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Railway applications - Communication, signalling and processing systems - Application Guide for EN 50129 -- Part 1: Cross-acceptance

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Railway applications - Communication, signalling and processing systems - Application Guide for EN 50129 - Part 1: Cross-acceptance

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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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.

The text of the draft was submitted to vote and was approved by CENELEC as CLC/TR 50506-1 on 2007-01-16.

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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)

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

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

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.