'General / Definitions' Refer to / taken from Integrated Quality Management System Framework

This item addresses the differences between the general quality management system (QMS) requirements in the European Union and the U.S. regarding the regulation of drug-device combination products

A. Definition Drug-Device Combination Product (DDC)

1. EU Requirements

- **EU MDR 2017/745**:
  a medical device (part) that falls under the second subparagraph of Article 1 (8) and Article 1 (9).

- **EMA Guideline on Quality Requirements for Medicinal Products used with a Medical Device** (EMA/CHMP/QWP/BWP/259165/2019, Section 1. Introduction, under "Integral" configuration):

  "Single Integral: 2. Devices intended to administer a medicinal product, where the device and the medicinal product are placed on the market in such a way that they form a single integral product intended exclusively for use in the given combination and which is not reusable (second sub-paragraph of Article 1(9)).Typically, these devices have measuring or delivery functions."

2. US Requirements

- **US 21 CFR 3.2(e)**:
  Single entity

Similarities or Differences

1. Similarities:

Definitions are similar, in the way that both refer to DDC that are produced to form a single integral product, placed as such on the market, and intended exclusively for use in the given combination.

2. Differences:

There are some regulatory differences:

- European regulation (MDR 2017/745) states that DDC with medicinal product being the principal mode of action falls under medicinal product directives 2001/83/EC. The Annex I of this Directive has been revised to include the requirements of Article 117 (see note) of MDR 2017/745 about the requirement to comply with GSPR of MDR 2017/745 (Annex I) only (see note 2).

- European regulations do also make distinction between integral and single integral, the latest referring to single use.

- For US, Single entity means *a product composed of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.*

Note: Article 117 does not apply in the case of combined advanced therapy medicinal products as defined under Article 2(1)(d) of Regulation (EC) No 1394/2007.
Note 2: GSPR is General Safety and Performance Requirements of the MDR.

B. DDC classification (As per device regulation

A. EU Requirements

EMA Questions & Answers (June 2021) on Implementation of the Medical Devices and In Vitro Diagnostic Medical Devices

- Regulations ((EU) 2017/745 and (EU) 2017/746) – Question & Answer 2.3 "*How will the MDR and in particular Article 117 impact marketing authorization applications?*"
- EU MDR 2017/745 – Article 51 & Annex VIII Classification rules

B. US Requirements

- **Classification** via description and intended use and matching definition in **21 CFR 862-892**

Similarities or differences

Please note that in EU classifications of the device part applies indirectly: There are mentioned for Single Integral DDC products in EMA Q&A (Rev. June 2021). EMA Guideline on DDC refers to this Q&A document in its section 5.4 Module 3.2.R., Regional Information, Medical Device, specifying therefore that in accordance with Article 117 of the MDR, all applications for an integral medicinal product should include evidence of the conformity of the device (part) with the relevant GSPRs set out in Annex I of Regulation (EU) 2017/745.

Similarities:
Device classification in the European regulation (MDR 2017/745) is similar to that of the US Quality Management System Regulation (QMSR) as both processes are based on risk to user and patients

Differences:
The classifications are also different between EU and US:

- **EU MDR** divided Device into four classes: I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. There are also three sub-classes under class I:
  Class Is: It's a class I product that is delivered sterile
  Class Im: It's a product with a measuring function
  Class Ir: New sub-class for products that are reprocessed.

- **In the U.S.**, medical devices are in 3 classes either Class I, Class II, or Class III. The FDA CDRH classification is based primarily on risk the medical device poses.

The preferred steps you can take to address these differences

- Map Out Classifications: Create a detailed mapping of your products under both EU MDR and US FDA classifications. This will help you understand how a device classified as Class IIb in the EU, for instance, aligns with a Class II or III in the US.

- Harmonize Quality Management Systems: Aim to harmonize your quality management system to meet both sets of requirements. This might involve adopting standards like ISO 13485. **The revision of the 21 CFR Part 820 mandatory per 2 February 2026 facilitates QMS-harmonization.**

C. QMS framework

1. EU Requirements

- **EMA Guideline on Quality Requirements**

EMA has stated clearly in its section 3 "Legal references, Application of Standards and Guidelines", that all other relevant directives and regulations forming part of the pharmaceutical *acquis*, the European Pharmacopeia and all relevant European Commission, ICH and CHMP guidelines, Q&A documents and other documents as linked to, or published on, the European Medicines Agency (EMA) website should be read in conjunction with Directives and Regulations already cited in this QMS comparison document.

Therefore ICH Q10 " *Pharmaceutical Quality System*" should be considered for developing and marketing single integral DDC in Europe. How to adapt it to DDC is not described yet.

2. US Requirements

- **21 CFR PART 4 Regulation of Combinations product part A**
- **21 CFR Part 210 and 211 (drug) and 21 CFR Part 820 (device) cGMPs**
- **21 CFR Part 600 cGMPS for Biologics**

Similarities or Differences

1. Similarities:

Using ICH Q10, industry can demonstrate an effective pharmaceutical quality system to enhance the quality and availability of medicines for both EU and US in the interest of public health.

- **EU Requirements**

In EU, single integral DDC are regulated under the medicinal product Directive 2001/83/EC and its QMS framework set forth in the EU GMP Guide, which is aligned on ICH Q10 Guideline.

- **US Requirements**

In US, 21 CFR Part 4 clarifies the application of current good manufacturing practice regulations to combination products, and provides a regulatory framework for designing and implementing the current good manufacturing practice operating system at facilities that manufacture co-packaged or single-entity combination products.

2. Differences

- **In EU**, without clarifying how to adapt the Pharmaceutical Quality System (PQS), the Pharma Company should produce evidence to demonstrate compliance with General Safety & Performance Requirements Annex I EU MDR 2017/745 (GSPR). All these activities and data remain under the oversight of EMA or national authority competent for medicinal products, and therefore cGMP rules do apply. This is also true for other key QMS elements not included in MDR Annex I, such as clinical data and evaluation requirements, post-market surveillance requirements and assessment of device part change type.

- **In US** the drug combination product needs compliance to 21 CFR Part 210 and 211 (drug) and 21 CFR Part 820 (device) cGMPs. In addition, for a

combination product that includes a biological product, the manufacturer must demonstrate compliance with the cGMP requirements specific to biological products in parts 600 through 680 (21 CFR parts 600 through 680).

21 CFR part 4 greatly clarified which elements of all applicable regulations must be included for drug-device single entity. Most of the Pharma companies chose the integrated approach, i.e., PQS plus additional chapters from 21CFR Part 820.

The preferred steps you can take to address these differences:

- Harmonize PQS: Align your PQS to address both EU and US requirements, ensuring a unified approach to quality management.
- Regular Audits: Conduct regular audits to ensure that both systems are compliant with the respective regulations.
- Maintain clear and comprehensive documentation to demonstrate compliance with both regulatory frameworks. This includes technical files, risk management reports, and clinical evaluations.
- Reporting: Develop standardized reporting procedures to streamline compliance efforts across both regions.

D. Harmonized Definitions

The Importance of Harmonized Definitions in Implementing Quality Management System (QMS) Regulation:

1. **Consistency**: Harmonized definitions ensure that all stakeholders within the QMS interpret terms and requirements uniformly. This consistency is vital for maintaining standardization across various departments, teams, and inter-organizational collaborations.
2. **Regulatory Compliance:** Utilizing standardized definitions, in addition to the regularly required ones, facilitates adherence to regulatory requirements. This is particularly significant in the medical device sector, where compliance with ISO 13485:2016 and ISO 14971:2019 is often essential for market authorization and regulatory approval.
3. **Operational Efficiency**: Harmonized definitions streamline internal and external communication and documentation processes. When consistent terminology is employed, it minimizes ambiguities and errors, thereby enhancing operational efficiency and effectiveness.
4. **Global Regulatory Recognition**: ISO 13485:2016 and ISO 9001:2015 are

globally recognized standards. Employing harmonized definitions ensures that the QMS is acknowledged and accepted worldwide, thereby easing international regulatory compliance and market access.

5. **Risk Management**: Clear and consistent definitions are crucial for effective risk identification, assessment, and management. This is essential for ensuring the safety, efficacy, and regulatory compliance of medical devices.

Below text lists the definitions of the ISO 13485:2016, ISO 9000:2015 and 21 CFR 820 QMSR.
ISO 13485:2016: This standard specifies requirements for a QMS where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
ISO 9000:2015: This standard provides the fundamental concepts, principles, and vocabulary used in the entire ISO 9000 series, helping ensure that organizations speak the same quality language.
21 CFR Part 820 QMSR: Part of the U.S. Code of Federal Regulations, it outlines the QMS requirements for medical device manufacturers to ensure that their products are safe, effective, and meet regulatory requirements.

The ISO 13485:2016 terms and definitions incorporated in the QMSR

3.1 advisory notice:
Notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:

- use of a medical device,
- modification of a medical device,
- return of the medical device to the organization that supplied it, or
- destruction of a medical device

Note 1 to entry: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.

3.2 authorized representative:
Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.
[SOURCE: GHTF/SG1/N055:2009,5.2]

3.3 clinical evaluation:
Assessment and analysis of clinical data pertaining to a medical device to verify the

clinical safety and performance of the device when used as intended by the manufacturer.
[SOURCE: GHTF/SG5/N4:2010, Clause 4]

3.4 complaint:
Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.
Note 1 to entry: This definition of "complaint" differs from the definition given in ISO 9000:2015.

3.5 distributor:
Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Note 1 to entry: More than one distributor may be involved in the supply chain.
Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.
[SOURCE: GHTF/SG1/N055:2009, 5.3]

3.6 implantable medical device:

- *Implantable medical device shall have the meaning of "implant" as defined in section 860.3 of this chapter:*
  21 CFR Part 860.3: Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health.

3.7 importer:
Natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.
[SOURCE: GHTF/SG1/N055:2009, 5.4]

3.8 labeling:
Label, instructions for use, and any other information that is related to the identification, technical description, intended purpose and proper use of the medical device, but excluding shipment documents.
[SOURCE: GHTF:SG1/N70:2011, Clause 4

3.9 life-cycle:

All phases in the life of a medical device, from the initial conception to final decommissioning and disposal.
[SOURCE: ISO 14971:2007, 2.7]

3.10 manufacturer:
The ISO definition of manufacturer is replaced with the following definition:
Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

3.11 medical device:
Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an
- injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means
Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: GHTF/SG1/NO71:2012,5.1]

3.12 medical device family:
Group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.

3.13 performance evaluation:
Assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use.

3.14 post market surveillance:
systematic process to collect and analyze experience gained from medical devices that have been placed on the market.

3.15 Product:
Result of a process
Note 1 to entry: 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. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver’s manual), and service (e.g. operation explanation given by the sales man).

Note 2 to entry: Service is the result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible. Provision of 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.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.
Note 3 to entry: This definition of "product" differs from the definition given in ISO 9000:2015.
[SOURCE: ISO 9000:2015, 3.4.2 MODIFIED]

3.16 purchased product:
Product provided by a party outside the organization´s quality management system

3.17 risk:
Combination of the probability of occurrence of harm and the severity of that harm
Note 1 to entry: This definition of "Risk" differs from the definition given in ISO 9000:2015
[SOURCE: ISO 14971:2007, 2.16]

3.18 risk management:
Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk
[SOURCE: ISO 14971:2007, 2.22]

3.19 sterile barrier system:
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use
[SOURCE: ISO 11607-1:2006, 3.2.2]

3.20 sterile medical device
Medical device intended to meet the requirements for sterility.
Note 1 to entry: The requirements for sterility of a medical device can be subject to applicable regulatory requirements of standards.

The terms and definitions in clause 3 of ISO 9000:2015:

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.

- *Organization shall have the meaning of "manufacturer" as defined in the QSMR.*

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 behavior 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 (to outsource):
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 (D&D):
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 D&D 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 D&D. The requirements are generally defined in terms of characteristics (3.10.1). In a project (3.4.2) there can be several D&D 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 D&D.
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) D&D, service (3.7.7) D&D or process D&D).

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 labeling.
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. tires). 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 program, 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.
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.
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 D&D (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 behavior, 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. behavioral (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, - (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.

- *Per QMSR, "rework" means action taken on a nonconforming product so that it will fulfil the specified requirements in the medical device file (MDF) before it is released for distribution.*

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 program:
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]

21 CFR Part 820 (a)

(a) The following terms, which are either not used or not defined in ISO 13485 or in Clause 3 of ISO 9000, also apply for the purposes of this part:

Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled device.

Federal Food, Drug, and Cosmetic Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.,* as amended.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a

device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) of this chapter and that is also regulated as a device.

Remanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

21 CFR Part 820.3 (b)

(b) All definitions in section 201 of the Federal Food, Drug, and Cosmetic Act shall apply to the regulation of quality management systems under this part and shall supersede the correlating terms and definitions in ISO 13485 (*e.g.*, the definitions of device and labeling in section 201(h) and (m) of the Federal Food, Drug, and Cosmetic Act apply to this part and supersede the definitions for the correlating terms in ISO 13485 (labeling and medical device)).

In addition, the following terms and definitions apply to this part and supersede the definitions for the correlating terms in ISO 13485 or ISO 9000:

Implantable medical device shall have the meaning of "implant" as defined in section 860.3 of this chapter:
Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health.

Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Organization shall have the meaning of "manufacturer" as defined in this part.

Rework means action taken on a nonconforming product so that it will fulfil the specified requirements in the medical device file (MDF) before it is released for distribution.

Safety and Performance shall have the meaning of "safety and effectiveness" in Clause 0.1 of ISO 13485. The phrase "safety and performance" does not relieve a manufacturer from any obligation to implement controls or other measures that provide reasonable assurance of safety and effectiveness.