RAUDTEEALASED RAKENDUSED – RAUDTEE KVALITEEDIJUHTIMISSÜSTEEM – ISO 9001:2015 JA RAUDTEESEKTORIS RAKENDAMISE ERINÕUDED

Railway applications - Railway quality management system - ISO 9001:2015 and specific requirements for application in the railway sector (ISO 22163:2023 + ISO 22163:2023/Amd 1:2024)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 22163:2024+A1:2025 sisaldab Euroopa standardi EN ISO 22163:2024+A1:2025 ja selle muudatuse A1:2025 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 22163:2024+A1:2025 consists of the English text of the European standard EN ISO 22163:2024+A1:2025 and its amendment A1:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 08.05.2024, muudatus A1 08.01.2025.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 08.05.2024, for A1 08.01.2025.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟨A1⟩ ⟨A1⟩. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags ⟨A1⟩ ⟨A1⟩. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 03.100.70; 45.020

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22163 + A1

May 2024, January 2025

ICS 03.100.70; 45.020

English Version

Railway applications - Railway quality management system - ISO 9001:2015 and specific requirements for application in the railway sector (ISO 22163:2023 + ISO 22163:2023/Amd 1:2024)

Applications ferroviaires - Système de management de la qualité ferroviaire - Exigences de l'ISO 9001:2015 et exigences particulières concernant les applications dans le secteur ferroviaire (ISO 22163:2023 + ISO 22163:2023/Amd 1:2024)

Bahnanwendungen - Eisenbahn-Qualitätsmanagementsystem - ISO 9001:2015 und spezifische Anforderungen für die Anwendung im Bahnsektor (ISO 22163:2023 + ISO 22163:2023/Amd 1:2024)

This European Standard was approved by CEN on 5 May 2024. Amendment A1 was approved by CEN on 22 December 2024.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 22163:2024 E
+ EN ISO 22163:2024/A1:2025 E

European foreword

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

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

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

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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

Endorsement notice

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

A1 Amendment A1 European foreword

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

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

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Foreword

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

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

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

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

The main changes are as follows:

— the scope has been simplified;

— the terms and definitions in Clause 3 have been revised;

— the previous subclause 6.4 “Business planning” has been moved to 4.1.1;

— a new subclause 4.1.2 on “Social responsibility” has been added;

— subclause 7.2.1 “Competence — Supplemental” has been revised;

— the previous subclause 8.11 “Innovation management” has been moved to 8.1.1.1;

— “Project review management” has been separated from the previous subclause 8.1.3.7 “Project communications management” as a new subclause 8.1.3.11;

— the previous subclauses 8.1.4 “Configuration management” and 8.1.5 “Change management” have been combined in 8.1.4 “Configuration management and change control”;

— product safety requirements have been integrated in the quality requirements;

— reliability, availability, maintainability, safety and life cycle costing requirements have been clarified in 8.8;

— the notion of performance indicators versus key performance indicators has been added;

— the performance indicators have been revised;

— Annex A on “List of processes” has been added;

— Annex B on “Subordinate concept of requirements for products and services” has been added;

— Annex C on “Performance indicators” has been added.

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[A1] Amendment A1 Foreword

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This document was prepared by Technical Committee ISO/TC 269, *Railway applications*, in accordance with Technical Management Board Resolution 75/2023.

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Introduction

0.1 General

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

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

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

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

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

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

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

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

— defined within a single process,

— combined with another process or other processes, or

— split in several processes

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

ISO 9001:2015, Quality management systems — Requirements

0.1 General

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

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

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

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

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

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

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

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

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

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

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

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

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

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

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

0.2 Quality management principles

ISO 9001:2015, Quality management systems — Requirements

0.2 Quality management principles

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

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

ISO 9001:2015, Quality management systems — Requirements

0.3 Process approach

0.3.1 General

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

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

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

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

a) understanding and consistency in meeting requirements;

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

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

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

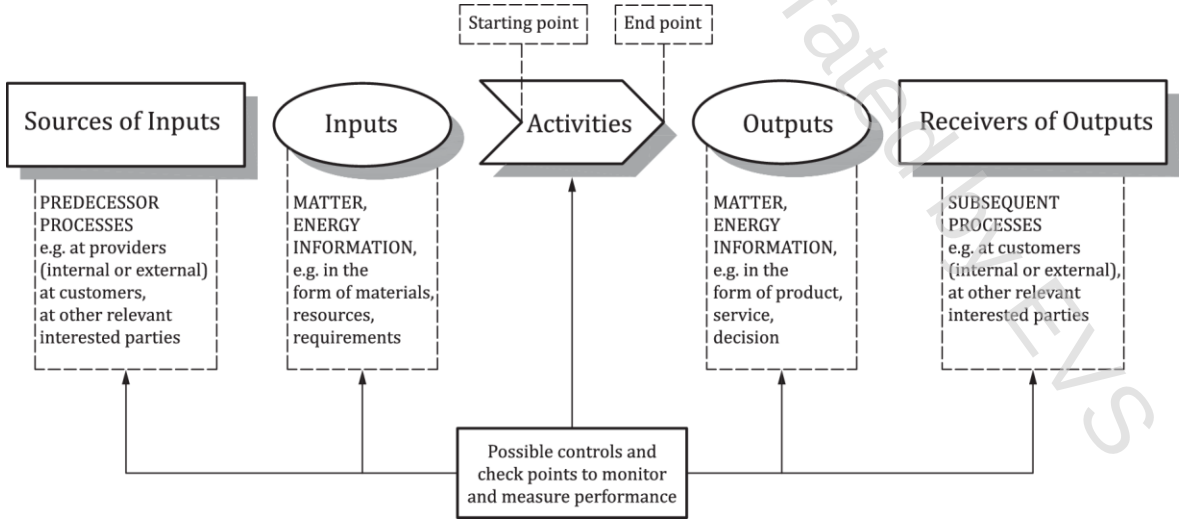


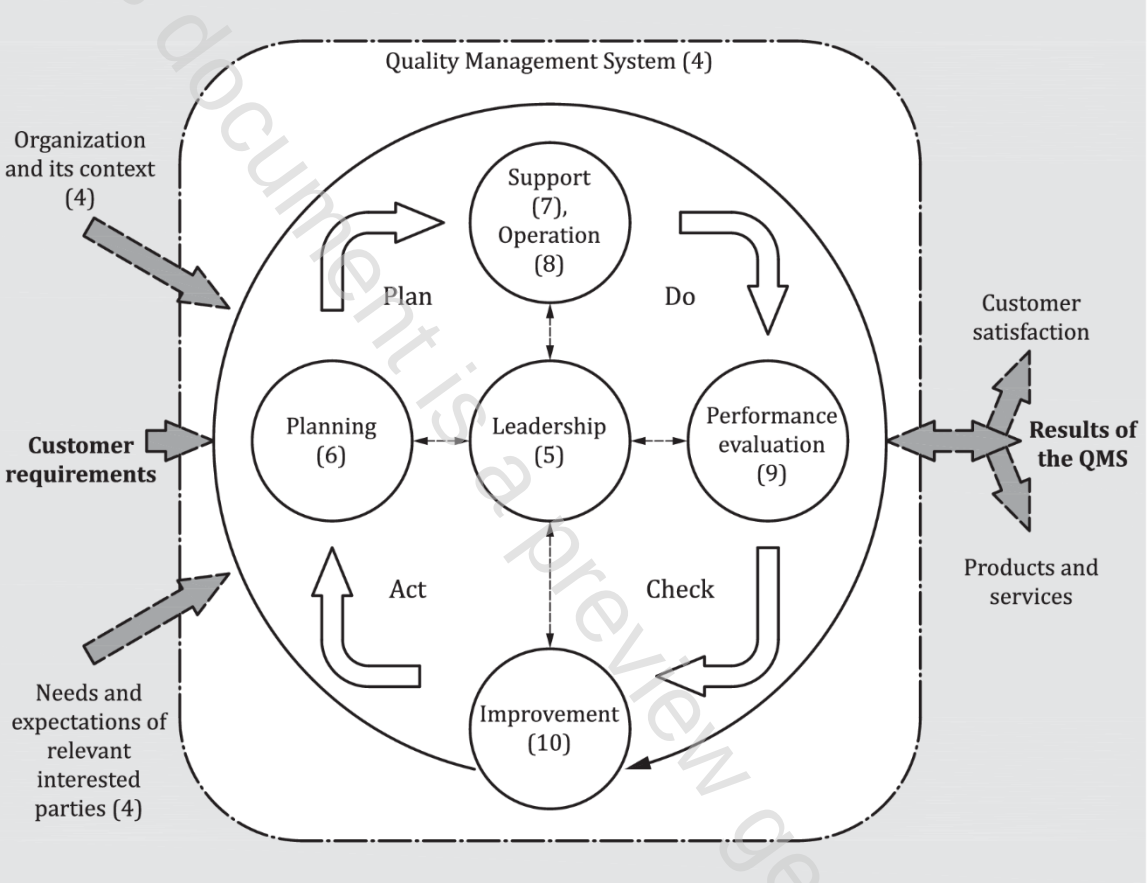
Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, Quality management systems — Requirements

0.3.2 Plan-Do-Check-Act cycle

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



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

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

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

ISO 9001:2015, Quality management systems — Requirements

0.3.3 Risk-based thinking

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

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

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

0.4 Relationship with other management system standards

ISO 9001:2015, Quality management systems — Requirements

0.4 Relationship with other management system standards

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

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

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

— ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this International Standard;

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

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

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

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

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

1 Scope

ISO 9001:2015, Quality management systems — Requirements

1 Scope

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

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

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

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

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

1.1 Scope — Supplemental

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

— applicable throughout the whole supply chain of the railway sector related to industrial products and services,

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

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

2 Normative references

ISO 9001:2015, Quality management systems — Requirements

2 Normative references

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

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