

**Assessment of quality and safety management processes**

Inspection program

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CENELEC EN 50126, EN 50128, EN 50129**

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**Scope**

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

It is also freely available to third parties.

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# 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 specification and proof of reliability, availability, maintainability and safety (RAMS) of railway applications, safety-relevant electronic systems for signaling and software for railway control and monitoring systems according to CENELEC;

the Inspection body provides inspections in the field of

assessment of the suitability and appropriateness of quality and safety management processes as well as the procedures, methods, tools and techniques used in the RAMS life cycle according to CENELEC;

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

## Content / Scope

The safety case conform CENELEC (EN50129) is a structured document and specification and proof of reliability, availability, maintainability and safety (RAMS) according to CENELEC (EN 50126) and requires a systematic, documented procedure for the demonstration of quality management, safety management as well as functional and technical safety

These documents form the content parts of the proof of safety in a RAMS life cycle according to CENELEC and include planning, implementation and verification, as well as an independent assessment of specified and general requirements..

This inspection program includes an independent assessment of the suitability and adequacy of

- quality management processes;
- safety management processes;
- the procedures, methods, tools and techniques used;;

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

This inspection program comprises document verification based on established planning documents, quality and safety management reports, and accompanying records.. On the basis of this documentation, a formal and substantive examination of compliance with the defined requirements for quality and safety management processes according to CENELEC is carried out acc. CENELEC. The necessary depth of the explanations and the scope of the accompanying evidence documentation depend on the safety requirements that are relevant for the management processes.

Depending on the findings and results of the documentation review, an assessment of the suitability and adequacy 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.

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**Methodology**

Document verification, Auditing/Witnessing.

**Inspection item / Objects**

Quality management and safety management processes as well as procedures, methods, tools and techniques used, including related management documentation

(RAMS lifecycle documentation of quality management and safety management according to CENELEC)

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**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 2018-11/  corrigendum 2019-04	Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling
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 Electro technical Commission
ISO	International Organization for Standardization

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## Contact

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

**TuMotus-ICB GmbH**

Inspection Body (IS)  
Volkmaroder Straße 8  
38104 Braunschweig

Tel.: +49 531 70221 - 0  
[info@ramboll.com](mailto:info@ramboll.com)

Location: Braunschweig  
District court Braunschweig HRB 208093  
VAT number DE 327350625