

RAUDTEEALASED RAKENDUSED. TÖÖKINDLUSE,
KASUTATAVUSE, HOOLDATAVUSE JA OHUTUSE (RAMS)
MÄÄRATLEMINE NING ESITLEMINE. OSA 2:
SÜSTEEMIDE LÄHENEMISVIIS OHUTUSELE

Railway Applications - The Specification and
Demonstration of Reliability, Availability,
Maintainability and Safety (RAMS) - Part 2: Systems
Approach to Safety

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN 50126-2:2017 sisaldab Euroopa standardi EN 50126-2:2017 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.10.2017.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN 50126-2:2017 consists of the English text of the European standard EN 50126-2:2017.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 13.10.2017.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
--	---

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

ICS 45.020

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele. Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety

Applications ferroviaires - Spécification et démonstration de la fiabilité, de la disponibilité, de la maintenabilité et de la sécurité (FDMS) - Partie 2: Approche systématique pour la sécurité

Bahnanwendungen - Spezifikation und Nachweis von Zuverlässigkeit, Verfügbarkeit, Instandhaltbarkeit und Sicherheit (RAMS) - Teil 2: Systembezogene Sicherheitsmethodik

This European Standard was approved by CENELEC on 2017-07-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
European foreword.....	5
Introduction.....	6
1 Scope.....	7
2 Normative references.....	8
3 Terms and definitions.....	8
4 Abbreviations.....	8
5 Safety process.....	9
5.1 Risk assessment and hazard control.....	9
5.2 A. Risk assessment.....	10
5.2.1 General.....	10
5.2.2 Conducting risk assessment.....	11
5.3 B. Outcome of the risk assessment.....	11
5.4 C. Hazard control.....	11
5.5 D. Revision of risk assessment.....	12
5.6 Responsibilities.....	13
6 Safety demonstration and acceptance.....	13
6.1 Introduction.....	13
6.2 Safety demonstration and safety acceptance process.....	13
6.3 Responsibility in managing the Safety Case.....	17
6.4 Modifications after safety acceptance.....	17
6.5 Dependencies between Safety Cases.....	17
6.6 Relationship between safety cases and system architecture.....	18
7 Organisation and Independence of Roles.....	19
7.1 General.....	19
7.2 Early phases of the lifecycle (phases 1 to 4).....	19
7.3 Later phases of the lifecycle (starting from phase 5).....	20
7.4 Personnel Competence.....	21
8 Risk assessment.....	22
8.1 Introduction.....	22
8.2 Risk Analysis.....	22
8.2.1 General.....	22
8.2.2 The risk model.....	22
8.2.3 Techniques for the consequence analysis.....	24
8.2.4 Expert Judgement.....	25
8.3 Risk acceptance principles and risk evaluation.....	25
8.3.1 Use of Code of Practice.....	25
8.3.2 Use of a reference system.....	26
8.3.3 Use of Explicit Risk Estimation.....	27
8.4 Application of explicit risk estimation.....	28
8.4.1 Quantitative approach.....	28
8.4.2 Variability using quantitative risk estimates.....	30
8.4.3 Qualitative and semi-quantitative approaches.....	31

9	Specification of System Safety Requirements	32
9.1	General	32
9.2	Safety requirements	32
9.3	Categorization of Safety Requirements	32
9.3.1	General	32
9.3.2	Functional safety requirements	33
9.3.3	Technical safety requirements	34
9.3.4	Contextual safety requirements.....	34
10	Apportionment of functional Safety Integrity requirements.....	35
10.1	Deriving and apportioning system safety requirements	35
10.2	Functional safety integrity for electronic systems	35
10.2.1	Deriving functional safety requirements for electronic systems.....	35
10.2.2	Apportioning safety requirements	35
10.2.3	Safety Integrity Factors.....	38
10.2.4	Functional safety integrity and random failures	38
10.2.5	Systematic aspect of functional safety integrity	38
10.2.6	Balanced requirements controlling random and systematic failures	38
10.2.7	The SIL table	39
10.2.8	SIL allocation.....	40
10.2.9	Apportionment of TFFR after SIL allocation	40
10.2.10	Demonstration of quantified targets	40
10.2.11	Requirements for Basic Integrity	41
10.2.12	Prevention of misuse of SILs	42
10.3	Safety Integrity for non-electronic systems – Application of CoP.....	42
11	Design and implementation.....	43
11.1	Introduction	43
11.2	Causal analysis	43
11.3	Hazard identification (refinement).....	44
11.4	Common cause analysis	44
Annex A	(informative) ALARP, GAME, MEM	46
A.1	ALARP, GAME, MEM as methods to define risk acceptance criteria	46
A.2	ALARP (As Low As Reasonably Practicable)	47
A.2.1	General	47
A.2.2	Tolerability and ALARP.....	48
A.3	Globalement Au Moins Equivalent (GAME) principle	48
A.3.1	Principle	48
A.3.2	Using GAME.....	49
A.3.2.1	General	49
A.3.2.2	Basic principles	49
A.3.2.3	Using GAME to construct a qualitative safety argument	49
A.3.2.4	GAME using quantitative risk targets	49
A.4	Minimum Endogenous Mortality MEM	50
Annex B	(informative) Using failure and accident statistics to derive a THR	52
Annex C	(informative) Guidance on SIL Allocation	53
Annex D	(informative) Safety target apportionment methods	55
D.1	Analysis of the system and methods	55

D.2 Example of qualitative apportionment method	55
D.2.1 General	55
D.2.2 Example of qualitative method for barrier efficiency	56
D.3 Example of quantitative apportionment method	58
D.3.1 Introduction	58
D.3.2 Functions with independent failure detection and negation mechanisms	59
D.3.3 Function and independent barrier acting as failure detection and negation mechanism	61
D.3.4 Apportionment of a probability safety target	62
D.3.5 Apportionment of a “per hour” safety target	62
Annex E (informative) Common mistakes in quantification.....	64
E.1 Common misuses	64
E.2 Mixing failure rates with probabilities	64
E.3 Using formulas out of their range of applicability	65
Annex F (informative) Techniques / methods for safety analysis	66
Annex G (informative) Key system safety roles and responsibilities.....	69
Annex ZZ (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 2008/57/EC.....	73
Bibliography	77

European foreword

This document (EN 50126-2:2017) has been prepared by CLC/TC 9X "Electrical and electronic applications for railways".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2018-07-03
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2020-07-03

This document supersedes CLC/TR 50126-2:2007.

The former edition of CLC/TR 50126-2:2007 is made obsolete by the new editions EN 50126-1:2017 and EN 50126-2:2017; the reason is that the scope of the present part was modified compared to the superseded edition.

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

EN 50126 "*Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS)*" consists of the following parts:

- Part 1: Generic RAMS process;
- Part 2: System approach to safety.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Introduction

EN 50126-1:1999 was aiming at introducing the application of a systematic RAMS management process in the railway sector. Through the application of this standard and the experiences gained over the last years, the need for revision and restructuring became apparent with a need to deliver a systematic and coherent approach to RAMS applicable to all the railway application fields Command, Control and Signalling, Rolling Stock and Fixed Installations.

The revision work improved the coherency and consistency of the standards, the concept of safety management and the practical usage of EN 50126 and took into consideration the existing and related Technical Reports as well.

This European Standard provides railway duty holders and the railway suppliers, throughout the European Union, with a process which will enable the implementation of a consistent approach to the management of reliability, availability, maintainability and safety, denoted by the acronym RAMS.

Processes for the specification and demonstration of RAMS requirements are cornerstones of this standard. This European Standard promotes a common understanding and approach to the management of RAMS.

EN 50126 forms part of the railway sector specific application of IEC 61508. Meeting the requirements in this European Standard together with the requirements of other suitable standards is sufficient to ensure that additional compliance to IEC 61508 does not need to be demonstrated.

With regard to safety, EN 50126-1 provides a Safety Management Process which is supported by guidance and methods described in EN 50126-2.

EN 50126-1 and EN 50126-2 are independent from the technology used. As far as safety is concerned, EN 50126 takes the perspective of safety with a functional approach.

The application of this standard should be adapted to the specific requirements for the system under consideration.

This European Standard can be applied systematically by the railway duty holders and railway suppliers, throughout all phases of the life-cycle of a railway application, to develop railway specific RAMS requirements and to achieve compliance with these requirements. The systems-level approach developed by this European Standard facilitates assessment of the RAMS interactions between elements of railway applications even if they are of complex nature.

This European Standard promotes co-operation between the stakeholders of Railways in the achievement of an optimal combination of RAMS and cost for railway applications. Adoption of this European Standard will support the principles of the European Single Market and facilitate European railway inter-operability.

In accordance with CENELEC editing rules ¹⁾, mandatory requirements in this standard are indicated with the modal verb "shall". Where justifiable, the standard permits process tailoring.

Specific guidance on the application of this standard for Safety aspects is provided in EN 50126-2. EN 50126-2 provides various methods for use in the safety management process. Where a particular method is selected for the system under consideration, the mandatory requirements of this method are by consequence mandatory for the safety management of the system under consideration.

This European Standard consists of the main part (Clause 1 to Clause 11) and Annexes A, B, C, D, E, F, G and ZZ. The requirements defined in the main part of the standard are normative, whilst Annexes are informative.

1) CEN/CENELEC Internal Regulations Part 3: Rules for the structure and drafting of CEN/CENELEC Publications (2017-02), Annex H.

1 Scope

This part 2 of EN 50126

- considers the safety-related generic aspects of the RAMS life-cycle;
- defines methods and tools which are independent of the actual technology of the systems and subsystems;
- provides:
 - the user of the standard with the understanding of the system approach to safety which is a key concept of EN 50126;
 - methods to derive the safety requirements and their safety integrity requirements for the system and to apportion them to the subsystems;
 - methods to derive the safety integrity levels (SIL) for the safety-related electronic functions.

NOTE This standard does not allow the allocation of safety integrity levels to non-electronic functions.

- provides guidance and methods for the following areas:
 - safety process;
 - safety demonstration and acceptance;
 - organisation and independence of roles;
 - risk assessment;
 - specification of safety requirements;
 - apportionment of functional safety requirements;
 - design and implementation.
- provides the user of this standard with the methods to assure safety with respect to the system under consideration and its interactions;
- provides guidance about the definition of the system under consideration, including identification of the interfaces and the interactions of this system with its subsystems or other systems, in order to conduct the risk analysis;
- does not define:
 - RAMS targets, quantities, requirements or solutions for specific railway applications;
 - rules or processes pertaining to the certification of railway products against the requirements of this standard;
 - an approval process by the safety authority.

This part 2 of EN 50126 is applicable to railway applications fields, namely Command, Control and Signalling, Rolling Stock and Fixed Installations, and specifically:

- to the specification and demonstration of safety for all railway applications and at all levels of such an application, as appropriate, from complete railway systems to major systems and to individual and

combined sub-systems and components within these major systems, including those containing software, in particular:

- to new systems;
 - to new systems integrated into existing systems already accepted, but only to the extent and insofar as the new system with the new functionality is being integrated. It is otherwise not applicable to any unmodified aspects of the existing system;
 - as far as reasonably practicable, to modifications and extensions of existing systems accepted prior to the creation of this standard, but only to the extent and insofar as existing systems are being modified. It is otherwise not applicable to any unmodified aspect of the existing system;
- at all relevant phases of the life-cycle of an application;
 - for use by railway duty holders and the railway suppliers.

It is not required to apply this standard to existing systems which remain unmodified, including those systems already compliant with any former version of EN 50126.

The process defined by this European Standard assumes that railway duty holders and railway suppliers have business-level policies addressing Quality, Performance and Safety. The approach defined in this standard is consistent with the application of quality management requirements contained within EN ISO 9001.

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.

EN 50126-1:2017, *Railway Applications — The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) — Part 1: Generic RAMS Process*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50126-1 apply.

4 Abbreviations

ALARP	As Low As Reasonable Practicable
CBA	Cost Benefit Analysis
CCF	Common Cause Failure (Analysis)
CoP	Code of Practice
COTS	Commercial Off-The-Shelf
DRA	Differential Risk Aversion
ERE	Explicit Risk Estimation
EMC	Electromagnetic compatibility
ETA	Event Tree Analysis
FMECA	Failure Mode Effect & Criticality Analysis
FTA	Fault Tree Analysis
GA	Generic Application
GASC	Generic Application Safety Case