SLOVENSKI STANDARD
SIST EN ISO 22163:2024

01-julij-2024

Železniške naprave - Sistem vodenja kakovosti v železniškem prometu - ISO 9001:2015 in posebne zahteve za uporabo v železniškem sektorju (ISO 22163:2023)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 22163:2024**

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ICS:

03.100.70	Sistemi vodenja	Management systems
03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
45.020	Železniška tehnika na splošno	Railway engineering in general

SIST EN ISO 22163:2024   **en,fr,de**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22163

May 2024

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)

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)

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

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

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EN ISO 22163:2024 (E)

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European foreword

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

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of an identical text or by endorsement, at the latest by November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

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

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Endorsement notice

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

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INTERNATIONAL STANDARD

ISO
22163

First edition
2023-07

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

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

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Foreword

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

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

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

The main changes are as follows:

— the scope has been simplified;

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

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

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

— subclause 7.2.1 "Competence — Supplemental" has been revised;

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

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

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

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

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

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

— the performance indicators have been revised;

— Annex A on "List of processes" has been added;

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

— Annex C on "Performance indicators" has been added.

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

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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.