TECHNICAL SPECIFICATION

ISO/TS 22163

First edition
2017-05

Railway applications — Quality management system — Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector

Applications ferroviaires — Système de management de la qualité — Exigences liées au système de management de l'activité à destination des organismes ferroviaires: ISO 9001:2015 et exigences particulières concernant les applications dans le secteur ferroviaire

Reference number
ISO/TS 22163:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on the 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 the following URL: www.iso.org/iso/foreword.html.

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

The aim of this document, which has been prepared by UNIFE, the European Rail Industry Association, is the development and continual improvement of a business management system to ensure product quality and safety in the global rail sector.

The content inside the boxed text of this document is ISO 9001:2015 text. The text outside the boxes has been originated by the UNIFE, IRIS Certification™ working group.

Whenever the ISO 9001:2015 text in this document refers to "quality management system", this term is understood hereinafter as "business management system", not limited to quality, so that it encompasses all business processes of the organization. Therefore, in the supplemental rail sector specific requirements, the term "business 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 sub-clauses are to be considered.

Whenever this document refers to "safety", the term is to be understood as "product safety", not to be confused with "occupational safety".

Whenever the ISO 9001:2015 text in this document refers to "quality policy" or "quality objectives" these terms apply to "safety policy" or "safety objectives" accordingly.

Whenever this document requires documented processes (e.g. calibration and production), these processes can be defined within a single documented process (e.g. both defined within a "production management" process).

0 Introduction

0.1 General

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 (see Clause A.4).

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.

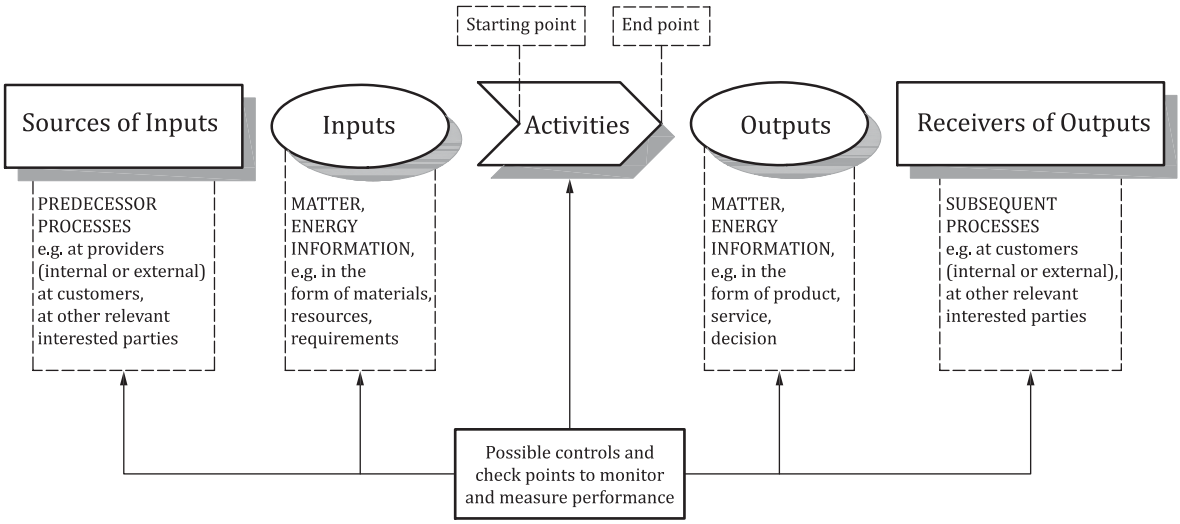


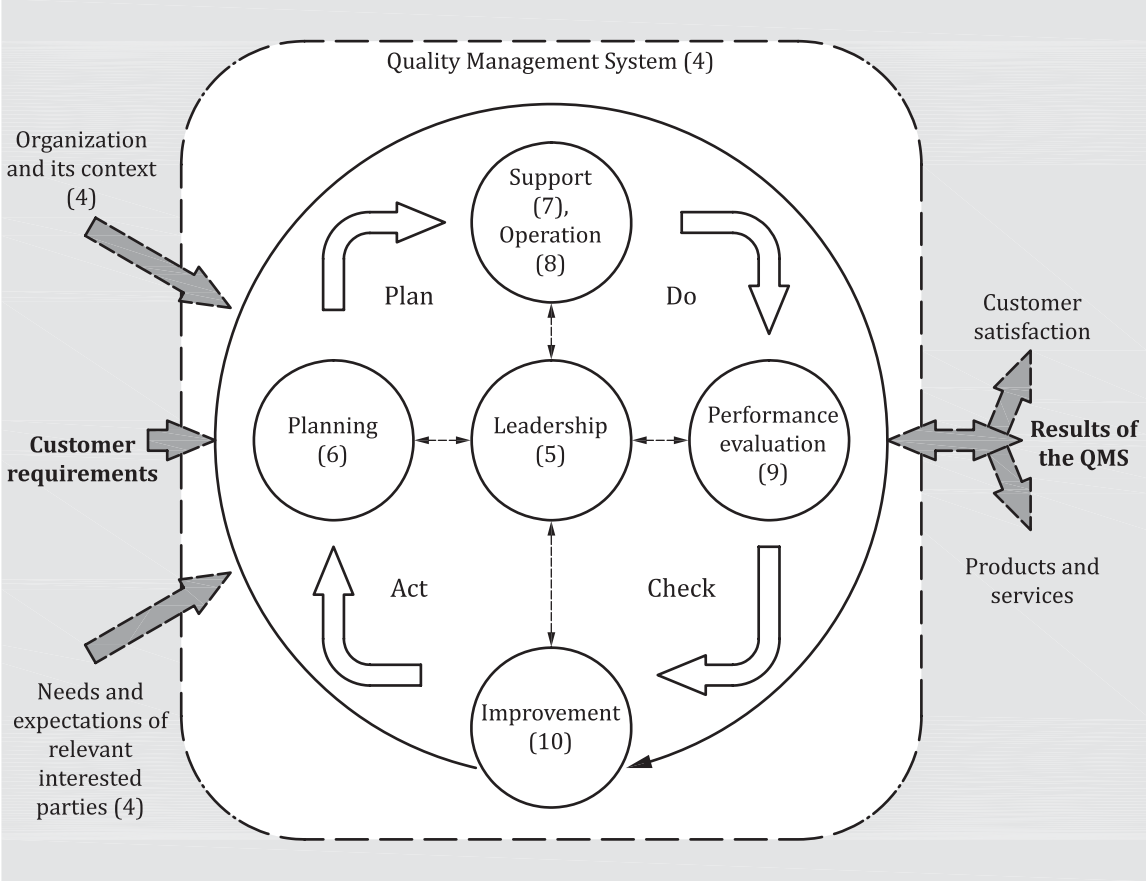
Figure 1 — Schematic representation of the elements of a single process

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 (see Clause A.4) 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 (see Clause A.1).

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.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

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 web site at: www.iso.org/tc176/sc02/public.

Railway applications — Quality management system — Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail 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 defines quality management system requirements in the rail sector (RQMS):

— applicable throughout the whole supply chain of railway industrial related products for the design and development, manufacturing and maintenance activities (excluding operations and services of rail transports);

— providing continual improvement, emphasizing defect prevention and defect reduction in the supply chain; and

— enhancing and sustaining product quality, including its safety aspects.

NOTE This document allows organizations to have the same flexibility when determining the boundaries and applicability of the quality management system as described in ISO 9001:2015, 4.3.

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 and definitions

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 terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1 Terms and definitions for the rail sector

3.1.1
application software
computer program that performs a set of functions to support the execution of a process

Note 1 to entry: This can be a software programme, database, computerized spreadsheet, electronic file or web tool, bought from the market or developed by the organization

3.1.2
availability
<item> ability to be in a state to perform as required

Note 1 to entry: Availability depends upon the combined characteristics of the reliability, recoverability, and maintainability of the item, and the maintenance support performance

[SOURCE: IEC 60050-192:2015, 192-01-23]

3.1.3
commissioning
phase before handover to a customer, in which a product is final tested under operational conditions to verify it functions according to its specifications

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

3.1.4
component
sub-device above the integration level of the smallest replaceable unit of a system in service or maintenance

3.1.5
configuration audit
audit performed in accordance with documented procedures to determine whether a product conforms to its requirements and product configuration information

[SOURCE: ISO 10007:2003, 5.6]

3.1.6
configuration baseline
approved product configuration information that establishes the characteristics of a product at a point in time that serves as reference for activities throughout the life cycle of the product

[SOURCE: ISO 10007:2003, 3.4]

3.1.7
configuration status accounting
formalized recording and reporting of product configuration information, the status of proposed changes and the status of the implementation of approved changes

[SOURCE: ISO 10007:2003, 5.5]

3.1.8
consignment stock
stock owned by an external provider, but held by the organization to ensure availability of parts

3.1.9
critical
critically
objects having the potential of introducing high risks that can threaten quality, safety or business performance, based on a risk assessment

3.1.10
deferred work
activity which is part of a predetermined sequence in a process that is delayed or postponed

3.1.11
deliverables
all types of output for the scope of supply to fulfil set requirements

EXAMPLE User manual, maintenance manual, test reports, test equipment, training, spare and support parts.

3.1.12
first article inspection
set of inspection and verification activities in order to validate a production process

3.1.13
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]

3.1.14
functional requirement
dedicated requirement or capability of a function within the functional breakdown structure

3.1.15
gate criteria
acceptance criteria for deliverables at gates in order to support the decisions to be taken, such as accepted, conditionally accepted or rejected

3.1.16
handover
acceptance criteria for deliverables at gates in order to support the decisions to be taken, such as accepted, conditionally accepted or rejected

3.1.17
installation
phase after delivery at customer premises and prior to commissioning

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

3.1.18
integration maturity
degree of fulfilment of the integration requirements of a product

EXAMPLE Already or never integrated in the organization's products.

3.1.19
integration requirements
requirements regarding integration of a system into a parent system and its fulfilment of functional requirements in this environment

3.1.20
key performance indicator
KPI
indicator, selected by the top management, to evaluate the performance of the business management system

3.1.21
life cycle costing
LCC
process of economic analysis to assess the cost of an item over its life cycle or a portion thereof

[SOURCE: IEC 60050-192:2015, 192-11-11]

3.1.22
maintainability
<item> ability to be retained in, or restored to a state to perform as required, under given conditions of use and maintenance

Note 1 to entry: Given conditions would include aspects that affect maintainability, such as: location for maintenance, accessibility, maintenance procedures and maintenance resources.

[SOURCE: IEC 60050-192:2015, 192-01-27]

3.1.23
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]

3.1.24
manufacturing
activities to realize products including overhaul and repair

Note 1 to entry: Part of an organizations value chain.

3.1.25
multidisciplinary approach
way of working involving different functions in one team on a specific subject

EXAMPLE Engineering, safety and procurement.

3.1.26
non-functional requirements
frame conditions under which functional requirements are met

Note 1 to entry: Some examples are:

— standards/regulations/requirements for approval by authorities;

— operating profile/configuration;

— additional, specific operator/customer non-functional requirements; and

— integration (physics/mechanics/electrics/control).

3.1.27
operational maturity
degree of fulfilment of the functional requirements of a product or service

EXAMPLE Not existing, under development, ready to use

3.1.28
product configuration information
requirements for product design, realization, verification, operation and support

[SOURCE: ISO 10007:2003, 3.9]

3.1.29
product life cycle
time of the entire life cycle of a product from inception, through design and manufacture, to service and disposal

3.1.30
product equipment
equipment used for production

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.

3.1.31
project core team
people from different functions appointed to support the project manager in leading and controlling the project

3.1.32
project management
planning, organizing, monitoring, controlling and reporting of all aspects of a project, and the motivation of all those involved in it to achieve the project objectives

[SOURCE: ISO 10006:2003, 3.6]

3.1.33
quality assurance methods
methods applied to qualify, verify or validate the implementation of requirements in order to focus on error prevention rather than detection

EXAMPLE In design and development.

Note 1 to entry: Quality assurance methods can be FMEA, FMECA, quality function deployment, etc.

3.1.34
quality deficiency cost
QDC
additional costs resulting from nonconforming products, processes or equipment

Note 1 to entry: QDC can be distinguished by causer (e. g. sales, engineering, production, purchasing, project management) and on phase of occurrence (e. g. tender, design, production, post-delivery)

Note 2 to entry: QDC can include:

a) additional labor, material or other direct costs in the context of failure or change due to incorrect design and the resulting actions taken (e. g. rework, redesign, repurchase, special shipments);

b) costs due to downtimes;

c) costs of scrap;

d) costs of products rendered unusable by or oversupply of storage;

e) costs due to accepted third-party claims and costs due to claims not asserted by the organization against third parties;

f) costs due to penalties for default or delays

Note 3 to entry: QDC can also be called nonconformity costs

3.1.35
reliability
probability of performing as required for the time interval (t1, t2), under given conditions

Note 1 to entry: Given conditions include aspects that affect reliability, such as: mode of operation, stress levels, environmental conditions, and maintenance, where applicable.

Note 2 to entry: It is usually assumed that the item is in a state to perform as required at the beginning of the time interval.

[SOURCE: IEC 60050-192:2015, 192-05-05]

3.1.36
safety
<product safety> freedom from unacceptable risk of harm

[SOURCE: IEC 62278, 3.35]

3.1.37
safety case
documented demonstration that the product complies with the specified safety requirements

[SOURCE: IEC 62278:2002, 3.36]

3.1.38
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 related systems

[SOURCE: IEC 62278:2002, 3.38]

3.1.39
safety-related
carries responsibility for safety

[SOURCE: IEC 62425:2007, 3.1.54]

3.1.40
site
organization, having activities in design and development and (or) manufacturing and (or) maintenance (fleet maintenance, refurbishment and component overhaul and (or) repairs) in defined scopes placed in a single location

3.1.41
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

3.1.42
transfer
complete or partial handover of process ownership for tasks or activities from internal product realization to an internal entity

3.2 Abbreviations

Abbreviations	Explanation
EPPPS	Externally Provided Process, Product 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 Costing
PDCA	Plan – Do – Check – Act
QDC	Quality Deficiency Cost
RAM	Reliability, Availability, Maintainability
RAMS	Reliability, Availability, Maintainability, Safety
RQMS	Rail Quality Management System
SIL	Safety Integrity Level

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.

4.2 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.

4.4 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

When this document requires a documented process, the process documentation shall cover as a minimum the requirements described in 4.4.1 a) to 4.4.1 e).

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

The organization shall:

a) document a hierarchical structure of its processes;

b) communicate processes (see 7.4) and ensure that people are aware of the processes;

c) train people on processes and ensure understanding (see 7.2.1 f));

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

e) ensure and maintain conformity of the business management system and its processes with applicable statutory or regulatory requirements and standards.

Documented processes required by this document 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 failure prevention and customer expectations.

5.2.4 Safety policy

Top management shall establish, implement, maintain and communicate a safety policy. The requirements described in 5.2.1 and 5.2.2 shall be applied for the safety policy accordingly.

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) appoint process owners (see 4.4.1 e);

b) document and communicate updates of ownership;

c) empower representatives independent, from the process execution, to stop the process or product or service provision, if quality or safety requirements are not met.

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

The organization shall retain related documented information.

5.3.2 Responsibilities and authorities of process owners

Process owner shall be responsible for the process compliance to requirements listed in 4.4 except availability of resources (see 4.4.1 d).

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

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

This process shall consider:

a) the requirements described in 6.1.1 and 6.1.2 ;

b) regular review and update of risks and actions ;

c) retention of documented information from risk assessments, reviews and actions.

NOTE 1 FMEA can be applied for managing risks in business planning, design and development, projects or production.

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

In addition, this process should:

i. involve customer and external providers in joint work on risk assessment and response ;

ii. require a multidisciplinary approach for risk reviews ; and

iii. evaluate its effectiveness based on QDCs.

The organization shall define criteria to determine the type and extent of controls in its processes by risk assessment methodology.

6.1.4 Contingency planning

The organization shall establish, validate, where applicable, and regularly review its contingency plan based on an evaluation of its business risks.

NOTE Business risks can concern utility interruptions, interruptions in the supply chain, labour shortages, critical technologies, key production equipment failure, field returns, succession plan, information and communication technology.

In case the organization identifies the need to outsource a process during the contingency planning, the outsourcing requirements described in 8.1.1 shall be applied.

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.

6.2.3 Safety objectives

The organization shall establish safety objectives. The requirements described in 6.2.1 and 6.2.2 shall be applied to the safety objectives accordingly.

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.

6.4 Business planning

The organization shall establish, implement and maintain documented business planning, reviewed on a yearly basis.

The business planning shall consider :

a) objectives (see 6.2) ;

b) market and product strategy, including development plans of new products and (or) processes and phase out strategies;

c) management reviews (see 9.3) ;

d) budget planning (see 7.1.1.1) ;

e) risks and opportunities of the organization (see 6.1) ;

f) contingency plan (see 6.1.4) ;

g) needs and expectations of customers ;

h) impact of changes in technologies and in statutory and regulatory requirements ;

i) company capacity considering the forecast ; and

j) merger, acquisition, outsourcing and transfer.

This business planning should consider :

i. change of external trends and interested parties needs (e.g. economic policies, environmental protection, social or cultural issues) ;

ii. the fiscal year calendar of the organization ; and

iii. an appropriate communication of planning outputs.

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 documented process for budget planning, approval and controlling.

This process shall consider:

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

b) the current order book and forecast ;

c) 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

Requirements specified in 7.1.5.1 and 7.1.5.2 shall apply to:

a) all monitoring and measuring resources used for verifying the conformity of products and services to their requirements;

b) tools used in special processes (e.g. torque wrench and crimper).

The organization shall establish, implement and maintain a documented process for verification or calibration, or both of monitoring and measuring resources. This process shall include:

c) requirements defined in 7.1.5.1 and 7.1.5.2;

d) how to react when monitoring or measuring resources 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 central application software).

NOTE Monitoring and measuring resources can be: test hardware, test software, Automated Test Equipment (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 another external provider.

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

e) establish related methods and acceptance criteria;

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

The records of measuring results shall provide:

g) the unique identification of the measuring resource used;

h) the date of measuring.

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

Regarding organizational knowledge, the organization shall:

a) manage return of experience including:

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

   2) communication of best practices and lessons learnt to relevant processes and active projects;

   NOTE Return of experience can be derived from and not limited to non-conformities, RAM / LCC data, customer complaints, internal audits, external provider audits, benchmarks.

b) allocate responsibilities for knowledge management regarding products, processes and projects;

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

Regarding organizational knowledge, the organization should:

i. use application software to share its knowledge;

ii. encourage knowledge sharing by networking;

iii. protect knowledge from unintended disclosure outside the organization (e.g. by access rights, intellectual property rights, documentation confidentiality classes).

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

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

NOTE 1 Competence can include product, process or project knowledge, application software, techniques and soft skills.

This process shall include:

a) requirements defined in 7.2;

b) identification of gap between actual and necessary competencies;

c) the identification, planning, organization, execution and monitoring of actions to acquire necessary competence;

d) induction for temporary workers and newcomers, covering as a minimum product quality and safety;

e) input from organizational knowledge (e.g. best practice used for trainings);

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

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

This process should:

i. include skill matrices for persons performing work that affect product quality and safety;

NOTE 2 Skill matrices can be used to compare the necessary competencies versus the actual state, considering progressive levels (e.g. learner, basic, advanced, coach).

NOTE 3 Persons performing work that affect product quality and safety are not limited to quality, engineering and production. Also people from procurement, field services or other functions of the organization can impact affect product quality and safety.

ii. ensure regular reviews and update of internal training materials;

iii. include input from nonconformities of products, services or processes (e.g. to evaluate the effectiveness of trainings).

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.

7.3.1 Awareness — Supplemental

Requirements defined in 7.3 shall apply to the safety policy and objectives accordingly.

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.

7.5 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 documented process for the control of documented information.

The process shall include:

a) the requirements defined in 7.5;

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

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

d) determination of the types of records (e.g. reports, measurement sheets, drawing) and their retention periods to comply with statutory and regulatory, contractual and business management system requirements.

The organization shall retain related documented information.

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

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

8 Operation

8.1 Operational planning and control

ISO 9001:2015, Quality management systems — Requirements

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 Planning for the outsourcing or transfer of processes

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

This process shall include:

a) a feasibility study;

b) a risk assessment (see 6.1);

c) planning of required actions for outsourcing;

d) the communication to customer when required;

e) a first article inspection (see 8.9), e.g. in case of outsourcing of production process;

f) retention of documented information from outsourcing activities.

This process shall be implemented by multi-sites organization transferring a process from one site to another.

NOTE 1 Planning for the outsourcing of processes can prepare a make or buy decision prior to implementing requirement from 8.4.

NOTE 2 The trigger for outsourcing can be the scarcity of resources or a strategic decision.

NOTE 3 The change management process (see 8.1.5) can be implemented for planning outsourcing or transfer of processes.

8.1.2 Tender management

The organization shall establish, implement and maintain a documented process to manage tenders. This process shall include:

a) requirements management (see 8.2) ;

b) the type and extent of controls (see 6.1.3) ;

c) risk and opportunity management (see 6.1), including monetary evaluation;

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

e) planning of deliverables including costs (e.g. time, pricing);

NOTE 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.

The organization shall define required competencies and related levels for persons dealing with tender, regarding requirement management.

8.1.3 Project management

The organization shall establish, implement and maintain a documented process to manage projects.

NOTE 1 The scope of the project management process depends on the business model of an organization. In most of the rail sector companies 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).

This process shall include:

a) requirement management (see 8.2);

b) the type and extent of controls (see 6.1.3);

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

c) the project phases and activities (e.g. planning, executing, monitoring, controlling and closing);

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

NOTE 3 Deliverables per phase can be defined in gates checklists.

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

NOTE 4 Conditional acceptance can be acceptance with an action plan.

f) requirements from 8.1.3.1 to 8.1.3.9;

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

This process should include:

i. an escalation process in case of rejection decision from phase reviews to facilitate problem solving;

ii. a review with the customer and key external providers regarding strengths and weaknesses, opportunities and threats;

iii. identification of best practices and lessons learned during project closure, as a minimum, (see 7.1.6).

The organization shall manage its project documented information including:

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

i) retaining documented information (e.g. plans, schedules, output of reviews, reports, etc.), as required in 7.5.

Phase reviews shall:

j) be performed:

   1) starting at defined level of work breakdown structure;

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

k) not be passed unless open issues of prior phase reviews are closed. Otherwise, waiver shall be approved by top management.

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

8.1.3.1 Project integration management

The organization shall establish and implement a project management plan. This plan shall include or refer to:

a) a project organization chart;

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

c) specific responsibilities and authorities of the project team members;

d) specific rules to follow during project execution;

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

   NOTE 1 Typical functions are sales, design, manufacturing, quality, production, purchasing, field support and other appropriate personnel including external provider 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 regulatory authorities, where required;

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

g) the control of changes (e.g. scope, time, costs) see 8.1.5.

NOTE 2 The project management plan can include any other subsidiary plans required in 8.1.3 (e.g. 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.

8.1.3.2 Project scope management

Regarding 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.

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.

8.1.3.3 Project time management

Regarding time management, the project management process shall include:

a) definition and sequences of activities;

b) estimation of resources and durations 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 8.5.7).

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

The project organization shall not change the schedule regarding the customer delivery dates unless authorized by the customer.

8.1.3.4 Project cost management

Regarding cost management, the project management process shall include:

a) definition of the budget based on calculation from tender;

b) assignment of budget to the respective work packages in a cost account structure;

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

The project organization should use standardized application software for cost tracking.

The project organization shall not increase the project budget unless authorized as defined by the organization.

8.1.3.5 Project quality management

Regarding quality management, the project management process shall include planning and implementation of quality assurance and control activities.

The project shall establish and implement a project quality management plan.

NOTE See ISO 10005 and ISO 10006 for guidance.

8.1.3.6 Project human resource management

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

a) 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 & loss responsibilities, etc.);

b) acquiring the project team;

c) managing the project team in terms of people, competence and awareness, according to requirements defined in 7.1.2, 7.2 and 7.3.

The project organization shall establish, implement and maintain a human resource plan. This plan shall include:

d) assignment of core team members;

e) staff assignments (e.g. organization chart).

The organization shall define required competencies and related levels for project managers and project core team members, regarding the following:

f) project management;

g) project management application software in use;

h) team work and communication;

i) project quality management;

j) risks and opportunities management;

k) products and services to be delivered.

The organization should define required competencies and related levels required for project managers regarding the following:

i. leadership;

ii. project financials.

8.1.3.7 Project communications management

Regarding communications management, the project organization shall:

a) apply requirements defined in 7.4 and 8.2.1 ;

b) establish, implement and maintain a project communication management plan;

c) perform regular project reviews to monitor project progress, with the attendance of the core team members (see 8.1.3.6).

In case of an imminent deviation to the project objectives, the project organization shall identify and implement appropriate countermeasures to avoid any impact on customer or the organization.

Project reviews shall include:

d) the project performance (actual situation vs. planned situation) based on KPIs as specified in 9.1.1 (e.g. requirements, time, costs);

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

f) the actual risks & opportunities, including status of related actions;

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

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

8.1.3.8 Project risk and opportunity management

Regarding risk and opportunity management, the project organization shall

a) apply requirements defined in 6.1;

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

c) retain documented information of risk and opportunity management.

Regarding risk and opportunity management, the project organization should:

i. involve the functional line managers in risk reviews;

ii. consider functional and integration maturity levels of the products agreed with the customer as inputs for risks management;

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

8.1.3.9 Project procurement management

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

8.1.4 Configuration management

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

NOTE 1 The configuration management process is applicable for hardware and software.

This process shall consider as a minimum:

a) the configuration management planning;

b) the product breakdown structure until the lowest replaceable units;

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

d) configuration baselines to be established, as a minimum for “as-designed”, “as-built” and “as-maintained” configurations;

e) the change control of the configuration according to 8.1.5;

f) configuration status accounting;

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

The organization shall retain related documented information.

This process should:

i. consider regular internal configuration audits;

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

iii. consider tools and software used in design, development, production and maintenance as configuration items;

iv. be supported by an application software.

NOTE 2 See ISO 10007 for guidance.

8.1.5 Change management

The organization shall establish, implement and maintain documented processes to manage changes. These processes shall include:

a) the requirements defined in this document, such as:

   1) in 8.2.4 applicable to requirements for products and services;

   2) in 8.3.6 applicable to design and development changes;

   3) in 8.5.6 applicable to production and service provision;

b) the change request;

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

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

e) verification of proposed changes to avoid adverse effects;

f) notification to and agreement with customers, external providers and authorities, based on criteria including, as a minimum, changes affecting their requirements;

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

   NOTE 2 A change request identified from 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) implementation of changes;

j) the verification of implementation and follow-up.

These processes shall be supported by an application software.

These processes should include:

i. planning of actions in order to minimize the impact of change;

ii. the traceability of changes supported by an application software.

For technical product or service changes, these processes shall include in addition:

k) 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 assurance plan, FMEA report);

l) the re-evaluation of functional, non-functional and integration requirements;

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

n) 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 (products or external providers), evolution of standards, regulations, laws, needs for operation, cost optimization, or specific event: accident, incident, weather or customer variation order.

For technical product or service changes, these processes should include in addition the re-evaluation of operational and integration maturity.

The change management requirements shall apply to:

o) project management (see 8.1.3);

p) requirements for products and services (see 8.2.4);

q) design and development of products and services (see 8.3.6);

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

s) production and service provision (see 8.5.6) encompassing production processes, production equipment, production programs (software) and production location.

NOTE 4 Changes can be initiated by external provider 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.

8.2 Requirements for products and services

8.2.1 Customer communication

ISO 9001:2015, Quality management systems — Requirements

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 to customer when delays are foreseen but cannot be avoided (e.g. delays from external providers).

8.2.2 Determining the requirements related to products and services

ISO 9001:2015, Quality management systems — Requirements

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

When determining the requirements, the organization shall consider:

a) functional, non-functional and integration requirements;

b) RAMS / LCC requirements.

When determining the requirements, the organization should consider:

i. experience from similar products / tenders / projects;

ii. requirements resulting from market analysis;

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

iv. critical product characteristics;

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

8.2.3 Review of requirements related to products and services

ISO 9001:2015, Quality management systems — Requirements

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

ISO 9001:2015, Quality management systems — Requirements

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 documented process to manage requirements.

This process shall:

a) consider the requirements defined in 8.2;

b) be applicable for:

1) design and development of new products or 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 8.1.5);

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

c) performed by a multidisciplinary approach including internal and external stakeholders where 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;

e) ensure that requirements are:

1) individually checked for compliance clause by clause;

2) evaluated and taken into account;

3) assessed related to risk and opportunities;

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

5) complete, unequivocal, verifiable and feasible;

6) are documented in a functional and performance specification for technical requirements;

NOTE 2 The functional and performance 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 or introduction of new technologies (e.g. composite products, laser welding).

The organization shall perform process FMEA for the implementation of new technologies.

The design and development process shall:

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

b) be documented;

c) require a safety case in accordance with IEC 62425 or equivalent for safety-related products in conjunction with IEC 62278 or equivalent.

The organization shall define required competencies and related levels for persons dealing with design and development, regarding the following:

d) requirement management;

e) configuration management;

f) quality assurance methods.

8.3.2 Design and development planning

ISO 9001:2015, Quality management systems — Requirements

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

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 control (see 8.1.4);

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 assurance plan).

NOTE 1 Design stages can be conceptual design, preliminary design, final design.

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

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

ii. the method to control non-functional, functional, performance and integration requirements;

iii. the method to control the integration and operational maturity.

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

ISO 9001:2015, Quality management systems — Requirements

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

Regarding design and development inputs, the organization shall consider the requirements defined in 8.2.2.1.

The organization shall retain related documented information.

In addition, the organization should consider:

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

ii. the application of design concepts (e.g. design for manufacturing, design for testing, design for maintainability).

8.3.4 Design and development controls

ISO 9001:2015, Quality management systems — Requirements

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:

i. the functional breakdown;

ii. the integration and operational maturity;

iii. 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 defined level of competencies and respective decision making authorities.

The organization shall retain documented information related to design reviews.

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).

8.3.4.3 Design verification

The organization shall ensure that performance requirements are verified.

The organization shall retain documented information related to design verification.

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

8.3.4.4 Design validation

Regarding design validation, the organization shall:

a) ensure that functional, non-functional and integration 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 are e.g. qualification tests, type tests, product approval tests, etc.

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

c) test plans, specifications or procedures define:

   1) test objectives;

   2) test conditions and reproducible environment;

   3) the product to be tested;

   4) resources needed;

   5) acceptance criteria;

   6) parameters to be recorded;

   7) the method of operation;

   8) the performance of the test;

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

e) the acceptance criteria are met.

The organization shall retain documented information of the test results.

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

The organization shall ensure that design and development outputs:

a) are verified and approved prior to release;

b) are verified against production process input requirement;

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

The organization should

i. ensure the traceability of outputs to the input requirements;

ii. define authorities and acceptance criteria for design approval;

iii. define escalation rules in case acceptance criteria for approval are not met;

iv. ensure that information for production and service provision include requirements for the preservation of product.

NOTE The design and development outputs can include e.g. specifications and drawings (also from external providers), information on materials, production process flow chart and (or) layout, inspection and test plan, work instructions for production, process and product approval acceptance criteria, results of error prevention activities (e.g. FMEA), as appropriate, 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

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

NOTE Internal providers are understood as entities from the same corporation delivering products, processes and services to the organization.

The organization shall establish, implement and maintain a documented process for externally provided processes, products and services (EPPPS) described in 8.4.1 to ensure conformity to requirements.

This process shall include requirements defined for:

a) classification of external providers and EPPPS (see 8.4.1.1.1);

b) external provider evaluation (see 8.4.1.1.2);

c) external provider approval (see 8.4.1.1.3);

d) external provider offer selection (see 8.4.1.1.4);

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 provider 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) retain documented information on external provider controls.

8.4.1.1.1 Classification of external providers and external provided products, process or service

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 6.1.3). As an output, key external providers shall be identified.

The organization shall retain related documented information.

Classification criteria shall include the ability of external provider to provide EPPPS according to requirements.

Classification criteria should include:

i. strategic needs;

ii. past experiences;

iii. available market information;

iv. external benchmarks;

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

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

8.4.1.1.2 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. certificates such as ISO 9001, or this document).

The organization shall establish, implement, maintain and monitor a strategy to enable the targeting of:

c) external providers compliant to this document;

d) external providers compliant to ISO 9001 or another similar quality management system.

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

The organization shall retain related documented information.

8.4.1.1.3 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.

The organization shall retain related documented information.

EPPPS shall be provided exclusively by approved external providers.

8.4.1.1.4 External provider offer selection

The organization shall ensure that the external provider's offer is selected only after thorough documented analysis prior to negotiation. The analysis shall take into account:

a) the level of compliance with the requirements, e.g. by clause by clause;

b) the total cost of ownership including LCC;

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

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

The organization shall retain related documented information.

The analysis should take into account:

i. the output of a risk analysis;

ii. the operational and integration maturity of externally provided products.

Prior to the issuance of a purchase order, the organization should ensure that the external provider has all functional and non-functional requirements fully understood, 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 External provided products, process or service approval of release

Approval of release for new or modified EPPPS shall include:

a) determination of approval methods;

b) planning of verification, validation and approval activities;

c) conducting FAI at external provider 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 baseline considering change management (see 8.1.5).

The organization shall retain related documented information.

Approval of release for new or modified EPPPS should consider:

i. pre-manufacturing reviews;

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

ii. first system integration.

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

8.4.2.2 External provided products, process or service 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 6.1.3);

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

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

d) release of the EPPPS;

e) documentation of verification activities;

f) management of non-conforming EPPPS.

The organization shall retain related documented information.

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, etc.

The organization shall establish, implement and maintain a plan for periodical verifications of raw material based on risks assessment.

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

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

8.4.2.3 Monitoring of external provider performance, re-evaluation and ranking

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

a) periodical reviews of external provider performance (see 9.1.1.1 for related KPI's);

b) definition of criteria to audit external providers;

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

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

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

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.

The organization shall retain related documented information.

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

Regarding information for external providers, the process required in 8.4.1.1 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.

In addition to the requirements in 8.4.3, the organization shall communicate to external providers its requirements for:

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

e) deliverables associated to the EPPPS (e.g. EPPPS documentation) 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, their customer 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;

— 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 to the external provider 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 provider in order to give inputs for their resources planning. This shall include delays to the deliveries of components from the organization to the external provider.

The organization should agree 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.

Supply chain information (e.g. delivery dates, quantities), exchanged with customers, external providers and internal functions (e.g. design, production), shall be managed and be maintained up-to-date with an application software (e.g. Enterprise Resource Planning).

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

NOTE Production in the spirit 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 documented process for production and service provision. This process shall:

a) include requirements for:

   1) production scheduling (see 8.5.7);

   2) activities to ensure controlled conditions (see 8.5.1.1.1);

   3) verification of the process for production and service provision (see 8.5.1.1.2);

   4) validation of the process for production and service provision (see 8.5.1.1.3);

   5) activities to control production equipment (see 8.5.1.3);

   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) first article inspections (see 8.9);

2) configuration management (see 8.1.4);

3) change management (see 8.1.5);

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

5) control of non-conforming outputs (see 8.7);

6) special processes (see 8.5.1.2).

8.5.1.1.1 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, traveller, work order, process cards);

2) a list of tools and numerical control machine programs 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) assessment of risk impact of deferred work to ensure control of work to be carried out without affecting quality and safety.

8.5.1.1.2 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;

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

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

8.5.1.1.3 Validation of the process for production and service provision

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) first article inspection is completed;

d) validation is completed prior to handover;

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

Validation of the process for production and service provision should include regular feedback to design and development in order to support continual improvement of production documentation.

8.5.1.2 Special processes

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

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 competences and qualification;

   6) control methods and related documented information;

   7) qualification of the special process;

   8) validation for each specific application, and

   9) re-validation after changes.

c) retention of documented information according to the previous requirements.

NOTE Special processes can be, for example, bonding and sealing, casting, crimping, heat treatment, riveting, surface treatment, including painting and coating, torque tightening, welding.

8.5.1.3 Production equipment

Regarding production equipment, the organization shall:

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

   1) verified according to defined methods and acceptance criteria;

   2) approved prior to first use;

   3) registered with individual numbers;

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

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

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

b) adjust the planned intervals and activities according to occurrence of failures;

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

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

e) retain documented information on the maintenance activities.

NOTE 1 Preventive maintenance activities can also be predictive.

The organization should:

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

ii. use methods which prevent errors in production (e.g. Poka Yoke).

NOTE 2 The verification of the production equipment can be part of the first article inspection (see 8.9).

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, regulatory or statutory norms, or configuration management (see 8.1.4).

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

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

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 should document traceability of property belonging to customer or external providers up to delivery or return.

In the event that property is lost, damaged or otherwise found to be unsuitable for use, the organization should perform 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, ana-lysed 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 provider, property belonging to customer, work in progress and products manufactured by the organization).

NOTE These documented specifications can apply to warehouse, 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 Post-delivery activities are after handover to the customer, until contract obligations end.

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

a) requirements defined in 8.5.5;

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

c) failure analysis and corrective actions methods (e.g. FRACAS) (see 8.8);

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

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

f) knowledge of customer complaints as inputs for design and development improvement.

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.

8.5.7 Production scheduling

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 production scheduling application software (e.g. Enterprise Resource Planning) 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 customer and external provider forecasts and orders to plan and adjust regularly its resources according to its workload, taking into account risks (e.g. extra order at the last minute, external provider failure);

d) identify bottlenecks in production.

Regarding production scheduling, the organization should:

i. consider:

   1) results of risk analysis;

   2) past experience;

   3) efficiency measurements;

ii. establish an improvement action plan accordingly.

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 6.1.3). Frequency shall be adopted in accordance with 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.

8.7 Control of nonconforming outputs

ISO 9001:2015, Quality management systems — Requirements

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

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

The process shall include:

a) requirements defined in 8.7.1, 8.7.2 and 10.2 ;

b) identification of criteria and authorities for :

   1) rework, repair or scrap ;

   2) internal and customer concessions ;

c) a register of nonconforming outputs ;

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

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

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 customer ;

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

NOTE This process can be part of the process nonconformity and corrective actions defined in 10.2.3.

8.8 RAMS / LCC

The organization shall establish, implement and maintain documented processes to manage RAM / LCC activities.

These processes shall include:

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

b) implementation of RAM / LCC 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 (FRACAS);

e) feedback on RAM / LCC data to relevant operational teams to improve design concepts, such as design for maintenance;

f) sharing the results of RAM / LCC data analysis with external providers regarding their supplies;

g) monitoring RAM / LCC objectives. In case objectives are not met the organization shall prioritize 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 and component allocation and impact (remedy and severity).

The organization shall retain related documented information.

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

Persons dealing with RAM / LCC matters shall have competencies in FRACAS.

The organization shall identify standards such as IEC 62278 or equivalent, which are applicable for:

h) RAMS activities;

i) tools developed by the organization for safety-related products or services (e.g. design, development, verification or testing tools).

In case the organization delivers safety-related Electrical/Electronic/Programmable Electronic products or services, it shall identify:

j) safety integrity levels in accordance with IEC standards (e.g. IEC 61508 and IEC 62425) or equivalent;

k) applicable standards such as:

1) IEC 62279 or equivalent for safety-related software provided by the organization;

2) IEC 62425 or equivalent for safety-related electronic systems provided by the organization.

NOTE Safety-related electronic systems can also be door systems, braking systems, power supplies.

8.9 First article inspection

The organization shall establish, implement and maintain a documented process for first article inspection (FAI).

This process shall include:

a) planning according to defined criteria in order to identify products subjected to the FAI (see 8.4.1.1);

b) preparation of 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.

In addition, this process should define:

i. pre-conditions to be evaluated before performing the FAI;

ii. participants of the FAI depending on the item;

iii. criteria and conditions to start FAI activities.

First article inspection process shall:

f) be applied to internal products and EPPPS (see 8.4) in order to release serial production and to validate production equipment (see 8.5.1.3) and production processes (see 8.5.1.1.3);

g) be conducted on a representative item from the first series production run of a new product or major upgrade of an existing product, following:

   1) the verification of the production process or

   2) a change that invalidates a previous first article inspection result.

8.10 Obsolescence management

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

This process shall include:

a) definition and regular review for update of a plan covering:

   1) second source strategy;

   2) storage approach;

3) form, fit and function compatibility approach, referring to the change management process (see 8.1.5);

b) risk management of obsolete parts according to 6.1;

c) communication with customer.

8.11 Innovation management

The organization should establish, implement, maintain a documented process to manage innovation of new products, services and technologies.

This process should include:

i. the identification of changes in the organization's business environment;

ii. planning of innovations;

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

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

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

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 General — Supplemental

The organization shall identify, establish, implement and maintain documented KPI's to monitor and improve the performance of its processes, products, services and projects.

The organization shall collect data relating to reports of internal and external technical failures, according to defined criteria.

The definition of each KPI shall specify:

a) the related process it belongs to;

b) how the KPI is calculated (e.g. formula);

c) the related target achievable in a defined period;

d) who provides the KPI measures;

e) when the KPI is reported and to whom;

f) who is in charge of defining related actions.

KPI's shall measure:

g) customer satisfaction (see 9.1.2);

h) customer on time delivery;

i) nonconformities raised by the customer (see 8.7);

j) internal nonconformities (see 8.7);

k) external providers' nonconformities (see 8.7);

l) external providers on time delivery;

m) quality deficiency costs;

n) project costs (see 8.1.3.8);

o) requirements management process (see 8.2.5);

p) design and development process (see 8.3).

KPI's should measure:

i. response time on non-conformities and complaints raised by customer;

ii. production capacity including forecast (including for manufacturing and infrastructure installation);

iii. resolution time of problems, e.g. such as open issues;

iv. first article inspections (see 8.9);

v. downtime of production equipment;

vi. internal audit process (see 9.2);

vii. tender management process (see 8.1.2).

9.1.2 Customer satisfaction

ISO 9001:2015, Quality management systems — Requirements

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.2.1 Customer satisfaction — Supplemental

The organization shall manage customer complaints by:

a) recording them and their responses in a centralized application software;

b) communication with the customer in terms of acknowledgment and related corrective actions according to 10.2.

9.1.3 Analysis and evaluation

ISO 9001:2015, Quality management systems — Requirements

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.1.3.1 Analysis and evaluation — Supplemental

When KPI targets are not achieved, corrective actions shall be managed according to 10.2.

The organization shall analyze and evaluate data collected in relation to reports of internal and external technical failures (see 9.1.1.1).

Results of analysis of data should be shared with defined interested parties, such as internal, customers, external providers.

9.2 Internal audit

ISO 9001:2015, Quality management systems — Requirements

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) the organization's own requirements for its quality management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.2.3 Internal audit — Supplemental

The organization shall establish, implement and maintain a documented process for internal audits to verify compliance of processes, projects, products and services with internal and external requirements.

This process shall include:

a) requirements defined in 9.2.1 and 9.2.2;

b) management of the audit programme (see 9.2.3.1);

c) management of the internal auditors (see 9.2.3.2).

The organization shall retain related documented information.

Internal audits shall provide inputs for return of experience (see 7.1.6).

9.2.3.1 Audit programme

In addition to 9.2.2, requirements for the audit programme shall consider the following:

a) processes identified on the process hierarchical structure of the business management system (see 4.4.3 a);

b) critical projects, products and services;

c) the frequency of audits takes into consideration the status and importance of the audit scope but shall be as a minimum of 3 years for processes;

d) auditors do not audit their own work;

e) the audit programme covers all production shifts, if applicable.

Requirements for the audit programme should consider multidisciplinary audits to ensure that the number of internal audits is optimized and redundancies are avoided.

NOTE 1 Multidisciplinary audits can be audits involving different functions (e.g. procurement, project management, production and finance) or a process and a project at the same time.

NOTE 2 Organization can plan combined audits (e.g. quality and environment) in order to improve efficiency provided coverage of the scope is properly balanced between the management system.

9.2.3.2 Auditors management

The organization shall ensure that the audit team auditing the requirements of this document have:

a) knowledge and skills about:

   1) audit principles (e.g. personal behaviour), process and methods;

   2) the audit scope (e.g. product or service, organizational function);

   3) relevant clauses of this document according to the audit scope;

   4) the audit criteria (e.g. internal procedures, this document);

b) audit experience (e.g. audit witness, regular conduct of audits or audit team leading).

Regarding auditors' management, the organization should:

i. appoint auditors from relevant functions (e.g. purchasing, engineering, project management);

ii. maintain and improve the knowledge, skills and experience as minimum through regular refresh trainings and number of performed audits;

iii. evaluate the performance of internal auditors by the auditees based on criteria and used as inputs for the management of auditors' competencies;

iv. establish and maintain a list of internal auditors containing their qualification and competencies in terms of audit scope (e.g. functional area, products, standards).

9.3 Management review

9.3.1 General

ISO 9001:2015, Quality management systems — Requirements

9.3 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.1.1 General — Supplemental

The organization shall ensure that planned intervals of management reviews do not exceed 12 months and are aligned with the business calendar of the organization.

The organization shall retain documented information related to management reviews, including inputs and outputs.

9.3.2 Management review inputs

ISO 9001:2015, Quality management systems — Requirements

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

   1) customer satisfaction and feedback from relevant interested parties;

   2) the extent to which quality objectives have been met;

   3) process performance and conformity of products and services;

   4) nonconformities and corrective actions;

   5) monitoring and measurement results;

   6) audit results;

   7) the performance of external providers;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

9.3.2.1 Management review inputs — Supplemental

Management reviews shall take into consideration:

a) key issues from project reviews;

b) selected results of process reviews;

   NOTE Process reviews can be used to provide analysis of mandatory KPI's.

c) reviews of the results from analysis of mandatory KPI's defined in 9.1.1 as a minimum;

d) analysis of actual and potential internal and external technical failures and their impact on safety.

9.3.3 Management review outputs

ISO 9001:2015, Quality management systems — Requirements

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

9.3.3.1 Management review outputs — Supplemental

The outputs of the management review shall include decisions and actions related to:

a) objectives achievement, including quality and safety objectives as a minimum;

b) customer satisfaction.

Corrective actions shall be managed according to 10.2 when objectives are not achieved.

9.4 Process reviews

Regarding process reviews, the organization shall:

a) review the mandatory processes required by this document at least every 12 months;

b) ensure that:

   1) process owners attend process reviews as well as top management representatives of the process stakeholders;

   2) process conformity with requirements of 4.4.1 is addressed during process reviews;

   3) actions from previous process reviews are monitored;

   4) decisions and actions are taken when required;

   5) outputs of process reviews are reported to the top management;

   6) inputs and outputs of process reviews are documented and retained;

   7) the nonconforming outputs of the process are monitored;

   8) resources are available and effective to perform the process.

In addition, process owners should ensure that process reviews address the following:

i. measurement analysis of KPI's related to the process (see 9.1.1.1), including review of KPI target achievement;

NOTE Requirements for analysis and evaluation in 9.1.3 can apply to KPI's for process reviews.

ii. review of the process KPI's relevance and actions to adjust as necessary;

iii. corrective actions resulting from audits;

iv. identification of any necessary acquisition of knowledge and changes with regard to competencies for the process.

10 Improvement

10.1 General

ISO 9001:2015, Quality management systems — Requirements

10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

ISO 9001:2015, Quality management systems — Requirements

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing and analysing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.2.3 Nonconformity and corrective action — Supplemental

The organization shall establish, implement and maintain a documented process for managing nonconformities and corrective actions that includes:

a) requirements defined in 10.2.1 and 10.2.2 ;

b) definition of criteria to evaluate the need for corrective actions;

c) application of problem solving methods (e.g. 4D, 8D);

d) monitoring of corrective actions.

The organization shall retain related documented information.

NOTE These requirements can apply to nonconformity of products, services, processes, project execution.

10.3 Continual improvement

ISO 9001:2015, Quality management systems — Requirements

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Bibliography

References from ISO 9001:2015

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

[2] ISO 9001:2015, *Quality management systems — Requirements*

[3] ISO 10006, *Quality management systems — Guidelines for quality management in projects*

[4] ISO 10007, *Quality management — Guidelines for configuration management*

[5] ISO 19011, *Guidelines for auditing management systems*

[6] IEC 60050-192:2015, *International electrotechnical vocabulary — Part 192: Dependability*

References specific to the railway sector

[7] IEC 62278:2002, *Railway Applications Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)*

[8] IEC 62279:2012, *Railway applications — Communication, signalling and processing systems - Software for railway control and protection systems*

[9] IEC 62425:2007, *Railway applications — Communication, signalling and processing systems — Safety related electronic systems for signalling*

[10] IEC 61508:2010, *Electronic Functional Safety Package*

ICS 03.100.70; 45.020

Price based on 69 pages

This page has been left intentionally blank.