



BSI Standards Publication

**Railway applications — Railway quality
management system — ISO 9001:2015 and specific
requirements for application in the railway sector**

National foreword

This British Standard is the UK implementation of EN ISO 22163:2024+A1:2025. It is identical to ISO 22163:2023, incorporating amendment 1:2024. It supersedes BS ISO 22163:2023+A1:2024, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee RAE/1/-/17, Railway applications – Railway quality management system.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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31 March 2024	Implementation of ISO amendment 1:2024
28 February 2025	This corrigendum renumbers BS ISO 22163:2023+A1:2024 as BS EN ISO 22163:2024+A1:2025

English Version

**Railway applications - Railway quality management
system - ISO 9001:2015 and specific requirements for
application in the railway sector (ISO 22163:2023)**

Applications ferroviaires - Système de management de
la qualité ferroviaire - Exigences de l'ISO 9001:2015 et
exigences particulières concernant les applications
dans le secteur ferroviaire (ISO 22163:2023)

Bahnanwendungen - Eisenbahn-
Qualitätsmanagementsystem - ISO 9001:2015 und
spezifische Anforderungen für die Anwendung im
Bahnsektor (ISO 22163:2023)

This European Standard was approved by CEN on 5 May 2024.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of ISO 22163:2023 has been prepared by Technical Committee ISO/TC 269 "Railway applications" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22163:2024 by Technical Committee CEN/TC 256 "Railway applications" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

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

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According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 22163:2023 has been approved by CEN as EN ISO 22163:2024 without any modification.

European foreword to amendment A1

The text of ISO 22163:2023/Amd 1:2024 has been prepared by Technical Committee ISO/TC 269 "Railway applications" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22163:2024/A1:2025 by Technical Committee CEN/TC 256 "Railway applications" the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 22163:2024 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

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

This document was prepared by Technical Committee ISO/TC 269, *Railway applications*.

This first edition of ISO 22163 cancels and replaces ISO/TS 22163:2017.

The main changes are as follows:

- the scope has been simplified;
- the terms and definitions in [Clause 3](#) have been revised;
- the previous subclause 6.4 “Business planning” has been moved to [4.1.1](#);
- a new subclause [4.1.2](#) on “Social responsibility” has been added;
- subclause [7.2.1](#) “Competence — Supplemental” has been revised;
- the previous subclause 8.11 “Innovation management” has been moved to [8.1.1.1](#);
- “Project review management” has been separated from the previous subclause 8.1.3.7 “Project communications management” as a new subclause [8.1.3.11](#);
- the previous subclauses 8.1.4 “Configuration management” and 8.1.5 “Change management” have been combined in [8.1.4](#) “Configuration management and change control”;
- product safety requirements have been integrated in the quality requirements;
- reliability, availability, maintainability, safety and life cycle costing requirements have been clarified in [8.8](#);
- the notion of performance indicators versus key performance indicators has been added;

- the performance indicators have been revised;
- [Annex A](#) on “List of processes” has been added;
- [Annex B](#) on “Subordinate concept of requirements for products and services” has been added;
- [Annex C](#) on “Performance indicators” has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

The aim of this document is to develop and continually improve a railway quality management system to ensure product quality including safety in the global railway sector, in order to satisfy customer needs.

This document adds the supplemental railway sector specific requirements to ISO 9001:2015.

The content inside the boxed text of this document is ISO 9001:2015 text.

Whenever the ISO 9001:2015 text in this document refers to “quality management system”, this term is understood hereinafter as “railway quality management system”, not limited to quality, so that it encompasses all railway quality processes of the organization. Therefore, in the supplemental railway sector specific requirements, the term “railway quality management system” is used outside the boxed text.

Whenever the ISO 9001:2015 text refers to “this International Standard”, this applies to this document, including the text outside the boxes.

Whenever this document refers to clause numbers, it is to be understood that all the requirements under this clause including subclauses are to be considered.

Whenever this document refers to “safety”, the term is to be understood as “safety of products and services”, not to be confused with “occupational safety”.

Whenever this document requires a process, this process can be either

- defined within a single process,
- combined with another process or other processes, or
- split in several processes

according to the railway quality management system defined by the organization.

ISO 9001:2015, Quality management systems — Requirements

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

- a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- b) facilitating opportunities to enhance customer satisfaction;
- c) addressing risks and opportunities associated with its context and objectives;
- d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

- uniformity in the structure of different quality management systems;
- alignment of documentation to the clause structure of this International Standard;
- the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

0.2 Quality management principles

ISO 9001:2015, Quality management systems — Requirements

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

0.3 Process approach

0.3.1 General

ISO 9001:2015, Quality management systems — Requirements

0.3 Process approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in [4.4](#).

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

- understanding and consistency in meeting requirements;
- the consideration of processes in terms of added value;
- the achievement of effective process performance;
- improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

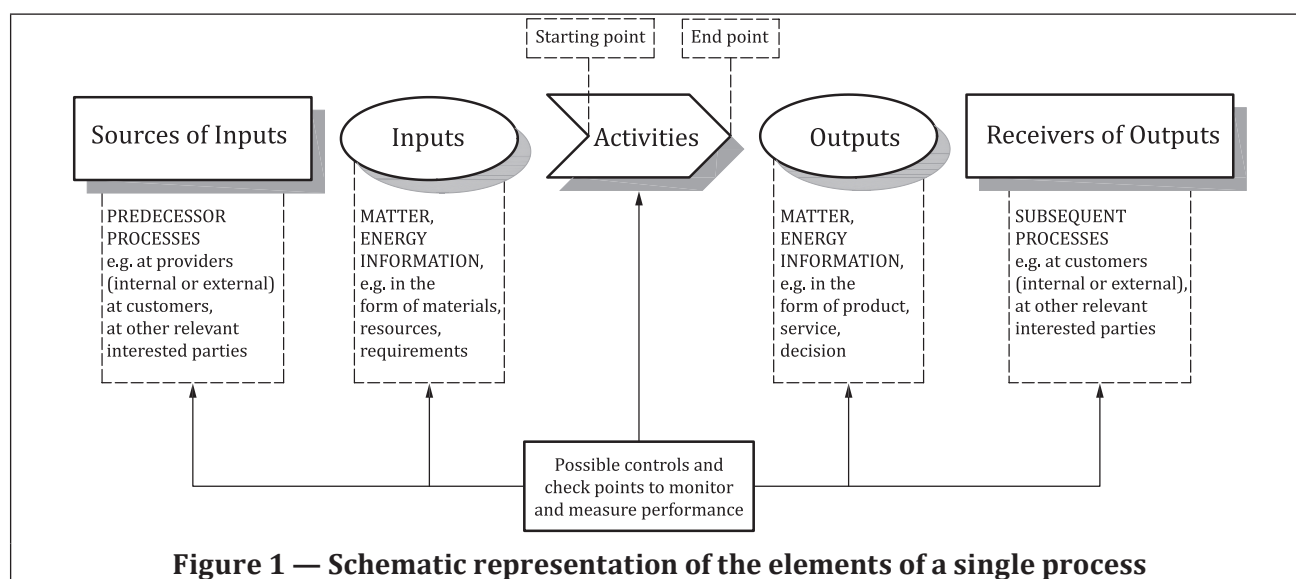


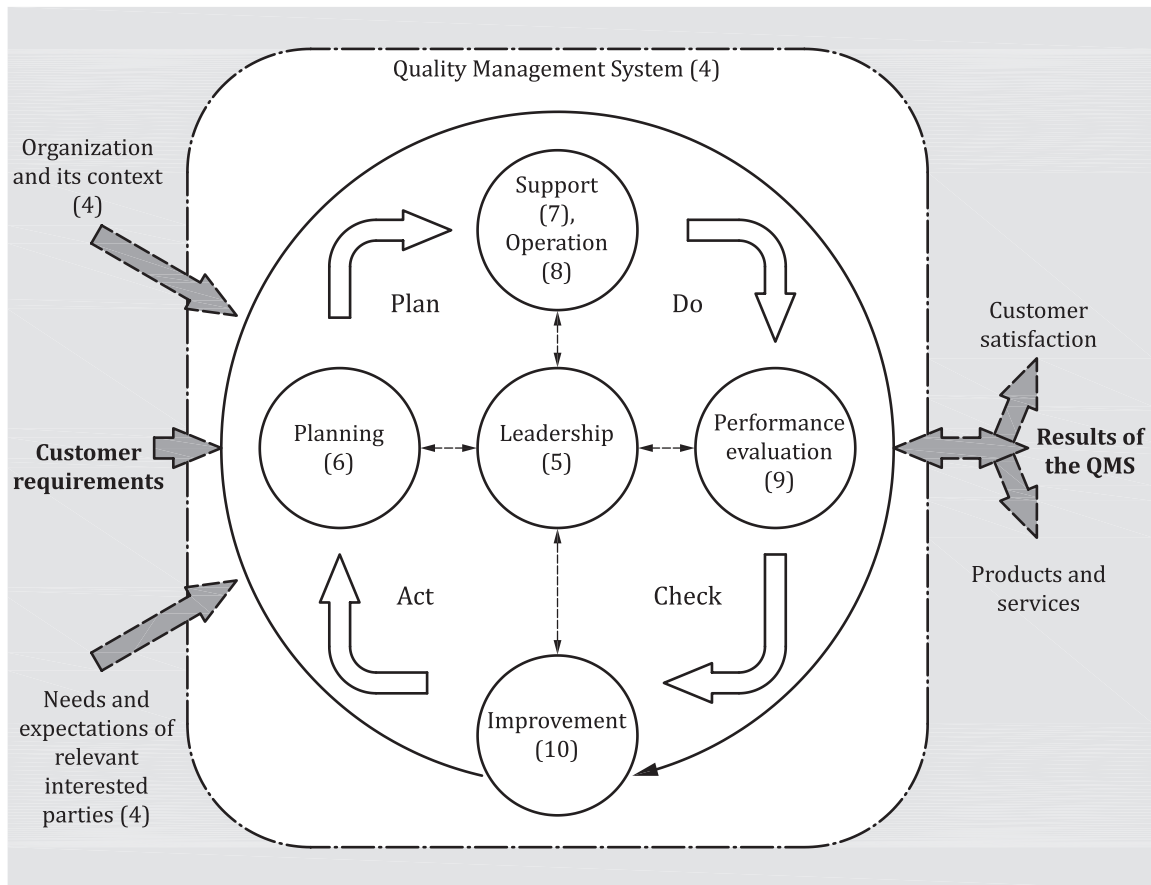
Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, Quality management systems — Requirements

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how [Clauses 4](#) to [10](#) can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

- **Plan:** establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;
- **Do:** implement what was planned;
- **Check:** monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;
- **Act:** take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

ISO 9001:2015, Quality management systems — Requirements

0.3.3 Risk-based thinking

Risk-based thinking is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

ISO 9001:2015, Quality management systems — Requirements

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems.

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

- ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this International Standard;
- ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access website at: <https://www.iso.org/tc176/sc02/public>.

Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector

1 Scope

ISO 9001:2015, Quality management systems — Requirements

1 Scope

This International Standard specifies requirements for a quality management system when an organization:

- a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms “product” or “service” only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

1.1 Scope — Supplemental

This document specifies the requirements for a railway quality management system (RQMS)

- applicable throughout the whole supply chain of the railway sector related to industrial products and services,
- providing continual improvement, emphasizing defect prevention and defect reduction in the supply chain, and
- enhancing and sustaining product quality, including its safety aspects.

2 Normative references

ISO 9001:2015, Quality management systems — Requirements

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms, definitions and abbreviated terms

ISO 9001:2015, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 Terms and definitions

3.1.1 System

3.1.1.1

business continuity

capability of an organization to continue the delivery of products and services within acceptable time frames at predefined capacity during a disruption

[SOURCE: ISO 22301:2019, 3.3]

3.1.1.2

business continuity plan

documented information that guides an organization to respond to a disruption and resume, recover and restore the delivery of products and services consistent with its business continuity objectives

[SOURCE: ISO 22301:2019, 3.4]

3.1.1.3

configuration audit

audit performed in accordance with documented information to determine whether a product or service conforms to its requirements and *configuration information* (3.1.1.5)

[SOURCE: ISO 10007:2017, 5.6]

3.1.1.4

configuration baseline

approved *configuration information* (3.1.1.5) that establishes the characteristics of a product or a service at a point in time that serves as reference for activities throughout the life cycle of the product or service

[SOURCE: ISO 10007:2017, 3.2]

3.1.1.5

configuration information

requirements for product or service design, realization, *verification* (3.1.3.12), operation and support

[SOURCE: ISO 10007:2017, 3.5]

3.1.1.6

configuration status accounting

formalized recording and reporting of *configuration information* (3.1.1.5), the status of proposed changes and the status of the implementation of approved changes

[SOURCE: ISO 10007:2017, 3.4]

3.1.1.7

critical

criticality

characteristic having the potential of introducing high risks that can threaten quality, safety or business performance, based on a risk assessment

3.1.1.8**information security**

preservation of confidentiality, integrity and availability of information

Note 1 to entry: In addition, other properties, such as authenticity, accountability, non-repudiation, and reliability can also be involved.

Note 2 to entry: Information security includes cybersecurity.

[SOURCE: ISO/IEC 27000:2018, 3.28, modified — Note 2 to entry has been added.]

3.1.1.9**multidisciplinary approach**

way of working involving different functions and expertise in one team on a specific subject

EXAMPLE Engineering, safety and procurement.

3.1.1.10**process owner**

person who has the responsibility for the definition, application, performance and improvement of a process in realizing its objectives measured by performance indicators, and has the authority and ability to make necessary changes

3.1.1.11**safety**

freedom from unacceptable risk of harm

[SOURCE: IEC 62278:2002, 3.35]

3.1.1.12**safety integrity level****SIL**

one of a number of defined discrete levels for specifying the safety integrity requirements of the safety functions to be allocated to the *safety* ([3.1.1.11](#)) related systems

[SOURCE: IEC 62278:2002, 3.38]

3.1.1.13**safety-related**

carries responsibility for *safety* ([3.1.1.11](#))

[SOURCE: IEC 62425:2007, 3.1.54]

3.1.1.14**site**

location of an organization, having activities related to industrial products and services

3.1.1.15**supply chain**

system of organizations, people, activities, information and resources involved in transforming materials and knowledge in a product or a service for the customer

3.1.2 Process**3.1.2.1****commissioning**

phase before *handover* ([3.1.2.8](#)) to a customer, in which a product is tested under operational conditions to verify that it functions according to its specifications

Note 1 to entry: The product is then prepared to start operation.

3.1.2.2

critical path

sequence of activities that determine the earliest possible completion date for the *project* ([3.1.2.18](#)) or phase

[SOURCE: ISO 21502:2020, 3.8]

3.1.2.3

deferred work

activity which is part of a predetermined sequence in a process that is delayed or postponed

3.1.2.4

first article inspection

FAI

set of inspection and *verification* ([3.1.3.12](#)) activities in order to validate a *production* ([3.1.2.16](#)) process

3.1.2.5

gate criteria

acceptance criteria for *deliverables* ([3.1.4.3](#)) at gates in order to support the decisions to be taken, e.g. accepted, conditionally accepted or rejected

3.1.2.6

gate methodology

project management practice to evaluate, at the end of each significant phase, the maturity of *deliverables* ([3.1.4.3](#)) for moving to the next phase, with the proper risk assessment and mitigation plan

Note 1 to entry: The transition between two phases is formalized by control milestones.

3.1.2.7

good practice

process or method that has been shown to work well, succeeds in achieving its objective(s), is acknowledged and therefore can be recommended as an approach

3.1.2.8

handover

passing control authority of the subject item from one organization to another, including transfer of responsibilities to the receiving organization

3.1.2.9

installation

phase after delivery at customer premises and prior to *commissioning* ([3.1.2.1](#))

Note 1 to entry: Installation is a typical phase of infrastructure activities.

3.1.2.10

life cycle cost

LCC

sum of the costs generated during the life cycle of the item

Note 1 to entry: For a user or an owner of an item, the total life cycle cost may include only those costs pertaining to acquisition, operation, *maintenance* ([3.1.2.12](#)) and disposal.

[SOURCE: EN 13306:2017, 11.1]

3.1.2.11

life cycle costing

process of evaluating the difference between the *life cycle cost* ([3.1.2.10](#)) of two or more alternative options

Note 1 to entry: Life cycle costing can involve quantitative and/or qualitative assessment.

[SOURCE: ISO 15663:2021, 3.1.27]

3.1.2.12 maintenance

combination of all technical and management actions intended to retain an item in, or restore it to a state in which it can perform as required

Note 1 to entry: Management is assumed to include supervision activities.

[SOURCE: IEC 60050-192:2015, 192-06-01]

3.1.2.13 new technology

set of techniques which offer a significant improvement over the established techniques for the development and *production* (3.1.2.16) of products and services which have never been part of the controlled activities of the organization, and which can be beyond the state of art

Note 1 to entry: The inputs are generally originated from research or innovation activities.

Note 2 to entry: A new technology can be linked to a complete system, e.g. brakes, HVAC, electronics.

3.1.2.14 overhaul

comprehensive set of *preventive maintenance* (3.1.2.15) actions carried out, in order to maintain the required level of performance of an item

Note 1 to entry: Overhaul may be performed at prescribed intervals of time or number of operations.

Note 2 to entry: Overhaul may require a complete or partial dismantling of the item.

[SOURCE: EN 13306:2017, 8.6]

3.1.2.15 preventive maintenance

maintenance (3.1.2.12) carried out to mitigate degradation and reduce the probability of failure

[SOURCE: IEC 60050-192:2015, 192-06-05, modified — Note 1 to entry has been deleted.]

3.1.2.16 production

activities to realize products including *installation* (3.1.2.9), *commissioning* (3.1.2.1), *overhaul* (3.1.2.14) and repair

Note 1 to entry: Production is part of an organization's value chain.

3.1.2.17 product life cycle

time of the entire life cycle of a product from inception to design and manufacture, service, *maintenance* (3.1.2.12) and disposal

3.1.2.18 project

unique process undertaken to achieve an objective

Note 1 to entry: A project generally consists of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.

Note 2 to entry: An individual project can form part of a larger project structure and generally has a defined start and finish date.

Note 3 to entry: In some projects, the objectives and scope are updated and the product or service characteristics defined progressively as the project proceeds.

Note 4 to entry: The output of a project can be one or several units of product or service.

Note 5 to entry: The project's organization is normally temporary and established for the lifetime of the project.

Note 6 to entry: The complexity of the interactions among project activities is not necessarily related to the project size.

[SOURCE: ISO 10006:2017, 3.3]

3.1.2.19

project core team

people from different functions appointed to support the project manager in leading and controlling the *project* ([3.1.2.18](#))

3.1.2.20

project management

planning, organizing, monitoring, controlling and reporting of all aspects of a *project* ([3.1.2.18](#)), and the motivation of all those involved in it to achieve the project objectives

[SOURCE: ISO 10006:2017, 3.4]

3.1.2.21

project management plan

document specifying what is necessary to meet the objective(s) of the *project* ([3.1.2.18](#))

Note 1 to entry: A project management plan should include or refer to the project quality plan.

Note 2 to entry: The project management plan also includes or references other plans such as those relating to organizational structures, resources, schedule, budget, risk management, environmental management, health and *safety* ([3.1.1.11](#)) management and security management, as appropriate.

[SOURCE: ISO 10006:2017, 3.5]

3.1.2.22

project organization

temporary structure that includes project roles, responsibilities and levels of authority and boundaries that need to be defined and communicated to all interested parties of the *project* ([3.1.2.18](#))

[SOURCE: ISO 10006:2017, 3.6]

3.1.2.23

quality assurance method

method applied to qualify, verify or validate the implementation of requirements in order to focus on error prevention rather than on error detection

EXAMPLE Failure mode and effects analysis (FMEA), failure mode, effects and criticality analysis (FMECA), quality function deployment, design reviews, finite element analysis.

Note 1 to entry: Quality assurance method can be used, for example, in design and development.

3.1.2.24

quality deficiency cost

additional costs resulting from nonconforming products, services, processes or equipment

Note 1 to entry: Quality deficiency cost can be distinguished by causes (e.g. failures in tender-, design and development-, production-, purchasing-project management processes) and by phase of occurrence (e.g. tender, design, *production* ([3.1.2.16](#)), post-delivery).

Note 2 to entry: Quality deficiency cost can include:

- additional labour, material or other direct costs in the context of failures or changes due to incorrect design and the resulting actions taken (e.g. rework, redesign, repair, repurchase, special shipments);
- costs due to downtimes;
- costs of scrap;

- costs of products rendered unusable or oversupply of storage;
- costs due to accepted third-party claims and costs due to claims not asserted by the organization against third parties;
- costs due to penalties for default or delays.

EXAMPLE Some examples of quality deficiency cost include nonconformity cost, cost of non-quality, cost of poor quality, lost cost, compensation cost.

3.1.2.25

project quality plan

specification of the actions, responsibilities and associated resources to be applied to a specific *project* ([3.1.2.18](#))

[SOURCE: ISO 10005:2018, 3.2, modified — the term has been changed from “quality plan” to “project quality plan” and “object” has been changed to “project” in the definition.]

3.1.2.26

transfer

complete or partial *handover* ([3.1.2.8](#)) of processes to an internal site (multi-site organizations) or an external organization

3.1.3 Requirement

3.1.3.1

availability

ability of a product to be in a state to perform a required function under given conditions at a given instant of time or over a given time interval assuming that the required external resources are provided

[SOURCE: IEC 60050-821:2017, 821-05-82]

3.1.3.2

functional requirement

requirement that specifies a function that a product or a service performs

EXAMPLE Railway loading gauge, possibility to add a car in a metro vehicle.

Note 1 to entry: See [Annex B](#).

3.1.3.3

integration requirement

requirement of a product or service to describe how a constitutive system/subsystem/component interfaces with others, to perform an integrated function

EXAMPLE Weight, external dimension, kinematic envelope, power supply requirements, network (communication).

Note 1 to entry: See [Annex B](#).

3.1.3.4

maintainability

ability of an item under given conditions of use, to be retained in, or restored to, a state in which it can perform a required function, when *maintenance* ([3.1.2.12](#)) is performed under given conditions and using stated procedures and resources

Note 1 to entry: Given conditions include aspects that affect maintainability, such as: location for *maintenance* ([3.1.2.12](#)), accessibility, maintenance procedures and maintenance resources.

[SOURCE: EN 13306:2017, 4.5, modified — Note 1 to entry from IEC 60050-192:2015, 192-01-27 has been added.]

3.1.3.5

non-functional requirement

technical requirement that defines attributes serving as constraints or restrictions and ensuring the usability and effectiveness but not affecting the functionality of products and services

Note 1 to entry: As shown in [Annex B](#), non-functional requirements include:

- *performance requirements* ([3.1.3.8](#));
- *integration requirements* ([3.1.3.3](#));
- other non-functional requirements.

Note 2 to entry: Some examples of other non-functional requirements are:

- colour;
- corrosion control;
- electro-magnetic interference/electro-magnetic compatibility (EMI/EMC);
- noise;
- reliability, availability, maintainability, safety (RAMS);
- aluminium car body;
- labels;
- obsolescence;
- usability.

3.1.3.6

non-technical requirement

requirement affecting the delivery of the product or service

Note 1 to entry: See [Annex B](#).

EXAMPLE Warranty, payments, quality assurance, training, communication, time, commercial.

3.1.3.7

operational maturity

degree of fulfilment of the *technical requirements* ([3.1.3.10](#)) of a product or service

EXAMPLE 1 Not existing, under development, ready to use, in use.

EXAMPLE 2 Not fulfilling, partially fulfilling, fully fulfilling.

3.1.3.8

performance requirement

requirement that specifies the result that a product or a service reaches

Note 1 to entry: See [Annex B](#).

EXAMPLE Maximum speed, maximum acceleration.

3.1.3.9

reliability

ability to perform as required, without failure, for a given time interval, under given conditions

Note 1 to entry: The reliability of an item can be calculated from the observed failures of it or/and a set of comparable items during a given time interval.

Note 2 to entry: The forecasted reliability of an item expresses the level of confidence on it, estimated from the observed reliability of comparable items and the knowledge about its actual state.

Note 3 to entry: In some cases, a given number of unit of use can be considered instead of a given time interval (number of cycles, number of running hours, number of km, etc.).

Note 4 to entry: The given conditions may include *preventive maintenance* ([3.1.2.15](#)) actions and operational modes and conditions.

[SOURCE: IEC 60050-192:2015, 192-01-24, modified — Notes 1, 2, 3 and 4 to entry from EN 13306:2017, 4.1 have been added.]

3.1.3.10

technical requirement

requirement that defines the features of the product or service

Note 1 to entry: A technical requirement can be functional or non-functional.

Note 2 to entry: See [Annex B](#).

3.1.3.11

validation

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

[SOURCE: ISO 9000:2015, 3.8.13, modified — Notes 1, 2 and 3 to entry have been deleted.]

3.1.3.12

verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled [SOURCE: ISO 9000:2015, 3.8.12, modified — Notes 1, 2 and 3 to entry have been deleted.]]

3.1.4 Product and tools

3.1.4.1

component

uniquely identifiable product that is considered indivisible for particular planning or control purpose and/or which cannot be disassembled without it being destroyed

Note 1 to entry: A component for one organizational group may be the final assembly of another group, e.g. an electric motor.

[SOURCE: EN 15380-2:2006, 3.11]

3.1.4.2

consignment stock

inventory owned by an external provider but held by the organization to ensure the *availability* ([3.1.3.1](#)) of parts

3.1.4.3

deliverable

output for the scope of supply to fulfil defined requirements

EXAMPLE Product, services, user manual, training manual, maintenance manual, test reports, test equipment, training, spare and support parts.

3.1.4.4

eight disciplines (of problem solving)

8D

team-oriented and systematic approach defining a sequence of steps to resolve problems in products, services and processes

Note 1 to entry: Its purpose is to identify, correct and eliminate recurring problems.

Note 2 to entry: The 8D problem solving model establishes a corrective action based on the analysis of the problem and focuses on the origin of the problem by determining its root causes.

Note 3 to entry: The 8D model can be reduced to four steps (4D).

3.1.4.5

failure reporting analysis and corrective action system

FRACAS

closed loop process used to improve dependability of current and future designs by feedback of testing, modification and use experience

[SOURCE: IEC 60050-192:2015, 192-12-04]

3.1.4.6

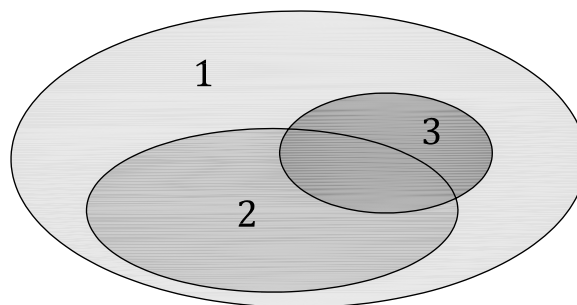
key performance indicator

KPI

performance indicator, selected by the top management, to evaluate the performance of the RQMS and its business objectives that is *critical* (3.1.1.7) to the sustained success of an organization

Note 1 to entry: A KPI can be a combination of several performance indicator (PIs).

Note 2 to entry: See [Figure 3](#).



Key

- 1 PI according to ISO 9001 (see 4.4.1)
- 2 PI according to supplemental ISO 22163 (see [9.1.1.1](#))
- 3 KPI according to supplemental ISO 22163 (see [5.3.1](#))

Figure 3 — Relation of PIs and KPIs

3.1.4.7

performance indicator

PI

indicator measuring the effective and/or efficient operation and control of a process but that is not limited to processes

Note 1 to entry: A performance indicator can be related to a single process or to multiple processes or any activity.

3.1.4.8

poka yoke

prevention method designed as a simple technique to prevent either anyone from making unplanned or unwanted changes to a system, or any errors from negatively impacting on a system

[SOURCE: ISO 13053-2:2011, 2.19]

3.1.4.9

production equipment

tool or device to make products and provide services

EXAMPLE Machineries, tools, jigs, fixtures, templates, textures, test benches, software production tools.

Note 1 to entry: Handcraft equipment (e.g. hammer, screwdrivers) is not considered as production equipment.

3.1.4.10**shelf life control**

technique aimed at ensuring that the inventory is not overaged or regarded as unserviceable for the purposes for which it was originally manufactured

EXAMPLE First-in-first-out (FIFO), monitoring of shelf life.

3.1.4.11**software tool**

computer programme that performs a set of functions to support the execution of a process

EXAMPLE Software programme, database, computerized spreadsheet, electronic file or web tool, bought from the market or developed by the organization.

3.2 Abbreviated terms

ATE	automated test equipment
EPPPS	externally provided processes, products and services
FAI	first article inspection
FMEA	failure mode and effects analysis
FMECA	failure mode, effects and criticality analysis
FRACAS	failure reporting analysis and corrective action system
KPI	key performance indicator
LCC	life cycle cost
LLRU	lowest line replaceable unit
OTD	on time delivery index
PI	performance indicator
RAM	reliability, availability, maintainability
RAMS	reliability, availability, maintainability, safety
RFT	right first time
RQMS	railway quality management system
SIL	safety integrity level
SMART	specific, measurable, achievable, relevant, time framed
SWOT	strengths weaknesses opportunities threats
8D	eight disciplines (of problem solving)

4 Context of the organization

4.1 Understanding the organization and its context

ISO 9001:2015, Quality management systems — Requirements

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

A1 The organization shall determine whether climate change is a relevant issue. **A1**

4.1.1 Understanding the organization and its context — Supplemental

4.1.1.1 When planning the strategic direction of an organization, business planning shall be considered to ensure sustainable product and service quality.

The organization shall document at least a summarized business plan and review it on a yearly basis.

NOTE 1 The organization can decide to exclude confidential information from the summarized business plan.

The business planning shall consider:

- a) business objectives;
- b) market strategy;
- c) product and service strategy, including development plans of new products and services, and/or processes, innovations and phase-out strategies;

NOTE 2 Research and development activities can be considered as part of innovation activities.

- d) outputs of management reviews (see [9.3.3](#));
- e) resource planning (see [7.1.1.1](#));
- f) risks and opportunities of the organization (see [6.1](#));

NOTE 3 SWOT analysis can be applied for managing risks in business planning.

- g) business continuity (see [6.1.4](#));
- h) needs and expectations of customers;
- i) inputs from interested parties (e.g. external providers);
- j) impact of changes in technologies and in statutory and regulatory requirements;
- k) organization capacity considering the forecast;
- l) merger, acquisition, outsourcing and transfer, if applicable.

4.1.1.2 This business planning should consider:

- a) change of external trends and interested parties' needs (e.g. economic policies, environmental protection, social or cultural issues, information security needs for products and services);
- b) the fiscal year calendar of the organization;
- c) an appropriate communication of business planning outputs;
- d) actions as output of business planning review.

4.1.2 Social responsibility

The organization should consider social responsibility principles.

NOTE Core subjects defined in ISO 26000 are organizational governance, human rights, labour practices, the environment, fair operating practices, consumer issues, community involvement and development.

4.2 Understanding the needs and expectations of interested parties

ISO 9001:2015, Quality management systems — Requirements

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

A1 NOTE Relevant interested parties can have requirements related to climate change. **A1**

4.3 Determining the scope of the quality management system

ISO 9001:2015, Quality management systems — Requirements

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

- a) the external and internal issues referred to in [4.1](#);
- b) the requirements of relevant interested parties referred to in [4.2](#);
- c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.3.1 Determining the scope of the quality management system — Supplemental

The organization shall also determine the boundaries and applicability of the specific requirements of the RQMS.

NOTE This additional requirement does not affect the flexibility of organizations. Activities, products, services and requirements that are linked to timely bounded organizational setups (e.g. multi-site, transfer of processes) can be put as not applicable.

4.4 Quality management system and its processes

ISO 9001:2015, Quality management systems — Requirements

4.4 Quality management system and its processes

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

- a) determine the inputs required and the outputs expected from these processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of [6.1](#);
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization shall:

- a) maintain documented information to support the operation of its processes;
- b) retain documented information to have confidence that the processes are being carried out as planned.

4.4.3 Quality management system and its processes — Supplemental

The documented information in 4.4.2 a) for the process description of mandatory and recommended processes (see [Annex A](#)) shall cover as a minimum the requirements described in 4.4.1 a) to 4.4.1 e).

NOTE 1 Processes can be documented in procedures, instructions, method descriptions, flowcharts or workflows etc. supported by software tool and templates.

NOTE 2 Processes can be covered by the organization according to their RQMS. They can be single, combined or split by the organizations, provided that all requirements of this document are fulfilled.

NOTE 3 Detailed requirements for performance evaluation of the processes are described in [9.1.1](#) and further explained in [Annex C](#).

The organization shall:

- a) document a hierarchical structure of its processes;
- b) communicate processes and process changes (see [7.4](#)) and ensure that people are aware of the processes;