
Železniške naprave - Specifikacija in prikaz zanesljivosti, razpoložljivosti, vzdrževalnosti in varnosti (RAMS) - 5. del: Funkcionalna varnost - Programska oprema

Railway applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 5: Functional Safety - Software

Bahnanwendungen - Spezifikation und Nachweis von Zuverlässigkeit, Verfügbarkeit, Instandhaltbarkeit und Sicherheit (RAMS) -- Teil 5: Funktionale Sicherheit - Software

Applications ferroviaires - Spécification et démonstration de la fiabilité, de la disponibilité, de la maintenabilité et de la sécurité (FDMS) - Partie 5: Sécurité fonctionnelle - Logiciel

Ta slovenski standard je istoveten z: prEN 50126-5:2012

ICS:

35.240.60	Uporabniške rešitve IT v transportu in trgovini	IT applications in transport and trade
45.020	Železniška tehnika na splošno	Railway engineering in general

oSIST prEN 50126-5:2013

en

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN 50126-5:2012](https://standards.iteh.ai/catalog/standards/sist/1c84981e-d3ec-4e38-a727-8dec066a9260/osist-pren-50126-5-2012)

<https://standards.iteh.ai/catalog/standards/sist/1c84981e-d3ec-4e38-a727-8dec066a9260/osist-pren-50126-5-2012>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 50126-5

October 2012

ICS 29.280; 45.020

Will supersede EN 50128:2011

English version

**Railway applications -
The Specification and Demonstration of Reliability, Availability,
Maintainability and Safety (RAMS) -
Part 5: Functional Safety -
Software**

Applications ferroviaires -
Spécification et démonstration de la fiabilité,
de la disponibilité, de la maintenabilité et de la
sécurité (FDMS) -
Partie 5: Sécurité fonctionnelle -
Logiciel

Bahnanwendungen -
Spezifikation und Nachweis von
Zuverlässigkeit, Verfügbarkeit,
Instandhaltbarkeit und Sicherheit (RAMS) -
Teil 5: Funktionale Sicherheit -
Software

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This draft European Standard is submitted to CENELEC members for CENELEC enquiry.
Deadline for CENELEC: 2013-03-29.

It has been drawn up by CLC/TC 9X.
<https://standards.iteh.ai/catalog/standards/sist/1c84981e-d3ec-4e38-a727-88a066985c1c/cenelec-pr-en-50126-5-2012>

If this draft becomes a European Standard, 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.

This draft European Standard was established by CENELEC 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

13001	Contents	Page
13002	Foreword	4
13003	Introduction	6
13004	1 Scope	9
13005	2 Normative references	10
13006	3 Terms and definitions	11
13007	4 Abbreviations	11
13008	5 Overall framework of EN 50126-5	12
13009	6 Software Management and Organisation	13
13010	6.1 Organisation, Roles and Responsibilities	13
13011	6.2 Personnel Competence	16
13012	6.3 Lifecycle Issues and Documentation	17
13013	7 Software assurance	21
13014	7.1 Analysis.....	21
13015	7.2 Software testing	23
13016	7.3 Software Verification.....	24
13017	7.4 Software Validation.....	27
13018	7.5 Independent Software Assessment.....	29
13019	7.6 Software Quality Assurance	31
13020	7.7 Safety Management.....	33
13021	7.8 Configuration Management and Modification Control	35
13022	7.9 Support Tools and Languages.....	36
13023	8 Generic Software Development	39
13024	8.1 Lifecycle and Documentation for Generic Software	39
13025	8.2 Software Requirements	39
13026	8.3 Architecture and Design	41
13027	8.4 Component Design	46
13028	8.5 Component Implementation and Testing.....	48
13029	8.6 Integration	49
13030	8.7 Final Validation and Independent Assessment	51
13031	9 Development of Application Data or Algorithms: systems configured by application data or algorithms	58
13032	9.1 Objectives	58
13033	9.2 Input	58
13034	9.3 Deliverables	58
13035	9.4 Requirements	59
13036	10 Software Deployment and Maintenance	63
13037	10.1 Software Deployment	63
13038	10.2 Software Maintenance	65
13039	Annex A (normative) Criteria for the Selection of Techniques and Measures	68
13040	Annex B (normative) Key Software Roles and Responsibilities	82
13041	Annex C (informative) Documents Control Summary	90
13042	Annex D (informative) Multi-core and Multi-threaded Programming	92
13043	Annex E (informative) Structure of Software Safety Case	94
13044	Annex F (informative) Bibliography of Techniques	103
13045	Bibliography	136
13046		

13047 **Figures**

13048	Figure 1 – Illustrative Software Route Map	8
13049	Figure 2 – Illustration of the preferred organisational structure	14
13050	Figure 3 – Illustrative Development Lifecycle 1	19
13051	Figure 4 – Illustrative Development Lifecycle 2	20
13052	Figure E.1 – Structure of Safety Case	95
13053	Figure E.2 – Structure of Technical Safety Report	96

13054 **Tables**

13055	Table 1 – Relation between tool class and applicable paragraphs of 7.9.4.14	38
13056	Table A.1 – Lifecycle Issues and Documentation (6.3)	69
13057	Table A.2 – Software Requirements Specification (8.2)	71
13058	Table A.3 – Software Architecture (8.3)	72
13059	Table A.4 – Software Design and Implementation (8.4)	73
13060	Table A.5 – Verification and Testing (6.2 and 7.3)	74
13061	Table A.6 – Integration (7.6)	74
13062	Table A.7 – Overall Software Testing (7.3 and 8.7)	74
13063	Table A.8 – Software Analysis Techniques (7.4)	75
13064	Table A.9 – Software Quality Assurance (7.6)	75
13065	Table A.10 – Software Maintenance (10.2)	75
13066	Table A.11 – Data Preparation Techniques (9.4)	76
13067	Table A.12 – Coding Standards	76
13068	Table A.13 – Dynamic Analysis and Testing	77
13069	Table A.14 – Functional/Black Box Test	77
13070	Table A.15 – Textual Programming Languages	78
13071	Table A.16 – Diagrammatic Languages for Application Algorithms	78
13072	Table A.17 – Modelling	79
13073	Table A.18 – Performance Testing	79
13074	Table A.19 – Static Analysis	79
13075	Table A.20 – Components	80
13076	Table A.21 – Test Coverage for Code	80
13077	Table A.22 – Object Oriented Software Architecture	81
13078	Table A.23 – Object Oriented Detailed Design	81
13079	Table B.1 – Software Requirements Manager Role Specification	82
13080	Table B.2 – Software Designer Role Specification	83
13081	Table B.3 – Software Implementer Role Specification	83
13082	Table B.4 – Software Tester Role Specification	84
13083	Table B.5 – Software Verifier Role Specification	84
13084	Table B.6 – Software Integrator Role Specification	85
13085	Table B.7 – Software Validator Role Specification	86
13086	Table B.8 – Software Assessor Role Specification	87
13087	Table B.9 – Software Project Manager Role Specification	88
13088	Table B.10 – Software Configuration Manager Role Specification	88
13089	Table B.11 – Software Safety Manager Role Specification	89
13090	Table C.1 – Documents Control Summary	90
13091		

13092 **Foreword**

13093 This document [prEN 50126-5:2012] has been prepared by CLC/TC 9X "Electrical and electronic
13094 applications for railways".

13095 This document is currently submitted to the Enquiry.

13096 EN 50126 "*Railway applications – The specification and demonstration of Reliability, Availability,
13097 Maintainability and Safety (RAMS)*" consists of the following parts:

- 13098 – Part 1: Generic RAMS process;
- 13099 – Part 2: Systems approach to safety;
- 13100 – Part 4: Functional safety – Electrical/Electronic/Programmable electronic systems;
- 13101 – Part 5: Functional safety – Software.

13102 This new edition of EN 50126 (all parts) will supersede EN 50126-1:1999, CLC/TR 50126-2:2007,
13103 CLC/TR 50126-3:2008, EN 50128:2011 and EN 50129:2003.

13104 This part of EN 50126 will supersede EN 50128:2011.

13105 This document has been prepared under a mandate given to CENELEC by the European Commission
13106 and the European Free Trade Association, and supports essential requirements of EU Directive(s).

13107 This European Standard supports the European Railway Directive 2004/49/EC (Railway Safety Directive)
13108 and the Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety
13109 method on risk evaluation and independent assessment as referred to in Article 6(3)(a) of Directive
13110 2004/49/EC of the European Parliament and of the Council.

<https://standards.iteh.ai/catalog/standards/sist/1c84981e-d3ec-4e38-a727-8dec066a9260/osist-pren-50126-5-2012>

Modifications intended to be made, mainly for part4 and 5

WG14 intended to incorporate the following modifications prior to the CENELEC-Enquiry. Due to TC9X resolution 46/11 their incorporation must be postponed to post enquiry.

Therefore, for information purposes the list is included here. The list should not preclude commenting on these issues, but should inform the reader regarding the intended direction of further changes.

The order of the points does not indicate their importance.

1	The activity-based approach from parts 1+2 will be further implemented in parts 4+5. The relationship between “activities” and “roles” will be improved.
2	With regard to verification requirements, the approach from parts 1+2 will be used for parts 4+5 as well.
3	Safety case documentation: remaining inconsistencies within part 1 and between part 1 and parts 4/5 will be rectified.
4	E/E/PE System/Software Assurance: Chapter 7 of parts 4/5 will be removed and the essence of the content moved to part 1.
5	Improve the consistency between part 4 chapter 8 and part1.
6	SIL0: the requirements will be reduced.
7	Improve consistency between part 1 and part 4 with regard to operation and maintenance.
8	Tailoring: the main text will better reflect the adaptability of the process according to the respective SIL.
9	Alignment of terms & definitions will be finalised.
10	Consistent use of terms & definitions will be improved.
11	The HW process defined in part 4 (e.g. in chapter9 and the annexes) will be revised and the same activity based approach as outlined in issues1 of this table will be applied.

13112 Introduction

13113 EN 50126-1:1999 was produced to introduce the application of a systematic RAMS management process
 13114 in the railway sector. For safety related electronic systems for signalling, EN 50128:2011 and
 13115 EN 50129:2003 were produced. Through the application of these European Standards and the
 13116 experiences gained over the recent years, the need for revision and restructuring became apparent with a
 13117 need to deliver a systematic and coherent approach to RAMS applicable to all the railway application
 13118 fields Signalling, Rolling Stock and Fixed Installations.

13119 The revision work improved the coherence and consistency of the European Standards, the concept of
 13120 safety management and the practical usage of EN 50126 and took into consideration the existing and
 13121 related Technical Reports as well.

13122 This European Standard provides railway duty holders and the railway suppliers, throughout the
 13123 European Union, with a process which will enable the implementation of a consistent approach to the
 13124 management of reliability, availability, maintainability and safety, denoted by the acronym RAMS.

13125 Processes for the specification and demonstration of RAMS requirements are cornerstones of this
 13126 standard.

13127 EN 50126 is the railway sector specific application of IEC 61508. Meeting the requirements in
 13128 this European Standard is sufficient to ensure that additional compliance to IEC 61508 does not
 13129 need to be evaluated.

13130 With regard to safety EN 50126-1 provides a Safety Management Process which is supported by
 13131 guidance and methods described in EN 50126-2.

13132 EN 50126-1 and EN 50126-2 are independent from the technology used. EN 50126-4 and EN 50126-5
 13133 provide guidance specific to safety related E/E/EP technology of railway applications and their application
 13134 depends on the outcome of the safety related methods described in EN 50126-2. As far as safety is
 13135 concerned, EN 50126 takes the perspective of functional safety. This does not exclude other aspects of
 13136 safety. However, these are not the focus.

13137 The aims set for revision of EN 50126 required a better understanding of the systems approach and
 13138 improved methods for applying the safety management process described in EN 50126-1. EN 50126-2
 13139 provides this guidance.

13140 The application of this European Standard shall be adapted to the specific requirements of the system
 13141 under consideration.

13142 This European Standard can be applied systematically by the railway duty holders and railway suppliers,
 13143 throughout all phases of the life cycle of a railway application, to develop railway specific RAMS
 13144 requirements and to achieve compliance with these requirements. The systems-level approach
 13145 developed by this European Standard facilitates independent assessment of the RAMS interactions
 13146 between elements of railway applications even if they are of complex nature.

13147 This European Standard promotes co-operation between the stakeholders of Railways in the
 13148 achievement of an optimal combination of RAMS and cost for railway applications. Adoption of this
 13149 European Standard will support the principles of the European Single Market and facilitate European
 13150 railway interoperability.

13151 The process defined by this European Standard assumes that railway duty holders and railway suppliers
 13152 have business-level policies addressing Quality, Performance and Safety. The approach defined in this
 13153 European Standard is consistent with the application of quality management requirements contained
 13154 within the ISO 9000 series of International standards.

13155 With the term document this European Standard rather means technical contents and not necessarily
 13156 single physical documents. Such technical contents can arbitrarily be combined to physical documents
 13157 dependent on the needs of the specific project. Technical contents can also be omitted in the process-
 13158 tailoring step which should take place in the early planning phase of a project. The omission of technical

13159 contents has however to be justified with technical arguments. The tailoring process is best documented
13160 in a Project Document List, declaring which documents with which technical contents are planned to be
13161 created, by whom and in which phase of the project. Omitted technical contents should be highlighted
13162 and the omission justified.

13163 The current state-of-the-art is such that neither the application of quality assurance methods (so-called
13164 fault avoiding measures and fault detecting measures) nor the application of software fault tolerant
13165 approaches can guarantee the absolute safety of the software. The proof of the absence of faults, in
13166 reasonably complex safety-related software, especially the absence of specification and design faults is
13167 currently a formidable if not unattainable task. Adopting a systematic principled process and employing
13168 competent resources constitute current best practice in software development. The principles applied in
13169 developing high integrity software include, but are not restricted to

- 13170 – top-down design methods,
- 13171 – modularity,
- 13172 – verification of each phase of the development lifecycle,
- 13173 – verified components and component libraries,
- 13174 – clear documentation and traceability,
- 13175 – auditable documents,
- 13176 – validation,
- 13177 – assessment,
- 13178 – configuration management and change control and
- 13179 – appropriate consideration of organisation and personnel competency issues.

13180 This European Standard does not mandate the use of a particular software development lifecycle.
13181 However, illustrative lifecycle and documentation sets are given in 6.3, Figure 3 and Figure 4 and in 8.1.

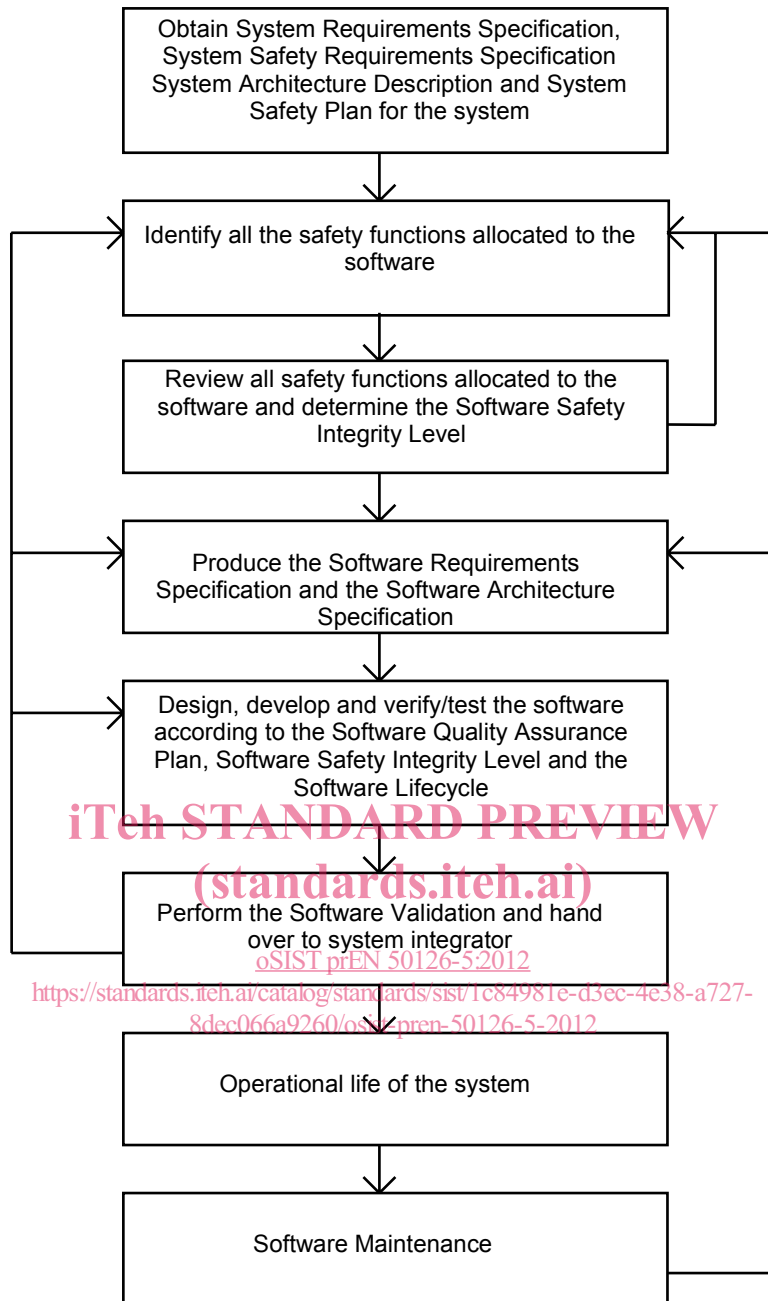


Figure 1 – Illustrative Software Route Map

13184 1 Scope

13185 This part of EN 50126

- 13186 • is intended to apply to all safety-related software aimed at electronic railway systems/sub-system.
13187 The relevant methods are provided by EN 50126-2. If analysis reveals that no safety requirements
13188 exist (i.e. the situation is non-safety-related), and provided the conclusion is not revised as a
13189 consequence of later changes, this part of EN 50126 ceases to be applicable;
- 13190 • specifies the process and technical requirements for the development of software for programmable
13191 electronic systems for use in railway monitoring, control and protection applications. These systems
13192 can be implemented using dedicated microprocessors, programmable logic controllers,
13193 multiprocessor distributed systems, larger scale central processor systems or other architectures.
- 13194 • is applicable exclusively to software and the interaction between software and the system/sub-
13195 system of which it is part.

13196 This European Standard

- 13197 • is primarily applicable to software which have been specifically designed and developed for railway
13198 applications. It should also be applied, as far as reasonably practicable, to general-purpose or
13199 industrial software which is procured for use as part of a safety-related railway system. As a
13200 minimum, evidence shall be provided in such cases to demonstrate:

- 13201 - either that the software is not relied on for safety,
- 13202 - or that the software can be relied on for those functions which relate to safety;

- 13203 • applies

- 13204 - to the specification, architecture, design, development, implementation, integration, installation,
13205 acceptance, deployment, operation, maintenance and modification/extension phases of the
13206 software in a system /subsystem. It also applies to individual sub-systems within the overall
13207 system as determined by the process in EN 50126-1 and supported by the methods in
13208 EN 50126-2,

- 13209 - to generic sub-systems (both application-independent and those intended for a particular class of
13210 application), and also to systems/sub-systems for specific applications;

- 13211 • does not define

- 13212 - RAMS targets, quantities, requirements or solutions for specific railway applications
- 13213 - rules or processes pertaining to the certification of railway products against the requirements of
13214 this European Standard
- 13215 - an approval process by the safety authority;

- 13216 • does not specify requirements for ensuring system security.

13217 This part EN 50126 is applicable

- 13218 • to the specification and demonstration of safety for all software in railway applications and at all
13219 levels of such an application, as appropriate, from complete railway systems to major systems and to
13220 individual and combined sub-systems within these major systems; in particular:

- 13221 - to new systems;
- 13222 - to new systems integrated into existing systems in operation prior to the creation of this European
13223 Standard, although it is not generally applicable to other aspects of the existing system;
- 13224 - for modifications of existing software on systems in operation prior to the creation of this
13225 European Standard, although it is not generally applicable to other aspects of the existing system.

- 13226 - at all relevant phases of the lifecycle of an application;
- 13227 - for use by railway duty holders, railway suppliers, assessors and safety authorities;
- 13228 • to all safety related software used in railway control and protection systems, including
- 13229 1. application programming,
- 13230 2. operating systems,
- 13231 3. support tools,
- 13232 4. firmware.
- 13233 Application programming comprises high level programming, low level programming and special purpose
13234 programming (for example: Programmable logic controller ladder logic).
- 13235 • not relevant for software that has been identified as having no impact on safety, i.e. software of
13236 which failures cannot affect any identified safety functions.
- 13237 This European Standard also addresses the use of pre-existing software and tools. Such software may
13238 be used, if the specific requirements in 7.6.4.12 and 8.3.4.1.6 on pre-existing software and for tools in 7.9
13239 are fulfilled.
- 13240 Existing systems compliant with any version of former EN 50126, EN 50128 or EN 50129 shall not be
13241 subject of reconsideration and are considered as compliant with this European Standard.
- 13242 Railway applications mean Command, Control & Signalling, Rolling Stock and Fixed Installations for
13243 Railways (e.g. Electric Power Supply).
- 13244 Application of EN 50126-5 builds on the results in applying the methods described by EN 50126-2.
- 13245 NOTE Guidance on the applicability is given in the requirements of this European Standard.
- 13246 **2 Normative references**
- 13247 The following documents, in whole or in part, are normatively referenced in this document and are
13248 indispensable for its application. For dated references, only the edition cited applies. For undated
13249 references, the latest edition of the referenced document (including any amendments) applies.
- 13250 EN 50126-1:1999 + corr. May. 2006 + corr. May. 2010, *Railway applications – The specification and
13251 demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Basic requirements
13252 and generic process*
- 13253 EN 50129:2003 + corr. May. 2010, *Railway applications – Communication, signalling and processing
13254 systems – Safety related electronic systems for signalling*
- 13255 EN ISO 9000, *Quality management systems – Fundamentals and vocabulary (ISO 9000)*
- 13256 EN ISO 9001, *Quality management systems – Requirements (ISO 9001)*
- 13257 ISO/IEC 90003:2004, *Software engineering – Guidelines for the application of ISO 9001:2000 to
13258 computer software*
- 13259 ISO/IEC 9126 (all parts), *Software engineering – Product quality*

13260 3 Terms and definitions

13261 For the purposes of this document, the terms and definitions given in EN 50126-1:1999 and the following
13262 apply.

13263 3.1

13264 independent assessment

13265 process of analysis to determine whether software, which may include process, documentation, system,
13266 subsystem hardware and/or software components, meets the specified requirements and to form a
13267 judgement as to whether the software is fit for its intended purpose. Safety assessment is an independent
13268 assessment focused on but not limited to the safety properties of a system

13269 3.2

13270 component

13271 constituent part of software, which has well-defined interfaces and behaviour with respect to the software
13272 architecture and design and fulfils the following criteria:

- 13273 – it is designed according to “Components” (see Table A.20);
- 13274 – it covers a specific subset of software requirements;
- 13275 – it is clearly identified and has an independent version inside the configuration management system
13276 or is a part of a collection of components (e. g. subsystems) which have an independent version

13277 3.3

13278 configuration manager

13279 entity that is responsible for implementing and carrying out the processes for the configuration
13280 management of documents, software and related tools including change management

13281 3.4

13282 customer

13283 entity which purchases a railway control and protection system including the software

13284 3.5

13285 programmable logic controller

13286 solid-state control system which has a user programmable memory for storage of instructions to
13287 implement specific functions

13288 3.6

13289 robustness

13290 ability of an item to detect and handle abnormal situations

13291 3.7

13292 supplier

13293 entity that designs and builds a railway control and protection system including the software or parts
13294 thereof

13295 3.8

13296 system safety integrity level

13297 classification number which indicates the required degree of confidence that an integrated system
13298 comprising hardware and software will meet its specified safety requirements

13299 4 Abbreviations

13300 For the purposes of this document, the abbreviations given in EN 50126-1:1999 and below apply.

13301	ASR	Assessor
13302	COTS	Commercial off-the-shelf
13303	DES	Designer
13304	HR	Highly Recommended
13305	IMP	Implementer
13306	INT	Integrator

iTeh STANDARD PREVIEW
(standards.itih.ai)

oSIST prEN 50126-5:2012

<https://standards.itih.ai/standards/50126-5-2012>
8dec066a9260/osist-pren-50126-5-2012

13307	JSD	Jackson System Development Method
13308	M	Mandatory
13309	MASCOT	Modular Approach to Software Construction, Operation and Test
13310	MBSA	Model Based Safety Assessment/Assurance
13311	NR	Not Recommended
13312	PM	Project Manager
13313	R	Recommended
13314	RQM	Requirements Manager
13315	SDL	Specification and Description Language
13316	SFC	Sequential Function Charts
13317	SOM	Service Oriented Modelling
13318	SSADM	Structured Systems Analysis & Design Methodology
13319	TST	Tester
13320	V&V	Verification and Validation
13321	VAL	Validator
13322	VER	Verifier

13323 **5 Overall framework of EN 50126-5**

13324 This part of the EN 50126 suite of European Standards addresses the application of the safety life cycle
 13325 to the development of software for incorporation in electronic hardware and integrated systems
 13326 comprising electrical, electronic and programmable electronic hardware. The principal purpose of this
 13327 suite of European Standards is to support the design, development, production and operation of
 13328 acceptably safe products, systems and processes aimed at railway applications. In this spirit, the
 13329 approval, acceptance or certification constitute a secondary potential benefit arising from compliance with
 13330 this suite of European Standards. EN 50126-4 and EN 50126-5 of the European Standard suite address
 13331 technology specific safety requirements and are complementary to the requirements and the framework
 13332 developed in EN 50126-1 and EN 50126-2 which shall also be complied with. This European Standard
 13333 addresses the management, organisation and overall assurance of software aimed at electronic systems
 13334 including the safety requirements applicable to generic and algorithmic software.

13335 The overall scope of this European Standard includes software developed for incorporation in electronic
 13336 and programmable electronic hardware systems with fixed or configurable logic.

13337 Apart from software, this European Standard places requirements for management, organisation and the
 13338 competency of the people who assume various roles in the safety life cycle of software. This is in
 13339 recognition of the major impact of the organisational and competency aspects on the overall reduction of
 13340 the systematic errors which are otherwise likely to remain embedded in the design and production of
 13341 software.

13342 The overall structure of this European Standard addresses key safety life cycle requirements in the
 13343 design, development, deployment and maintenance of software for electronic and programmable
 13344 electronic systems. Where appropriate, the structure in this European Standard is aligned with the
 13345 hardware and system standard in EN 50126-4 to provide a familiar and systematic approach across the
 13346 related disciplines.

13347 Clauses 6 and 7 of this European Standard set out the common requirements for life cycle phases
 13348 defined in Clauses 8-10. These clauses are structured to state the objectives, inputs, requirements and
 13349 the outputs pertinent to each phase of the life-cycle.

13350 Clause 6 sets out the generic management and organisational requirements, pertinent to software for
 13351 electronic systems, addressing documentation, roles, requisite competencies, responsibilities of key
 13352 personnel and the required independence between the roles.

13353 Clause 7 sets out the generic software assurance requirements addressing quality management, safety
13354 management, configuration and change management and support tools.

13355 Clause 8 sets out the requirements for the development of generic software addressing architecture,
13356 design, implementation, integration, installation and commissioning and validation. It additionally provides
13357 requirements and guidelines for development of Software Safety Cases.

13358 Clause 9 sets out the requirements for the development of software systems configured by application
13359 data or algorithm addressing architecture, design, implementation, integration, testing, installation and
13360 commissioning and validation. Many of the requirements of the generic software are equally applicable to
13361 configurable variants.

13362 Clause 10 sets out the requirements for a systematic approach to the safe deployment, operation and
13363 maintenance of safety related software in railways. It details the requisite processes that have to be
13364 implemented to ensure safe software is safely put into use and safely maintained throughout its
13365 operational life.

13366 The annexes to this European Standard provide normative and informative requirements and guidance
13367 considered supplementary to the main sections of this European Standard. These comprise guidance on
13368 selection of techniques and measures, key safety roles and competencies for development of software,
13369 multi-core programming, guidance on the structure of Software Safety Cases and an updated generic
13370 bibliography of the software and system design and development techniques.

13371 **6 Software Management and Organisation**

13372 **6.1 Organisation, Roles and Responsibilities**

13373 **6.1.1 Objective**

13374 6.1.1.1 To ensure that all personnel who have responsibilities for the software are organised,
13375 empowered and capable of fulfilling their responsibilities.

13376 **6.1.2 Requirements**

13377 6.1.2.1 As a minimum, the supplier shall implement EN ISO 9001, Clauses 4 and 5, dealing with the
13378 organisation and management of the personnel and responsibilities.

13379 6.1.2.2 Responsibilities shall be compliant with the requirements defined in Annex B and assessed.

13380 6.1.2.3 The personnel assigned to the roles involved in the development or maintenance of the software
13381 shall be recorded in the Quality Management Report or in another document referenced by the Quality
13382 Management Report.

13383 6.1.2.4 An Assessor shall be appointed by the supplier, the customer or the Safety Authority.

13384 6.1.2.5 The assessor may be part or not of the supplier organization, but shall be in any case
13385 independent from the project organizations (Design, Testing, Integration, Safety, Verification and
13386 Validation). National legislation / Safety Authority may ask for additional independence requirements.

13387 NOTE The independent assessment body may be identified by national legislation.

13388 6.1.2.6 The Assessor shall be given authority to perform the independent assessment of the software.

13389 6.1.2.7 The Validator shall give agreement/disagreement for the software release.

13390 6.1.2.8 Throughout the software lifecycle, the parties involved shall be independent, in accordance with
13391 6.1.2.9 to 6.1.2.13, to the extent required by software SIL.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

oSIST prEN 50126-5:2012

<https://standards.iteh.ai/catalog/standards/sis/1c84091e-d3ec-4e38-a727-8d5c066a9260/osist-pr-en-50126-5-2012>