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Railway applications — Communication, signalling and processing systems — Application Guide for EN 50129 —

Part 1: Cross-acceptance

ICS 93.100

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National foreword

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CENELEC

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

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Foreword

This Technical Report was prepared by SC 9XA, Communication, signalling and processing systems, of Technical Committee CENELEC TC 9X, Electrical and electronic applications for railways.

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Introduction

EN 50129 was developed in CENELEC and is now regularly called up in specifications. In essence, it lists factors that influence RAMS (see EN 50126) and adopts a broad risk-management approach to safety. EN 50129 is the basic standard for safety related electronic systems for signalling.

Use of EN 50129 has enhanced the general understanding of the issues, but has also shown that items like cross-acceptance need further explanation and clarification. Therefore CENELEC decided to address those items in this application guide for cross-acceptance.

1 Scope

This application guide for cross-acceptance is a Technical Report about the basic standard. It is applicable to the same systems and addresses the same audience as the standard itself. It provides additional information on the application of EN 50129 to cross-acceptance. Therefore it deals with the acceptance by a safety authority of a previously accepted system or product in a different environment and/or context, often referred to as cross-acceptance. It is mainly dedicated to safety assessors, safety authorities, validators, and safety managers.

In drafting this guide, it is assumed that the reader is familiar with the basic structure of the standard.

2 Normative references

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

NOTE Additional informative references are included in the bibliography.

EN 50124-1, *Railway applications - Insulation coordination - Part 1: Basic requirements - Clearances and creepage distances for all electrical and electronic equipment*

EN 50126, *Railway applications - The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS)*

EN 50128, *Railway applications - Communication, signalling and processing systems - Software for railway control and protection systems*

EN 50129, *Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling*

EN 61508 series, *Functional safety of electrical/electronic/programmable electronic safety-related systems* (IEC 61508 series)

EN/ISO 9001:2000, *Quality management systems – Requirements* (ISO 9001:2000)

EN/ISO/IEC 17020, *General criteria for the operation of various types of bodies performing inspection (*ISO/IEC 17020)

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3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50126, EN 50128, EN 50129 and the following apply. Other definitions not included in these documents have been added to eliminate any doubts regarding their interpretation.

3.1.1
generic application
system with specific functions that are related to "*a category of applications*" associated with a general environmental and operational context, which is developed on the basis of criteria of standardization and parameterization of its elements, so as to render it serviceable for various tangible applications. By combining generic products or combining these with other generic applications, it is possible to obtain a new generic application

3.1.2
generic product
component/product capable of performing certain functions, with a specific performance level, in the environmental and operational conditions stated in the reference specifications. It can be combined with other products and generic applications to form other generic applications

3.1.3
specific application
a specific application is used for only one particular installation

3.1.4
risk analysis
identification of hazards associated with a product, process or system, scrutiny of their causes and systematic determination of their consequences in an operational context. Risk analysis results in the identification of the nature of likely sources of harm arising from a product, process or system and their impact in terms of nature of likely accidents and the severity of harm caused

3.1.5
safety analysis
subset of risk analysis solely focused on hazards which have a potential for causing accidents which may cause harm to people

3.2 Abbreviated terms

For the purposes of this document, the abbreviated terms used in EN 50126, EN 50128 and EN 50129 and the following apply. Other abbreviations not included in these standards have been added to eliminate any doubts regarding their interpretation.

CMP	configuration management plan
COTS	commercial-off-the-shelf
CRS	customer requirements specification
CTC	centralised traffic control
DRACAS	data reporting and corrective action system
FMECA	failure mode effects and criticality analysis
FRACAS	failure reporting and corrective actions system
FTI	formal technical inspection
FTP	field trial plan

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FTR	field trial report
FPGA	field programmable gate array
HAZAN	hazard analysis
HAZOP	hazard and operability study
I/O	input / output
IHA	interface hazard analysis
ISA	independent safety assessor
LRU	line replaceable unit
OSHA	operation and system hazard analysis
PCB	printed circuit board
PHA	preliminary hazard analysis
PLC	programmable logic controller
QAP	quality assurance plan
QMS	quality management system
RAM-P	RAM-plan
SC	safety case
SAD	system architecture description
SADT	structured analysis and design techniques
SAP	safety plan
SEEA	SW error effects analysis
SHA	system hazard analysis
SRS	system requirements specification
SSHA	subsystem hazard analysis
SSRS	subsystem requirements specification
VAP	validation plan
VHDL	VHSIC hardware description language
VHSIC	very high speed integrated circuit
VLSI	very large scale integration
VTR	validation test report
V&V	verification & validation

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4 Cross-acceptance

4.1 General

Clause 4 describes the requirements and conditions necessary to achieve the acceptance of a product or application for use in a different environment from that for which it was originally developed and approved. One field of application of this Technical Report could be interoperability (for example TSI for Control Command Subsystem) and in general fields where cross-acceptance is needed.

4.2 Definition and importance of cross-acceptance

Cross-acceptance is defined in EN 50129.

Cross-acceptance is an aspect of the technical and legal process principally aimed at establishing the fastest route to the deployment of Product, System or Process in a target (new) context or environment. The Product, System or Process considered for cross-acceptance is generally assumed to satisfy the qualifications for reliability, tolerable safety and environmental performance in their native (original) context or environment.

The target application is also assumed to possess significant synergies with the native environment, thus making the deployment technically feasible viable/advantageous without significant alterations. However, the essence of cross-acceptance currently relates to the assurance of safety and potentially environmental performance of product, system or process which are subject to a regulatory regime.

4.3 Lifecycle for cross-acceptance

4.3.1 General

The cross-acceptance life cycle can be seen as a branch of the life cycle model defined in EN 50126, starting after the original approval of the generic product or generic application. Cross-acceptance life cycle mainly comprises

– phases, planning and documents (including role of field testing),

– safety assurance processes,

– approval processes.

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Table 1 – Lifecycle for cross-acceptance of safety related/safety critical systems/products/equipment

Phase	Customer	Supplier	Output documents
Start cross-acceptance	Define requirements / specifications (functional, environment, operation, safety, maintenance, etc.).	Prepare safety plan, validation plan, RAM-plan, field trial plan.	Follow life cycle, plan.
Specification	Attend hazard identification meeting with members from approval authority, assessor, operator, operation and maintenance.	Create SRS; create preliminary hazard analysis (PHA) and hazard analysis (HAZ-AN) on the base of CRS and risk analysis.	SRS, preliminary hazard analysis, hazard analysis.
Evaluation of differences	Evaluation of differences between originally approved application and new customer application.	Evaluation of differences between originally approved application and new customer application.	Verification report of specification, updated hazard-log (if identified).
Validation	**Assessor:** assess validation plan.	Start system validation of system requirement specification against customer requirement specification.	Life cycle; **validation test report, field trial report** (post pilot).
Assessment	**Assessor:** create assessment report; safety case will be examined by an assessor. The result of his work will be presented in an assessment report, forming the background for the decision taken by the railway authority.	Assessment of the differences, the assessor must be familiar with the operating conditions.	Assessment report.
System acceptance	System acceptance; validation of the system following findings in risk analysis; prepare test report or/and application safety case, start pre-pilot phase.		Application safety case, compliance report, system acceptance by customer and railway authority.
Operation and maintenance	Operate and maintain the system; introduce a DRACAS system.		
RAMS-demonstration	Update field trial report.		**Field trial report** (pre-pilot).

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4.3.2 Specification

As with the original approval, a cross-acceptance approval is based on a specification prepared by the infrastructure owner or railway undertaking. This specification should normally contain details on the following key points:

– environmental conditions (climatic, mechanical, EMI, EMC, etc.),

– reliability and availability,

– safety target (THR),

– interfaces,

– functional requirements based on operational rules,

– operational limits and dimensions,

– non functional requirements (necessary documents, size, weight, etc.).

In addition, all functional and safety requirements should be defined. The quoted safety target (THR = Tolerable Hazard Rates) should be calculated based on a risk analysis. The specification prepared by the infrastructure owner or railway undertaking will then form the basis for examining the differences between the originally approved system and the cross-acceptance system.

4.4 Cross-acceptance process

A structured and risk based framework for cross-acceptance of product, system or process is developed in this guidance comprising seven core principles. The principles are universal and are particularly pertinent to safety critical systems where no systematic and efficient framework for their adoption and application in new applications or environments exists.

4.4.1 The basic premise

The cross-acceptance of a product, system or process is implicitly founded on a number of key assumptions and conditions namely

a) the product, system or process has been specified, designed and developed by a competent, capable and reputable organisation,

b) the product, system or process has been scrutinised, analysed and assessed through a rigorous process to assure its relevant safety, environmental and technical performance and this process has been documented at an appropriate level of detail,

c) the product, system or process has been evaluated for its compliance with regulatory requirements and best practice standards and codes of practice,

d) the assessment has been peer reviewed and the product, system or process approved or certified by a relevant competent body or authority in its native environment implying tolerability of its risks subject to specified constraints and controls,

e) the product, system or process has preferably got a demonstrable record of adequate verification, validation and testing or trouble free operation in its native environment,

f) the product, system or process has potential for a wider scope of application beyond its initial native environment either in its original state, or through small-scale redesign and adaptation,

g) there is a perceived or real safety or environmental benefit or need in adapting the product, system or process for use in new (target) environments,

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h) there is an implicit or explicit record of the above conditions and assumptions which can be made available to relevant third parties as deemed appropriate.

Even though not always stated, these conditions and assumptions are required or perceived to hold true for the purpose of cross-acceptance.

4.4.2 Principles of cross-acceptance

The framework for systematic cross-acceptance developed and proposed here essentially comprises 7 key principles as detailed below.

a) Establish a credible case for the native (baseline) application

b) Specify the target environment and application

c) Identify the key differences between the target and native cases

d) Specify the technical, operational and procedural adaptations required to cater for the differences

e) Assess the risks arising from the differences

f) Produce a credible case for the adaptations adequately controlling the risks arising from the differences

g) Develop a generic or specific cross-acceptance case

a) Establish a credible case for the native (baseline) application

Cross-acceptance is broadly applicable to generic product/system/process and generic application cases. In this spirit, specific applications require further scrutiny and justification. Cross-acceptance is essentially a differential case and requires a credible native (baseline) and a target environment and associated arguments for safety.

1) To construct a baseline, the product, system or process shall be specified and documented in its native environment including (whenever applicable)

   – a record of technical, operational, environmental, quality and safety performance requirements including applicable rules and standards,

   – specification or description of relevant operational environment, scope, boundary and interfaces,

   – description of the system architecture and composition including rules & procedures, people and competence issues and automation aspects,

   – description of the operational, maintenance and retrofit processes,

   – description of the operational scenarios under normal, degraded and failed modes of the system,

   – description of emergency response arrangements and procedures.

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2) Justification of the baseline case in the native application comprising

- evidence based on analysis, simulation, testing, verification and validation of core safety functions,
- evidence of in service performance,
- evaluation of hazard log and incident reports,
- user and operator interviews,
- maintenance records,
- integrity and quality metrics and statistics,
- reference standards, licences and certificates.

The above evidence should be embodied within the cross-acceptance safety case.

b) Specify the target environment and application

To construct a systematic view of the target application, the product, system or process shall be specified and documented in the new environment including

- a document addressing technical, operational, environmental, quality and safety performance requirements,
- specification of operational environment, scope, boundary and interfaces in the target application,
- description of the system architecture and composition including applicable rules & procedures, people and competence issues and automation aspects,
- description of the operational, maintenance and retrofit processes in the new environment,
- description of the operational scenarios under; normal, degraded and failed modes of the system in the new environment,
- specification of the emergency response strategy and processes.

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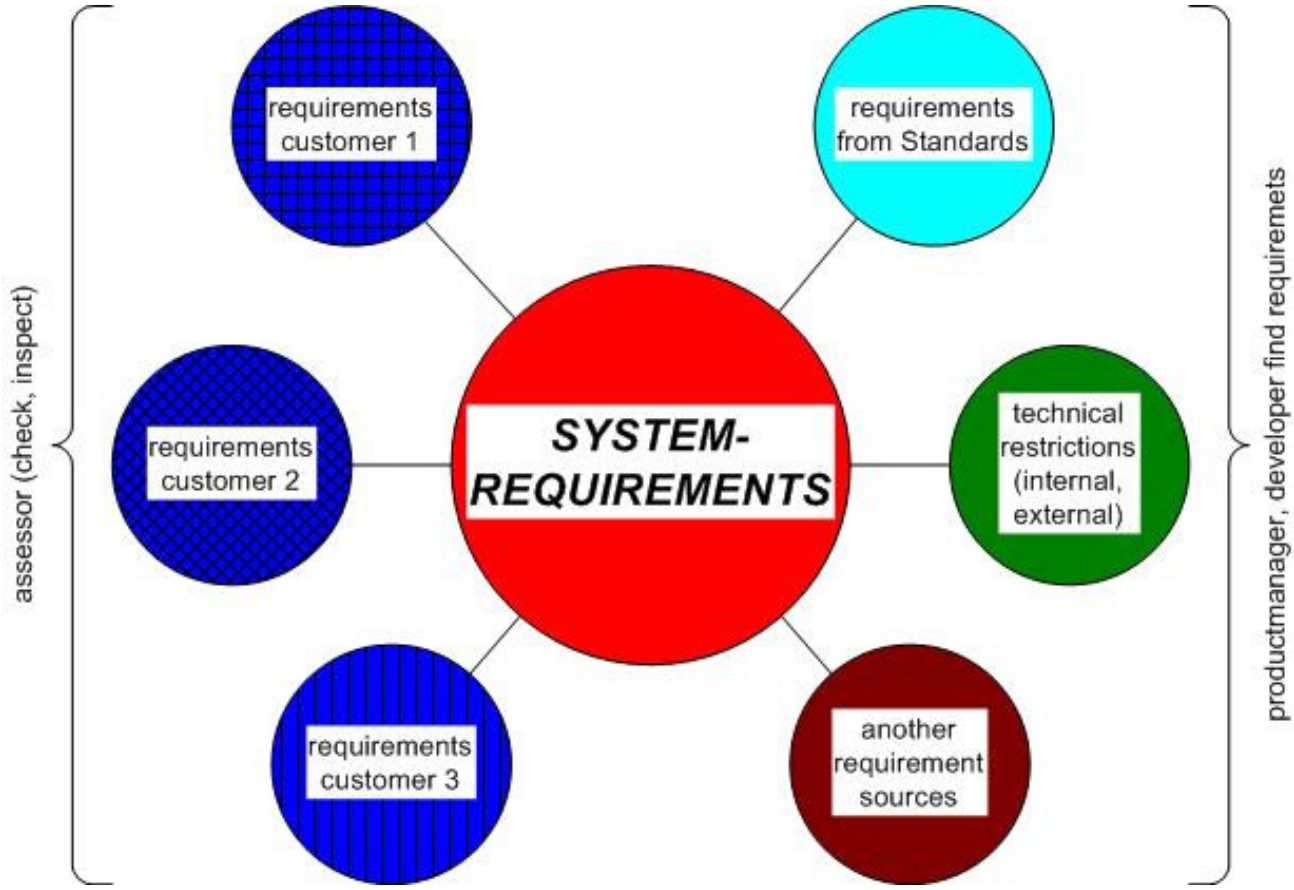

Figure 1 – The role of assessor and developer in maintaining system requirements

c) Identify the key differences between the target and native cases

Identification of the differences between the native and target applications including significant changes in

– technical, operational, environmental, quality and safety performance requirements,

– scope, boundary, operational environment and interfaces,

– system architecture and composition including rules & procedures, people and competence issues and automation aspects,

– operation, maintenance and retrofit processes,

– operational scenarios under normal, degraded and failed modes of the system,

– emergency arrangements.

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d) Specify the technical, operational and procedural adaptations

Identification of the adaptations required to cater for the differences between the native and target applications including

– identification of the scope and boundary of the invariant aspects of the system (similarities),

– technical, procedural or operational changes to the product, system or process to address the demands of the target environment,

– establishing the feasibility and viability of such adaptations,

– communicating the scope and extent of required adaptations with all stakeholders.

e) Assess the risks arising from the differences

Identify the hazards and assess the risks arising from differences between the native and target applications including

– assessment of risks arising from the differences in technical, operational, environmental adaptation of the product, system or process for target application,

– verification and validation of the assumptions and evidence,

– identification of all additional measures which could mitigate and reduce the risks further including estimates for their potential impact.

f) Produce a credible case for the adaptations adequately controlling the risks arising from the differences

Ensure the adaptations have resulted in the reduction and control of the risks to a target level namely:

– justification of the adaptation strategy (technical, procedural, compliance etc.),

– evaluation of the impact of the adaptations in risk reduction,

– explanation of the rationale and Justification of the efficacy of the adopted measures,

– determination of residual risk after adaptations and demonstration of compliance with best practice standards and legal framework.

g) Develop a generic or specific cross-acceptance safety case

This involves developing a generic or specific application safety case and an appropriate safety management system for the implementation/deployment in the target environment.

In the spirit of a risk based systemic framework, the scope and depth of application and compliance with each principle should be commensurate with the scale of perceived risks.

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4.4.3 Safety cases for cross-acceptance

The approval procedures for cross-acceptance requires a set of interrelated safety cases as follows:

– generic system/sub-system/product safety case for cross-acceptance based on the safety case for the original application,

– generic system/sub-system/product application safety case,

– specific application safety case as applicable.

Generic safety case covers general aspects of the introduction of a new system. It will apply to all future projects. Subject matter such as operational and maintenance procedures is dealt with within the generic safety case. Requirements for the application are derived from these safety cases.

The specific application safety case is produced by the main contractor and serves the purpose of demonstrating that all the safety and functional requirements of the standard and the safety case are met by the application.

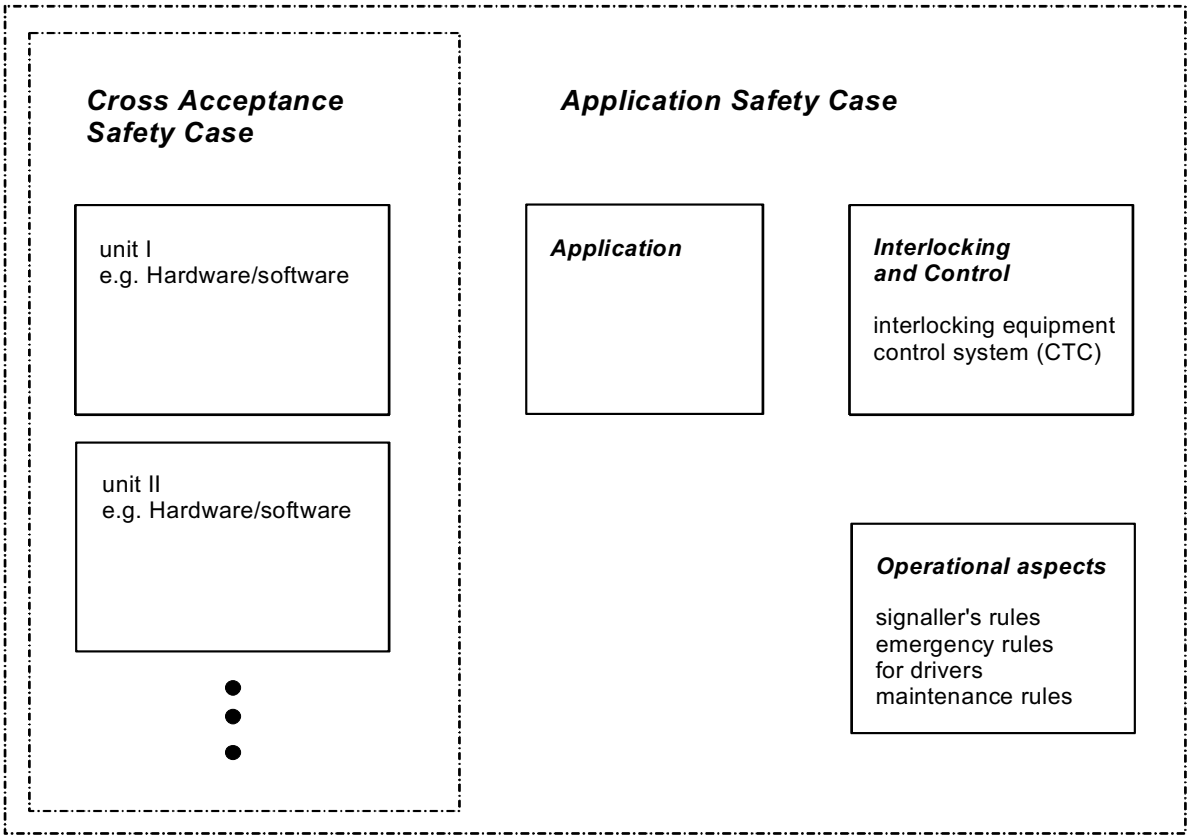

Figure 2 – The three types of safety case involved in cross-acceptance process

4.4.4 Generic product / application safety case for cross-acceptance

A key point in the preparation of a generic system/product/equipment safety case for cross-acceptance is to define the technical boundary of the cross-acceptance and the differences to the original application as detailed above. It is also necessary to address all relevant standards and local application rules (reference set), which have been applied during the development of the product and the final application.

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The generic product safety case for cross-acceptance covers as a minimum the following fields:

– proof, that the differences in the target environment do not prevent meeting the tolerable hazard rates and safety targets,

– proof that the target rules and conditions are fulfilled,

– proof that the specific requirements in the target environment are met, specifically those not covered by the safety case for the original application,

– proof that unused parts or unused code of the system do not adversely affect the system.

4.4.5 Field testing

Field testing is generally required to demonstrate compatibility of the system with the environment and to provide reliability data. A trial site should be installed in advance of the main project and chosen to represent the operational environment of the final application. The tasks to be performed during field testing are generally derived from the initial safety impact analysis.

A fault management system should be installed to log and analyse any faults or anomalies which occur during the field testing. All faults and anomalies are required to be closed out before the approval. This can be done by showing that they are

– not caused by a system failure,

– have been dealt with by a subsequent change to the hardware or software,

– have been mitigated by other means (e.g. by operational or maintenance guidelines).

4.4.6 Compliance report

The compliance report covers references to the documentation for the purpose of closing out hazards and ensuring that all safety and functional requirements are met as follows:

– system requirements specification,

– architecture design specification,

– integration test report,

– qualification test report,

– technical safety report,

– system manual (operational and maintenance).

The compliance report containing a complete list of all the application requirements, both generic and application specific, should be reported in the safety case.

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