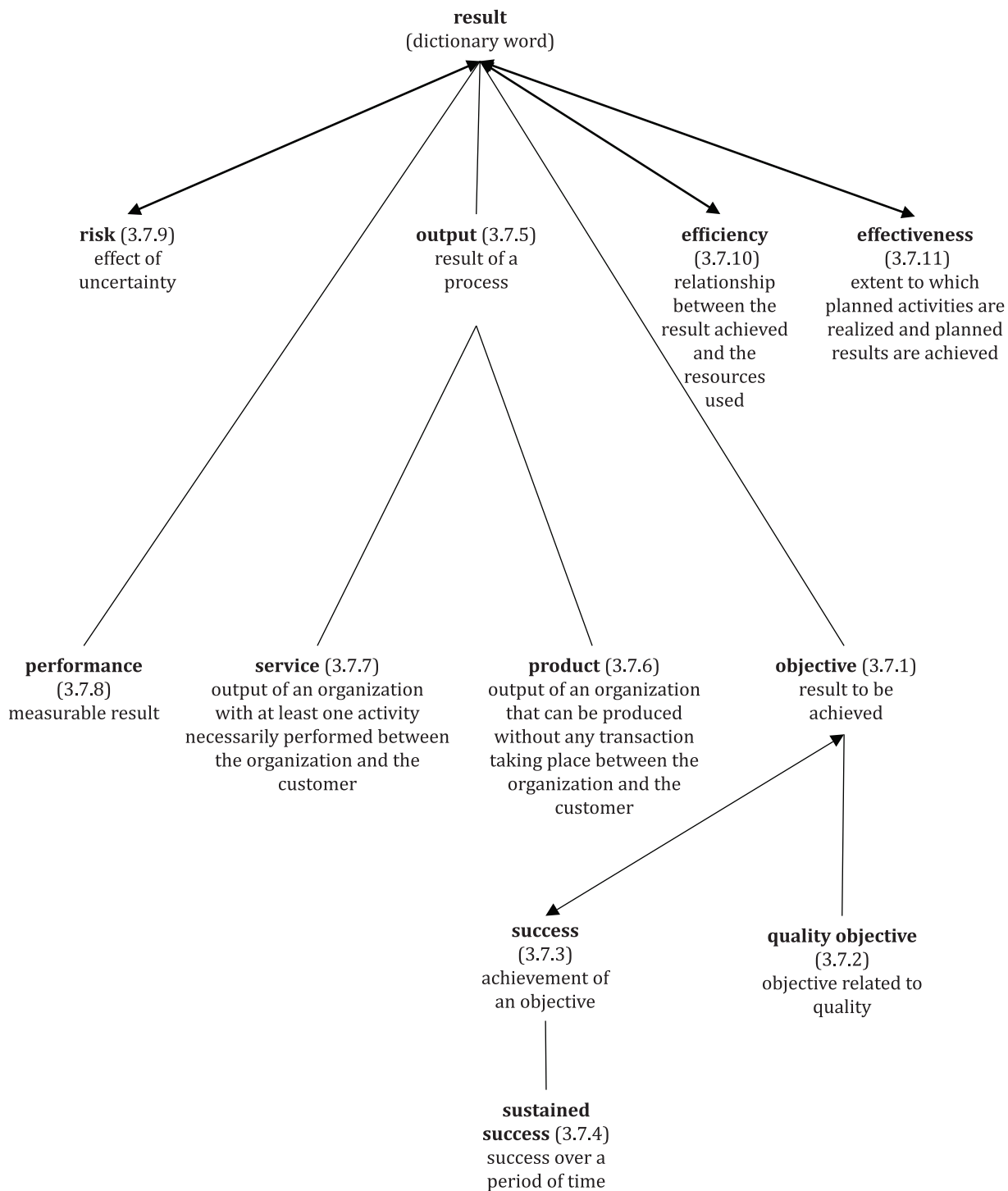


Figure A.10 — 3.7 Concepts of the class “result” and related concepts

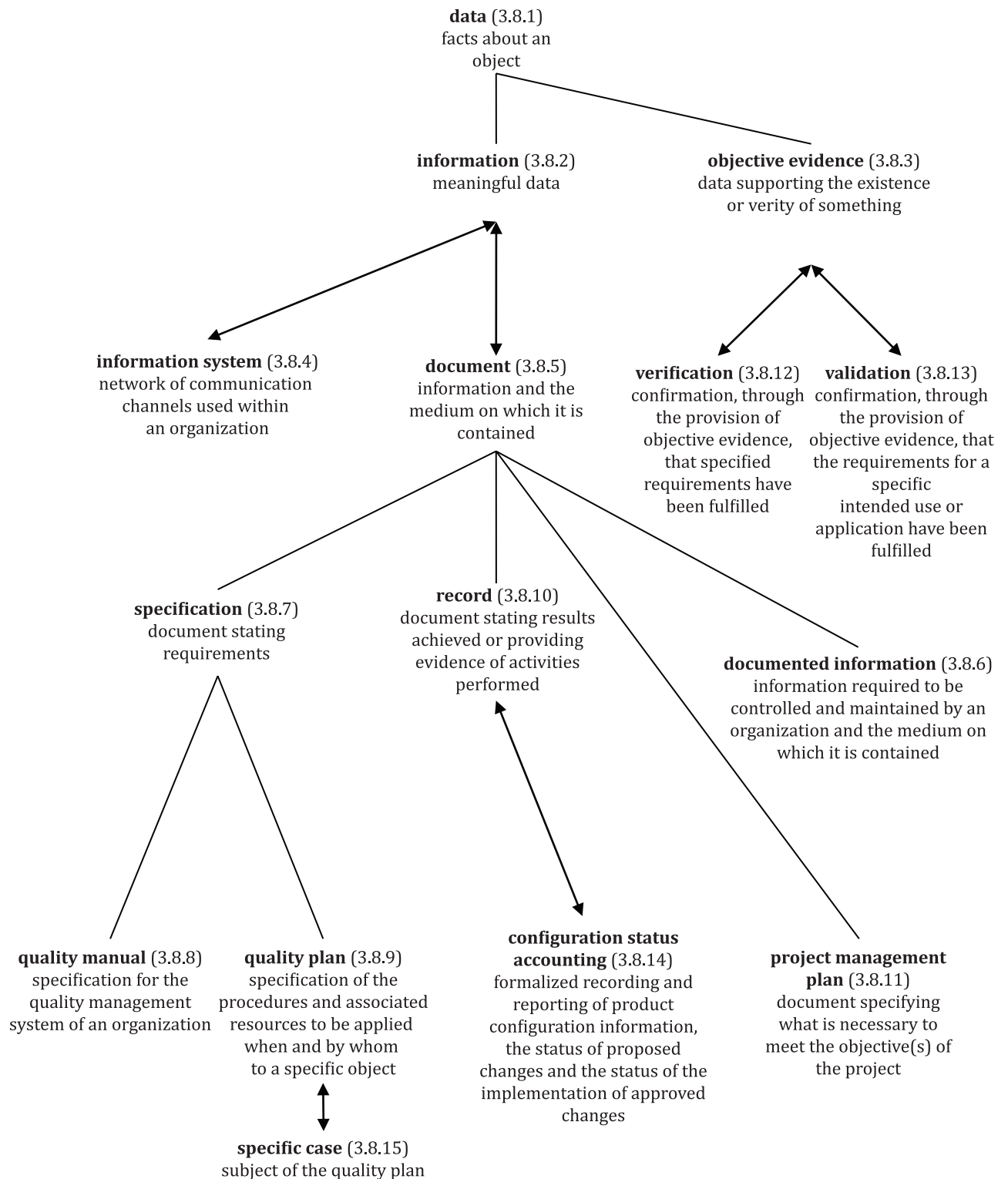


Figure A.11 — 3.8 Concepts of the class “data, information and document” and related concepts

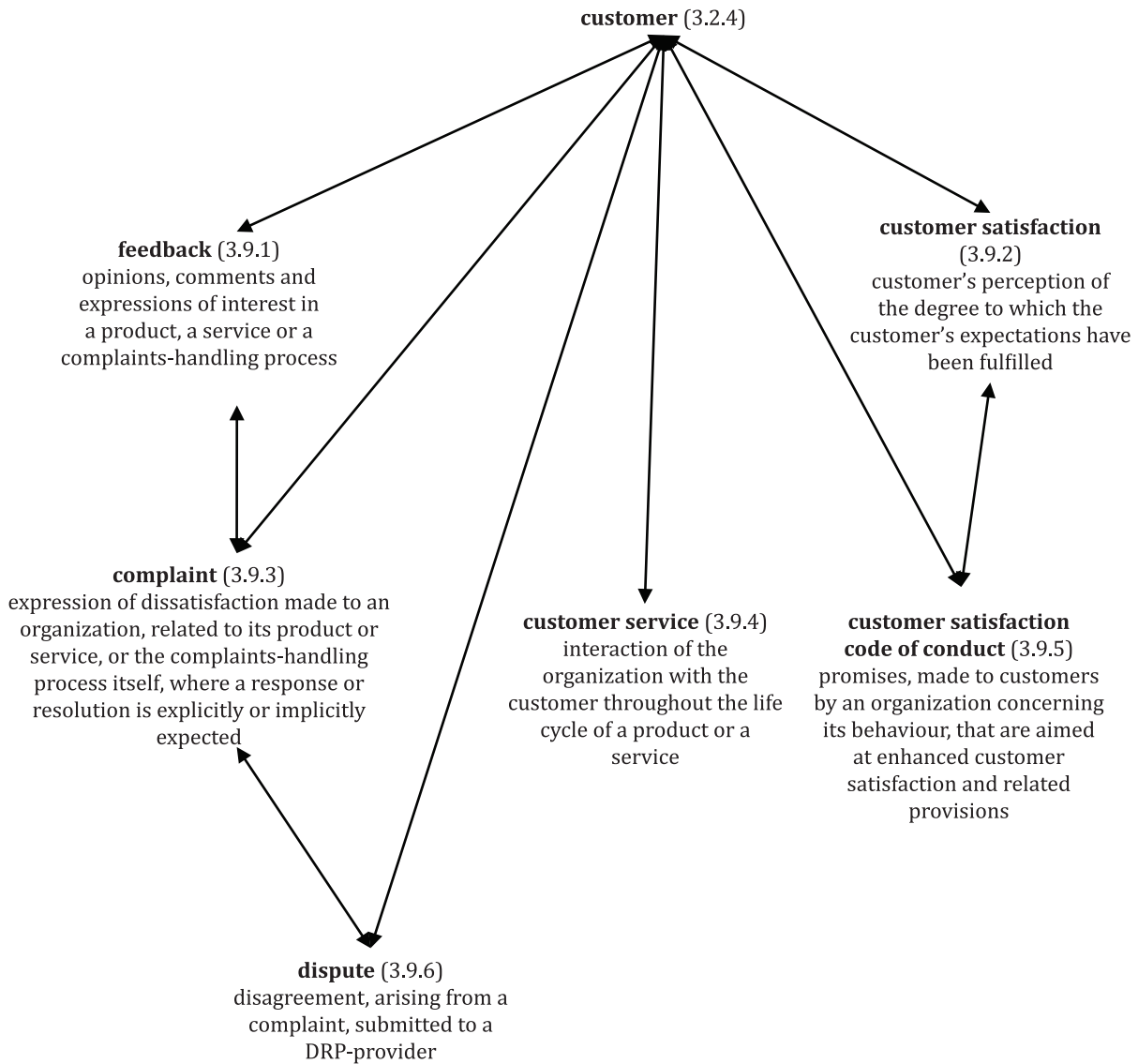


Figure A.12 — 3.9 Concepts of the class “customer” and related concepts

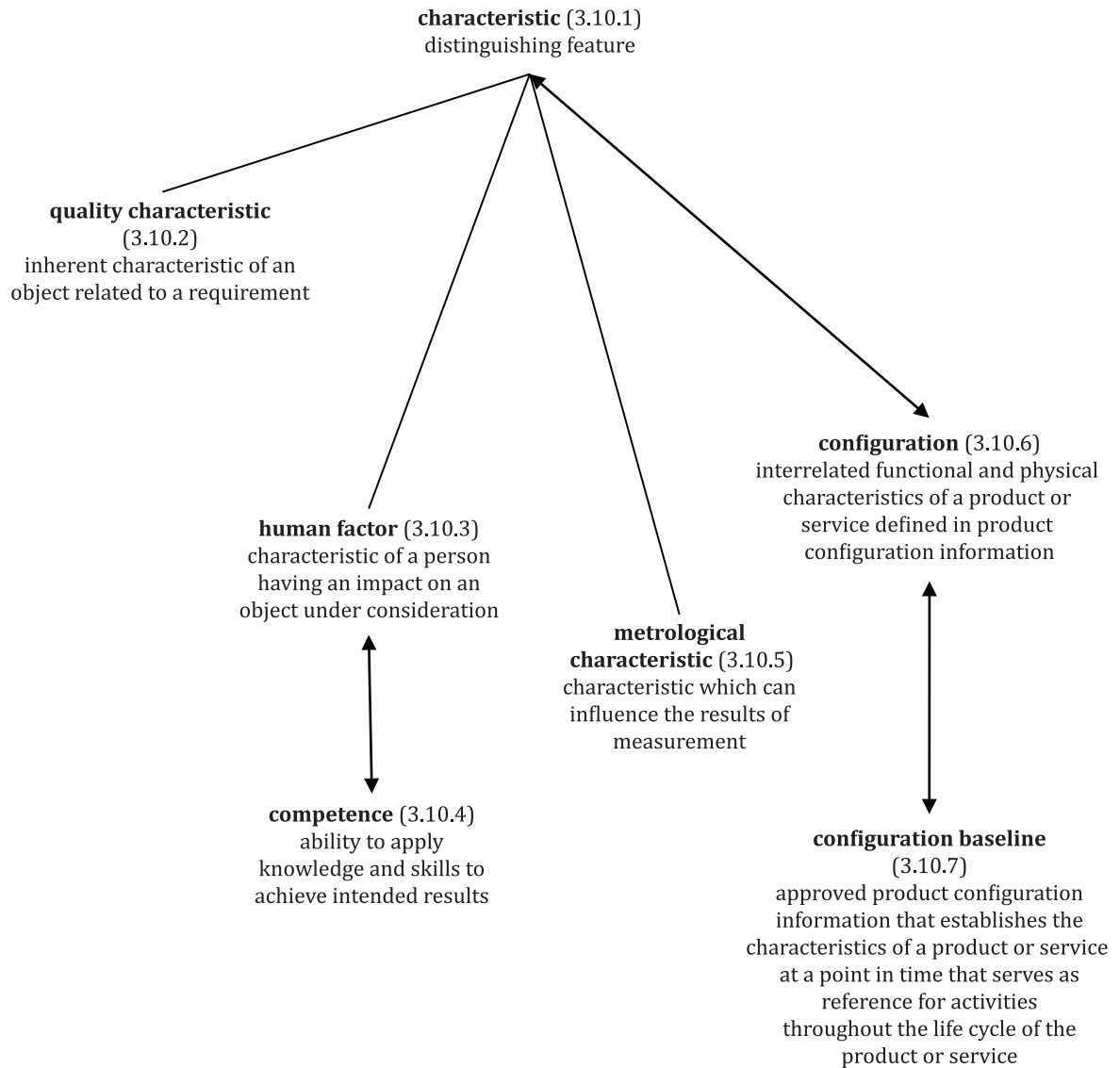


Figure A.13 — 3.10 Concepts of the class “characteristic” and related concepts

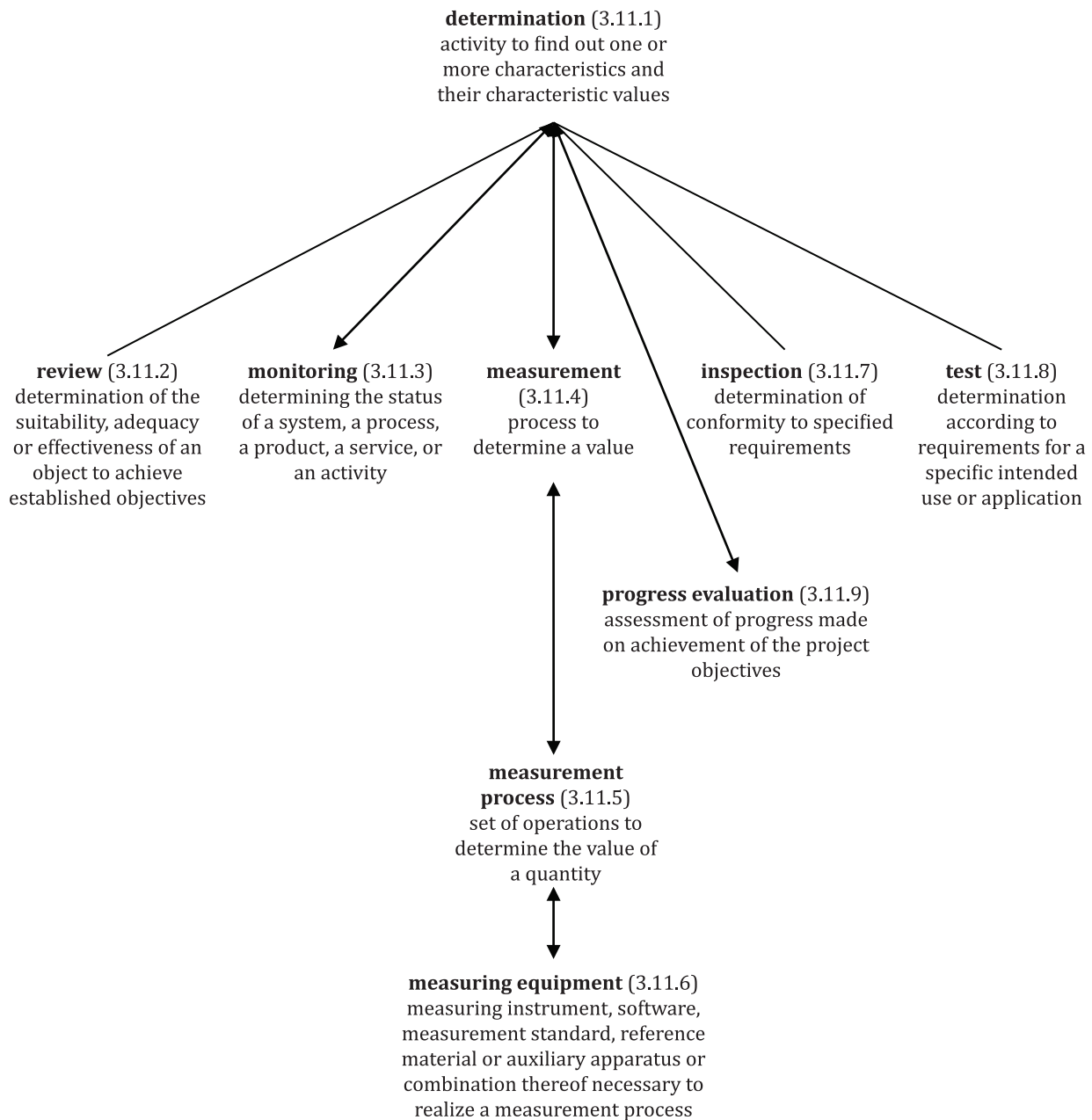


Figure A.14 — 3.11 Concepts of the class “determination” and related concepts

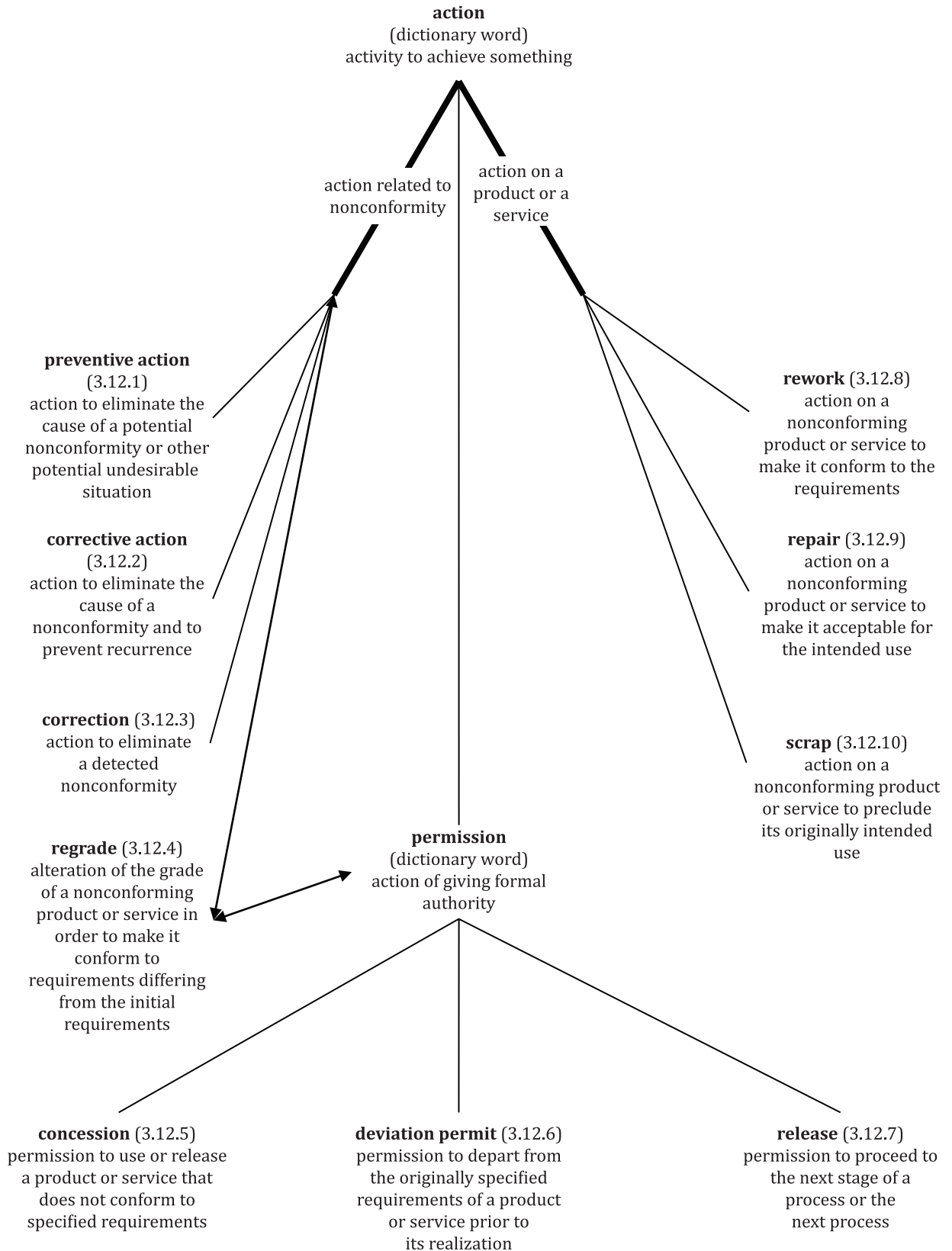


Figure A.15 — 3.12 Concepts of the class “action” and related concepts

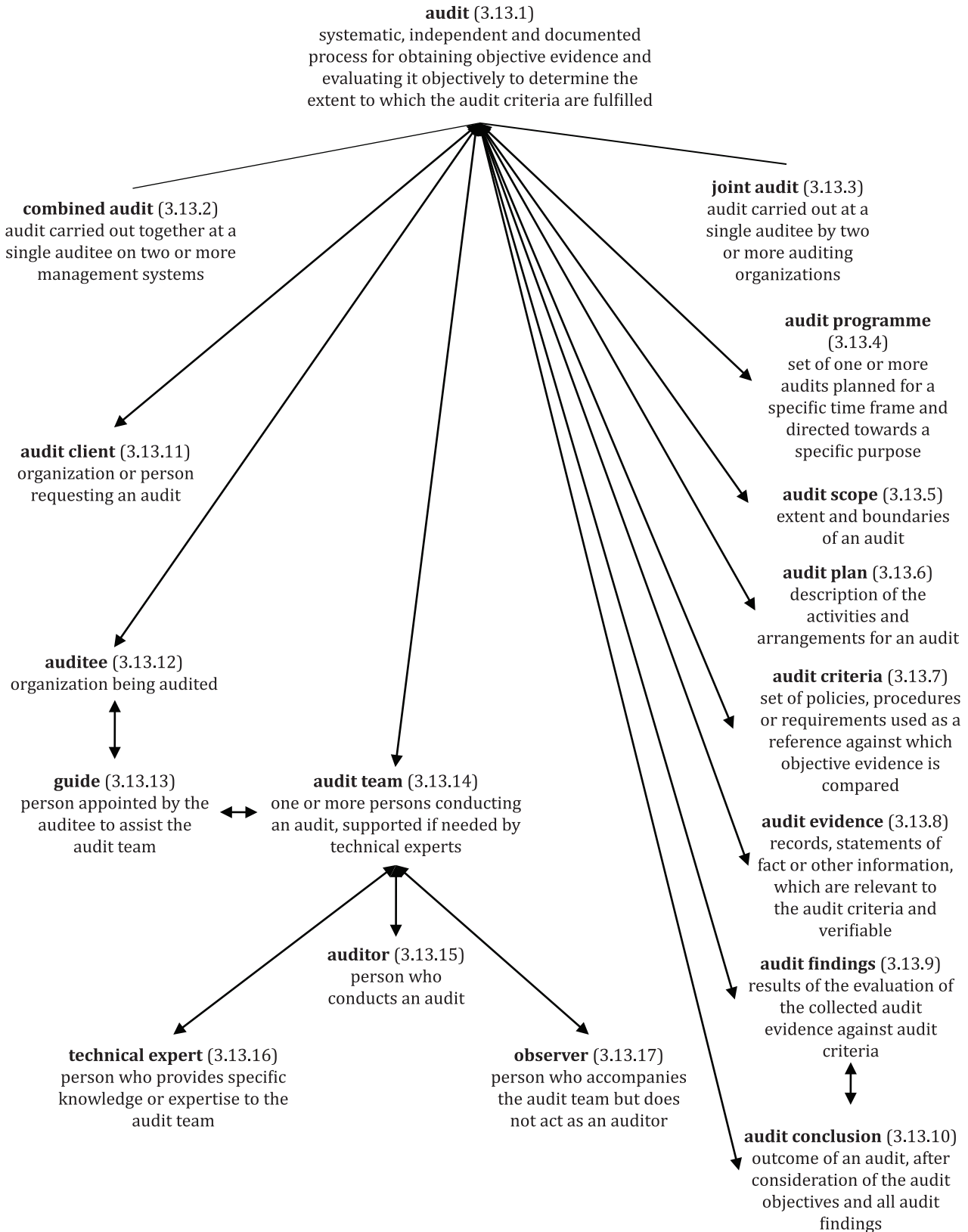


Figure A.16 — 3.13 Concepts of the class “audit” and related concepts

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