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INTRODUCTION TO

NOTIFIED BODY (NOBO)

APPLICATION AND ASSESSMENT

RAIL BALTICA

GUIDANCE FOR CONTRACTORS


CONFIDENTIAL

LIST OF SUCCESSIVE VERSIONS

Version	Date	Objet
1	28/01/2021	First issue of the report
2	24/09/2021	Update including some Energy subsystem elements.
3	27/06/2022	Update widening some aspects of the document (compliance matrix exchange, construction stage assessment, TSI ENE specificities, etc.) -

The latest version supersedes the previous.

VALIDATION

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1. Purpose.

This document is issued with the intention of summarizing the more relevant texts contained in the Interoperability Directive (IOD) regulatory framework, in order to give to contractors information for RB Rail to set-up a harmonized process for interoperability assessment of all packages relevant to subsystems Infrastructure and Energy.

The IOD establishes the conditions to be met to achieve interoperability within the Union rail system in a manner compatible with Directive (EU) 2016/798 in order to define an optimal level of technical harmonisation, to make it possible to facilitate, improve and develop rail transport services within the Union and with third countries and to contribute to the completion of the single European railway area and the progressive achievement of the internal market.

Those conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of that system as well as the professional qualifications of, and health and safety conditions applying to, the staff who contribute to its operation and maintenance.

It is expected that RB Rail teams in charge of delivering the technical documentation and conformity matrices would read this document before issuing any delivery to CERTIFER.

WARNING: This guidance is considered to have been read by the contractors before the kick-off meetings.

2. Accreditation, regulatory context and reference documents.

CERTIFER is a Notified Body (NoBo), under the European directive 2016/797/EU by the European Commission for High Speed and Conventional Rail Interoperability (all subsystems).

To carry out this activity, CERTIFER apply a certification process, under its COFRAC accreditation # 5-0572 according to ISO 17065:2012 (accreditation scope available on www.cofrac.fr).

The Regulatory context of the assessment described in the present Assessment Plan is defined by the following Legal texts:

Reference	Legal Text	Sub system
2010/713	2010/713/EU: 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 (notified under document C(2010) 7582) Text with EEA relevance.	All
2014/897	Commission Recommendation (EU) 2014/897 of 5 December 2014 on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC of the European Parliament and of the Council.	All
2016/797	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 (Text with EEA relevance).	All
2016/798	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety	All

Reference	Legal Text	Sub system
2019/777	Commission Implementing Regulation (EU) 2019/777 of 16 May 2019 on the common specifications for the register of railway infrastructure and repealing Implementing Decision 2014/880/EU	All
1299/2014	the Commission Regulation (EU) N° 1299/2014 of 18 November 2014 on the technical specifications for interoperability relating to the ' infrastructure ' subsystem of the rail system in the European Union.	Infrastructure
1300/2014	the Commission Regulation (EU) N° 1300/2014 of 18 November 2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility (PRM) .	Infrastructure (Rolling Stock clauses out of scope)
1303/2014	the Commission Regulation (EU) N° 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to ' safety in railway tunnels ' (SRT) of the rail system of the European Union.	Infrastructure and Energy (ccs clauses out of scope)
1301/2014	the Commission Regulation (EU) N° 1301/2014 of 18 November 2014 on the technical specifications for interoperability relating to the ' energy ' subsystem of the rail system in the Union.	Energy
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 (Text with EEA relevance.).	All
RFUs and QCs	<p>Recommendations For Use issued and Questions and Clarifications issued by NB-Rail.</p> <p>RFU Application is mandatory starting from the date from which the application is mandatory Depending on the impact of the RFU, the Plenary Meeting chooses a reasonable date. As an RFU is not changing any legal text, the application of RFUs should have no big impact on any projects.</p> <p>Note: For all existing RFUs published before entering into force of this RFU, the transition period has already expired and all these RFUs (RFU-STR-702 issue 03) are fully applicable.</p> <p>Link to these documents: http://nb-rail.eu/co/co_docs_en.html</p>	All
Links to TSIs Application Guides:	<p>https://www.era.europa.eu/sites/default/files/activities/docs/tsi-application-guide_en.pdf</p> <p>https://www.era.europa.eu/sites/default/files/activities/docs/guide_application_of_ene_tsi_en.pdf</p> <p>https://www.era.europa.eu/sites/default/files/activities/docs/iu_tsi_guide_annex01_inf_tsi_en.pdf</p> <p>https://www.era.europa.eu/sites/default/files/activities/docs/srt-tsi_application_guide_2019_en.pdf</p> <p>https://www.era.europa.eu/sites/default/files/activities/docs/iu_tsi_guide_annex01_srt_tsi_en.pdf</p> <p>https://www.era.europa.eu/sites/default/files/activities/docs/iu-prm-tsi-application_guide_1.2_en.pdf</p> <p>https://www.era.europa.eu/sites/default/files/activities/docs/iu_tsi_guide_annex01_prm_tsi_appendices_en.pdf</p>	

Some relevant definitions included in 2016/797 are:

- **'interoperability'** means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance;
- **'network'** means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the Union rail system;
- **'subsystems'** means the structural or functional parts of the Union rail system, as set out in Annex II of this Interoperability Directive;
- **'interoperability constituents'** means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly, including both tangible objects and intangible objects;
- **'essential requirements'** means all the conditions set out in Annex III II of this Interoperability Directive which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces;
- **'technical specification for interoperability'** (TSI) means a specification adopted in accordance with this Directive by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the Union rail system;
- **'basic parameter'** means any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSI(s);
- **'specific case'** means any part of the rail system which needs special provisions in the TSI(s), either temporary or permanent, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system, in particular railway lines and networks isolated from the rest of the Union, the loading gauge, the track gauge or space between the tracks and vehicles strictly intended for local, regional or historical use, as well as vehicles originating from or destined for third countries;

2.1. Scope of Assessment.

2.1.1. Technical Scope of Energy and Infrastructure subsystems.

The essential requirements defined in the previous paragraph are the following:

- environmental protection
- technical Compatibility
- accessibility
- safety
- reliability & availability
- health

A railway system in terms of interoperability comprises the following subsystems for the structural areas as defined in Annex II of the directive (EU) 2016/797:

- Energy
- Infrastructure
- Trackside control-command and signalling (T-CCS)
- On-board control-command and signalling (O-CCS)
- Rolling stock

As mentioned in §1., the scope of this document is limited to Energy and Infrastructure subsystems. Their technical scope would include the following elements:

Energy subsystem

The Energy subsystem will be assessed against the following TSI:

- › TSI Energy;
- › TSI Safety in railway tunnels for items related to energy

Subsystem definition

The energy subsystem consists of substations, sectioning equipment, separation sections, contact line system, return circuit.

The objective of the power supply system is to supply every train with power in order to meet the planned timetable.

The energy subsystem interfaces with other subsystems of the rail system in order to achieve the envisaged performance as following: Rolling stock, Infrastructure, Trackside control command and signalling, On-board control command and signalling, Operation and traffic management.

Interfaces of TSI with the Safety in railway tunnels and requirements related to the energy subsystem

Verification of subsystem includes verification of the subsystem compliance with the basic parameters and integration of interoperability constituent into the subsystem.

The usual technical topics to assess are:

Pantograph

- › Contact strips, horns, arms including manufacturing processes;
- › Kinematic pantograph gauge calculation;

Overhead contact lines

- › Contact wire materials including manufacturing processes;
- › Geometry of the overhead contact line including mechanical design and behaviour;
- › Dynamic behaviour of the overhead contact line and its interaction with the pantograph;
- › Execution of site dynamic measurements and interpretation of the results from the tests of the contact forces exerted by the pantograph to the overhead contact line;
- › Interpretation of data and use of the simulation tools applied for assessment of dynamic behaviour and quality of current collection;
- › Methodology and execution of current measurement tests;

Power supply

Energy power supply for railways: voltage, frequency, sizing power supply subsystem;

Knowledge on the power supply domain, and in particular of the of EU railway traction electrification;

Performance of the power supply subsystem and interface with rolling stock;

Electrical protection coordination arrangements including interface with rolling stock protections and earthing and grounding system for electrical substations;

Harmonics and dynamic effects for AC traction power supply systems;
Knowledge of low voltage, medium voltage and high voltage distribution systems; equipment and connection of the neutral wire;
Knowledge on rolling stock's interaction with power supply system both in sizing/dimensioning and harmonics and dynamic effects;

Electrical safety rules

› General knowledge of safety rules and protective provisions against electric shock.

Infrastructure subsystem

The infrastructure subsystem will be assessed against the following TSI(s) (cf. §2.2):

- › TSI Infrastructure;
- › TSI Persons Reduced Mobility for items related to infrastructure;
- › TSI Safety in Railway Tunnels for items related to infrastructure.

The technical topics included in the scope of infrastructure assessment are:

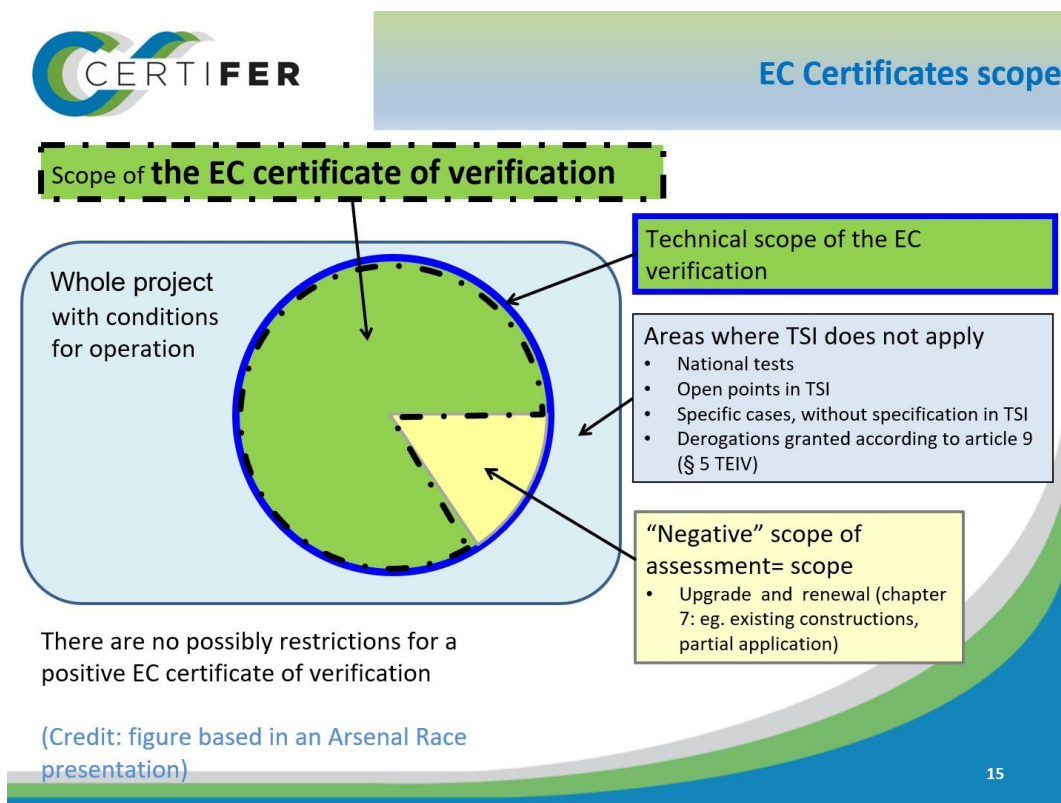
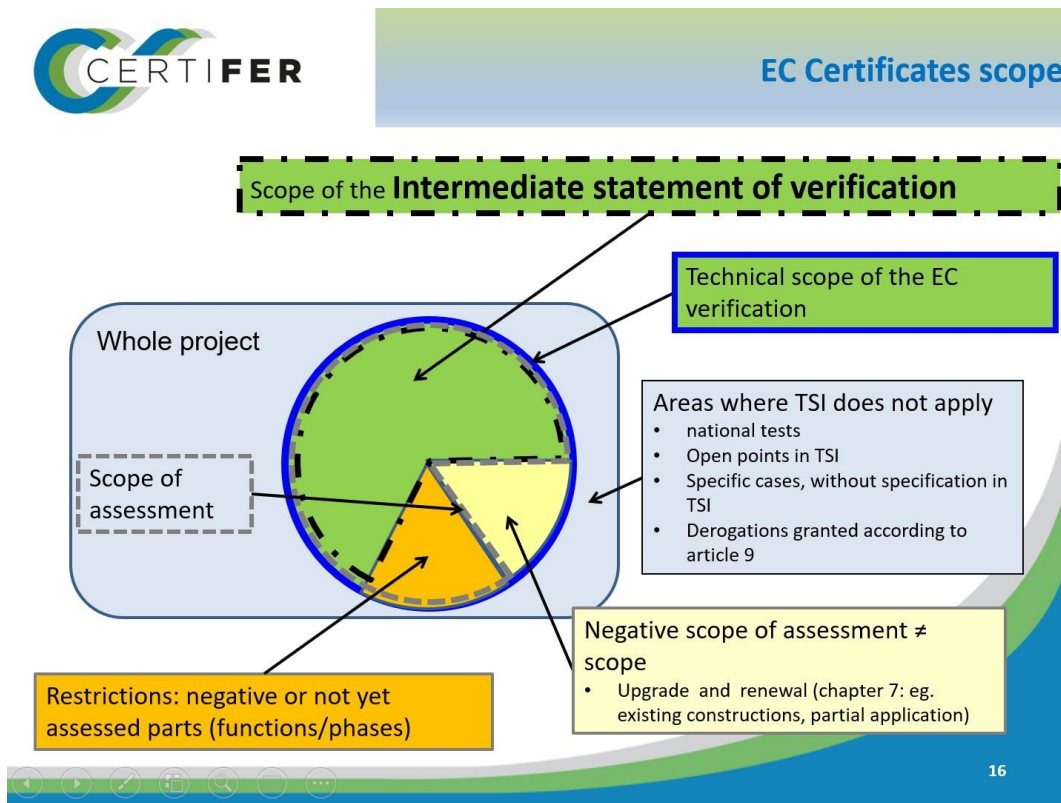
Civil works and installations

- › Bridges, retaining walls, noise barriers and other structures withstanding traffic loads or aerodynamic effects;
- › Earthworks withstanding traffic loads;
- › Structure gauge;
- › Tunnels including basics of tunnel construction, fire behaviour of tunnel elements and equipment, evacuation facilities in tunnel including emergency lighting, communication and procedures, including safety analysis (e.g. risk assessment);
- › Passengers' stations building and installations, including visual, tactile and spoken information relevant parameters and tests;
- › Platforms;
- › Level track crossings for passengers;

Permanent way

- › Track components (e.g. rails, sleepers, fastening systems, etc.) including manufacturing processes, and concepts of track resistance to traffic loads;
- › Track alignment and layout;
- › Switches and crossings.

2.1.2. Project scope vs assessment scope.



2.2. Certification of stages of implementation within TSI(s).

Up to 2016/797 Annex IV the subsystems characteristics, or certain parts of the subsystem, shall be checked at each of the following stages: (a) overall design; (b) production: construction, manufacturing, constituent assembly and overall adjustment; (c) final testing.

Nevertheless, in the TSI(s) relevant to this assessment plans, the phases split is slightly different

Subsystem	TSI	Design phase	Construction/Production phase/Putting into service		
Energy	TSI ENE	Design review	Construction, assembly, mounting	Assembly before putting into service	Validation under full operating conditions
Infrastructure	TSI INF	Design review		Assembly before putting into service	
	TSI PRM	Design review			Site inspection.
	TSI SRT	Design review		Assembly before putting into service	

As described in [R2] and [R3] verifications will be done for parts of subsystems or may be limited to certain stages of the verification procedure.

An Intermediate Statement of Verification (ISV) can be requested for any part into which the subsystem is split to document the result of a partial assessment. Each part shall be checked at each stage as set out in the beginning of this chapter.

In these cases, the results of verification may be documented in an 'intermediate statement of verification' (ISV) issued by the notified body chosen by the applicant.

2.2.1. Scope of Assessment Requirements for Conformity Assessment by NoBos.

2016/797 defines essential requirements relating to rail interoperability which should apply to its rail system. Specific essential requirements to subsystems Infrastructure and Energy are Safety, Accessibility, Environmental protection and Technical Compatibility.

Nevertheless, interoperability assessment is not performed against essential requirements, but against requirements included in each TSI (RFU-STR-088 Issue 1):

- TSI text on Parameters formulated as directly assessable requirement (scope 1);
- TSI text on Parameters not formulated as directly assessable requirement. In this case assessment must be done in combination with further and more specific requirements defined under scope 3 below (scope 2).
- Requirements contained within (parts of) Harmonised Standards or (parts of) Voluntary Standards or Alternative Solutions - as defined by the Applicant and related to the TSI text on parameters under scope 2).

Additional information about alternative solutions can be found in the mentioned RFU-STR-088. About.

NoBo scope of work is defined by (RFU-STR-703 Issue 01):

- the relevant TSI(s) and
- the module/modules chosen by the client amongst those which are allowed in the relevant TSI(s). This aspect will be discussed later in chapter 4.

In each TSI an annex for the assessment of Interoperability Constituents (if existing) and subsystem is present. This annex defines in a table which requirements of TSI(s) chapter 4 (for subsystem) or of TSI(s) chapter 5 (for IC) must be assessed in which phase. These table form the basis for the assessment scope of the NoBo.

The basic requirements to be assessed by the Notified Body within TSI(s) covering subsystems infrastructure and energy and the phases when they need to be assessed would be:

Subsystem	Basic Parameters per TSI	Project Phase			
		Design review	Construction , assembly, mounting	Assembly before putting into service	Site Inspection/ Test stage (ENE)
	TSI INF				
Infrastructure	Structure gauge (4.2.3.1)	X		X	
Infrastructure	Distance between track centres (4.2.3.2)	X		X	
Infrastructure	Maximum gradients (4.2.3.3)	X			
Infrastructure	Minimum radius of horizontal curve (4.2.3.4)	X		X	
Infrastructure	Minimum radius of vertical curve (4.2.3.5)	X			
Infrastructure	Nominal track gauge (4.2.4.1)	X		X	
Infrastructure	Cant (4.2.4.2)	X		X	
Infrastructure	Cant deficiency (4.2.4.3)	X			
Infrastructure	Abrupt change of cant deficiency (4.2.4.4)	X			
Infrastructure	Assessment of design values for equivalent conicity (4.2.4.5)	X			
Infrastructure	Railhead profile for plain line (4.2.4.6)	X			
Infrastructure	Rail inclination (4.2.4.7)	X			
Infrastructure	Design geometry of switches and crossings (4.2.5.1)	X			
Infrastructure	Use of swing nose crossings (4.2.5.2)	X			
Infrastructure	Maximum unguided length of fixed obtuse crossings (4.2.5.3)	X			
Infrastructure	Track resistance to vertical loads (4.2.6.1)	X			
Infrastructure	Longitudinal track resistance (4.2.6.2)	X			

Infrastructure	Resistance of new bridges to traffic loads (4.2.7.1)	X			
Infrastructure	Equivalent vertical loading for new earthworks and earth pressure effects (4.2.7.2)	X			
Infrastructure	Resistance of new structures over or adjacent to tracks (4.2.7.3)	X			
Infrastructure	Usable length of platforms (4.2.9.1)	X			
Infrastructure	Platform height (4.2.9.2)	X		X	
Infrastructure	Platform offset (4.2.9.3)	X		X	
Infrastructure	Track layout along platforms (4.2.9.4)	X			
Infrastructure	Maximum pressure variation in tunnels (4.2.10.1)	X			
	TSI PRM				
Infrastructure	Parking facilities for persons with disabilities and persons with reduced mobility	X			X*
Infrastructure	Obstacle-free routes	X			X*
Infrastructure	Route identification	X			X*
Infrastructure	Doors and entrances	X			X*
Infrastructure	Floor surfaces	X			X*
Infrastructure	Transparent obstacles	X			X*
Infrastructure	Toilets	X			X*
Infrastructure	Furniture and free-standing devices	X			X*
Infrastructure	Ticketing/Counter or vending machine/Information counter/ Ticket control machine/Turnstiles/ Customer Assistance points	X			X*
Infrastructure	Lighting	X			X
Infrastructure	Visual information: signposting, pictograms, dynamic information)	X			X*

Infrastructure	Spoken information	X			X*
Infrastructure	Platform width and edge of platform	X			X*
Infrastructure	End of platform	X			X*
Infrastructure	Level track crossing at stations	X			X*
	TSI SRT				
Infrastructure	Prevent unauthorised access to emergency exits and technical rooms	X		X	
Infrastructure	Fire resistance of tunnel structures	X			
Infrastructure	Fire reaction of building material	X			
Infrastructure	Fire detection in technical rooms	X		X	
Infrastructure	Evacuation facilities	X		X	
Infrastructure	Escape walkways	X		X	
Infrastructure	Evacuation and rescue points	X		X	
Infrastructure	Emergency communication	X			
Infrastructure	Electricity supply for emergency response services	X			
Infrastructure	Reliability of electrical systems	X			
Energy	Sectioning of contact line	X		X	
Energy	Earthing of contact line	X		X	
	TSI ENE				
Energy	Application of Interoperability Constituents			X	
Energy	Voltage and frequency — 4.2.3	X			
Energy	Parameters relating to system performance — 4.2.4	X			
Energy	Current capacity, DC systems, trains at standstill — 4.2.5	X to be carried out only if			

		the OCL has not been assessed as IC			
Energy	Regenerative braking — 4.2.6	X			
Energy	Electrical protection coordination arrangements — 4.2.7	X		X	
Energy	Harmonics and dynamic effects for AC systems — 4.2.8	X			
Energy	Geometry of the overhead contact line — 4.2.9	X to be carried out only if the OCL has not been assessed as IC		X to be carried out as an alternative assessment (see 6.2.4.5)	
Energy	Pantograph gauge — 4.2.10	X			
Energy	Mean contact force — 4.2.11	X to be carried out only if the OCL has not been assessed as IC			
Energy	Dynamic behaviour and quality of current collection — 4.2.12	X to be carried out only if the OCL has not been assessed as IC		X to be carried out as an alternative assessment method in case the dynamic behaviour of the OCL integrated into the subsystem is not measured (see 6.2.4.5)	Validation under full operating conditions shall only be done when the validation in the phase “Assembly before putting into service” is not possible
Energy	Pantograph spacing for OCL design — 4.2.13	X to be carried out only if			

		the OCL has not been assessed as IC			
Energy	Contact wire material — 4.2.14	X to be carried out only if the OCL has not been assessed as IC			
Energy	Phase separation sections — 4.2.15	X			
Energy	System separation sections — 4.2.16	X			
Energy	On-ground energy data collecting system — 4.2.17				
Energy	Protective provisions against electric shock — 4.2.18	X	X to be carried out in case the check is not done by another independent body	X to be carried out in case the check is not done by another independent body	
Energy	Maintenance rules — 4.5			X	

(*) As-built drawings shall be provided or a site inspection shall be carried out when the realization differs from the design rules or drawings that were examined

Quoting 2016/797, if certain technical aspects corresponding to the essential requirements are not explicitly covered in a TSI, those aspect should be identified and addressed as open points in an annex to that TSI.

2.2.2. TSI PRM specificities.

TSI PRM basic parameters are divided into those ones where technical details are explicitly specified in the TSI and functional requirements which fulfilment can be proved using different technical solutions, as displayed in table 3 of the TSI.

Regarding the functional ones (or “parameters of the 2nd Category”), the Application Guide lists some international and European standards that the applicant may apply in order to meet this functional requirement. The application of these standards remains voluntary, and the applicant can always apply other standards to meet the requirements. As a matter of fact, the functional requirements are also generally covered by national, regional or local standards and sometimes even by company rules.

The principles for the application of other standards than the ones that are listed in the Application Guide are the following:

- National/regional/local standards can be applied when they provide an equivalent solution than the one specified in the standards listed in this guide.
- National/regional/local standards can only be applied on the territory they cover: one of the reasons for removing some detailed requirements from the TSI is to allow some harmonization at local level. An applicant that would intend to use a “foreign” standard would strictly be in contradiction with this objective.
- Company rules can be used when they are derived from the above standards or when they have been validated by a representative group of users.

Equivalence is to be understood as “having the same or a similar effect” as per the definition of Collins dictionary:

Equivalent, adjective

1. equal or interchangeable in value, quantity, significance, etc.
2. having the same or a similar effect or meaning.

Examples of equivalent solutions are given in appendix 1 of the Application Guide. In the following points, those requirements are called “parameters of the 2nd category”.

It is recommended to read carefully the Application Guide.

2.2.3. TSI Energy specificities.

Overall catenary design, installation and tests are described in the standards referenced in the appendix E to TSI ENE. These standards present technical conditions in relation to energy subsystem design, construction and validation.

It must be emphasised that TSI ENE should not be considered as a design manual. The requirements set out in the TSI include only those elements which are important from the interoperability point of view, for the compatibility of the energy subsystem with TSI compliant vehicle.

EC verification of the energy subsystem particular assessment procedures are indicated in above table and in point 6.2.4 of the TSI Energy.

The main concerns in the assessment of energy subsystem refer to the incorporation of the OCL into it.

As a rule, the energy subsystem must contain an OCL – Interoperability Constituent which holds an EC declaration of conformity. In this case the assessment of the OCL is already done and the assessment will focus on the integration into subsystem.

If the energy subsystem consists of an OCL which does not hold an EC declaration of conformity (as specified in 6.3 of the ENE TSI), the assessment of the energy subsystem will cover verification of basic parameters indicated in above table as to be carried out only if the OCL has not been assessed as IC. The RFU-ENE-096 OCL IC assesment - test phase describes the condition for subsystem EC verification with regards to Interoperability constituent certification.

With regards to subsystem verification described by TSI ENE, the energy subsystem is verified within the three stages:

- design stage
- construction stage
- test stage

At design stage the conformity of the basic parameters is checked against the requirement as described in above table in the column Design stage.

At Construction phase the verification is performed for the basic parameters mentioned in the column Construction, assembly, mounting and Assembly before putting into service.

In case of Test phase verification is performed for the parameters mentioned in the column Validation under full operating conditions.

Interoperability Constituent (for info, not in the scope of Certifer assessment nor this document).

Overhead contact line is an Interoperability Constituent. Overhead contact line is defined as assembly of following components, associated design and configuration rules.

The components of an overhead contact line are an arrangement of wire(s) suspended over the railway line for supplying electricity to electric trains, together with associated fittings, in-line insulators and other attachments including feeders and jumpers. It is placed above the upper limit of the vehicle gauge, supplying vehicles with electrical energy through pantographs.

The supporting components such as cantilevers, masts and foundations, return conductors, auto-transformer feeders, switches and other insulators are not part of the interoperability constituent overhead contact line. They are covered by subsystem requirements so far as interoperability is concerned.

2.2.1. Construction/assembly/site inspection stages specificities.

It is not possible to deal with all issues related to construction stage assessment (sensu lato) in a single explanation, but we will try to cover as much as possible the common aspects among TSIs ENE, INF, SrT and PRM.

These requirements are listed above in this chapter, in any case the subsystem requirements assessment stages are defined in an Appendix in each TSI.

Generally speaking, proving compliance with this requirements involves proving that the design which was assessed as compliant at design stage has been constructed or assembled in a way that the subsystem fulfils the TSI requirements.

The means to prove so are specific to each one of the requirements, but would include in general a combination of as built drawings, measurements, test results, etc. In some cases, the NoBo will perform a site inspection to verify the subsystem onsite. The NoBo will conduct site inspections mostly in the framework of TSI PRM, SrT and ENE.

The TSIs, the RFUs and the application guides detail the kind of evidence expected regarding a few requirements.

For those not detailed, we could gather them in these general approaches:

- Verification of physical features of the subsystem. We would expect a quality approved as built drawing, a quality approved construction supervision document, etc., to be complemented in some cases with a NoBo site inspection (TSI PRM required width dimensions, absence of steps, irregularities, colours, etc ; TSI SrT facilities, etc.).
- Verification of the achievement of expected values to attain up to a specified standard where a test is required. In this case, we will in general assess the test result, and in some cases (mostly when the testing body being is not accredited against EN ISO/IEC 17025, which shall be the general case) on top of that we will perform on top of that a documentary audit on the company quality system and the test procedures. The NoBo might request to witness the test. In any case RFU-STR-22 details how to deal with these matters.

- Verification of requirement achievement not able to be checked through a site inspection and either not able to be verified up to a specific standard mentioned in the TSI by a testing body, for instance because there are no testing bodies performing these kind of checks. This would be the case of structural gauge at construction stage and other measurements alike, or some TSI ENE features, where only Infrastructure Managers would have the means to perform the tests or verifications. We would suggest to deal with these requirements one by one with the NoBo, and in any case we would apply the wise of the RFU-STR-22.

CERTIFER has provided some details on testing bodies and RFU-STR-22 in § 3.1.

2.3. NoBo vs DeBo assessment.

NoBo and DeBo assessment would only roughly differ in the scope. In both assessments, the applicant is responsible for demonstration of compliance, while the Notified Body and the Designated Body are in charge of verification of conformity with TSI(s) and Notified National Rules respectively.

For those open points mentioned in precedent chapter, as well as for specific cases, and with the aim of compliance with the existing systems, National Rules are to be adopted in by any competent national, regional or local authority. Once they are adopted and notified to the EU, they will be called Notified National Technical Rules (NNTR).

As per 2016/797 and as developed in RFU-STR-703 Issue 01, NoBo scope of work includes specific cases where no national rules are needed and excludes those specific cases that require the application of technical rules not included in the relevant TSI annexes of each TSI (different numbering in each TSI).

Ideally, the NNTR should cover the essential requirements to the extent the TSI(s) don't cover them. Nevertheless, the scope of these NNTR is different in every EU country and generally speaking they are far from being able to cover essential requirements.

On the other hand, DeBo scope of work includes:

- a. where the TSI(s) do not cover, or do not fully cover, certain aspects corresponding to the essential requirements, including open points explicitly identified in the TSI;
- b. where non-application of one or more TSI(s) or parts of them has been notified under Interoperability Directive Article 7 (Art. 9) i.e. derogation of TSI requirements;
- c. where a specific case requires the application of technical rules not included in the relevant TSI;
- d. national rules used to specify existing systems, limited to the aim of assessing technical compatibility of the vehicle with the network;
- e. networks and vehicles not covered by TSI(s);
- f. as an urgent temporary preventive measure, in particular following an accident.

2.4. NoBo vs AsBo assessment and Safe integration

The essential requirements of interoperability (NoBo) are

- Safety,
- Reliability and Availability,
- Health,
- Environmental Protection,
- Technical compatibility, and
- Accessibility.

Nevertheless, the sole compliance of a design or a project with TSI(s) and NNTR does not ensure safety is fully covered as outlined in the precedent chapter. For that sake, the Safety Directive 2016/798

requires the application of the Reg. 403/2013 on CSM-RA in order to ensure a project manages safely the changes when these changes are found significant.

The compliance with TSI(s) will ensure compliance with the essential requirements to the extent they are covered by the basic requirements listed in §2.2., but not all identified risks triggered by a safety significant change or a new project. Designated Bodies will assess the Notified National Technical Rules, theoretically to ensure compliance with aspects of the essential requirements not covered in TSI(s). In the practice, this doesn't happen yet.

On the other hand, when applying CSM-RA the proposer is entitled to apply the methodology and demonstrate that all risks are controlled, while the assessment body (sometimes called the ISA) check the correct application and the suitability of the results.

The range of this synergy would depend of the nature of the change, the amount of National Rules verified by the DeBo and in which way TSI(s) basic requirements application are able to prove that a number of risks are controlled.

This way, the CSM-RA and AsBo assessment at subsystem level should cover the whole scope of the change, where the NoBo and DeBo outputs will be useful for the proposer to prove that some risks are covered. Other risks not covered by these two missions would be proven to be covered by one of the three risk acceptance principles defined in the Reg. 402/2013.

Therefore, not only at overall level, but at subsystem level CSM-RA must also be applied to demonstrate safety is fully controlled.

Finally, safe integration is a part of the CSM-RA process performed at overall or subsystem level. At this level the proposer will need to prove that all safety requirements exported among subsystems have been properly transferred and endorsed by receivers, and that shared risks are controlled by the relevant subsystems.

The proposer needs to prove as well that (a) SRAC(s) and requirements exported to system level are controlled, (b) system level risks are controlled, and (c) the safety integration with operation and maintenance has been successfully performed.

In order to assess the essential requirement of safety and the safe integration of the railway system, CERTIFER refers to 2014/897/UE recommendation, CSM-RA regulation and CENELEC standards.

CERTIFER would support Rail Baltica and coordinate with any other assessment body or notified body to ensure that the interfaces for each of the assessed subsystems are understood and covered by the relevant assessments and certifications.

3. Interoperability assessment methodology.

In this chapter we'll describe the assessment methodology as per the Interoperability Directive and the chosen assessment module, as well as the regulatory context and strategy of ISV and EC Certificates issuing.

Within the Infrastructure and Energy subsystems EC verification assessment, CERTIFER will perform along each one of the required phases in the related TSI's (INF, ENE, SRT, PRM) and draw up Intermediate Statements of Verification and EC Certificate of Verification, in order to fulfil NoBo requirements.

Each certificate of verification will provide reference to the subsystem with which the conformity has been assessed, and the scope of the assessment.

CERTIFER's task shall begin at the design stage and continue through the construction or installation steps before the subsystems are placed into service. It shall, when required in the relevant TSI, also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.

3.1. SG module application.

The assessment module selected (see [R2] §9) for infrastructure and energy assessment is SG module (EC verification based on unit verification) as defined in the commission decision 2010/713/EU 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 amended by Directive (EU) 2016/797.

CERTIFER will describe here this module methodology and the tasks to be undertaken by the applicant and the assessor, up to 2016/797, 2010/713 and RFU-STR-092 Issue 3.

Commission Decision 2010/713/EU	Guide of Application		CERTIFER duties and remarks or comments.
	Applicant / Contractor	NoBo duties	
<p>Module SG. EC verification based on unit verification.</p> <p>1. EC verification based on unit verification is the EC verification procedure whereby the applicant fulfils the obligations laid down in points 2, 3, 4, 6.2 and 6.4, and ensures and declares on his sole responsibility that the subsystem concerned, which has been subject to the provisions of point 5, satisfies the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.</p> <p>2. The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice.</p> <p>The application shall include: — name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well, and — the technical documentation.</p>	<p>1. '[Lodges] an application for the EC verification of the subsystem with a NoBo of his choice'. Applicant on Rail Baltica is Rail Baltica AS</p>	<p>1.n/a</p>	<p>Infrastructure/Energy are the subsystems.</p> <p>CERTIFER has been chosen as Notified Body by Rail Baltica acting as the Applicant.</p>
<p>3. Technical documentation The applicant shall establish the technical documentation and make it available to the notified body referred to in point 5. The documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s).</p> <p>The technical documentation shall specify the requirements and cover, as far as relevant for the assessment, the design, manufacture,</p>	<p>2. 'When the subsystem (...) is subject to derogation(s) (...) [informs] the NoBo thereof' and documents NSA agreements.</p> <p>3. RB rail AS requires the Contractor or the Implementing Body to establish technical documentation that must 'make it possible</p>	<p>2. The NoBo gains full knowledge on the scope of the subsystem(s) and scope reductions or derogations</p> <p>3. '[Carries] out appropriate design phase examinations on technical documents and evidences to check the conformity of</p>	<p>The derogation we are interested in would be the derogations to TSI requirements.</p> <p>In any case, provided Rail Baltica project is a greenfield project, no derogations would be expected since it'd prevent the NoBo from issuing an EC Certificate.</p> <p>It's needed for the assessor to have a complete definition of the assets or parts of the subsystems (Infrastructure and</p>

<p><i>installation/construction and operation of the subsystem.</i></p> <p>The technical documentation shall, wherever applicable, contain the following elements:</p> <ul style="list-style-type: none"> — a general description of the subsystem, its overall design and structure, — a separate file with the set of data required by the relevant TSI(s) for each relevant basic parameter, — <i>a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,</i> — <i>conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),</i> — <i>conceptual design and manufacturing and construction drawings and schemes of components, sub-assemblies, circuits,</i> — <i>descriptions and explanations necessary for the understanding of those drawings,</i> — <i>results of design calculations made, examinations carried out, etc.,</i> — <i>test reports,</i> — <i>documentation regarding the manufacture and the assembly of the subsystem,</i> — <i>descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,</i> — <i>conditions for maintenance and technical documentation regarding the maintenance of the subsystem,</i> — <i>any technical requirement specified in the relevant TSI(s) that shall be taken into account</i> 	<p>to understand the design, manufacture, maintenance and operation of the subsystem, and to assess the conformity with the requirements of the TSI(s), that apply to it'.</p>	<p>the subsystem with the requirements of the relevant TSI(s).</p>	<p>Energy) to be object of an ISV or an EC Certificate, and its location and interfaces regarding the whole subsystem/s to assess.</p> <p>The technical documentation described in the legal text (refer to first column of this table) should be accompanied with a Document List in order for all parties to be able to follow and understand updates and new versions.</p> <p>As mentioned in the regulation the level of detail and exhaustivity should be such that would allow the assessor to fully understand the Infrastructure project.</p> <p>The Contractor will fill the TSI Clause by Clause model (matrix) supplied by CERTIFER. In each clause, on top of including values or parameters that would fit with the requirement, should reference the document, chapter or paragraph where the parameter is stated, derived or calculated. All these referenced documents should be part of the technical documentation and be listed in the document list.</p> <p>The Contractor (or Implementing Body) will submit the documents, the documents list, and the TSI CbC to RB Rail AS, who will issue the package to the NoBo. NoBo will provide comments until no remarks would remain opened.</p> <p>The assessment cannot be done by sampling and need to cover the whole subsystem. Only parts of the system with identical design don't need to be checked individually. For instance, track sections or elements, catenary system design, or</p>
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<p>during production, maintenance or operation of the subsystem, — other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies, — conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems, — evidence of conformity with other regulations deriving from the Treaty (including certificates, if any), — a list of manufacturers involved in the subsystem’s design, manufacturing, assembly and installation, and — any further information, if required by the relevant TSI(s).</p> <p>The applicant shall keep the technical documentation at the disposal of the relevant national authorities throughout the service life of the subsystem.</p> <p>4. Manufacturing The applicant shall take all measures necessary so that the manufacturing and/or installation/construction process and its monitoring ensure conformity of the subsystem with the requirements of the relevant TSI(s).</p> <p>5. EC verification. 5.1. A notified body chosen by the applicant shall carry out appropriate examinations and tests, set out in the relevant TSI(s), harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the subsystem with the requirements of the relevant TSI(s), or have them carried out. In the absence of such a harmonised standard and/or technical specification the appropriate tests to be carried out shall be decided</p>	<p>4. ‘[Draws] up a (ISV) procedure [draws] up (...) [an] EC declaration of intermediate subsystem conformity’ at design stage.</p>	<p>4. ‘[Issues] an intermediate statement of verification (ISV)’.</p>	<p>certain structures which are designed using a number of predefined types.</p> <p>4. RB Rail AS as the Applicant will elaborate the necessary measures for controlling the manufacturing / installation / construction process, such measure could foresee transfer of responsibility to respective contractors, and/or setting-up of specific supervision / auditing services.</p>
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<p><i>between the applicant and the notified body concerned. (design phase)</i></p>			<p>As already discussed, ISV can be issued to certificate parts of subsystems or to perform partial assessments.</p> <p>When it'll come to issue either ISV or EC Certificates, CERTIFER will follow the last version of RFU-STR-001 (Content of EC Certificate / QMS Approval / ISV) and RFU-STR-011 (Content of the NoBo-File).</p> <p>It is worth to remind that the NoBo would only be in position of issuing an EC Certificate of Verification regarding a defined subsystem, in case of new assets, when all the subsystem (energy or infrastructure) elements included in the railway segment have been assessed and without any non-conformity.</p> <p>Otherwise, an ISV can be issued. The NoBo File includes the terms "Conditions", "Restrictions" and "Derogations". Its definitions would be:</p> <p>Conditions (for use) represent explanations of important issues for safety reasons, warnings, or operational choices within the TSI limits. Conditions (for use) do not mean any nonconformity to the TSI requirement(s).</p> <ul style="list-style-type: none"> - Examples of conditions for use: <ul style="list-style-type: none"> • TSI-compliant high cant deficiency on a curve implying limitation of speed
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			<ul style="list-style-type: none"> • TSI-compliant high longitudinal gradient in a station implying that shunting is forbidden - NoBos cannot issue EC certificate of verification based on a reduced set of requirements asked by the Applicant. - Note: Part of subsystem which is out of assessment scope is not considered as a condition of use (could lead to an ISV or derogation). The scope of assessment shall be agreed by the NSA. Restrictions shall not be used as it doesn't exist legally in the IOD. Derogations are out of NoBo assessment scope but must also be declared and justified in the Technical File by the Applicant.
<p><i>The notified body may take into account evidence of examinations, checking or tests that have been successfully performed, under comparable conditions by other bodies (1) or, when this is specified by the relevant TSI(s), by (or on the behalf of) the applicant</i></p> <p><i>The notified body will then decide as to whether it shall use the results of these checks or tests. The evidences gathered by the notified body shall be suitable and sufficient to show the conformity with the requirement of the relevant TSI(s) and that all required and appropriate checks and tests have been carried out.</i></p> <p><i>The extent to which the evidence originating from other parties is taken into account by the notified body shall be justified by documented analysis using the factors listed in the following paragraph.</i></p> <p>5.2. The notified body shall examine: — the use of existing equipment and systems — used identically as before,</p>	<p>5. '[Keeps] the NoBo that has issued the ISV design stage informed of any modification to the approved design that may affect the conformity with the requirements of the relevant TSI(s) or the conditions for validity of the certificate until its expiry date'.</p> <p>6. '[Takes] all measures necessary so that the manufacturing and/or installation/construction process (...) [ensures] conformity of the subsystem with the requirements of the relevant TSI(s)'.</p> <p>'In the absence of [relevant] harmonised standard and/or technical specification' decides with the NoBo 'the appropriate tests to be carried'.</p> <p>Agrees with the NoBo 'the locations where the tests and the final testing of the subsystem will be carried out'.</p>	<p>5 N/A</p> <p>6. '[Carries] out appropriate examinations and tests, set out in the relevant TSI(s), harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the subsystem with the requirements of the relevant TSI(s), or have them carried out'.</p> <p>'In the absence of (...) a harmonised standard and/or technical specification' decides with the applicant 'the appropriate tests to be carried' and the conditions set in RFU-STR-022.</p>	<p>(construction, assembly, site inspection phases).</p> <p>Before starting to plan and procure the performance of tests and examinations that could be relevant to TSI requirements, the applicant and the assessor should agree on the way to perform the tests in order to fulfil the RFU-STR-022 requirements.</p> <p>Many of the verifications to be performed at this stage, would be performed by site inspection verification, such as some TSI PRM, SRT or ENE requirements.</p> <p>Regarding TSI INF structural gauge and track geometry assembly phase verification, the assessment procedure will be agreed with the applicant in advance, with the criteria of balancing reliable information and witnessing activities in the site.</p>

<p>— used before but adapted for use in the new work, — the use of existing designs, technologies, materials and production techniques, — the arrangements for design, production, testing and commissioning, — previous approvals from other competent bodies, — the accreditations of other involved bodies: — it is permissible for the notified body to take account of valid accreditation to relevant European standards, provided that no conflict of interest exists, that accreditation covers the testing being performed and that accreditation is current, — where no formal accreditation exists, the notified body shall confirm that the systems for control of competence, independence, testing and material handling processes, facilities and equipment and other processes relevant to the contribution to the subsystem are controlled, — in all cases, the notified body shall consider the appropriateness of the arrangements and decide the level of witnessing required. In all cases, the notified body keeps the responsibility of final results of the examinations, tests and checks.</p> <p>5.3. The notified body shall agree with the applicant the locations where the tests will be carried out and shall agree that final subsystem tests and, whenever required in the TSI, tests under full operating conditions, are carried out by the applicant under direct supervision and attendance of the notified body.</p> <p>5.4. When the subsystem referred to in point 2 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof. The applicant shall also provide the notified body with a precise reference to the TSI(s) (or their parts) for which the derogation is requested.</p>	<p>‘Whenever required in the relevant TSI(s)’, carries out ‘tests or validation under full operating conditions (...) under direct supervision and attendance of the NoBo’.</p>	<p>‘[Agrees] with the applicant the locations where the tests and the final testing of the subsystem will be carried out’.</p>	<p>The RFU-STR-022 issue6 applies for all tests and gives criteria for acceptance of tests performed by other testing bodies.</p> <p>Regarding the attendance to site tests when required in Construction/Production/Putting into service stages as per each one of the TSI(s).</p> <p>In all cases (testing body being accredited against EN ISO/IEC 17025 or not), the No Bo shall consider the appropriateness of the arrangements and decide the level of witnessing required; where the risk does not justify high cost it may not be necessary for the notified body to participate fully in the tests. They may be able to intervene on a limited sample basis only. For instance, tests are often possible only as an integral and continuous part of production.</p> <p>CERTIFER shall confirm that the systems for control of competence, independence, testing and material handling processes, facilities and equipment and other processes relevant to the contribution to the subsystem are controlled. Based on this check, a risk-based approach will be applied whether to participate in all tests, partially or even intervene on a limited sample basis only.</p> <p>The evaluation activities related to testing shall follow the applicable requirements of ISO/IEC 17025. The NoBo shall ensure that the test used in its evaluation activities have been carried out according the following acceptance criteria: (i) In competent, independent and reproducible</p>
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<p><i>The applicant shall communicate to the notified body the outcome of the derogation procedure.</i></p>			<p>manner according to the requirements of ISO/IEC 17025, and (ii) in accordance with the applicable requirements of normative documents for products and their manufacturing process.</p>
<p>6. EC declaration of verification 6.1. Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.</p> <p>Where the subsystem referred to in point 2 is subject to derogation, upgrade, renewal or specific case the EC certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.</p> <p>If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.</p> <p>6.2. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up.</p> <p>Where the subsystem referred to in point 2 is subject to derogation, upgrade, renewal or specific case, the EC declaration for the subsystem shall also indicate the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.</p>	<p>7. '[Draws] up a (...) EC declaration of verification' for the scope the Project.</p>	<p>7. '[Issues] an EC certificate of verification' Compiles 'the technical file that has to accompany the EC declaration of verification, provided the conditions to issue an EC Certificate would be fulfilled. Otherwise, issues an ISV.</p>	<p>Contractors could be requested to assist RB Rail AS in assembling the technical file</p>

<p>In case of ISV procedure, the applicant shall draw up a written EC ISV declaration. The EC declaration and the accompanying documents shall be written in accordance with Annex V to Directive 2008/57/EC. A copy of the EC declaration of verification and/or EC ISV declarations, if any, shall be made available to the relevant authorities upon request.</p> <p>6.3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.</p> <p>6.4. The technical file accompanying the EC certificate of verification shall be lodged with the applicant. A copy of the EC certificate of verification and the technical file shall be made available to the Commission, the Member States and the relevant authorities upon request. The applicant shall keep a copy of the technical file throughout the service life of the subsystem; it shall be sent to any other Member State which so requests.</p> <p>7. Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of EC certificates of verification it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of EC certificates of verification which it has issued.</p>			
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3.2. Contractors duties overview

CERTIFER is not in charge of managing the relationship to Contractors and Implementing Bodies. This responsibility lays with RB Rail AS.

Recommendations for smooth implementation of the NoBo services are provided below.

3.2.1. Interoperability compliance plan

Contractor must prepare an [interoperability compliance](#) plan for RB Rail AS review, with overview scope and schedule of required NoBo assessment services for each Design stage, in accordance with National Law and with Building Permit strategy.

3.2.2. Start of assignment for NoBo assessment service

Contractor must deliver full package allowing the start of NoBo services as below:

1. Definition of the system under consideration,
2. Filled-in a single Compliance matrix per applicable TSI and package, according to CERTIFER template,
3. List of documents delivered along to justify TSI compliance, with references, versions and titles of documents,
4. Full set of Design documentation according to the list, uploaded in NoBo Projectwise directory. The assessor will only assess compliance matrices including evidence of conformity for every requirement applicable. All documents referenced as evidence shall be RBRail QA/QCed and will have the status of “approved” in the framework of the Project.

NB: This part is detailed in the RB Rail document “Instruction - RB RAIL Deliverables - Information traceability quality requirements for AsBo/NoBo”.

3.2.3. Maturity of design

Contractor shall deliver full package for NoBo assessment only for completed design including relevant evidences for conformity of compliance of all requirements. [If there is a master design assessment milestone, the maturity of the evidence provided can be adapted to this fact. The conformity assessment at this stage will not be declared compliant, but “acceptable at this stage” by the assessor.](#)

3.2.4. Update of design after NoBo assessment

Any design update after NoBo assessment shall be brought to the knowledge of RB Rail AS who will inform NoBo as required.

After any requirement has been assessed as compliant by the NoBo at any assessment stage (see § 2.2), no further assessment related with that requirement will be performed by the NoBo as a principle. The issued NoBo-File supporting the EC Certificate of Verification will reference the specific assessed version of each document provided as evidence of conformity.

Before the issue of the final EC Certificate, the Project will issue a statement declaring that further versions of document used as evidence do not include changes in a way that could engage the interoperability conformity of the sub system. These new versions would include enough information (change control, etc.) in a way that would allow the assessor to check these changes.

If any feature (object of assessment) of a subsystem would change after a related requirement would have been assessed as compliant at any stage, the applicant shall inform the NoBo explicitly about that and shall deliver the new evidence to the assessor in a way that would allow the assessor to recognise the changes made in the document (change control, information on the change, etc.).

3.2.5. Conformity Matrix exchange.

The conformity matrices are to be used by applicants to reference the technical documentation requested in 2010/713 (please see § 3) through the different assessment stages. Version 1 of these matrices will be delivered to the applicants by RB Rail for each TSI.

		Columns reserved for the applicant		Columns reserved for CERTIFER			
Identification	TSI INF (2014/1299/EU amended by 2019/776/EU)	Particular Assessment Procedures	Applicable to the project or not (A/NA)	Proof Design phase	Remark	Assessor name / Date of verification	Compliant at design phase (Y/N)

The applicant is kindly requested, before the first delivery to the assessor, to do the following:

- Fill in the version control log included in the Summary sheet. This first delivery will be recorded as the second document version. It will include as well the date and the name of the persons in charge of filling in the document within the applicant organisation (writers, approver, etc.). The applicant is free to add an additional sheet including a version control of its own, but is kindly requested to add the information in the Summary sheet as well.
- Fill in the Clause by Clause sheet with evidence of conformity of every TSI subsystem requirement (those included in § 4. TSIs). § 6.2 lists particular assessment procedures for some of the requirements listed in § 4, but these procedures are not additional requirements: they advise how the verification shall be performed.
- The applicant will fill in the cells corresponding to the brown heads. In case the requirement is declared not applicable (N/A), the applicant will justify why, including in general a reference to the document/s that would support the mentioned justification.
- If the requirement is applicable, the documents being evidence of conformity will be referenced in the column "Proof Design Phase" (same for other assessment stages). **There shall be a reference, if suitable, to the chapter or subchapter containing the evidence of conformity.** Finally, there shall be a short explanation or statement on the fulfilment of the requirement including if needed limits of use, constraints, partially conformity, etc.). The evidence expected typically consists of a combination of technical and calculation notes, standards, drawings, etc.

The assessor will review the technical documentation delivered by the applicant using the cells under the green headings, informing about the conformity of the requirement or asking for more information or clarifications. Assessment management steps.

CERTIFER lists here, to complement the more legal assessment steps listed in previous chapter, the steps to be followed at least conceptually along Rail Baltica assessment from a practical approach. Some of these steps activities could overlap among them due to time constraints.

Certain additional tasks that may be specific to each subsystem/design build contract will be described in future assessment plans updates.

These tasks will be discussed and defined during the different kick-off meetings/workshops that will take place at the beginning of each specific assessment.

Project management task	Actions	Parties involved
First PM step, Rail Baltica level. This step is performed through meetings, document assessment and other exchanges:	<ul style="list-style-type: none"> - Identification of Program level certification strategy. - Delivery of assessment plan first version. - Program level Technical Guidelines Assessment. identification of current technical specifications for interoperability (TSI) (see §2.8), discussion on the study of the impact of any modification of the TSI's (see §4.2.3) - Other. 	- NoBo / RB Rail AS
Second PM step, Meeting organized at Country level to present this guidance and identify specific local conditions	<ul style="list-style-type: none"> - Meeting involve NoBo RB rail AS (S&O, PM, Country Manager) - Presentation of NoBo guidance - Discuss national law related to building permit and their impact on NoBo activity 	- NoBo / RB Rail AS
Third PM step, meeting presenting the guidance to contractors	<ul style="list-style-type: none"> - Meeting involve RB rail AS (S&O, PM) and contractors - Presentation of NoBo guidance - Discuss practical implementation 	- RB Rail AS / Contractors
First step, kick-off meetings at Working package level to deal with the following issues:	<ul style="list-style-type: none"> - System Definition identification and understanding of the scope of each Project (or asset). - TSI's scope preliminary discussion. Agreement on the way to exchange information (CbC) - Interoperability Compliance Project strategy (system level compliance, use of constituents, required schedule, etc.). - Resources previewed by the Project to fulfil the TSI requirements. - Certificate issuing calendar agreement. - If it is the case, previewed non compliances, restrictions, particular cases, etc. - Creation of a Master Scope Document including all Rail Baltica assets split following the wise of required in the future ISV and identifying, at least preliminary, the interfaces and shared among assets or Project basic parameters compliance requirements. 	- NoBo / RB Rail AS / Contractors
Second step. Master Design phase assessment at WPS level. Documentary	<ul style="list-style-type: none"> - The target is to build a common understanding about the evidences needed for the future achievement of 	- NoBo / RB Rail AS / Contractors

Project management task	Actions	Parties involved
exchange and technical meetings on demand.	<p>each one of the clauses' compliance, using as a baseline the Project.</p> <ul style="list-style-type: none"> - The Project describes, prior to the detailed design development, the way each one of the TSI clauses is going to be fulfilled (documents, drawings, procedures, references, etc.). - The Project prepares the design phase technical documents containing the evidences proposed to prove each clauses compliance. - Identification and record of interfaces with other Projects or assets. - The assessor provides comments, remarks, and answers clarifications requests for each one of the clauses. 	
Third step. Detailed design assessment WPS Level Documentary exchange and technical meetings on demand.	<ul style="list-style-type: none"> - The Project updates a technical file containing the documents proposed to prove each clauses compliance. - The Assessor answers back including comments/remarks/clarification requests for each one of the document/clauses. - The process is repeated until the achievement of no-remarks status. - Identification of construction/assembly/site inspections activities and discussion and agreement on the way the tests will be performed (regulation, limit values, etc) and the way the Assessor will supervise these tests. - Delivery of Design level ISV. - Update of Master Scope Document taking in account the actual content of the ISV scope and reviewing interfaces if needed. 	- NoBo / RB Rail AS / Contractors
Fourth step. Construction/Assembly/Site inspection phase assessment, Project or asset level. Documentary exchange and technical meetings on demand.	<ul style="list-style-type: none"> - Witnessing tests, site inspection activities, results assessment, etc. - Assessment and discussion, until the achievement of no-remarks status. - Update of ISV or EC Certificate at Project Level following the agreed strategy. 	- NoBo / RB Rail AS / Contractors
Fifth step. Rail Baltica/ Overall event level.	<ul style="list-style-type: none"> - Resolution in case of basic requirements whose conformity demonstration is shared by different stake holders, interfaces, closing requirements pending to be closed. - Issue of Authorisation event level EC Certificates. 	- NoBo / RB Rail AS / Contractors