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Railway applications The specification and demonstration of Reliability, Availability,
Maintainability and Safety (RAMS) Part 2: Guide to the application of EN 50126-1 for safety

Applications ferroviaires -Spécification et démonstration de la fiabilité, de la disponibilité, de la maintenabilité et de la sécurité (FDMS) -Partie 2:Guide pour l'application de l'EN 50126-1 à la sécurité Bahnanwendungen Spezifikation und Nachweis
der Zuverlässigkeit, Verfügbarkeit,
Instandhaltbarkeit, Sicherheit (RAMS) Teil 2: Leitfaden zur Anwendung
der EN 50126-1 für Sicherheit

This Technical Report was approved by CENELEC on 2007-01-22

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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

The European Standard EN 50126-1:1999, which was prepared jointly by the Technical Committees CENELEC TC 9X, Electric and electronic applications for railways, and CEN TC 256, Railway applications, under mode 4 co-operation, deals with the specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) for railway applications.

A guide to the application of EN 50126-1 for safety of railway systems (this CLC/TR 50126-2) and a guide for the application to EN 50126-1 for rolling stock RAM (CLC/TR 50126-3:2006) have been produced to form informative parts of EN 50126-1:1999. Whilst this CLC/TR 50126-2 is applicable to all railway systems, including rolling stock, CLC/TR 50126-3:2006 is applicable to rolling stock RAM only.

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.:mitted to the vot. This Technical Report, which was prepared by WG 8 of the Technical Committee CENELEC TC 9X, forms an informative part of EN 50126-1:1999 and contains guidelines for the application of EN 50126-1 for the safety of railway systems.

The text of the draft was submitted to the vote and was approved by CENELEC as CLC/TR 50126-2 on 2007-01-22.

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Introduction

EN 50126-1 was developed in CENELEC under a mode 4 co-operation with CEN and is now regularly called up in specifications. In essence, it lists factors that influence RAMS and adopts a broad risk-management approach to safety. The standard also gives examples of some risk acceptance principles and defines a comprehensive set of tasks for the different phases of a generic life cycle for a total rail system.

Use of EN 50126-1 has enhanced the general understanding of the issues involved in dealing with safety and in achieving RAMS characteristics within the railway field. However, a number of issues have arisen that suggest that there are differences in the way that safety principles and/or requirements of this standard are being interpreted and/or applied to a railway system and its sub-systems.

Therefore, the guidelines included are to remove such differences and to enable a coherent and pragmatic approach, within Europe, for setting safety targets, assessing risks and generally dealing with safety issues. The report is not intended to set any specific safety targets (which will remain the responsibility of the relevant regulatory authorities) but only to provide guidance on different methods that can be used for setting targets, assessing risks, deriving safety requirements, demonstrating satisfactory safety levels, etc., with examples, where appropriate. The responsibility for accepting the methods to be used and for setting targets remains with the Railway Authority (RA) in conjunction with the Safety Regulatory Authority (SRA).

Furthermore the introduction of the proposed safety directive (European Directive on the development of safety on the Community's railways through development of common safety targets and common safety methods) should lead to a common safety regulatory regime within Europe. Such a regime will require that there is a common European approach to the methods for setting safety targets and for assessing risks.

The Technical Report is intended to cover the full spectrum of railway systems and for use by all the different user groups of the standard EN 50126-1. User groups may be part of any of the different players (bodies/entities) involved during the life cycle phases of a system, from its conception to disposal.

However, this Technical Report deals with only those items covered by the standard EN 50126-1 that are identified by the scope of work and with clarification of areas where EN 50126-1 could be misinterpreted. Clauses in the report are structured to cover clarifications of definitions and concepts and then to reflect the items in the scope and in order of the risk assessment process. But the contents are limited to include guidance and explanations for only those items that were remitted by resolution 26/5 of TC 9X and any related issues.

1 Scope

- **1.1** This Technical Report provides guidance on specific issues, listed under 1.3 below, for applying the safety process requirements in EN 50126-1 to a railway system and for dealing with the safety activities during the different system life cycle phases. The guidance is applicable to all systems covered within the scope of EN 50126-1. It assumes that the users of the report are familiar with safety matters but need guidance on the application of EN 50126-1 for safety issues that are not or could not be addressed in the standard in detail.
- **1.2** EN 50126-1 is the top-level basic RAMS standard. This application guide, CLC/TR 50126-2 forms an informative part of EN 50126-1 dealing explicitly with safety aspects as limited by the scope defined in 1.3 below.

1.3 Limitation of scope

The scope is limited to providing guidance only for the following issues related to EN 50126-1.

- i) Production of a top-level generic risk model for the railway system down to its major constituents (e.g., signalling, rolling stock, infrastructure, etc.) with definition of the constituents of the model and their interactions.
- ii) Development of a checklist of common functional hazards within a conventional railway system (including high speed lines, Light Rail Train's, metro's, etc.).
- iii) Guidance on the application of the risk acceptance principles in EN 50126-1.
- iv) Guidance on the application of functional safety in railway systems and qualitative assessment of tolerable risk with examples.
- v) Guidance for specifying relevant functional safety requirements and apportionment of safety targets to the requirements for sub-systems (e.g. for rolling stock: door systems, brake systems, etc.).
- vi) Guidance on the application of safety integrity level concept, through all the life cycle phases of the system.
- vii) Guidance on methods for combining probabilistic and deterministic means for safety demonstration.
- viii) Guidance on the essentials (incl. maintenance, operation, etc.) for documented evidence or proof of safety (safety case) with proposals for a common structure for such documentation.
- 1.4 A diagrammatic representation of the scope and limitations of the scope cross linking with the safety activities within the life cycle phases of EN 50126-1 and the roles/responsibilities of the principal players is given in Table 1 below. However, for full comprehension it is suggested that these clauses are considered only after the whole document has been read:

Table 1 – Cross-reference between certain life cycle phase activities and clauses of the report

| | Lifecycle phase of EN 50126-1 | Bodies/Entities involved | Relevant clause |
|-----|---|---|--------------------|
| 1. | CONCEPT | | Not in the scope |
| 2. | SYSTEM DEFINITION AND APPLICATION CONDITIONS | Generally, Railway Authority (RA) for railway system level, Railway Support Industry (RSI) for lower system levels. | 4.3, 5.3.2.1 |
| 3. | RISK ANALYSIS | RA or RSI, depending on the life cycle phase. | 4.4, 5.3, 5.4 |
| 4. | SYSTEM REQUIREMENTS | Generally, RA for railway system level. RSI for lower system levels. | 5.3.2.1, 6.2 |
| 5. | APPORTIONMENT OF SYSTEM REQUIREMENTS | Body/entity responsible for the design of the system under consideration. | 5.4.6, 6.2, 6.3, 8 |
| 6. | DESIGN AND IMPLEMENTATION | RSI | 4.3, 5.4, 6 |
| 7. | MANUFACTURING | | Not in the scope |
| 8. | INSTALLATION | | Not in the scope |
| 9. | SYSTEM VALIDATION (INCLUDING SAFETY ACCEPTANCE AND COMMISSIONING) | SRA and RSI | 7.1, 9 |
| 10. | SYSTEM ACCEPTANCE | RA and SRA | 7.1, 9 |
| 11. | OPERATION AND MAINTENANCE | RA | 5.4.6, 9.5 |
| 12. | PERFORMANCE MONITORING | | Not in the scope |
| 13. | MODIFICATION AND RETROFIT | RA, SRA and RSI as relevant | Part of 9.8 |
| 14. | DECOMMISSIONING AND DISPOSAL | | Not in the scope |

1.5 This Technical Report is structured generally to reflect the order of the safety process. However, the issues within the scope of the report, as listed under 1.3 above, are covered in the clauses as tabulated below.

Table 2 - Clauses of the report covering scope issues

| Clause 1 | Scope. |
|----------|--|
| Clause 2 | References. |
| Clause 3 | Interpretations and explanations of the definitions in EN 50126-1 and definition of additional terms and abbreviations used in the report. |
| Clause 4 | Provides guidance on system hierarchy, on bodies/entities involved and their responsibilities and on safety concepts implicit in the safety process as covered by the scope. |
| Clause 5 | Items i) and ii) of the scope. |
| Clause 6 | Items iv), v) and vi) of the scope. |
| Clause 7 | Item vii) of the scope. |
| Clause 8 | Item iii) of the scope. |
| Clause 9 | Item viii) of the scope. |

2 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.

| EN 50126-1:1999 | Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Basic requirements and generic process |
|------------------------|---|
| CLC/TR 50126-3:2006 | Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 3: Guide to the application of EN 50126-1 for rolling stock RAM |
| EN 50128:2001 | Railway applications – Communication, signalling and processing systems – Software for railway control and protection systems |
| EN 50129:2003 | Railway applications – Communication, signalling and processing systems – Safety related electronic systems for signalling |
| CLC/TR 50506 series 1) | Railway applications – Communication, signalling and processing systems – Application Guide for EN 50129 |
| EN 60300-3-1:2004 | Dependability management – Part 3-1: Application guide – Analysis techniques for dependability – Guide on methodology (IEC 60300-3-1:2003) |
| EN 61508:2001 (series) | Functional safety of electrical/electronic/programmable electronic safety-related systems (IEC 61508 series) |
| EN 61078:1993 | Analysis techniques for dependability – Reliability block diagram method (IEC 61078:1991) |
| EN 61160 | Design review (IEC 61160) |
| EN 61703 | Mathematical expressions for reliability, availability, maintainability and maintenance support terms (IEC 61703) |
| IEC 60050-191 | International Electrotechnical Vocabulary – Chapter 191: Dependability and quality of service |
| IEC 60300-3-9:1995 | Dependability management – Part 3: Application guide – Section 9: Risk analysis of technological systems |
| IEC 60812:1985 | Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA) |
| IEC 61025:1990 | Fault tree analysis (FTA) |
| IEC 61165:1995 | Application of Markov techniques |
| IEC 61882:2001 | Hazard and operability studies (HAZOP studies) – Application guide |
| ISO/IEC Guide 51:1999 | Safety aspects – Guidelines for their inclusion in standards |

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¹ At draft stage.