INTERNATIONAL STANDARD

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

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

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Foreword

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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).

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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:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) 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.

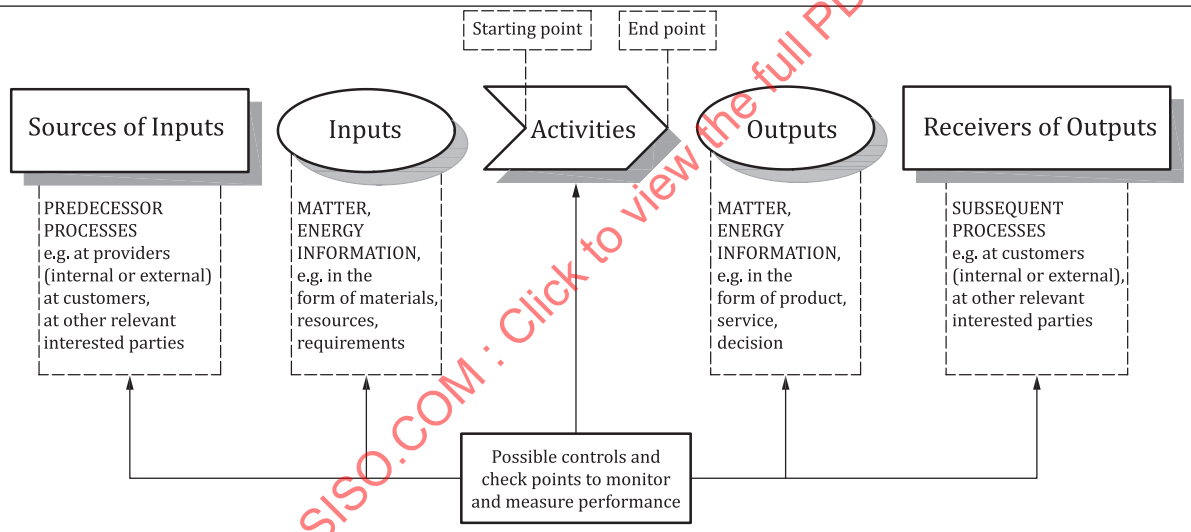


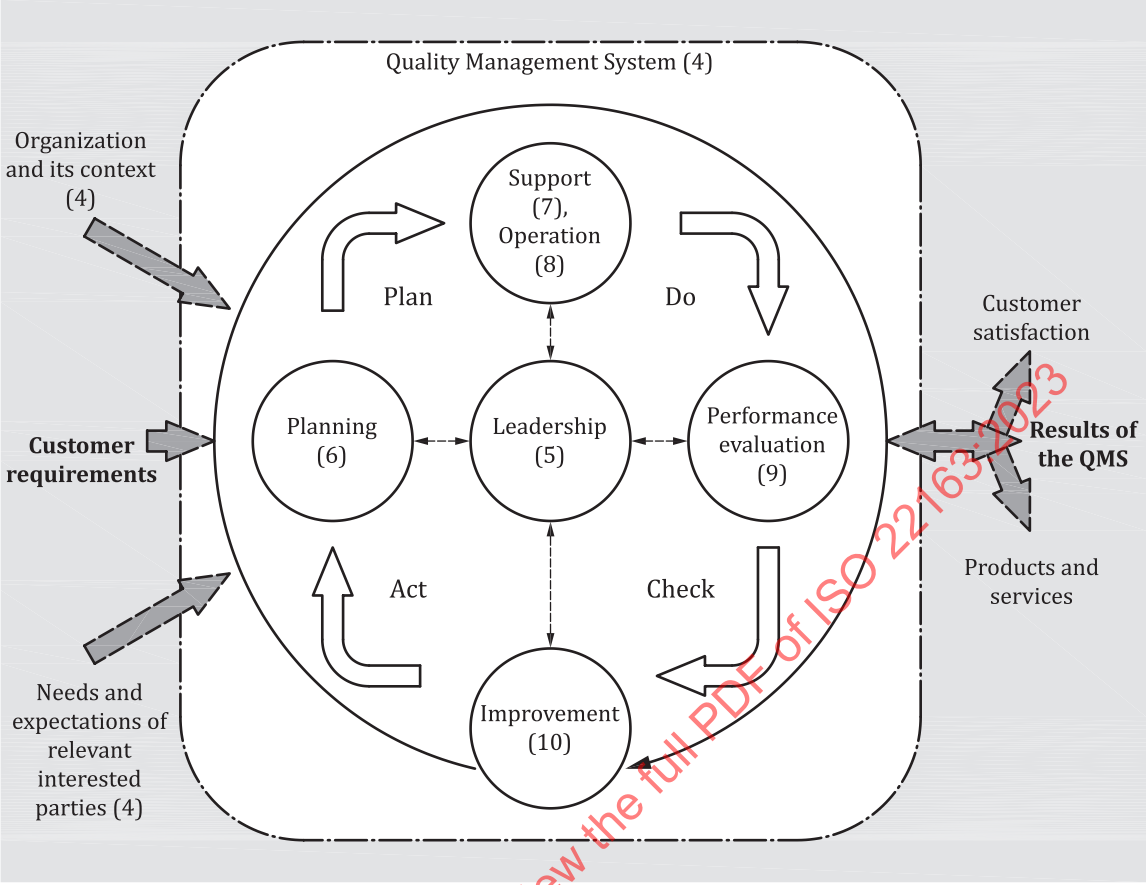
Figure 1 — Schematic representation of the elements of a single process

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).

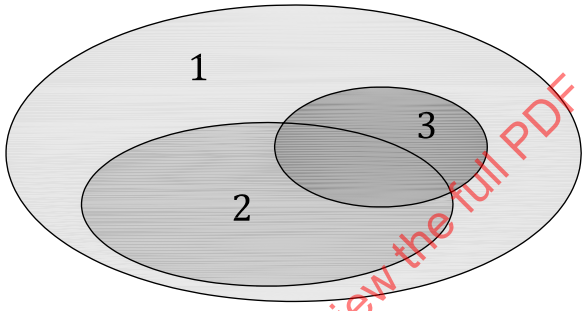
3.1.4.5
failure reporting analysis and corrective action system
FRACAS
closed loop process used to improve dependability of current and future designs by feedback of testing, modification and use experience

[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.

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.

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;

c) train people on processes by:

   1) defining criteria when training is needed;

   2) identifying people to be trained on processes;

   3) executing training;

   4) ensuring understanding of training content [see 7.2.1.1 d)];

d) ensure processes are applied and people adhere to processes (see 9.2);

e) ensure and maintain conformity of the RQMS and its processes to applicable standards;

   NOTE Statutory and regulatory requirements can apply.

f) define criteria, utilizing a risk-based methodology (e.g. FMEA, SWOT) to determine the type and extent of controls in its processes.

Implemented processes shall be verified against the applicable requirements of this document.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

ISO 9001:2015, Quality management systems — Requirements

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c) ensuring the integration of the quality management system requirements into the organization's business processes;

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the quality management system are available;

f) communicating the importance of effective quality management and of conforming to the quality management system requirements;

g) ensuring that the quality management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.2 Customer focus

ISO 9001:2015, Quality management systems — Requirements

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the quality policy

ISO 9001:2015, Quality management systems — Requirements

5.2 Policy

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

ISO 9001:2015, Quality management systems — Requirements

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.2.3 Quality policy — Supplemental

The quality policy shall address:

a) failure prevention;

b) customer expectations;

c) safety aspects.

NOTE 1 Safety in this document means safety of products and services.

NOTE 2 Quality and safety policies can be addressed separately.

NOTE 3 The quality policy forms a part of the overall corporate policy. For more information, see ISO 9004:2018, 7.2.

5.3 Organizational roles, responsibilities and authorities

ISO 9001:2015, Quality management systems — Requirements

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.3.1 Organizational roles, responsibilities and authorities — Supplemental

The top management shall:

a) define KPIs to enable steering and control of the RQMS (see Annex C);

b) appoint process owners [see 4.4.1 e)];

c) document and communicate updates of responsibilities and authorities for relevant roles (e.g. process ownership);

d) appoint representatives independent from the process execution and empower them to stop the process or production or service provision if quality, including safety requirements, are not met.

NOTE The required degree of independence of the representatives is proportionate to the size of the organization, e.g. small organizations.

The organization shall retain related documented information.

In case of delegation of tasks, this delegation should be defined and communicated.

5.3.2 Responsibilities and authorities of process owners

Process owners shall be responsible for the process conformity to requirements listed in 4.4 except availability of resources [see 4.4.1 d)].

This responsibility shall be defined and ensured by top management.

6 Planning

6.1 Actions to address risks and opportunities

ISO 9001:2015, Quality management systems — Requirements

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.1.3 Actions to address risks and opportunities — Supplemental

6.1.3.1 The organization shall establish, implement and maintain a risk and opportunity management process.

This process shall include:

a) the requirements described in 6.1.1 and 6.1.2;

b) a regular review and update of risks, opportunities and actions;

c) the retention of documented information from risk and opportunity assessments, reviews and actions;

d) the definition of criteria to determine the need for action;

e) the evaluation of its effectiveness (e.g. based on quality deficiency costs).

NOTE 1 A methodology (e.g. FMEA, SWOT) can be applied for managing risks, e.g. in processes, design and development, projects or production.

NOTE 2 A methodology like FMECA can be applied for managing risks of critical functions or items (e.g. safety-related).

6.1.3.2 In addition, this process should:

a) involve customers and external providers in joint work on risk and opportunity assessments, reviews and actions;

b) require a multidisciplinary approach for risk and opportunity reviews.

6.1.4 Business continuity

The organization shall:

a) establish, verify, validate, if applicable (e.g. by means of periodical tests), and regularly review its business continuity plan based on an evaluation of its business risks;

b) manage its business continuity;

c) define responsibilities for business continuity actions.

NOTE 1 Business risks can concern:

— interruptions;

— interruptions in the supply chain;

— labour shortages;

— critical technologies;

— key production equipment failures;

— field returns;

— succession plan, in particular for key roles critical to quality;

— information technology;

— communication;

— losses;

— emergencies or crisis.

NOTE 2 For details on business continuity, see ISO 22301.

6.2 Quality objectives and planning to achieve them

ISO 9001:2015, Quality management systems — Requirements

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

ISO 9001:2015, Quality management systems — Requirements

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

ISO 9001:2015, Quality management systems — Requirements

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

7.1.1.1 General — Supplemental

The organization shall establish, implement and maintain a process for resource planning, approval and control.

This process shall include:

a) the resources needed for people and infrastructure as a minimum for the execution of processes [see 4.4.1 d)];

b) the impact of the current order book and forecast;

c) the impact linked to risk provisions (e.g. in case of potential scarcity of resources).

The organization shall retain related documented information.

7.1.2 People

ISO 9001:2015, Quality management systems — Requirements

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

ISO 9001:2015, Quality management systems — Requirements

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

7.1.4 Environment for the operation of processes

ISO 9001:2015, Quality management systems — Requirements

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

ISO 9001:2015, Quality management systems — Requirements

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

ISO 9001:2015, Quality management systems — Requirements

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.5.3 Monitoring and measuring resources — Supplemental

The organization shall establish, implement and maintain a process for calibration or verification, or both, of monitoring and measuring resources as well as of tools used in special processes.

This process shall include:

a) the requirements defined in 7.1.5.1 and 7.1.5.2;

b) how to react when monitoring or measuring resources or tools are found to be unfit for their intended purpose (see 7.1.5.2).

The organization shall retain related documented information.

The organization shall maintain a register of these resources recording their type, unique identification, location or person in charge, intervals for calibration or verification (e.g. in a software tool).

NOTE 1 Monitoring and measuring resources can be: test hardware, test software, ATE or plotters used to produce inspection data. This also includes equipment that is personally owned, developed in house or supplied by the customer or an external provider.

NOTE 2 See also ISO 10012.

In case of internal calibration or verification, the organization shall:

c) establish related methods and acceptance criteria;

d) ensure that ambient conditions are suitable to carry out calibration or verification.

The records of calibration or verification results shall provide:

e) the unique identification of the measuring resource calibrated or verified;

f) the date(s) of when the calibrations or verifications were carried out;

g) the reference standard (e.g. gauge blocks) used to calibrate;

h) the procedure used for calibration or verification.

7.1.6 Organizational knowledge

ISO 9001:2015, Quality management systems — Requirements

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.1.6.1 Organizational knowledge — Supplemental

7.1.6.1.1 Regarding organizational knowledge, the organization shall:

a) manage return of experience including:

1) identification, documentation, implementation and update of good practices and lessons learned;

2) communication of good practices and lessons learned to relevant processes and active projects;

NOTE Return of experience can be derived from, but not limited to, nonconformities, RAMS/LCC data, customer complaints, internal audits, external provider audits and benchmarks.

b) allocate responsibilities for knowledge management regarding products, processes and projects (e.g. in the job descriptions);

c) transfer knowledge when required, e.g. people joining or leaving the organization.

7.1.6.1.2 The organization should establish, implement and maintain an organizational knowledge management process for adequacy to achieve conformity of products and services.

Regarding organizational knowledge, the organization should:

a) use a software tool to share its knowledge;

b) encourage knowledge sharing by networking;

c) protect knowledge from unintended disclosure outside the organization (e.g. knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services).

7.2 Competence

ISO 9001:2015, Quality management systems — Requirements

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.2.1 Competence — Supplemental

7.2.1.1 The organization shall establish, implement and maintain a competence management process.

NOTE Competence can include technical skills such as product, process or project knowledge, software tools, techniques (e.g. quality assurance methods) and social (e.g. teamwork, communication) as well as individual (e.g. analytical thinking, business acumen) skills.

This process shall include:

a) the requirements defined in 7.2;

b) identification of gaps between actual and necessary competencies;

c) planning, organizing, executing and monitoring of actions taken [see 7.2 c)];

d) the requirements for training:

   1) including inputs from organizational knowledge such as good practice, management of experience (see 7.1.6); e.g. inputs from nonconformities of products, services or processes;

   2) providing evidence that trainees understood the training content (e.g. by results of written or oral examinations, by keeping samples of practical exercises) for training defined by the organization.

The process shall apply to all employees including the induction for temporary workers and newcomers, covering as a minimum product quality and safety.

The organization shall retain documented information related to competence management activities.

7.2.1.2 This process should:

a) include a method to compare the necessary competencies versus the actual state, for persons performing work that affects product quality and safety;

   NOTE 1 As a method, a skill matrix can be used to compare the necessary competencies versus the actual state, considering progressive levels (e.g. learner, basic, advanced, coach).

   NOTE 2 Persons performing work that affects product quality and safety are not limited to quality, engineering and production. People from procurement, field services or other functions of the organization can also impact product quality and safety.

b) ensure regular reviews and updating of internal training materials.

7.3 Awareness

ISO 9001:2015, Quality management systems — Requirements

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d) the implications of not conforming with the quality management system requirements.

7.4 Communication

ISO 9001:2015, Quality management systems — Requirements

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

7.4.1 Communication — Supplemental

The organization should establish, implement and maintain a communication management process for internal and external communication relevant to the RQMS.

7.5 Documented information

7.5.1 General

ISO 9001:2015, Quality management systems — Requirements

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this International Standard;

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

ISO 9001:2015, Quality management systems — Requirements

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

ISO 9001:2015, Quality management systems — Requirements

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

7.5.3.3 Control of documented information — Supplemental

The organization shall establish, implement and maintain a process for the control of documented information.

The process shall include:

a) the requirements defined in 7.5.1, 7.5.2, 7.5.3.1, 7.5.3.2;

b) the determination of the hierarchy of documented information of the RQMS (e.g. policies, procedures, instructions, templates);

c) authorities for and identification of persons creating, verifying, approving and updating documented information;

d) the determination of the types of records (e.g. reports, measurement sheets, drawings) and their retention periods that comply with statutory and regulatory, contractual and RQMS requirements.

The organization shall retain documented information in relation to b), c) and d).

The process should include the determination of level of confidentiality (e.g. public, internal, confidential), storage media and method of destruction.

The organization should use information systems to control documented information and define their back up routines.

8 Operation

8.1 Operational planning and control

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8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

   1) the processes;

   2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

   1) to have confidence that the processes have been carried out as planned;

   2) to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

8.1.1 Operational planning and control — Supplemental

8.1.1.1 Innovation management

The organization should establish, implement and maintain an innovation management process for new products, services and technologies.

This process should include:

a) the identification of changes in the organization's business environment;

b) planning of innovations;

c) prioritization of innovations based on the balance between their urgency, the availability of resources and the organization's strategy;

d) involvement of interested parties (e.g. external providers).

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

8.1.1.2 Planning of the transfer of processes

The organization shall establish, implement and maintain a process for the planning of the transfer of processes that can affect the organization's products and services quality.

The implementation of this process shall be linked to business planning (4.1.1), business continuity (6.1.4), production and service provision (8.5), design and development of products and services (8.3) related decisions:

— by multi-sites organization when transferring a process from one site to another;

— by single site or multi-sites organizations when transferring processes to external organizations.

This process shall include:

a) a feasibility study;

b) a risk assessment (see 6.1);

c) planning of required actions for transfer;

d) communication to customers when required;

e) FAI (see 8.9);

f) retention of documented information from transfer activities.

Whenever the organization identifies the need to transfer a process, the requirements regarding the planning of the transfer of processes described in this subclause shall be applied and controlled in case of changes (see 8.1.4.2).

NOTE 1 Planning for the transfer of processes can be an input for a make or buy decision prior to implementing the requirements of 8.4, e.g. based on scarcity of resources or a strategic decision.

NOTE 2 Processes not covered by 8.1.1.2 are covered under 8.4.

8.1.2 Tender management

The organization shall establish, implement and maintain a tender management process.

This process shall include:

a) requirements management (see 8.2);

b) the type and extent of controls [see 4.4.3 f)];

c) risks and opportunities management (see 6.1), including monetary evaluation;

d) inputs from organizational knowledge (e.g. return of experience) (see 7.1.6);

e) planning of deliverables including costs;

NOTE 1 The standard cost account structure of projects can be used for the calculation in the tender.

f) planning of resources for contract execution;

g) offer approval.

The organization shall retain documented information related to their tender management activities.

NOTE 2 In this document, tender management includes several activities commonly called tendering, offering, open bidding, bidding, etc.

8.1.3 Project management

8.1.3.1 General

8.1.3.1.1 The organization shall establish, implement and maintain a project management process.

NOTE 1 The scope of the project management process depends on the business model of an organization. In most railway sector organizations, it is from tender phase until the end of warranty period. However, in other cases it can be limited to:

— design and development only (e.g. for the development of a new product family or platform);

— development of the production process;

— repetition of approved products and services (e.g. make to stock);

— order and contract management (e.g. make to order).

This process shall include:

a) requirement management (see 8.2);

b) the type and extent of controls [see 4.4.3 f)];

NOTE 2 The organization can classify projects depending on the risk and consequently define the type and extent of controls.

c) the project phases and activities;

NOTE 3 Project activities can be, but are not limited to planning, executing, monitoring, controlling and closing.

d) milestones and deliverables per phase, managed by gate methodology;

NOTE 4 Deliverables per phase can be defined in gate checklists.

e) gate criteria to decide, in phase reviews, on acceptance, conditional acceptance or rejection, to authorize progression to the next phase;

NOTE 5 Conditional acceptance can be acceptance with an action plan.

f) the requirements defined in 8.1.3.2 to 8.1.3.11;

g) records and control of open issues, putting appropriate resources in place to close them.

8.1.3.1.2 This process should include:

a) an escalation process in case of rejection decision as an output of phase reviews to facilitate problem solving;

b) a review with the customer and key external providers regarding SWOT;

c) the identification of good practices and lessons learned during project closure as a minimum (see 7.1.6).

8.1.3.1.3 The organization shall manage its project's documented information as required in 7.5 including:

a) review, storage (e.g. standardized folder structure), control and maintenance of project information;

b) retaining documented information (e.g. plans, schedules, output of reviews, reports).

Phase reviews shall:

c) be performed:

1) starting at defined level of work breakdown structure;

2) at project level considering the reviews of the deliverables;

d) not be passed unless open issues of prior phase reviews are closed. Otherwise, approval shall be given by top management or its authorized high-level representative.

The organization shall define mandatory and identify optional participants of phase reviews.

8.1.3.2 Project management plan

The organization shall establish, implement and maintain a project management plan and retain related documented information. This plan shall include or refer to:

a) project organization chart;

b) project targets, frame conditions, assigned resources, exclusions;

c) specific responsibilities and authorities of the project organization;

d) specific rules to follow during project execution;

e) aligned plans from involved functions, sites and consortium partners, in order to come up with a harmonized project management plan;

NOTE 1 Typical functions are sales, design, production, quality, purchasing, field support and other appropriate personnel including external providers and customer when appropriate.

f) deliverables per phase (e.g. contractual deliverables for customers or documented information of the design outputs intended for product approval) including:

1) identification of deliverables to be approved by the customer (e.g. customer product acceptance points) or statutory and regulatory authorities, where required;

2) external providers' deliverables (e.g. documents, material, services);

3) customer deliverables, such as customer properties, as applicable;

g) the control of project changes (e.g. scope, time, costs).

NOTE 2 The project management plan can include any other subsidiary plans required in 8.1.3 (communication, human resource, quality).

In cases where a project involves multiple sites or consortium partners, the project management plan shall additionally include or refer to:

h) work split and operational interfaces;

i) specific responsibilities and authorities;

j) communication channels (project internal and with the customer or interested parties);

k) applicable processes and other documented information related to the processes.

8.1.3.3 Project scope management

Regarding project scope management, the project management process shall include:

a) identification of project requirements (e.g. time, commercial, technical) (see 8.2);

b) definition of the scope of work;

c) subdivision of work into work packages (e.g. work breakdown structure);

d) assignment of work packages to work package owners;

e) verification of work packages.

The project organization shall not change the project scope unless a change has been approved (see 8.1.4.2) as defined by the organization.

Regarding scope management, the project management process should include a standardized work breakdown structure.

NOTE Scope management in design and development is detailed in 8.3.2.

8.1.3.4 Project time management

Regarding project time management, the project management process shall include:

a) definition and sequences of activities;

b) estimation of resources and duration of activities;

c) scheduling, considering:

   1) past experience;

   2) long lead time items, managed jointly with external providers.

The project schedule shall:

d) include duration, start, finish and interdependencies of the work packages including those of external providers;

e) include the critical path;

f) provide input to the master production schedule (see 8.5.1.2).

The project organization shall not change the schedule regarding the customer delivery dates unless a change request has been timely addressed to the customer (see 8.1.4.2).

The project organization should use a software tool for scheduling and activity tracking.

8.1.3.5 Project cost management

Regarding project cost management, the project management process shall include:

a) allocation of the project budget based on calculation from tender;

b) the assignment of project budget in a cost account structure, considering all requirements (e.g. including organizational, statutory and regulatory requirements in work packages);

c) a regular control of costs including actual and estimated cost at completion.

The project organization shall not increase the project budget unless authorized as defined by the organization (see 8.1.4.2).

The project organization should use a software tool for cost tracking.

8.1.3.6 Project quality management

Regarding project quality management, the organization shall establish, implement and maintain a project quality plan, that includes at least quality assurance and control activities, and retain related documented information.

NOTE 1 See ISO 10005 and ISO 10006 for guidance.

NOTE 2 The project quality plan establishes the project quality management system, i.e. the application of the organization's RQMS to the project, with the addition of contractual requirements (if available).

NOTE 3 The project quality plan can include or refer to specific project procedures (e.g. project nonconformity management procedure), project quality control plan, templates or forms.

8.1.3.7 Project human resource management

Regarding project human resource management, the project management process shall include:

a) the definition and description of project roles (e.g. project manager, project buyer, project quality manager) and responsibilities versus those of line functions, reporting relationships and empowerment (e.g. financial approval authorities, profit and loss responsibilities);

b) acquiring the project organization;

c) managing the project organization in terms of people, competence and awareness, in accordance with requirements defined in 7.1.2, 7.2 and 7.3;

The project organization shall establish, implement and maintain a project human resource plan and retain related documented information. This plan shall include, at related levels:

d) the assignment of project core team and staff (e.g. nomination letters);

e) the definition of required specific competencies (e.g. project management software tool, team work and communication, products and services to be delivered, building information modelling, work breakdown structure) in addition to competencies defined in 7.2;

f) the identification of related training, if necessary.

8.1.3.8 Project communication management

Regarding project communication management, the project organization shall:

a) apply requirements defined in 7.4 and 8.2.1;

b) establish, implement and maintain a project communication plan and retain related documented information.

Regarding project communication management, in case of imminent deviation, the project organization should communicate relevant impacts and countermeasures to customers and interested parties (see 8.1.3.11).

8.1.3.9 Project risk and opportunities management

8.1.3.9.1 Regarding project risk and opportunities management, the project organization shall:

a) apply the requirements defined in 6.1;

b) establish, implement and maintain a register including a cost and benefit analysis of risks and opportunities;

c) retain documented information of risk and opportunities management.

8.1.3.9.2 Regarding risk and opportunities management, the project organization should:

a) involve the functional line managers in risk reviews;

b) consider operational maturity levels of the products agreed with the customer as inputs for risks management;

NOTE Risk analysis can consider operational maturity relevant to technical requirements.

c) manage opportunities for cost savings (to balance losses) or cost enhancements (to increase margin), especially in order to recover the project budget deteriorations.

8.1.3.10 Project procurement management

Regarding project procurement management, the project organization shall apply requirements defined in 8.4.

8.1.3.11 Project review management

The organization shall perform regular project reviews to monitor project progress, with the attendance of the project core team (or empowered deputies) (see 8.1.3.7).

In case of an imminent deviation to the project objectives, the project organization shall identify and implement appropriate countermeasures to mitigate the impact on customer, the organization and/or other interested parties.

Project reviews shall include:

a) the project performance (actual situation versus planned situation) based on PIs as specified in 9.1.1.1 (e.g. requirements, time, costs);

b) the forecast (e.g. time, estimated cost at completion);

c) the risks and opportunities, including status of related actions;

d) tracking of open issues and actions from previous reviews.

The output of project reviews should be reported to management level higher than the project manager including issues for decision or escalation.

NOTE Project reviews are intended to monitor the progress of the complete project. Project phase reviews (see 8.1.3.1) are intended to check whether a project phase can be closed and whether the next project phase can begin.

8.1.4 Configuration management and change control

8.1.4.1 Configuration management

8.1.4.1.1 The organization shall establish, implement and maintain a configuration management process appropriate to the product.

NOTE The configuration management process is applicable for hardware and software.

This process shall include:

a) the configuration management plan;

b) the definition of a product breakdown structure until the LLRU;

c) the identification of configuration items, at least the safety-related ones;

d) the definition of configuration baseline(s) (e.g. “as-designed”, “as-built” and “as-maintained” configurations) to be established in a timely manner;

e) the change control of the configuration in accordance with 8.1.4.2;

f) configuration status accounting;

g) the definition of criteria for identification of traceability (e.g. serialization, batch number).

The organization shall retain documented information for the configuration management process.

8.1.4.1.2 This process should:

a) include regular internal configuration audits;

b) integrate external providers' configuration management system (e.g. interfaces for data transfer);

c) include tools and software used in design, development, production and maintenance as configuration items;

d) be supported by a software tool.

NOTE See ISO 10007 for guidance.

8.1.4.2 Change control

The organization shall establish, implement and maintain a change control process.

This process shall include:

a) the requirements defined in Clause 8 related to changes;

b) change requests;

c) a cause analysis in case of changes deriving from failures;

d) an impact analysis of the change considering risks and opportunities;

e) the verification of proposed changes to avoid adverse effects;

f) notification to and agreement with customers, external providers and authorities in the event of, as a minimum, changes affecting their requirements (e.g. fit, form and function);

NOTE 1 A change affecting customer requirements can trigger a deviation permit.

NOTE 2 A change request triggered by a deviation permit can be closed when the change is approved by the customer.

g) the assignment of responsibilities and authorities for the approval of changes (e.g. change control board);

h) the approval of change before implementation;

i) the implementation of changes;

j) the verification of implementation and follow-up of the effectiveness of the change;

k) the traceability of changes (e.g. supported by a software tool).

This process should include planning of actions in order to minimize the impact of change.

For technical changes on products and services, this process shall include in addition:

l) an analysis of the change impact on:

1) constituent parts and products already delivered;

2) customer specification and configuration;

3) related documented information (e.g. quality plan, FMEA results);

4) technical requirements;

m) the re-evaluation of technical requirements depending on the results of the impact analysis;

n) the re-validation activities depending on the results of the impact analysis;

o) requirements for retention of documented information about the date and/or the serial number of the changed products and services.

NOTE 3 Changes can be generated by lack of reliability, obsolescence of products and services, evolution of standards, regulations, laws, needs for operation, cost optimization, or specific events: accident, incident, weather or customer variation order.

For technical changes on products and services, these processes should also include the re-evaluation of operational maturity.

The change control requirements shall apply to:

p) project management (see 8.1.3);

q) the requirements for products and services (see 8.2.4, 8.2.5);

r) design and development of products and services (see 8.3.1.1, 8.3.6);

s) control of externally provided processes, products and services (see 8.4);

t) production and service provision (see 8.5.1.3 and 8.5.6) encompassing production processes, production equipment, production programmes (software) and production location.

NOTE 4 Changes can be initiated by external providers or the organization in order to improve or to correct the design or by the customer in case of variation order.

NOTE 5 The trigger point to start the change process is the intended change of approved documented information.

NOTE 6 The change control process can be designed in such a way that any change is implemented in a controlled manner (risk based) so as to not adversely affect quality, e.g. impact analysis, classification to enable adoption of different procedures, verification and validation methods and approval levels.

8.2 Requirements for products and services

8.2.1 Customer communication

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8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.1.1 Customer communication — Supplemental

The organization shall communicate with customers when delays are foreseen but cannot be avoided (e.g. delays from external providers).

NOTE For project communication management, see also 8.1.3.8.

8.2.2 Determining the requirements related to products and services

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8.2.2 Determining the requirements related to products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:

   1) any applicable statutory and regulatory requirements;

   2) those considered necessary by the organization;

b) the organization can meet the claims for the products and services it offers.

8.2.2.1 Determining the requirements related to products and services — Supplemental

8.2.2.1.1 When determining the requirements (see Annex B), the organization shall consider:

a) functional and non-functional requirements;

b) RAMS/LCC requirements;

c) obsolescence requirements, as applicable (e.g. information coming from market, external providers, regulations);

d) critical product characteristics as defined by the organization and/or the customer.

8.2.2.1.2 When determining the requirements, the organization should consider:

a) experience from similar products/tenders/projects;

b) requirements resulting from market analysis;

c) requirements regarding end of product life (e.g. disposal, recycling).

8.2.2.1.3 The organization shall retain documented information in relation to 8.2.2 a) to b) and 8.2.2.1.1 a) to b) and, if considered, 8.2.2.1.2 a) to c).

NOTE The subordinate concept of requirements is shown in Annex B.

8.2.3 Review of requirements related to products and services

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8.2.3 Review of requirements related to products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

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8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.2.5 Requirements for products and services — Supplemental

The organization shall establish, implement and maintain a requirement management process for products and services.

This process shall:

a) include the requirements defined in 8.2;

b) be applicable for:

1) design and development of new products and services meeting market expectations prior to tender (e.g. platform, product family);

2) tender management (e.g. submission of tenders, acceptance of contracts or orders);

3) project execution (e.g. acceptance of changes to contracts or orders);

4) change control (see 8.1.1.2, 8.1.4.2, 8.2.4, 8.3.6, 8.4.3.1 and 8.5.6);

NOTE 1 This process can be included in the project management process.

c) be performed by a multidisciplinary approach including internal and external interested parties as applicable;

d) include as a minimum these steps:

1) determination (see 8.2.2.1);

2) review (see 8.2.3);

3) verification;

4) validation;

NOTE 2 For definitions of "verification" and "validation", see 3.1.3.12 and 3.1.3.11.

e) ensure that requirements are:

1) individually checked for conformity clause by clause;

2) evaluated and taken into account;

3) assessed in relation to risks and opportunities (see 6.1);

4) properly transferred, understood, acknowledged, cascaded down and committed to, by the involved persons;

5) complete, unequivocal, verifiable and feasible;

6) documented in a technical specification including functional and non-functional requirements;

NOTE 3 The technical specification can be provided by the customer or established by the organization.

7) updated in case of change.

8.3 Design and development of products and services

8.3.1 General

ISO 9001:2015, Quality management systems — Requirements

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.1.1 General — Supplemental

The requirements defined in 8.3 shall apply to the design and development of products and services, as well as to the introduction of new technologies, if appropriate.

The organization shall identify new technologies and assess their risks (e.g. through process FMEA).

The design and development process shall:

a) include the requirements regarding planning, inputs, controls, outputs and changes described in 8.3.2, 8.3.3, 8.3.4, 8.3.5 and 8.3.6;

b) include the requirements related to the product architecture, including interfaces, e.g. software products;

c) include the requirements regarding 'reliability', 'availability', 'maintainability', 'safety' and, if applicable, 'life cycle costing' described in 8.8;

d) require conformity for safety-related products with IEC 62278 or an equivalent, as applicable.

8.3.2 Design and development planning

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8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable design and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for subsequent provision of products and services;
i) the level of control expected for the design and development process by customers and other relevant interested parties;
j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.2.1 Design and development planning — Supplemental

8.3.2.1.1 In determining the stages and controls for design and development, the organization shall consider:

a) the objectives for each process stage;

b) the product architecture (e.g. product breakdown structure);

c) the configuration management (see 8.1.4.1);

d) design reviews, verification and validation at defined levels of the product architecture (e.g. starting from component design review, then sub-system design review and up to system design review);

e) design reviews, verification and validation for special processes.

The stages and controls for design and development shall be documented (e.g. in a quality plan).

NOTE Design stages can be conceptual design, preliminary design and final design.

8.3.2.1.2 In determining the stages and controls for design and development, the organization should consider:

a) the quality assurance methods for each design and development stage in order to meet the objectives (e.g. defined in a quality plan);

b) the method to control technical requirements;

c) the method to control the operational maturity.

NOTE 1 Controls can consider operational maturity including maturity of non-functional requirements, such as performance, integration and other non-functional requirements.

NOTE 2 If requirements of special processes are inputs to the design, the risk assessment of these special processes can be part of the design and development process.

NOTE 3 Collaboration with external engineering can be considered as externally provided services (see 8.4).

8.3.3 Design and development inputs

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8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements;
b) information derived from previous similar design and development activities;
c) statutory and regulatory requirements;
d) standards or codes of practice that the organization has committed to implement;
e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.
Conflicting design and development inputs shall be resolved.
The organization shall retain documented information on design and development inputs.

8.3.3.1 Design and development inputs — Supplemental

8.3.3.1.1 Regarding design and development inputs, the organization shall consider:

a) the requirements defined in 8.2.2;

b) identification and traceability.

8.3.3.1.2 In addition, the organization should consider:

a) production and routine testing requirements, including special processes, so far as the production facilities are known at this stage;

b) preservation requirements.

8.3.4 Design and development controls

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8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.4.1 Design and development controls — Supplemental

The organization should apply controls to the design and development process considering:

a) the functional breakdown;

b) the operational maturity;

c) the implementation of quality assurance methods.

8.3.4.2 Design reviews

Regarding design reviews, the organization shall define:

a) criteria for authorization of progression to the next stage (e.g. checklist, rules for acceptance);

b) mandatory and optional participants.

Representatives of functions joining design reviews shall have the authority to make decisions.

The organization should perform design reviews with a multidisciplinary approach.

NOTE 1 Participants can be head of functions (e.g. RAMS, services), internal and external customers, experts in production.

NOTE 2 Design reviews can be part of or an input for project phase reviews (see 8.1.3.1).

8.3.4.3 Design verification

The organization shall ensure that technical requirements are verified.

NOTE Design verification activities can be finite element analysis, calculations, mock-up and design accompanying tests.

8.3.4.4 Design validation

Regarding design validation, the organization shall:

a) ensure that technical requirements are validated;

b) complete validation prior to the delivery or end of commissioning or agree on control plans with customers and monitor them until completion.

NOTE Design validation activities can be, for example, qualification tests, type tests and product approval tests.

8.3.4.5 Design verification and validation test requirements

When tests are necessary for verification and validation, the organization shall plan, control and review these tests. The organization shall ensure that:

a) test plans, test specifications or test procedures provide reproducibility and define:

   1) test objectives;

   2) test conditions and environment;

   3) the product to be tested;

   4) resources needed;

   5) test acceptance criteria;

   6) parameters to be recorded;

   7) the test method of operation;

   8) the performance of the test;

b) the correct configuration of the product is submitted for the tests and recorded as a configuration baseline;

c) the test acceptance criteria are met.

8.3.5 Design and development outputs

ISO 9001:2015, Quality management systems — Requirements

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

8.3.5.1 Design and development outputs — Supplemental

8.3.5.1.1 The organization shall ensure that design and development outputs:

a) are verified and approved prior to release;

b) are verified against production process inputs (see 8.5.1.1.3);

c) include the documented information (e.g. operations, maintenance manuals) and training related to the application.

8.3.5.1.2 The organization should:

a) ensure the traceability of outputs to the input requirements;

b) define authorities and acceptance criteria for design approval;

c) define escalation rules in case acceptance criteria for approval are not met;

d) ensure that information for production and service provision includes requirements for the preservation of product.

NOTE The design and development outputs can include, for example, specifications and drawings (also from external providers), information on materials, production process flow charts and/or layouts, inspection and test plans, work instructions for production, process and product approval acceptance criteria, identification requirements, results of error prevention activities (e.g. FMEA), methods of rapid detection and feedback of product and/or production process nonconformities.

8.3.6 Design and development changes

ISO 9001:2015, Quality management systems — Requirements

8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General

ISO 9001:2015, Quality management systems — Requirements

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 General — Supplemental

8.4.1.1.1 External providers

The organization shall determine the type and extent of requirements from 8.4 that apply to external providers, with risk assessments based on defined criteria.

The organization shall establish, implement and maintain a process for EPPPS described in ISO 9001:2015, 8.4.1 to ensure conformity to requirements.

This process shall include requirements defined for:

a) classification of external providers and EPPPS (see 8.4.1.1.2);

b) external providers' evaluation (see 8.4.1.1.3);

c) external providers' approval (see 8.4.1.1.4);

d) external providers' offer selection (see 8.4.1.1.5);

e) information for external providers (see 8.4.3);

f) EPPPS approval of release (see 8.4.2.1);

g) EPPPS verification after release (see 8.4.2.2);

h) monitoring of external providers' performance, re-evaluation and ranking (see 8.4.2.3).

In addition, the organization shall:

i) manage the EPPPS risks throughout the supply chain;

j) identify risks to be communicated to external providers and ask external providers for their feedback;

k) in addition to ISO 9001:2015, 8.4.1, also retain documented information on external providers in accordance with a) to g).

8.4.1.1.2 Classification of external providers and external provided products, processes and services

Classification of external providers and EPPPS shall be performed on defined criteria to determine the type and extent of control applied to external providers and the EPPPS [see 4.4.3 f)]. As an output, key external providers shall be identified.

Classification criteria shall include the ability of external providers to provide EPPPS in accordance with requirements.

In addition, the organization shall regularly review the classification of external providers.

Classification criteria should include:

a) strategic needs;

b) past experiences;

c) available market information;

d) external benchmarks;

e) the operational maturity of externally provided products (e.g. ready to use).

8.4.1.1.3 Evaluation of external providers

External providers' evaluation shall include:

a) people, infrastructure and processes of external providers;

b) availability of external providers' qualifications (e.g. certifications according to this document, ISO 9001), supplemented, when appropriate, by other means (e.g. audit).

The organization shall determine and monitor a strategy to enable the targeting of:

c) external providers that meet the requirements of this document;

d) external providers that meet the requirements of ISO 9001 or an equivalent quality management system.

Targeted external providers shall be identified considering their product scopes, strategic relevance, annual spend volume, product criticality, design activities, turnover in the railway sector and delivery and quality performance.

8.4.1.1.4 Approval of external providers

The organization shall:

a) establish criteria to approve external providers;

b) ensure that functions having the authority to approve have also the authority to reject already approved external providers;

c) maintain a register of approved external providers, including the definition of their scope of approval.

EPPPS shall be provided exclusively by approved external providers.

8.4.1.1.5 External provider offer selection

8.4.1.1.5.1 The organization shall ensure that the external provider's offer is selected on the basis of an analysis which takes into account:

a) conformity with the requirements, e.g. by clause by clause;

b) the total cost of ownership including, as applicable, LCC;

c) the quality, cost and delivery performance of the external provider for previous EPPPS, including quality deficiency costs caused by the external provider;

d) the classification of the external providers concerned by the offer.

8.4.1.1.5.2 The analysis should take into account:

a) the output of a risk analysis;

b) the operational maturity of externally provided products.

Prior to the issuance of a purchase order, the organization should ensure that the external provider has fully understood all technical requirements, e.g. by a joint contract review.

8.4.2 Type and extent of control

ISO 9001:2015, Quality management systems — Requirements

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

   1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.2.1 Externally provided products, processes and services approval of release

8.4.2.1.1 Approval of release for new or modified EPPPS shall include:

a) determination of approval methods;

b) planning of verification, validation and approval activities;

c) as applicable, conducting FAI at external providers' premises (see 8.9), or appropriate incoming/outgoing inspection;

d) validation of externally provided products or technologies (e.g. new design software) before first use in a customer contract unless otherwise agreed with the customer;

e) approval of release (e.g. to start serial production);

f) definition or update of configuration baseline considering change control (see 8.1.4).

8.4.2.1.2 Approval of release for new or modified EPPPS should consider:

a) pre-production reviews;

NOTE Pre-production reviews can provide evidence of controlled conditions and readiness for the start of the first article production.

b) first system integration.

The organization should report progress in achieving design and development objectives and status of quality assurance activities to its external providers.

8.4.2.2 Externally provided products, processes and services verification after release

The EPPPS shall not be used or processed until it has been verified as conforming to specified requirements or unless it is released under authorized concession (see 8.7.3).

Activities for EPPPS verification after release shall include:

a) planning of activities [e.g. in an inspection and test plan, including the determination of the extent, frequency, sample size and methods of control, see 4.4.3.1 f)];

b) provision of instructions, checklists or templates for verification activities;

c) obtaining evidence that the EPPPS is conforming to requirements (e.g. by check of accompanying documented information such as certificate of conformity, test reports, statistical records, process control sheets);

d) confirmation of release of the EPPPS;

e) management of nonconforming EPPPS.

Where the organization utilizes test reports to verify EPPPS, the data in those reports shall be comparable with acceptance criteria stated on the report, that are derived from purchasing information, e.g. specifications, standards.

The organization shall determine a plan for periodical verifications of raw material based on risks assessment.

NOTE 1 Verification of raw material composition or conformity can be done by checking, for example, certificates, chemical analyses, own laboratory tests.

Inspection and testing requirements as defined in 8.6 shall apply for EPPPS verification.

In case of delegation of verification activities to the external provider, the organization shall define the requirements for delegation and shall define controls, e.g. regular audits at external provider premises.

Where the organization delegates verification activities to the external provider, there shall be evidence that the external provider has accepted such agreement.

A register of external provider delegations shall be established and maintained.

Any delegation should be reviewed after subsequent changes.

NOTE 2 EPPPS verification after release can be the incoming inspection or part of a quality gate at external provider premises.

8.4.2.3 Monitoring of external providers' performance, re-evaluation and ranking

Monitoring performance, re-evaluation and ranking of key external providers shall consider:

a) periodical reviews of external providers' performance (see 9.1.1.1 for related PIs);

b) definition of criteria to audit external providers;

c) results of these reviews as a basis for establishing the type and extent of controls to be implemented;

d) actions planned to be taken when the external provider does not meet technical requirements and/or performance targets;

e) feedback of their performance to be given to the external providers;

f) regular joint performance reviews.

In addition, the organization shall:

g) identify external providers to be developed;

h) implement action plans based on agreed objectives to improve their capabilities.

8.4.3 Information for external providers

ISO 9001:2015, Quality management systems — Requirements

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

   1) products and services;

   2) methods, processes and equipment;

   3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.4.3.1 Information for external providers — Supplemental

Information for external providers shall consider:

a) that customer requirements are cascaded down through the supply chain;

b) in case of changes, the traceability of requirements (see 8.2);

c) approval of special processes by the organization or its customer, where required.

The organization shall also communicate to external providers its requirements for:

d) identification and applicable revisions of specifications, drawings, process requirements including the ones for special processes, inspection instructions, appropriate details from the organization's project quality plan and other relevant technical data;

e) deliverables associated to the EPPPS (e.g. EPPPS documented information) and the related schedule;

f) management of changes and nonconforming outputs;

g) delivery schedule of EPPPS;

h) information about the product criticality (e.g. safety critical);

i) right of access by the organization, its customers or other relevant parties (e.g. regulatory authorities) to facilities involved in the order and to applicable documented information.

NOTE Further requirements communicated to external providers can be related to:

— design reviews;

— test samples (e.g. production method, number, storage conditions) for investigation or design approval;

— production: routine testing, inspection and acceptance, including related instructions;

— obsolescence management;

— auditing;

— supply chain logistics including packaging and labelling;

— cascading requirements to its external providers.

8.4.4 Supply chain management

The organization shall:

a) request acknowledgement of its purchase orders from the external providers until receipt, and retain documented information of this acknowledgement;

b) document requests of changes sent to the external providers (see 8.4.3.1).

The organization shall communicate updated delivery schedules and forecasts to its external providers in order to give inputs for their resources planning. This shall include delays to the deliveries of processes, products and services from the organization to the external providers.

Supply chain information (e.g. delivery dates, quantities), exchanged with customers, external providers and the organization (e.g. design, production), shall be managed and be maintained up-to-date (e.g. by a software tool).

The organization should agree on an early warning policy with its external providers regarding their delayed provisions foreseen, otherwise the organization should regularly check the delivery schedule. This early warning policy should also include obsolescence issues.

8.5 Production and service provision

8.5.1 Control of production and service provision

ISO 9001:2015, Quality management systems — Requirements

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

   1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

   2) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities.

8.5.1.1 Control of production and service provision — Supplemental

8.5.1.1.1 General

NOTE Production in the context of this clause can also apply at customer premises (e.g. during commissioning or installation until handover).

The organization shall establish, implement and maintain a process for production and service provision.

This process shall:

a) include requirements for:

   1) activities to ensure controlled conditions (see 8.5.1.1.2);

   2) verification of the process for production and service provision (see 8.5.1.1.3);

   3) validation of the process for production and service provision (see 8.5.1.1.4);

   4) production scheduling (see 8.5.1.2);

   5) activities to control production equipment (see 8.5.1.4);

   6) activities to ensure identification and traceability (see 8.5.2);

7) management of property belonging to customers or external providers (see 8.5.3);

8) preservation (see 8.5.4);

b) refer to:

1) configuration management (see 8.1.4.1);

2) change control (see 8.1.4.2);

3) special processes (see 8.5.1.3);

4) release of products and services (see 8.6);

5) control of nonconforming outputs (see 8.7);

6) FAIs (see 8.9).

8.5.1.1.2 Controlled conditions

Controlled conditions shall include:

a) approved data for production and service provision activities. These data shall contain:

1) drawings, bill of material, production process flow charts, inspection and test planning, production documents (e.g. work instructions, production schedules, work order, process cards);

2) a list of tools and numerical control machine programmes required and any specific instructions associated with their use;

b) monitoring of production and service provision in all shifts (e.g. parts quantities, split orders, nonconforming outputs);

c) evidence that all production and service provision, including inspections, have been authorized and completed as planned;

d) actions to prevent recurrence of past problems;

e) risk assessment covering all the production and service provision activities with the applicable method(s);

f) assessment of risk impact of deferred work to ensure control of work to be carried out without affecting quality and safety;

g) rework and repair of nonconforming outputs (see 8.7.3);

h) use of statistical process control, if applicable.

8.5.1.1.3 Verification of the process for production and service provision

Verification of the process for production and service provision shall include:

a) verification of production process inputs against design and development outputs regarding completeness (see 8.3.5.1);

b) verification of production equipment ability to comply with design and development requirements (e.g. regarding production equipment tolerances or precision classes);

c) risk assessment at an early stage of the process with applicable methods (e.g. production process FMEA).

8.5.1.1.4 Validation of the process for production and service provision

8.5.1.1.4.1 Validation of the process for production and service provision shall ensure that:

a) design and development requirements are fulfilled;

b) controlled conditions are achieved;

c) FAI is completed (see 8.9);

d) validation is completed prior to handover of the products and services to the customer;

e) re-validation is completed as part of changes implementation;

f) feedback to design and development is given in order to support continual improvement of production and the related documented information.

8.5.1.1.4.2 Validation of the process for production and service provision should include:

a) measurement capability studies;

b) process capability studies;

c) analysis of tolerances to ease the production process.

8.5.1.2 Production scheduling

8.5.1.2.1 Regarding production scheduling, the organization shall:

a) schedule production (including production equipment) in short-, mid- (master production schedule) and long-term (sales and operation plan) in order to meet the customer delivery requirements;

b) be supported by a software tool which:

   1) covers the production phases;

   2) captures updated production status information;

   3) content is updated on each event/change of customer contract (variation order);

c) use customers' and external providers' forecasts and orders to plan and adjust regularly its resources in accordance with its workload, taking into account risks (e.g. extra order at the last minute, external providers' failure);

d) identify bottlenecks in production.

8.5.1.2.2 Regarding production scheduling, the organization should:

a) consider:

   1) results of risk analysis;

   2) past experience;

   3) efficiency measurements;

b) establish an improvement action plan accordingly.

8.5.1.3 Special processes

The organization shall establish, implement and maintain a process for the management of special processes.

This process shall include:

a) the identification of special processes that the organization is planning to use;

b) for each special process, the definition of:

   1) responsibilities and authorities;

   2) applicable standards;

   3) risk assessment with the applicable method(s) (e.g. process FMEA);

   4) work instructions, as a minimum when there is no applicable standard, including:

      — management;

      — manpower;

      — machine;

      — methods;

      — material;

      — mother nature (environmental conditions);

   5) personnel qualification;

   6) quality assurance and control methods and related documented information;

   7) qualification of the special process;

   8) validation for each specific application;

   9) re-validation after changes;

c) retention of documented information in relation to the above requirements.

NOTE Special processes as defined in ISO 9000:2015, 3.4.1, Note 5 to entry, can be, for example, bonding and sealing, casting, crimping, heat treatment, riveting, surface treatment, including painting and coating, torque tightening, and welding.

8.5.1.4 Production equipment

8.5.1.4.1 Regarding production equipment, the organization shall:

a) develop its production equipment if applicable;

b) plan and implement preventive maintenance activities to ensure that production equipment is:

   1) verified in accordance with defined methods and acceptance criteria;

   2) validated prior to first use (see 8.9);

   3) registered with individual identification;

   4) protected against deterioration, including storage and preservation as appropriate, when the equipment is not in use;

5) inspected for its condition at planned intervals (e.g. regarding degradation, by visual inspection);

6) re-verified at planned intervals, depending on risk and failure rate;

c) adjust the planned intervals and activities in accordance with occurrence of failures;

d) periodically review the production equipment with the future in mind (inputs for 7.1.1);

e) ensure the availability of spare parts and consumables with long lead time;

f) consider methods which prevent errors in production (e.g. poka yoke);

g) retain documented information on the maintenance activities.

8.5.1.4.2 The organization should:

a) apply the design and development process (see 8.3) for production equipment as appropriate;

b) implement predictive maintenance activities, if applicable.

8.5.2 Identification and traceability

ISO 9001:2015, Quality management systems — Requirements

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.2.1 Identification and traceability — Supplemental

Items shall be traceable from their origin up to at least the end of warranty where traceability is required by contract or configuration management (see 8.1.4.1).

The organization shall define the method to identify items (e.g. by machine readable codes, stamping, labelling).

NOTE 1 The method to identify items can be agreed with the customer.

NOTE 2 Statutory or regulatory norms can require traceability.

If the status of a product or its identification is not known, the organization shall manage the product as a nonconforming product.

The organization should use machine readable identification.

8.5.3 Property belonging to customers or external providers

ISO 9001:2015, Quality management systems — Requirements

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.3.1 Property belonging to customers or external providers — Supplemental

The organization shall manage traceability of property belonging to customers or external providers up to delivery or return.

NOTE The traceability requirements can be defined by the parties.

In the event that property is lost, damaged or otherwise found to be unsuitable for use, the organization should perform a cause analysis and take required actions.

8.5.4 Preservation

ISO 9001:2015, Quality management systems — Requirements

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.4.1 Preservation — Supplemental

The organization shall have documented specifications for preservation in accordance with product specifications and applicable regulations, addressing the following until handover:

a) marking and labelling regarding identification;

b) special handling for sensitive products;

c) cleaning regarding contamination control and storage;

d) shelf life control and stock rotation (e.g. first in, first out);

e) environmental condition (e.g. temperature, humidity).

Conditions regarding preservation having impact on product conformity shall be identified, analysed and taken into account as inputs for these documented specifications.

These documented specifications shall be applied to physical items managed in the organization's premises (e.g. material received from external providers, property belonging to customers, work in progress and products manufactured by the organization).

NOTE These documented specifications can apply to warehouses, internal processing, delivery processes to the final destination.

8.5.5 Post-delivery activities

ISO 9001:2015, Quality management systems — Requirements

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.5.1 Post-delivery activities — Supplemental

NOTE 1 Post-delivery activities are performed after handover to the customer, until contract obligations end (e.g. on-site technical training, solving quality problems).

The organization shall establish, implement and maintain a process for post-delivery activities.

This process shall include:

a) requirements defined in ISO 9001:2015, 8.5.5;

b) the control and updating of technical documented information (e.g. operational instructions, maintenance manuals, spare parts list);

c) problem solving methodology (e.g. 8D, FRACAS) (see 8.8 and 10.2.3);

d) the approval, control and use of repair instructions;

e) the provision of spare parts and/or the management of consignment stock, where agreed upon between the customer and the organization;

f) knowledge of customer complaints as inputs for improving the organization's RQMS (e.g. for design and development improvements, production, maintenance activities).

NOTE 2 During first delivery activities, adequate data can be collected to support RAM data collection [e.g. failure symptoms, mileage, operating hours; see 8.8.2 c)] and for LCC data collection [see 8.8.4 c)].

8.5.6 Control of changes

ISO 9001:2015, Quality management systems — Requirements

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

ISO 9001:2015, Quality management systems — Requirements

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

8.6.1 Release of products and services — Supplemental

The organization shall define:

a) the sequence of inspection and testing activities along the production flow in an inspection and test plan, including the determination of the extent, frequency, sample size and methods of control [see 4.4.3 f)]; frequency shall be adopted in accordance with the risk level in order to prevent nonconforming outputs;

b) requirements for product and service acceptance in inspection and test instructions;

c) authorities for release.

These instructions and plans shall be part of the production inputs (see 8.5.1).

In case planned arrangements are not satisfactorily completed, the organization shall request a concession to the customer (see 8.7.3) prior to the release of products and services.

Inspection and test instructions shall include:

d) the criteria for acceptance;

e) documented information for inspection and test results;

f) the type of monitoring and measuring resources required and any specific instructions associated with their use.

Inspection and test records shall include actual results data in accordance with the inspection and test instructions.

The organization should establish, implement and maintain a process to release products and services.

8.7 Control of nonconforming outputs

ISO 9001:2015, Quality management systems — Requirements

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

8.7.3 Control of nonconforming outputs — Supplemental

The organization shall establish, implement and maintain a process for the control of nonconforming outputs.

NOTE 1 All processes can cause nonconforming outputs (e.g. design and development outputs).

NOTE 2 The process for the control of nonconforming outputs can be combined with the process for managing nonconformity and corrective action defined in 10.2.3 or the change control process in 8.1.4.2.

The process shall include:

a) requirements defined in 8.7.1, 8.7.2 and 10.2;

b) a register of nonconforming outputs.

For nonconforming outputs resulting from 8.5, the process shall include:

c) identification of criteria and authorities for:

   1) rework, repair and scrap;

   2) internal and customer concessions;

d) a register of concessions from the organization and external providers, recording expiration date and authorized quantities;

e) regular monitoring of the concessions (e.g. validity) and of the correction of nonconforming outputs.

Regarding control of nonconforming outputs, the organization shall ensure:

f) when the authorization of the concessions expires, then the product cannot be used anymore;

g) in case of concessions requiring customer approval:

   1) customer approvals shall be obtained prior to delivery;

   2) concessions from external providers shall be internally approved before submission to the customer;

   3) identification of product under concession is agreed with the customer;

   4) recording of concessions on the product declaration of conformity.

8.8 Reliability, availability, maintainability, safety and life cycle costing

8.8.1 General

The organization shall address the following processes:

a) RAM (see 8.8.2);

b) safety (see 8.8.3).

The organization should address the LCC process (see 8.8.4).

The organization shall retain related documented information in relation with these processes.

8.8.2 Reliability, availability and maintainability

The organization shall establish, implement and maintain a RAM management process for products and services. Therefore, the organization shall identify regulations, standards (e.g. IEC 62278 or an equivalent) or guidelines, which are applicable for RAM process.

This process shall include:

a) calculation of RAM data during tender or design stages, to be considered through the entire product life cycle;

b) implementation of RAM requirements into the design and development along the supply chain;

c) data collection (e.g. field data or repair data) during post-delivery activities, maintenance, replacement or repair contracts;

d) analysis and comparison with field data from previous similar products (e.g. 8D, FRACAS);

e) feedback on RAM data to relevant operational teams to improve design;

f) feedback on RAM data to relevant external providers regarding their supplies;

g) monitoring RAM objectives; in case objectives are not met, the organization shall analyse field data, perform corrective actions as required in 10.2 and follow up field data until objectives are met.

Cause analysis should be executed based on failure category, component allocation and impact (remedy and severity).

In case the organization does not execute maintenance, replacement or repair contracts, it should request field data from customers also after warranty.

8.8.3 Safety

In case the organization delivers safety-related mechanical and/or electrical/electronic/programmable products and services, it shall establish, implement and maintain a safety management process for products and services. Therefore, the organization shall identify regulations, standards (e.g. IEC 62278, IEC 62425, IEC 62279 or an equivalent) or guidelines, which are applicable for safety activities.

NOTE 1 This process can apply to self-designed measuring resources used to verify safety related products and services.

NOTE 2 Safety activities are meant to cover SILs as well as safety-related electronic systems which can also be door systems, braking systems and power supply systems.

8.8.4 Life cycle costing

The organization should establish, implement and maintain a life cycle costing management process for products and services by taking into account the need of the market as well as their interest (as operator, system integrator, equipment manufacturer).

This process should include:

a) calculation of LCC data;

b) implementation of actions into the design and development, production and maintenance along the supply chain;

c) data collection (e.g. field data, repair data) during post-delivery activities, maintenance, replacement or repair contracts;

d) analysis and comparison with field data and LCC from previous similar products (e.g. 8D, FRACAS);

e) monitoring LCC objectives.

8.9 First article inspection

8.9.1 The organization shall establish, implement and maintain a FAI management process.

This process shall include:

a) planning in accordance with defined criteria in order to identify products subjected to the FAI;

b) preparation of the FAI;

c) inspection and verification activities, including review of production processes with focus on critical and special processes;

d) criteria:

   1) for release of the serial production;

   2) for conditional release;

   3) for rejection.

e) follow-up of corrective actions.

The organization shall retain related documented information.

8.9.2 In addition, this process should define:

a) pre-conditions to be evaluated before performing the FAI;

b) participants of the FAI depending on the item.

8.9.3 The FAI process shall be applied:

a) to internal products and EPPPS (see 8.4) in order to release serial production and to validate production equipment (see 8.5.1.4) and production processes (see 8.5.1.1.4);

b) on a representative item from the first series production run of a new product or significant change of an existing product, following:

   1) the verification of the production process; or

   2) a change that invalidates a previous FAI result.

NOTE Significant changes of existing products can include:

— major design changes (such as relating to performance, reliability, availability, maintainability, safety or other important features);

— major production process changes (such as process methods, test methods, production or measuring equipment, or other changes);

— transfer from one factory to another;

— restart of production if process conditions have changed;

— other changes that can affect the conformity of the product.

8.10 Obsolescence management

The organization shall establish, implement and maintain an obsolescence management process to ensure the availability of the supplied products and spare parts, as contractually required or defined by the organization, as a minimum until the end of the warranty.

This process shall include:

a) undertaking obsolescence risk assessment of the products to be supplied;

b) the definition and regular review of an obsolescence management plan for the supplied products to proactively prevent or mitigate obsolescence risks;

c) communication with customers.

In addition, this process should define the monitoring of the product portfolio to prevent future obsolescence problems.

NOTE 1 Obsolescence issues can be technical, functional or concern knowledge.

NOTE 2 IEC 62402 provides requirements and guidance for obsolescence management.

NOTE 3 Obsolescence can be managed, for example, by:

— means of a second source strategy;

— storage approach;

— modular design with standardized interfaces;

— upgrade to more modern technology.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

ISO 9001:2015, Quality management systems — Requirements
9 Performance evaluation
9.1 Monitoring, measurement, analysis and evaluation
9.1.1 General
The organization shall determine:
a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analysed and evaluated.
The organization shall evaluate the performance and the effectiveness of the quality management system.
The organization shall retain appropriate documented information as evidence of the results.

9.1.1.1 Monitoring and measurement — Supplemental

9.1.1.1.1 The organization shall identify, establish, implement and maintain documented PIs to monitor and improve the performance of its processes [see 4.4.1 c)], products, services and projects. For further explanation, see Annex C.

The organization shall collect data relating to reports of internal and external failures, in accordance with defined criteria.

NOTE Some PIs can be deemed as KPIs [see 5.3.1 a)].