

Conformity Assessment
Inspection program

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Conformity Assessment
TSI „Control, Command and Signalling“

Conformity Assessment

Inspection program

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Scope

The inspection program Conformity Assessment has been established for the Inspection Body (IS) of Ramboll ICB GmbH and it is binding for the employees working on conformity assessments TSI CCS (KBS) in the department Conformity Assessments (KB).

It is also freely available to third parties.

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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:

Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system in the Community;

or

Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No. 881/2004;

and their amendments and the Commission Decision of 9 November 2010 on modules for procedures for the assessment of conformity and suitability for use as well as the EC verification to be used in the technical specifications for interoperability adopted pursuant to Directive 2008/57/EC of the European Parliament and of the Council (2010/713/EU);

the Inspection body provides inspections in the field

Assessment of the adequacy and correctness of the proof of conformity for interoperability constituents and subsystems in accordance with the technical specifications for interoperability for the control, command and signaling subsystems (TSI CCS)

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

Content / Scope

The safety case according to CENELEC (EN50129) is a structured document and In order to issue an EC declaration of conformity or suitability for use for an interoperability constituent or subsystem, according to the above mentioned interoperability directive, the relevant rules of the Technical Specifications for Interoperability (TSI), are to be applied. The conformity or suitability for use of an interoperability constituent is generally assessed by a Notified Body. The Technical Specification of Interoperability for the subsystems “control, command and signaling” (TSI CCS, (EU) 2016/919 + (EU) 2019/776) sets all the conditions and the procedure to be followed for the conformity assessment, with which an interoperability constituent or subsystem has to comply with. The procedures for the conformity assessment and the assessment of suitability for use of components and subsystems are based on pre-defined modules according to 2010/713/EU.

Subject to statutory rules or progressive requirements, this inspection program ensures that the procedures, content, scope and results of the conformity assessment by TuMotus-ICB GmbH can be used by the Notified Body, in the context of our cooperation.

This inspection Program includes the independent assessment of the adequacy and the correctness of the proof of conformity (or partial aspects thereof) for

Interoperability constituents;

Subsystems;

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

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This inspection program takes into account the following modules of 2010/713/EU:

CCS interoperability components (onboard / wayside)

EC type examination procedure (module CB) for the technical design and development phases in connection with the quality assurance procedure for the production phase (module CD).

EC type examination procedure (module CB) for the design and development phases in connection with the quality assurance procedure for the production phase (module CF)

Conformity based on full quality management system plus design examination (module CH1).

CCS subsystems (onboard / wayside)

EC type examination procedure (module SB) for the planning and development phase in connection with the quality assurance procedure for the production phase (module SD)

EC type examination procedure (module SB) for the planning and development phase in connection with the product verification (module SF) or

EC verification based on full quality management system plus design examination (module SH1).

CCS subsystems (wayside only)

Unit verification (module SG)

This inspection program ensures that the application of the modules reliably takes into account all requirements appropriate to the scope of work, as far as these are applicable and binding. The definition of the mandatory requirements to be assessed is based on a defined version of the TSI CCS (baseline) as well as the definition of the object to be inspected (interoperability constituent or subsystem).

This inspection program, according to the modules, includes the inspection of defined input documents and accompanying documents and records. Based on this documentation, a formal and substantive examination of compliance with established, binding requirements and basic parameters of the TSI CCS is performed.

In addition, this inspection program, according to the modules, includes the assessment of the suitability and appropriateness of the documented processes, methods, tools, and techniques, for instance through on-site auditing. In doing so, binding requirements for process steps, methods, tools, or techniques used are verified on-site and their implementation is monitored, comprehended and assessed with regard to its conformity.

Methodology

Document verification, Auditing/Witnessing.

Inspection item / Objects

Proof of conformity including proof of accompanying documentation and records

(Application for conformity assessment, technical documentation, documentation of the quality assurance system)

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Normative Basics

2010/713/EU 2010-11	COMMISSION DECISION of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council
2012/88/EU 2012-01	COMMISSION DECISION of 25 January 2012 on the technical specification for interoperability relating to the control-command and signalling subsystems of the trans-European rail system
2012/696/EU 2012-11	COMMISSION DECISION of 6 November 2012 amending Decision 2012/88/EU on the technical specifications for interoperability relating to the control-command and signalling subsystems of the trans-European rail system
2015/14/EU 2015-01	COMMISSION DECISION (EU) 2015/14 of 5 January 2015 amending Decision 2012/88/EU on the technical specification for interoperability relating to the control-command and signalling subsystems of the trans-European rail system
(EU) 2016/919 2016-05	COMMISSION REGULATION (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union
L 279/94 2016-10	Corrigendum to Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union
(EU) 2019/776	COMMISSION IMPLEMENTING REGULATION (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474
(EU) 2020/387 2020-03	COMMISSION IMPLEMENTING REGULATION (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases

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(EU) 2020/420 2020-03	COMMISSION IMPLEMENTING REGULATION (EU) 2020/420 of 16 March 2020 correcting the German language version of Regulation (EU) 2016/919 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union
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Abbreviations used:

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

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