PD ISO/TS 22163:2017

BSI Standards Publication

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

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National foreword

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TECHNICAL SPECIFICATION

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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

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Foreword

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

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

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

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

For an explanation on the 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).

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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).

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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.

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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.

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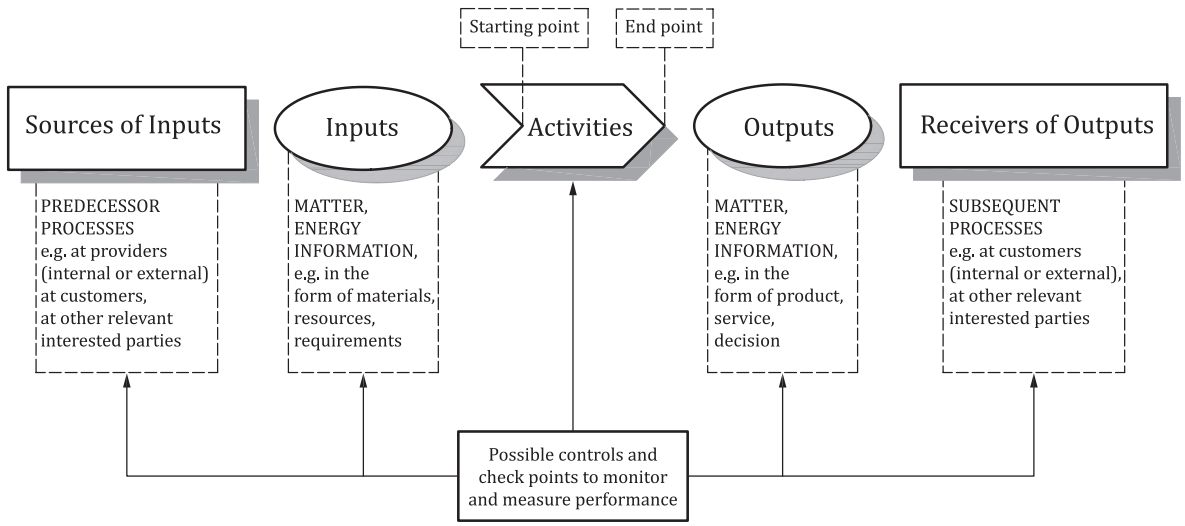

Figure 1 — Schematic representation of the elements of a single process

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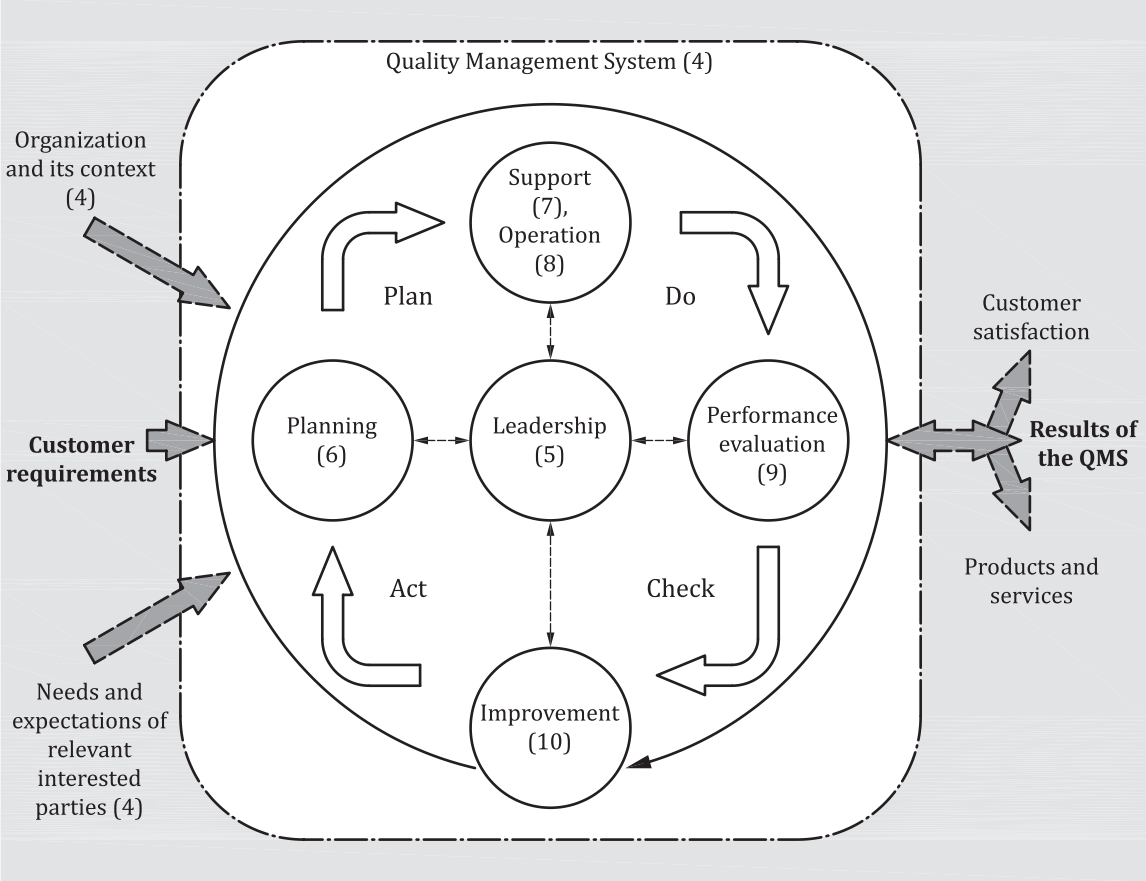
0.3.2 Plan-Do-Check-Act cycle

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

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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.

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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.

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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.

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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

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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

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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.

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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]

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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]

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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

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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.

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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.

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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.

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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.

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