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RECOMMENDATION FOR USE

NB-RAIL COORDINATION GROUP

Administrative Decision according to Interoperability Directive
(EU) 2016/797 art. 30.6



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RFU-STR-016

Issue 03
Date 05/07/2022

TITLE

ACCEPTANCE OF ASSESSMENT REPORTS ON SAFETY PREPARED BY OTHER PARTIES

ORIGINATOR

SG STR, SG CCS, SG RST

SUBJECT RELATED TO

TSI CCS 2012/88/EU, 2012/696/EU and (EU) 2015/14
TSI CCS (EU) 2016/919 without any amendments
TSI LOC&PAS No (EU) 2014/1302, (EU) 2016/919, (EU) 2018/868, (EU) 2019/776, (EU) 2020/387

AMENDMENT RECORD

ISSUE 02: RESTRICTION OF THE USE OF THIS RFU TO SPECIFIC TSI VERSIONS

ISSUE 03: DELETED REFERENCE TO RFU-STR-706. NOTE: THIS ISSUE IS ONLY APPLICABLE TO THE TSI CCS VERSIONS/AMENDMENTS AS INDICATED IN THE "SUBJECT RELATED TO" FIELD

DESCRIPTION AND BACKGROUND EXPLANATION

Scope/ Background for both CCS and RST

As part of the EC Verification the NoBo must evaluate whether safety related generic products or their application in subsystems have been designed, validated and are produced using a systematic approach – this is an important aspect of the evaluation of the essential requirements 'safety' as defined in IOD and TSIs.

Note: for the reason of simplification, distinction between generic product and application is only used when necessary.

In this context the essential requirement for 'safety':

1. includes aspects which are in the industry called product safety, rail safety, functional safety, occupational health and safety of railway related staff, protection of health and safety of passengers, protection of health and safety of other people such as people living near to a railway line. Here a limited overlap with the essential requirement for 'health' exists.
2. 'safety' management must consider all reasonably foreseeable hazards, it is however not required to include protection against significant criminal or military attacks which may cause the product/installation under evaluation to malfunction. This means, that small predictable abuse should be included but more severe attack aspect can be evaluated by the applicant under self-assessment outside of the TSI evaluation scope.
3. is often considered to include also the protection against significant damage of the environment or the protection against significant material loss. An applicant may therefore decide to include these aspects also into his safety management

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activities. As these are not required by the TSI, they are outside the scope of the NoBo.

Further: In this context the evaluation of safety is limited to the scope which is defined by the TSIs and it is limited to the scope of the product/installation and the impacts of this product/installation to the rest of the railway system.

In this context it is typical, that the NoBo evaluation is in parts informed by ISA Reports and/or AsBo Safety Assessment Reports which often have been contracted by the Applicant separately from the NoBo activities.

This RFU addresses the conditions for acceptance of such reports as evidence within a TSI based NoBo evaluation.

The NoBo is responsible to check if such reports are conforming to the related TSI requirements in order to determine if the Applicant has fulfilled these requirements.

Note: There might be additional evidences used within the ISA report and/or AsBo Safety Assessment Reports. These additional evidences shall be subject to the same acceptance requirements as defined in this RFU.

Where necessary, this RFU distinguishes between the safety assessment of:

- Interoperability Constituents (IC) and
- Subsystems (SubS).

Introduction for both CCS and RST

The IOD (ref. 1) and the related TSIs mandate for certain parameters of ICs and for SubSs the assessment of the essential requirement for 'safety'. There are two different cases to be considered:

Case1: The TSIs or the associated lists of Standards in the EU Official Journal either mandate or recommend the application of the CENELEC range of standards (EN 50126, 50128, 50129, 50159, 50657) or of the CSM-RA. These standards/this regulation are considered to represent good industry practice for systematic design and production and validation of safety related products/installations.

Case2: Some TSIs mandate the use of parts of the CSM-RA regulation for the assessment of certain precisely defined basic parameters of a SubS (e.g. "4.2.5.5.9 *door emergency opening*" in the TSI LOC&PAS 1302/2014). Which parts of the CSM-RA and to which extent the CSM-RA regulation shall be applied has to be defined in the calling TSI itself (refer to §3 (a) of ref. 2). This case is currently only relevant for TSI LOC&PAS.

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Evidence of compliance to the above requirements (the CENELEC standards and/or the CSM-RA) may be provided in format of an ISA Report if it confirms conformance to the CENELEC standards and/or through an AsBo safety assessment report if it confirms conformance to (the required parts of) CSM-RA.

Note: Alternatively to the acceptance of such evidence by other parties, the NoBo may perform the related conformity assessments by itself as part of the TSI evaluation.

The tasks of the three Conformity Assessment Bodies (CAB) ISA, AsBo and NoBo require good co-ordination:

- 1) The Applicant must ensure, that his product/installation satisfies all related requirements of TSI + CENELEC + CSM-RA + other legislative or contractual requirements relating to 'safety'. Note: This causes typically no problem, as the different requirements overlap and integrate well.
- 2) The Applicant must ensure, that all safety related aspects of the product/installation are systematically evaluated by either ISA, AsBo or NoBo as appropriate. Double assessment should be avoided. Gaps between the assessments shall be avoided.
- 3) The responsibility for evaluation against the TSI requirements lies with the NoBo. The evidence for this evaluation will in parts be contained in the relevant ISA and/or AsBo reports. When contracting such a combination of activities to ISA, AsBo or NoBo, it must be ensured by the Applicant when allocating the tasks that the NoBo must eventually become able to trace that all requirements are fulfilled in order to provide the EC Certification.
- 4) The Applicant or the manufacturer must decide, whether the development life cycle for his product/installation will either:
 - a. directly aim to demonstrate the safety of that specific application, or
 - b. (based on commercial interest / based on the re-useability of the product design) also the safety of the generic product or the generic application shall be evaluated.

As a generic product may be evaluated, long before AsBo or NoBo are contracted, this task is often contracted from applicants to an ISA.

The evaluation of the generic application is largely compatible with the concept of NoBo IC evaluation. This task may be assigned partially to both ISA and NoBo.

The evaluation of the specific application is largely compatible with the concept of SubS evaluation. Depending on the applicable TSIs, this task may be assigned partially to a combination of ISA, AsBo and NoBo.

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- 5) If the Applicant decides to contract the tasks for ISA, for AsBo and for NoBo to the same body, the Applicant must ensure that this body is competent and accredited/notified as required to perform all the tasks.

Note: Interdependence between a CSM-assessment and a NoBo assessment may arise. It is recommended, that AsBo and NoBo coordinate their tasks in this respect.

The following drawings offer a comprehensive view of the CMS present situation both in the RST and CCO/CCT fields, in order to show the different shares of workload and scope of activities.

RFU PROPOSAL

I) OVERALL PROJECT CSM-RA VERSUS TSI BASED CSM-RA

Currently only CCS and LOC&PAS TSIs make reference to CSM-RA activities. In order to distinguish the TSI based CSM-RA from the overall project level CSM-RA this document uses in the following the terms TSI-CSM and CSM. The TSI-CSM and/or ISA reports are a mandatory input into the NoBo assessment. The CSM assessment on project level has typically no input into the TSI assessment, but the TSI assessment itself will be an important input for the project level CSM assessment.

I.1) OVERALL PROJECT LEVEL CSM-RA EVALUATION:

In relation to the overall project scope CSM may apply, only if the applicant (often the manufacturer) considers that the change introduced to the rail system by the project scope is significant (otherwise the safety management requirements of CSM-RA will not apply).

Overall project level CSM-RA assessment is beyond the TSI compliance assessment performed by the NoBo.

In case of TSI LOC&PAS and TSI CCS different scopes must be covered by TSI-CSM:

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I.2) LOC&PAS TSI BASED CSM-RA ASSESSMENT BY NOBO:

Typical situation in RST projects:

TSI-CSM-RA assessment will cover requirements that are essential to NoBo and DeBo and those covered by the safety management of the full scope of the project.

In RST projects TSI-CSM is only mandatory for very small sections of the project scope.



TSI LOC&PAS demands mandatory application of TSI-CSM for certain specific and isolated requirements covering very small areas scope. The safety assessment report(s) for this TSI-CSM required from TSI LOC&PAS shall be used as evidence document for the TSI assessment by the NoBo. They must therefore be completed before the NoBo can finish its evaluation. A substitution by ISA reports is not possible because of the strict TSI requirements.



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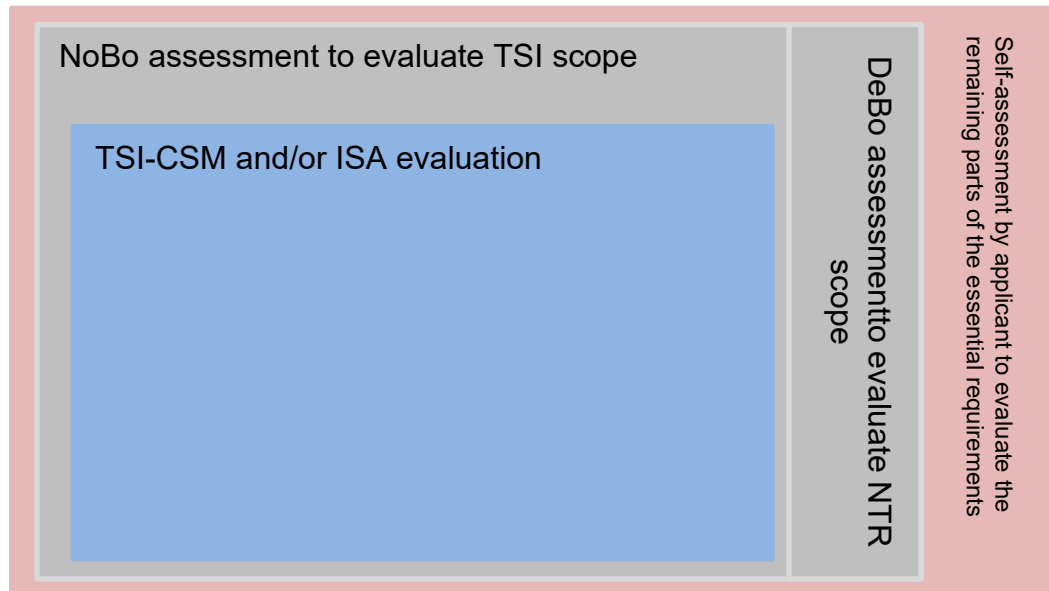
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I.3) CCS TSI BASED CSM-RA ASSESSMENT BY NOBO:

Typical situation in CCO/CCT projects:

TSI-CSM Assessment will cover requirements that are essential to NoBo and DeBo and those covered by the safety management of the full scope of the project.

TSI-CSM/ ISA evaluations cover very large sections of project scope.



The CCS TSI refers to TSI-CSM as “supporting evidence” (table 6.2 and 6.3) regarding safety assessment.

The TSI CCS does not necessarily require TSI-CSM safety assessment reports (it is only one option). If the safety requirements are alternatively covered within other evidence documents (e.g. an ISA report following the CENELEC standards), then a TSI-CSM safety assessment report could be replaced by an ISA report.

Combinations of both are acceptable, as long as there is no gap.



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II) ACCEPTANCE OF SAFETY ASSESSMENT REPORTS BY THE NOBO

II.1) ACCEPTANCE OF A TSI-CSM ASBO REPORT

To accept for TSI-CSM scope an AsBo safety assessment report about the conformity to the TSI requirements, the NoBo shall check that:

The AsBo performing the assessment is registered in ERADIS (<https://pdb.era.europa.eu/>) for the relevant scope of assessment.

The item under assessment of the AsBo safety assessment report fully covers the TSI evaluation by the NoBo.

In case of a combined approach, the combination of the sub-scopes for AsBo, ISA or NoBo assessment shall cover the complete product/installation scope.

The AsBo safety assessment report covers all the relevant aspects of TSI-CSM as required in the TSI(s) related to the project (see Annex III in ref.2).

The AsBo safety assessment report as evidence in the TSI evaluation shall allow retracing of all applicable safety requirements.

II.2) ACCEPTANCE OF AN ISA REPORT

Note: This RFU considers the definitions of CENELEC GUIDE 50506 Parts 1 and 2 (ref. 10 and 11).

ISA Independence and competency

The ISA shall have the level of independence as defined in the CENELEC standard EN 50128 (fig. 2 of ref. 8)/EN 50129 (fig. 6 of ref. 9) depending on the SIL of the item under assessment.

The NoBo shall assess if the proposed ISA fulfils the requirements of at least one of the following three cases:

1. Accreditation to ISO/IEC 17020 (ref. 3) for CENELEC standards EN 50126 (ref. 7 or 12), EN 50128 (ref. 8), EN 50129 (ref. 9) or EN 50657 (ref. 14) covering the relevant technical scope (RST, CCO, CCT).
 - a. Type A meets the requirements for independence and competence without additional provisions.¹
 - b. Type B and C meet the requirements for competence and additionally require the demonstration of the necessary level of independence

¹ Compliant with independence requirements of ERA report on NoBo monitoring (ref. 5) PART 2B, §6.2



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including impartiality requirements to EN 50128 (ref. 8) respectively EN 50657 (ref. 14) and EN 50129 (ref. 9).

2. Accreditation to ISO/IEC 17065 (ref. 4) for CENELEC standards EN 50126 (ref. 7 or 12), EN 50128 (ref. 8), EN 50129 (ref. 9) or EN 50657 (ref. 14) and covering the relevant technical scope (either RST, CCO, CCT) in respect to the product. Note: In this case the CAB's certificate and associated evaluation reporting shall be provided to the NoBo.
3. Non-accredited ISAs shall demonstrate to the NoBo how they meet the level of competence and independence as defined in subsection 1). The NoBo shall also take into account the civil and penal liability context in which the NoBo operates, because especially in this case the responsibility for evaluation lies with the NoBo. If a NoBo receives an ISA report from the same non-accredited ISA (in the same project or in another project) again within 24 months, then the NoBo may decide to accept the previous assessment of the competence and independence and no new assessment is necessary. If the NoBo receives an ISA report of a non-accredited ISA after 24 months of the last assessment of the competence and independence of this ISA, a new assessment is necessary by this NoBo.

Should none of the three above cases be fully met by the proposed ISA, then the reports from this ISA shall be rejected.

ISA Assessment Results

The following acceptance criteria apply to the ISA-report. These shall be evaluated by the NoBo. Additional evidence or supporting information may be requested by the NoBo if required to enable the evaluation of these criteria:

1. The assessment techniques applied by the ISA (review of documents, audits, testing, modelling, simulations, combinations of methods, etc.) are well defined and documented and can be evaluated by the NoBo based on the received evidence as appropriate.
2. The definition of the product/installation (which includes its description, documentation, hardware and software configuration, the configuration of the tools for development, test, maintenance, environmental and operational conditions, etc.) matches the assessment scope of the NoBo and no conditions have been identified which are in contradiction to the intended use.
3. The specifications, standards and other normative documents used as basis for the independent safety assessment are well defined, complete, appropriate and traceable to all requirements of the applicable TSI and CENELEC standards.

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4. The complete set of requirements (functional, safety, environmental, etc.) to the product/installation is traceable and consistent with the requirements established by the Applicant for the intended use of the product/installation.
5. The hazards are systematically and comprehensively identified, well documented and analysed. The associated risks have been systematically assessed and suitable mitigation measures have been identified throughout as safety requirements.
6. All safety requirements have been allocated to functions of the product/installation, to operational measures or to associated SRACs. This shall include appropriate allocation of SIL.
7. Verification & Validation evidence demonstrates that the product/installation fulfils the complete set of requirements (including associated SIL). Any deviations identified during Verification & Validation are appropriately identified and their impact has been analysed to still fulfil the set of requirements.
8. SRACs (including exported constraints) have been established by the applicant and are confirmed by the ISA.
9. The ISA report
 - a. covers the complete scope of the product/installation/environmental and operational conditions,
 - b. is clear and positive in its statements,
 - c. covers the relevant aspects of the safety & quality management process (requirements management, design techniques including modelling or simulations, configuration management, change management, independent review of documents, auditing, testing, verification, validation, etc. - list may not be exhaustive),
 - d. is in accordance with the conclusions of the validation report and the safety case.
10. The NoBo can confirm by its evaluation that the product/installation in a specific project is covered by the scope of the ISA report. If necessary, several ISA reports may in combination cover this scope.

It is possible that the NoBo's tasks regarding checking the Essential Requirements for "Safety" are wider than the tasks performed by the ISA. Therefore, the NoBo must analyse if a gap exists between the tasks performed by the ISA and the tasks a NoBo is obliged to perform according to TSI. E. g. the TSI may require a type test to be performed by an independent party whereas an ISA may have accepted a type test performed by the applicant. Also the ISA may have used results gained by testing a different type version from that presented to the NoBo. Possible gaps must be covered by the NoBo and justification must be given.

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Abbreviations and acronyms

AsBo:	Assessment Body (CSM-RA)
CAB:	Conformity Assessment Body
CCS:	Control-Command and Signalling
CCO:	Onboard Control-Command and Signalling
CCT:	Trackside Control-Command and Signalling
CSM-RA:	Common Safety Method for Risk Evaluation and Assessment
IC:	Interoperability Constituent
ISA:	Independent Safety Assessor as defined in CENELEC standards 5012x
LOC&PAS:	Locomotives and passenger rolling stock
NoBo:	Notified Body
RAMS:	Reliability, Availability, Maintainability, Safety
IOD:	Railway Interoperability Directive
RST:	Rolling Stock
SubS:	Subsystem
SIL:	Safety Integrity Level
SRAC:	Safety Related Application Conditions
TSI:	Technical Specification for Interoperability

References

1. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union
2. Commission Implementing Regulation (EU) No 402/2013² of 30 April 2013 on the common safety method for risk evaluation and assessment
3. ISO/IEC 17020:2012; Conformity assessment - Requirements for the operation of various types of bodies performing inspection.
4. ISO/IEC 17065:2012; Conformity assessment - Requirements for bodies certifying products, processes and services
5. Technical document Requirements for Conformity Assessment Bodies seeking Notification; Ref. 000MRA1044; v. 1.1, 14/06/2017 (containing NoBo Assessment Scheme)

² TSI CCS up to 2012/88/EU incl. amendments explicitly refers to Regulation (EC) No 352/2009 for CSM-RA. Regulation (EC) No 352/2009 has been repealed by Implementing Regulation (EU) No 402/2013. In this RFU it is assumed that projects, which use older TSI CCS than 2016/919 (with derogation), use Implementing Regulation (EU) No 402/2013 instead of the regulation stated in the older TSI CCS.

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6. Explanatory Note ERA/GUI-01-2014-SAF on the CSM Assessment Body in Regulation (EU) N°402/2013 and in OTIF UTP GEN-G of 1.1.2014 (Version 1.0) on the CSM for risk assessment.
7. CENELEC EN 50126-1:1999; Railway applications - The specification and demonstration of reliability, availability, maintainability and safety (RAMS) - Part 1: Basic requirements and generic process
8. CENELEC EN 50128:2001/2011; Railway applications - Communications, signalling and processing systems - Software for railway control and protection systems
9. CENELEC EN 50129:2003; Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling
10. CLC/TR 50506-1:2007, "Application Guide for EN 50129, Part 1 - Cross acceptance"
11. CLC/TR 50506-2:2009, "Application Guide for EN 50129, Part 2 - Safety assurance"
12. CENELEC EN 50126-1:2017; "Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 1: Generic RAMS Process"
13. CENELEC EN 50126-2:2017; "Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety"
14. CENELEC EN 50657:2017; "Railways Applications - Rolling stock applications - Software on Board Rolling Stock"

THIS RFU WAS AGREED ON

PLENARY MEETING 065 – 23/06/2022

THIS RFU ENTERS INTO FORCE ON

05/07/2022 (DATE OF PUBLICATION)

FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.

RFU APPLICATION IS MANDATORY STARTING FROM

05/07/2022

RFUs SHALL BE APPLIED BY ALL NOBOS. PLEASE REFER TO RFU-STR-702, CHAPTER 3 OF THE SECTION "DESCRIPTION AND BACKGROUND EXPLANATION", FOR THE LEGAL BASIS SUPPORTING THIS OBLIGATION.

ERA COMMENTS

PLE 065 – 23/06/2022: NO COMMENTS

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