Assessment of proof of safety
Inspection program

Reference: DIN EN ISO/IEC 17020:2012, Inspection program

Keywords: Safety Case, CENELEC

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EN 50126, EN 50128, EN 50129, EN 50159, EN 50155

Table of contents

Scope

The inspection program Assessment of Safety Cases has been established for the Inspection Body (IS) of Ramboll ICB GmbH and it is binding for the employees working on assessments of Safety Cases (SBS) in the department Safety Assessments (SB).

It is also freely available to third parties.

Inspection program

This program comprehensively describes a part of the service offered by the inspection body regarding inspections in the regulated and unregulated area.

Abstract

Combined with

the safety approval of railway applications, safety-relevant electronic systems for signalling technology and software for railway control and monitoring systems in a RAMS life cycle according to CENELEC;

the inspection body provides inspections in the field of

assessment of the adequacy, completeness and correctness of safety cases for railway applications, safety-relevant electronic systems for signaling and software for railway control and monitoring systems according to CENELEC;

as well as the determination of compliance with specific and general requirements, on the basis of an expert assessment.

Contents / Scope

The safety case according to CENELEC (EN50129) is a structured document. It serves as a proof that a product meets the specified safety requirements for the safety approval. . The conditions for safety approval must be met at subsystem and system level, as well as on establishment level, before the safety-relevant system can be recognized as adequately safe.

The safety case collects, documents and summarizes the safety reasons in detail. It is a fixed component of the safety approval process in a RAMS life cycle according to CENELEC (EN 50126). It includes an independent assessment of specified and general requirements.

This inspection program comprises the independent assessment of the adequacy, completeness and correctness of safety cases consisting of

- Proof of quality management
- Proof of safety management
- proof of functional and technical safety

as well as the determination of compliance with specified and general requirements.

This inspection program comprises comprehensive document verification on the basis of determined records (safety case and accompanying evidence documentation on the relevant RAMS lifecycle phases). Based on this documentation, a formal and substantive examination of the conformity with the specified requirements according to CENELEC on the records of quality- and safety management, as well as records of functional and technical safety is carried out.

The depth of the demonstration in the safety case and the extent of the accompanying documentation depend on the safety requirements that are relevant for the verification, which are documented in the safety case for the safety approval..

Depending on the findings and results of the documentation review, an assessment of the adequacy and consistency of documented processes, procedures, methods, tools and techniques by means of on-the-spot auditing is carried out at the discretion of the commissioned inspector. For this the selected process steps, applied methods, methods, tools or techniques are observed, tracked and assessed on site during their application and implementation.

Methodology

Document verification check, Auditing/Witnessing.

Inspection item / Objects

Safety Case including accompanying documentation and records

(RAMS life cycle documentation according to CENELEC)

Normative Basics

EN 50126-1 1999-09/ corrigendum 2006-05 corrigendum 2010-05	Railway Applications - The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Basic requirements and generic process
EN 50126-1 2017-10	Railway Applications - The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Generic RAMS process
EN 50126-2 2017-10	Railway Applications - The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 2: System approach to Safety
EN 50128 2001-03/ corrigendum 2010-05	Railway applications - Communications, signalling and processing systems - Software for railway control and protection systems
EN 50128 2011-06 corrigendum 2014-02 amendm. A1 2020-02 amendm. A2 2020-07	Railway applications - Communication, signalling and processing systems - Software for railway control and protection systems
EN 50129 2003-02/ corrigendum 2010-05	Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling
EN 50129 2018 corrigendum 2019-04	Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling
EN 50155 2007-07/ corrigendum 2010-05	Railway applications - Electronic equipment used on rolling stock

Assessment of proof of safety
Inspection program

EN 50155 2017-10	Railway applications - Rolling stock – Electronic equipment
EN 50159-1 2001-03/ corrigendum 2010-05	Railway applications - Communication, signalling and processing systems - Part 1: Safety-related communication in closed transmission systems
EN 50159-2 2001-03/ corrigendum 2010-05	Railway applications - Communication, signalling and processing systems - Part 2: Safety-related communication in open transmission systems
EN 50159 2010-09 amendm. A1 2020-02	Railway applications - Communication, signalling and processing systems - Safety-related communication in transmission systems
EN 50657 2017-08	Railways Applications - Rolling stock applications - Software on Board Rolling Stock

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Abbreviations used:

DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
EC	European Community
EN	European Standard
en	Englisch Version
EU	European Union
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization

Contact

The current version of this inspection program is available on the Internet:
https://ramboll.com/Ramboll-ICB-global

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