UNIFE position on VA simplification

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Introduction

The European Commission aims to simplify rail vehicle authorisation (VA) to cut costs, reduce burdens on applicants, Conformity Assessment Bodies (CABs), and Authorising Entities (AEs), accelerate projects and increase competitiveness—an approach supported by UNIFE. Yet, proposed amendments to ERA Guidelines and Regulation (EU) 2018/545 risk misalignment with the Fourth Railway Package and broader EU objectives, while current interpretations already create hurdles. UNIFE nevertheless supports that any regulatory change must enhance efficiency without compromising safety. UNIFE is also fully supportive of ERA's digitalisation and automation efforts to try streamline the VA process.

UNIFE's paper proposes VA process improvements, calling for greater trust in industry responsibility. These changes would save time and resources for all stakeholders, especially as demand for VA is expected to rise in the coming years. An annex is provided at the end of this document with more detailed reasoning of the same points hereunder and proposals for legal texts amendments.

This list is not exhaustive - other areas may also deserve attention and improvement.

A. Implementing Regulation (EU) 2018/545 ("PAVA")

1. PAVA Article 13 – Requirements Capture

UNIFE advocates for deletion of Article 13 "Requirements Capture" from PAVA to maintain consistency with Interoperability Directive (IOD) and avoid unnecessary regulatory burdens on applicants and CABs alike. IOD article 21 defines the need for TSI compliance evidence, without mentioning "requirement capture". This provision oversteps regulatory scope and duplicates compliance to other "Union laws", which exists independently and does not require separate verification.

2. Removing existing and added complexity (PAVA Articles 15, 16 and documentation)

UNIFE believes that the proposed amendments to Articles 15 and 16 **add complexity** to the PAVA, which undermines their risk-based intent through prescriptive interpretations. AEs should not intervene in Article **15.1.b** cases (applicant's responsibility) nor use Article **15.1.d** as default for full re-authorisation, especially for older vehicles, special vehicles or missing Basic Design Characteristics. VA type documentation must focus solely on safety and interoperability, aligning with PAVA Article 29; and conformity-to-type (CTT) proof should be limited to an applicant declaration per IOD Article 25. UNIFE **rejects ERA's "Subsequent Conformity to Type**", as it copies existing CTT with no additional value. Moreover, the VA process needs a **common language for documentation**, to reduce time and cost spent on certification and authorisation, especially for multi-national projects.

3. PAVA Article 34 - Timeframe for the application

A **legal binding deadline for NSAs' assessment** – shorter than the ERA deadline - of an application part of an ERA authorisation project should be introduced to help the agency respect and improve its own binding deadline. Late document requests not identified during completeness check are also slowing down the process, especially for multi-NSAs projects. UNIFE proposes adding a chapter in Article 34, to limit NSA completeness check period to maximum 3 weeks before informing ERA, and to allow not more than 3 months to any NSA to issue their assessment report to ERA.

4. Universal Assessment to avoid multiple assessments on an existing assessed solution

With numerous upcoming retrofits (e.g., DAC, FRMCS, ETCS) involving similar changes across multiple vehicle types, a

procedure should **allow universal assessments to avoid repeating evaluations** of already approved solutions. Universal approach shall minimise specific assessments and significantly cut time and cost for authorising retrofitted vehicles. ERA's proposed Standard Retrofit Package (SRP) concept might be a good step in that direction but needs further refinement with the sector.

B. Directive (EU) 2016/797 ("IOD") and ERA Regulation (EU) 2016/796

1. Eliminate Double Assessments

Double assessments by CABs and AEs create costly inefficiencies, adding delays and duplicating charges. EC certificates and reports from CABs are often questioned by AEs, despite IOD not requiring this. **UNIFE calls for automatic cross-acceptance, to improve trust between CABs and AEs, and eliminate double-assessment**.

2. Voluntary Interoperability Constituents

Interoperability Constituents (ICs), intended for reuse across projects, largely failed except for CCS. ICs remain mandatory but offer little reuse due to varying requirements and layouts, creating heavy administrative burdens. **UNIFE proposes making ICs voluntary - except for CCS (Control Command and Signaling) - in IOD Article 8,** while not entirely deleting ICs. As alternative, applicants may provide subsystem-level evidence.

3. Structure of EC-Declaration of Verification and accompanying technical file

Revision management of documents parts of EC-Declaration and accompanying technical file should be more agile, and **revision of subsequent documents should not be mandatory**. Currently, revision management of documents, associated with request date, from design phase to final CAB report, needs version updating for administrative purpose only. These updates require important administrative effort from the applicant for no tangible benefit, especially during the process of managing changes when agility and time are key. Decision on whether to assess a new revised document should be made by the CAB based on a proposal from the applicant.

4. IOD Article 21 (12) b) - Classification of Overall Safety Level

The use of Article 21.(12) b) and especially the terminology "Overall Safety Level" is not yet sufficiently clarified. Various Railway sector stakeholders have different interpretations and ways of working leading to uncertainty for all stakeholders involved. **Clarification Note ERA1209/039 V1.1 should be withdrawn** as it created more confusion than clarification. UNIFE strongly advocates to **come back to the well-established criteria of the CSM-RA 402/2013/EU** of significance and safety-relevance. Only in case of a change being significant and safety-relevant, further assurance is required that the Overall Safety Level is not adversely affected, thus leading to new authorisation.

5. Vehicle in conformity to type in full responsibility of the applicant

UNIFE questions the added value of CTT process. For the time being, before a vehicle is placed on the market, three process steps have to be concluded: Vehicle type authorisation, APM via Conformity to Type (CTT) process and finally Registration of the vehicle. The conformity to type process today requires a lot of time and efforts, whereas documents already submitted in the vehicle type authorisation need to be re-submitted. The steps of APM and Registration are not much differing from a content perspective, only from responsibility perspective. Therefore, UNIFE advocates for elimination of the application for CTT, and **CTT to be only under applicant responsibility through applicant's declaration.**

6. ERA role in facilitating NSA cross-border agreements

Still today, few official NSA cross-border agreements as established in the Interoperability Directive are in place, leading to additional complexity and cost to authorisation and certification cases. Visibility of those in place are low and many of the agreements which are in place still require full compliance with national rules and designated body certification, demanding additional efforts by the authorisation applicants. In the absence of agreements, reduction of the scope of requirements can only be achieved by mutual agreements, requiring significant case by case efforts. Giving ERA an official role in the facilitation of concluding NSA cross-border agreements will help coordinate their establishment and overcome a missed opportunity experienced today to benefit from simplification for cross-border vehicle authorisation and operations, impacting international traffic and border regions.

C. Additional improvement proposals with a potential larger impact on the legal framework

1. Acceleration of NNTRs phasing-out and reduction of involved CABs and NSAs in European projects

Having remaining **NNTRs integrated as specific cases** in a future TSI revision would avoid further maintaining RDD and lift the need to assess national input. **For all authorisation purposes, only one AE can then be assigned.** For multi-national projects, conformity assessment should be carried out only by NoBo with no DeBo involved. Similarly, one AsBo should be used for the final assessment they are responsible for. It would reduce interfaces, assessment time and effort the applicant has to deal with during authorisation process, while keeping the same level of requirements.

2. Revision of Module decision

Quality Management Systems (QMS) assessments mentioned in conformity assessment modules and which should be performed by a NoBo (or DeBo) can find an **alternative in IRIS certification®** (**ISO 22163**) of the manufacturer. In this case, an overall manufacturer QMS certification could be applied to declare conformity of a QMS for this manufacturer's products, but an individual CAB product assessment for each individual product could still be performed as alternative. Furthermore, minor changes to ICs or subsystems should not trigger re-validation of QMS.
Creation of a specific module (“SA”) that would allow self-declaration by the applicant for the on-board CCS subsystem would also help simplifying the CCS authorisation process.

D. Improvement proposals specific to on-board Control Command and Signalling (CCS)

1. On-board CCS retrofit should be exempt from Rolling Stock related TSIs

The current VA process requires applying sub-system Rolling Stock TSIs for ERTMS retrofitting, even though the impact on the sub-system is minimal and interface requirements not defined. This leads to time-consuming, project-specific analyses and formal documentation, with limited benefit. The proposal suggests **eliminating the mandatory use of Rolling Stock TSIs for CCS retrofits**. Instead, applicants should focus on CCS TSI requirements only and provide proof that the vehicle remains safe and fit for purpose, verified by an Assessment Body.

2. On-board subsystem CCS EC verification should not require a Notified Body

The CCS on-board sub-system’s NoBo verification is redundant since CCS interoperability constituents (ICs) like ETCS or radio components are already validated at IC level. Assessment of the integration of ICs in on-board CCS sub-system should be limited to the Safety Assessment Body as per CSM or the CENELEC RAMS standards to ensure safe integration. For non-safety-related ICs with an EC declaration of conformity, no additional third-party assessment of the interface should be required. We suggest amending Section 6 of the CCS TSI to **allow self-declaration for on-board CCS subsystem** and creating a specific module (“SA”) for on-board CCS sub-system self-declaration by the applicant.

3. ETCS system compatibility (ESC)

ESC process is criticised as being costly and time-consuming, with inconsistent implementation across countries, leading to little flexibility and expansive commissioning. UNIFE/UNISIG presents **key proposals to streamline ESC** and reduce its cost. Elimination of notified body assessments, stabilisation of ETCS specifications as well as harmonisation of operational rules and trackside engineering and reduction of process diversity among infrastructure managers are points of focus to reduce ESC efforts. Cross-accepting ESC evidence for all vehicle types and ETCS versions and improving test lab availability would also simplify the process as well as the addition or removal of ESC types for PAVA assignments.

List of abbreviations

ERA WP VA:	Europe's Rail Agency 's Working Party focused on Vehicle Authorisation
IOD	Interoperability Directive (EU) 2016/797
PAVA	Commission Implementing Regulation (EU) 2018/545 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process
AE	Authorising entity: which can be the European Railway Agency (ERA), or a National Safety Authority (NSA).
CAB:	Despite definition in IOD Article 2 (42), in this paper Conformity Assessment Bodies means: Bodies responsible for the certification of a file before authorisation by Authorising Entities. CABs include Notified bodies (NoBos), and Designated Bodies (DeBos), while Assessment Bodies (AsBos) are inspection bodies.
CTT:	Conformity To Type
APM:	Authorisation for Placing on the Market
VA:	Vehicle Authorisation
RDD:	Reference Document Database
Old vehicles:	Vehicles not holding a technical file and authorisation according to IoD.
SRP:	Standard Retrofit Package: Idea being developed by ERA of a reusable documentation set describing a common change for multiple vehicles or platforms, for authorisation without repeated assessments.
Universal assessment:	Defines a common approach per solution authorisation for different projects.
EVR:	European Vehicle Register
Cross-acceptance:	Acceptance by an AE or CAB of a decision on an assessment performed by another AE or CAB, with no need to reassess the result of the previous assessment considered as complete.
NNTR	Notified National Technical Rule
CCS	Control Command and Signalling

Annex – Detailed reasoning of the changes and proposals for legal texts amendments.

A. Implementing Regulation (EU) 2018/545 (“PAVA”)

1. PAVA Article 13 – Requirements Capture

UNIFE recommends the complete deletion of Article 13 from PAVA to maintain consistency with the Interoperability Directive and avoid unnecessary regulatory burdens with the following supporting reasons:

- **No legal requirement in Article 21 of the IOD :** Article 21 of the Interoperability Directive (EU) 2016/797 (IOD) defines the requirements for the vehicle authorisation process, including evidence of compliance with Technical Specifications for Interoperability (TSI), national rules, technical compatibility, and safe integration. A "Requirements Capture" process is neither mentioned nor implied and is an additional requirement included in PAVA compared to the IOD requirements.

- **Overregulation caused by expansion of regulatory scope:** While the IOD includes a general reference to comply with other EU legislation (IOD, Article 15 and IOD annex IV 2.4 d), this obligation exists independently and does not require separate assessment by AsBos and AEs.
  Current interpretations of Article 13 by ERA and National Safety Authorities (NSAs) introduce unnecessary documentation requirements and efforts beyond IOD, for applicants, CABs and AEs, without clear benefit. This not only contradicts the Fourth Railway Package’s goals of simplification and efficiency, but also undermines broader EU objectives to reduce bureaucracy and support innovation and increases unpredictability of the procedural outcome, which is unacceptable from a legal point of view.
  Requirement management is already in place and performed as part of organisation management (e.g. QMS, ISO / IRIS certification®), making additional assessments redundant.

Legislative text amendment proposal

Article 13 Requirements capture : deleted

~~1. In accordance with the overall objective of managing and mitigating identified risks to an acceptable level, the applicant shall, before submitting an application, undertake a requirements capture process which shall ensure that all the necessary requirements covering the design of the vehicle for its life cycle have been:~~
~~(a) identified properly;~~
~~(b) assigned to functions or subsystems or are addressed through conditions for use or other restrictions; and~~
~~(c) implemented and validated.~~

~~2. The requirements capture performed by the applicant shall in particular cover the following requirements:~~
~~(a) essential requirements for subsystems referred to in Article 3 and specified in Annex III to Directive (EU) 2016/797;~~
~~(b) technical compatibility of the subsystems within the vehicle;~~
~~(c) safe integration of the subsystems within the vehicle; and~~
~~(d) technical compatibility of the vehicle with the network in the area of use.~~

~~3. The risk management process set out in Annex I to Commission Implementing Regulation (EU) No 402/2013 (1) shall be used by the applicant as the methodology for requirements capture as regards the essential requirements ‘safety’ related to the vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules.~~

[In PAVA Guidelines related to] Article 13 Requirements capture :

Although requirement capture is part of a fundamental task for an applicant, in accordance with existing standards, the evidence of compliance to this process doesn't have to be provided for assessment by Conformity Assessment Bodies or Authorising Entities.

Deletion of requirement capture doesn't mean that the overview of requirements cannot be provided as part of the pre-engagement phase. Anyhow, neither requirement capture nor pre-engagement include the possibility of a requirement freeze.

2. Removing existing and added complexity (PAVA Articles 15, 16 and documentation)

PAVA Article 15 and 16

The current authorities' interpretation of PAVA Article 15 and 16 about changes to already authorised vehicles and vehicle types already contributes to an increasingly prescriptive framework which contradicts the risk-based approach these articles should support. It has to be clarified that:

- No Authorising Entity (ERA and/or NSA) should be involved in Article 15.1.b change cases which should stay under the entire responsibility of the applicant. It should be possible for the applicant to update ERATV out of a 15.1.b change without launching a new authorisation, with deviation of non-coded restrictions.

- Article 15.1.d change classification - requiring a full new authorisation - should not be used as a default classification, especially for old vehicles, special vehicles and/or missing Basic Design Characteristics parameters.
  Classifying changes on old vehicles and special vehicles as default 15.1.d contributes to significant increase in cost and time for railway undertaker which see their fleet immobilised for a long period while the authorisation is being processed. Consequently, the appropriate infrastructure conditions may not be available to ensure the effective implementation of new rolling-stock technologies, which is of outmost importance. This issue is particularly relevant for vehicles which are one of a series or small series (e.g. special vehicles or small fleets).

Legislative text amendment proposal

Article15

Changes to an already authorised vehicle type

1. Any changes to an authorised vehicle type shall be analysed and categorised as only one of the following changes. Involvement of the Authorising Entity is only required in case an authorisation according to 15.1.d is needed.
~~and shall be subject to an authorisation as provided below~~:
…

2. When a change falls under point (b) or (c) of paragraph 1, the technical files accompanying the EC declarations for verification for the subsystems shall be updated. No involvement of the Authorising Entity is required. ~~and the holder of the vehicle type authorisation shall keep available the relevant information upon request of the authorising entity and/or the NSAs for the area of use.~~
…

Article 16

…
2. Any other changes to a vehicle shall be analysed and categorised in accordance with Article 15(1). The classification of a change should be on the responsibility of the entity managing the change with no involvement of the Authorising Entity. Changes where the entity managing the change does not have enough evidence of the modifications performed since previous authorisation; or in the absence of technical documentation equivalent to the

files accompanying the EC declarations of verification; should not be automatically classified as modifications pursuant to Article 15(1)d.

Documentation

In addition, the documentation requirements should be limited to what is essential for safety and interoperability:

- **Documentation for Vehicle type authorisation** :
  Content of the Technical File is already defined in the IOD annex IV 2.4 d).
  No deviating definition to PAVA Article 29 and Annex I, Chapter 18, of the information to be included in the application should be introduced.

- **Language Regime:** For projects in several member states, each NSA can demand documentation in their own official language. While this can be handled with an increased effort for the high-level documentation, it requires massive effort to ensure translations for multiple languages in a vehicle authorisation process on every layer of documentation. We recommend choosing one language (e.g. English) that has to be accepted also by national safety authorities for VA documentation. The change proposed hereunder in PAVA Article 10 would trickle down to a change to point 2.6 of Annex IV to Directive (EU) 2016/797 (IOD) as well.

- **Documentation for Conformity To Type (CTT)** :
  Documentation for CTT should be limited to Declaration in Conformity to Type, when the applicant for CTT is also the holder of the vehicle type authorisation, and according to IOD Article 25 : "*A vehicle or a series of vehicles which is in conformity with an authorised vehicle type shall, without further checks, receive a vehicle authorisation in accordance with Article 21 on the basis of a declaration of conformity to that vehicle type submitted by the applicant*."
  To go even further, UNIFE proposes later in this same document to have CTT in full responsibility of the applicant. Consequently, the ERA proposal of “Subsequent Conformity to Type” is not accepted by UNIFE, as this one only refers to the original content of the “regular” Conformity to Type application.

Legislative text amendment proposal

[Recital]
…

(13) Where the Agency acts as the authorising entity, the applicant should, without prejudice to the provisions of point 2.6 of Annex IV to Directive (EU) 2016/797, have the right to submit its application to the Agency in one of the official languages of the Union. During the course of the assessment, the NSAs should ~~have the right to~~ address documents pertaining to the assessment to the Agency in the language of its Member State or in English language if requested to do so by the Agency ~~by a language of its Member State, without any obligation to translate them~~.

…

Article 10

Language

1. Where the vehicle type authorisation and/or vehicle authorisation for placing on the market is to be issued in accordance with the provisions of Article 21(5) to (7) of Directive (EU) 2016/797, the applicant shall:

(a) submit the application and the file accompanying the application in English language or one of the official languages of the Union;
(b) If the language chosen by the applicant is the English language, it also has to be accepted by all national safety authorities. The applicant should not be obliged to translate parts of the file accompanying the application if it is already provided in the English language~~, in accordance with point 2.6 of Annex IV to Directive (EU) 2016/797. In this case, the language to be used is determined by the NSA and indicated in the guidelines referred to in Article 7(6).~~

…

Article 14

Identification of the relevant authorization

…
1.(e) authorisation in conformity to type: the vehicle authorisation for placing on the market for a vehicle or a series of vehicles that conform to an already authorised and valid vehicle type ~~on the basis of~~ by only a declaration of conformity to that type, pursuant to Article 25(1) of Directive (EU) 2016/797. Where applicable, there shall be a clear identification of the vehicle type version and/or the vehicle type variant to which the vehicle or series of vehicles is conform.

…

ANNEX I
…

18. Annexes (M):

The information that shall be included in the application is specified per authorisation case.

18.3 The relevant decisions for non-application of TSIs according to Article 7 of Directive (EU) 2016/797 (when applicable) [“Authorisation in conformity to type” to be crossed out]

18.4 Declaration of conformity to the type ~~and associated documentation~~ (Article 24 Directive (EU) 2016/797)

…

Annex II

[“Authorisation in conformity to type” to be crossed out from the table for points 1,2,5,11,12,20,21]

(…)
Declaration of conformity to the type by the holder of the vehicle type authorisation ~~and supporting documents~~ (Article 24 Directive (EU) 2016/797)

3. PAVA Article 34 - Timeframe for the application

A legal binding deadline for NSAs' assessment of an application part of an ERA authorisation project should be introduced to facilitate exchange of information between national authorising entities and the Agency. Today, no tool or rule exists to make sure authorising entities follow the necessary timeline to avoid postponement of the authorisation file and thus increase the authorisation costs. This would also help the agency to respect and improve its own binding deadline. Late document requests not identified during completeness check are also slowing down the process, especially for multi-NSAs projects. Additional assessment delays having important impact and domino effect on the project delivery schedule have to be avoided.

Today, according to Article 34(1), authorising entities must inform the applicant when the application is complete. UNIFE proposes adding a text in Article 34, to limit NSA completeness check period to maximum 3 weeks before informing the agency. Similarly, not more than 3 months should be allowed to any NSA to issue their assessment report to the agency. If decision about completeness check and assessment has not been shared by the Agency to the applicant before the deadline, the application should automatically be considered complete.

Legislative text amendment proposal

Article 34

Time frame for the assessment of the application

1. The authorising entity ~~and the concerned NSAs for the area of use~~ shall evaluate ~~each for their own part~~ the completeness of the application as specified in Article 32 within one month following the date of receipt of the application. The authorising entity shall inform the applicant accordingly.
The concerned NSAs for the area of use shall evaluate, each for their own part, the completeness of the application as specified in Article 32 within 3 weeks following the date of receipt of the application - within the Agency's one month timeframe - to avoid postponement of the authorisation file. The NSA shall inform the applicant accordingly.

If decision about completeness check has not been shared by the Agency to the applicant after one month, the application is automatically considered complete. Evidence that is solely for the purpose of completeness is no longer admissible by the authorising entity after this point in time.

2. Where the applicant is informed that their file is complete, the final decision over the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be taken no later than four months after the acknowledgement that the file is complete. When an NSA is involved in the authorisation process with the Agency, decision on the vehicle type authorisation and/or vehicle authorisation for placing on the market from the NSA should be performed by the concerned NSA in no more than three months after the acknowledgement that the file is complete. A progress report should be updated by the authorising entity during the assessment process, digitalised and easily accessible through OSS.

3. The decision of the authorising entity shall be issued within one month following the date of receipt of the application in case of authorisation in conformity to type in accordance with Article 14(1)(e).

4. If the applicant is informed that its file is not complete, the final decision over the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be taken no later than four months following the submission of the missing information by the applicant, unless the application is fundamentally deficient, in which case it shall be rejected.

5. In the course of the assessment, even if the application is complete as referred to in paragraph 2, the authorising entity or the concerned NSAs for the area of use may, at any time, request supplementary information, setting a reasonable deadline for the provision thereof, without suspending the assessment unless the provisions of paragraph 6 apply and with exception of evidence pursuant point 1.

6. When a justified doubt has been raised by the authorising entity or the concerned NSAs for the area of use and the applicant is required to provide supplementary information, the authorising entity may suspend the assessment and in duly recorded agreement with the applicant extend the time frame beyond what is set out in Article 21(4) of Directive (EU) 2016/797. The time frame for providing the supplementary information shall be proportionate to the difficulty for the applicant to provide the information requested. The assessment and the time frame shall resume after the applicant provides the requested information. In the absence of agreement with the applicant, the authorising entity or the concerned NSAs for the area of use shall take its decision based on the available information without introducing additional delay. If a justified doubt is raised on a particular point in the application, the authorising entity should not stop assessing the remaining parts of the application as part of the agreement.

4. Universal Assessment to avoid multiple assessments on an existing assessed solution

With numerous upcoming retrofits (e.g., DAC, FRMCS, ETCS) involving similar changes across multiple vehicle types, a procedure should **allow universal assessments to avoid repeating evaluations** of already approved solutions. Universal approach shall minimise specific assessments and significantly cut time and cost for authorising retrofitted vehicles. ERA's proposed SRP concept might be a good step in that direction but needs further refinement with the sector.
ERA opened a workstream on their draft proposal of a Standard Retrofit Package. UNIFE's contribution for refinement of the concept will be done in this workstream.

B. Directive (EU) 2016/797 ("IOD") and ERA Regulation (EU) 2016/796

1. Eliminate Double Assessments

Article 21(5) says "*the Agency shall:*

(a) assess the elements of the file specified in points (b), (c) and (d) of the first subparagraph of paragraph 3 in order ***to verify the completeness, relevance and consistency of the file in relation to the relevant TSIs****; and*

*(b) refer the applicant's file to the national safety authorities concerned by the intended area of use for assessment of the file i****n order to verify its completeness, relevance and consistency in relation*** *to point (d) of the first subparagraph of paragraph 3 and to the elements specified in points (a), (b) and (c) of the first subparagraph of paragraph 3 in relation to the relevant national rules."*

where only the completeness, relevance and consistency of the file - nothing else - has to be verified by the Agency and/or NSAs.

The principle implemented in 4th RP is that evidence on essential requirements provided by the applicant is assessed by dedicated and skilled bodies (AsBo, NoBo and DeBo) to ensure the accuracy of the evidence. As a consequence, the accuracy of the assessments done by AsBos, NoBos and DeBos has to be ensured by an appropriate accreditation and surveillance of these Assessment Bodies to ensure that in all applications failures are avoided.
Similarly, both ERADIS entry checks and availability of the documents to be checked for the IOD, should be performed at the same time to avoid them being checked again during the approval process. No different and divergent approach in the mandatory application of EU legislation and TSIs (currently possible in some member states) should be allowed.

Legislative text amendment proposal

IOD

Article 21

___
(6)
(…)
The Agency shall only take ~~full~~ responsibility for the verification of the completeness, relevance and consistency of the authorisation file ~~it issues~~ for the assessment under its remit.

(…)

(8)
(…)
The national safety authority shall take ~~full~~ responsibility for the verification of the completeness, relevance and consistency of the authorisation file ~~it issues~~. Same applies for multi-national authorisation projects where NSAs are involved.

ERA Regulation

Article 24 - Support for notified conformity assessment bodies, and designated-bodies
1. The Agency shall support the activities of ~~notified~~ conformity assessment bodies as referred to in Article 30 of Directive (EU) 2016/797. That support shall include, in particular, the issue of drafting guidelines for assessing the conformity or suitability for use of an interoperability constituent as referred to in Article 9 of Directive (EU) 2016/797 and of guidelines for the 'EC' verification procedure referred to in Articles 10 and 15 of Directive (EU) 2016/797. The certificates delivered by the conformity assessment bodies shall be proof of conformity for interoperability constituents and subsystems which are certified, without further checks."

Article 34 - Monitoring of notified conformity assessment bodies, and designated-bodies
1. For the purposes of Article 41 of Directive (EU) 2016/797, the Agency shall support the Commission in establishing a continuous monitoring system of the ~~notified~~ conformity assessment bodies through the provision of assistance to accreditation bodies and to the relevant national authorities, and through audits and inspections covering all Member

States, as provided for in paragraphs 2 to 6, in order to ensure presumption of conformity for interoperability constituents and subsystems which are certified.

The support and monitoring of the Conformity Assessment Bodies should ensure the quality of the certificates delivered and therefore shall be accepted by the Agency without further checks. This was an original principle of the Fourth Railway Package and use of third-party assessment. Double assessment and duplication shall be avoided to reduce burden and costs on the processes and sector. Such shift of responsibility should require that the Agency builds a continuous monitoring system on the quality of the work performed by the conformity assessment bodies, as well as on the follow-up/remedy actions.

2. Voluntary Interoperability Constituents

Except for CCS ICs, and due to different requirements, interfaces and layouts, there is hardly re-use of ICs throughout different vehicle platforms. Nonetheless, for all ICs, the administrative burden to create certificates, making available on ERADIS and keeping valid throughout the lifetime of any vehicle type is an administrative burden and cost driver for all stakeholder (including authorising entities) without any real benefit.
UNIFE does not propose to delete Interoperability Constituents, but to add a clause in Article 8 of the IOD stating that the **application of Interoperability Constituents is voluntary**. The applicant not choosing Interoperability Constituents, would have to demonstrate compliance with the requirements at Subsystem level.

Legislative text amendment proposal

IOD Article 8

Conditions for the placing on the market of interoperability constituents

1. Member States shall take all necessary steps to ensure that interoperability constituents are:
(a) placed on the market only if they enable interoperability to be achieved within the Union rail system while at the same time meeting the essential requirements;
(b) used in their area of use as intended and suitably installed and maintained. This paragraph shall not prevent the placing on the market of those constituents for other applications.
(c) when existing, the use of Interoperability Constituents in an authorisation file is voluntary. The applicant not choosing to use Interoperability Constituents in their authorisation file would have to prove evidence at Subsystem level. The Interoperability Constituents used for CCS systems authorisation are excluded from this point 1. (c) of Article 8.

2. Member States shall not, in their territory and on the basis of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the Union rail system where these constituents comply with this Directive. In particular, they shall not require checks which have already been carried out as part of the procedure for 'EC' declaration of conformity or suitability for use as provided for in Article 10.

3. Structure of EC-Declaration of Verification and accompanying technical file

The EC-Declaration as well as the accompanying technical file are clarified in IOD Article 15 (2) and (4). Besides the documents to be referenced, administrative obligations, especially the request dates and thus revision management are also critical. The need for a controlled document configuration for Vehicle authorisation purposes is not questioned. However, the obligation to have those documents referenced within the whole chain starting from design documents, towards assessment reports ("NoBo-File", "DeBo-File"), and EC-Certificates from any CAB until the technical file and EC-Declaration of Verification is causing a huge effort for updating multiple times all documents only for administrative purposes. Indeed, one minor change during application can trigger down a lot of administrative version changes and re-assessment of modified document by CAB which bring no added value to the process. It is proposed to have a more agile system. In the case a document is revised, it should not be mandatory to revise its subsequent documents as well.

4. IOD Article 21 (12) b) - Classification of Overall Safety Level

UNIFE strongly advocates to not further insist on the wording “Overall Safety Level”, but to come back to the well-established criteria of the CSM-RA 402/2013/EU of significance and safety-relevance. Further assurance shall only be required when a change has an impact on safety and is classified as a significant change in accordance with Regulation 402/2013/EU. In such cases, it must be assessed whether the Overall Safety Level is adversely affected. **A New Authorisation shall only be required if the assessment confirms that the Overall Safety Level is adversely affected.** The Overall Safety Level is considered adversely affected when the safety level of the vehicle is reduced compared to its level prior to the change. For example, the removal of a safety function in order to increase reliability.

The Clarification Note (CN) ERA1209/039 V1.1, “Changes that may adversely affect safety pursuant to Article 21(12)(b) of Directive (EU) 2016/797” **should be withdrawn** as the approach developed created more confusion than clarification and introduces **additional work with little or no safety benefit**.
In particular, the note omits to mention that Article 21(12)(b) only applies in the case of a renewal or upgrading of existing vehicles. Consequently - and in accordance with the definitions of Directive (EU) 2016/797 - consideration shall be limited to major substitution or modification work on a subsystem, thus excluding minor changes.
ERA asserts that the assessment regarding the overall safety level of the vehicle should occur at the concept stage of the change rather than after its validation and implementation. It is understood that the objective is to identify changes to the risk assessment of the vehicle rather than changes to the achieved safety performance of the vehicle after the change, to assess if a new authorisation is required.
This approach creates confusion since traditional risk management focuses on ensuring the validated product is safe. Consequently, ERA1209/039 note effectively adds a new objective to the risk management process, resulting in additional work instead of simplifying.
In addition, ERA’s approach described in this Clarification Note is not risk-based, as it relies on criteria that do not fully consider both consequence and likelihood - the two pillars of safety risk. It also introduces an additional layer of assessment beyond the existing significance assessment. Moreover, the approach outlined in the clarification note uses the CSM RA 402/2013/EU significance criteria whilst stipulating a new logic in their evaluation, creating potential conflicts.
Finally, the additional burden affects both the proposer in assessing the changes and the AsBo in reviewing that assessment. Whilst the clarification note states that AsBos are not required to evaluate or endorse the proposer’s decision, they are still required to report on the topic of overall safety level. Consequently, they review the decision by default.

Legislative text amendment proposal

IOD Article 21
(...)
12. In the event of renewal or upgrading of existing vehicles which already have a vehicle authorisation for placing on the market, a new vehicle authorisation for placing on the market shall be required if:
(a) changes are made to the values of the parameters referred to in point (b) of paragraph 10 which are outside the range of acceptable parameters as defined in the TSIs;
(b) ~~the overall safety level of the vehicle concerned may be adversely affected by the works envisaged; or~~
the result of the Risk Assessment of the change on the vehicle according to CSM-RA proves being safety relevant and significant;
(c) it is required by the relevant TSIs.

5. Vehicle in conformity to type in full responsibility of the applicant

UNIFE questions the application and effectiveness of the CTT procedure. UNIFE understands the CTT procedures´ objectives, however the administrative character of the system application diminishes their true purpose. UNIFE believes that the manufacturers have at their disposal sufficient expertise and capacities to assess the products against the type authorisation and hold the full responsibility of the final delivery as it is intended also in the existing EU legislation. For the time being, before a vehicle coming into operation, 3 process steps have to be concluded: Vehicle type authorisation, Authorisation for Placing on the Market (APM) via Conformity to Type process and Registration of the vehicle. The current conformity to type process requires a lot of time and efforts, whereas documents already submitted in the vehicle type authorisation need to be re-submitted. The steps of APM and Registration are not much differing from a content

perspective, only from responsibility perspective. Therefore, UNIFE advocates for **elimination of the application for CTT**, for CTT to be only under applicant responsibility through **applicant's declaration**. The vehicle declared in conformity to type would still need to be registered and this step would not be altered.

Legislative text amendment proposal

IOD Article 25

Conformity of vehicles with an authorised vehicle type

1. A vehicle or a series of vehicles which is in conformity with an authorised vehicle type shall, without further checks, receive a vehicle authorisation in accordance with Article 21 on the basis of a declaration of conformity to that vehicle type submitted by the applicant.
A vehicle or a series of vehicles which receive a declaration of conformity with an authorised vehicle type, issued under the sole responsibility of the holder of the vehicle type authorisation or of the entity entrusted by it, shall be deemed as authorised in accordance with Article 21. In that case, the declaration of conformity with the approved vehicle type shall form part of the application referred to in Article 22 and shall be stated in the register referred to in Article 47.

2. The renewal of the authorisation of a vehicle type as referred to in Article 24(3) shall not affect vehicle authorisations for placing on the market already issued on the basis of the previous authorisation to place that vehicle type on the market.

6. ERA role in facilitating NSA cross-border agreements

Still today, few official NSA cross-border agreements as established in the Interoperability Directive are in place, leading to additional complexity and cost to authorisation and certification cases. Visibility of those in place are low and many of the agreements which are in place still require the full compliance with national rules and designated body certification, demanding additional efforts by the authorisation applicants. In the absence of the agreements, reduction of the scope of requirements can only be achieved by mutual agreements, requiring significant case by case efforts. Giving ERA an official role in the facilitation of concluding NSA cross-border agreements will help coordinate their establishment and overcome a missed opportunity experienced today to benefit from simplification for cross-border vehicle authorisation and operations, impacting international traffic and border regions.

It is still an administrative burden to capture the exact list of applicable (local instead of national) requirements of the concerned NSAs and/or Infrastructure Managers. These requirements are sometimes clearly stated in cross-border agreements, however sometimes missing. The Agency shall help the sector by supervising existence and available documents for such cross-border agreements.

Legislative text amendment proposal

ERA Regulation Article 20

Authorisations for the placing on the market of vehicles

The Agency shall issue authorisations for the placing on the market of railway vehicles, and shall be empowered to renew, amend, suspend and revoke authorisations issued by it. For that purpose, the Agency shall cooperate with national safety authorities in accordance with Article 21 of Directive (EU) 2016/797.

Without prejudice to Article 21 of Directive (EU) 2016/797, the Agency shall have a role in facilitating the establishment of cross-border agreements between national safety authorities and harmonising their approach across Member States. The Agency shall maintain a publicly accessible list of available cross-border agreements and their necessary supporting documents.

C. Additional improvement proposals with a potential larger impact on the legal framework

1. Acceleration of NNTRs phasing-out and reduction of involved CABs and NSAs in European projects

UNIFE asks for a significant reduction of NNTRs. The **remaining NNTRs should be integrated as specific cases** in a future TSI revision. This has already been applied in the case of “Coaches in predefined formation” in TSI LOC&PAS 2023 § 7.1.1.5.1. In addition to removing the need to maintain the RDD, integrating NNTRs in the TSIs would lift the need to further breakdown the assessment towards other authorising entities as no specific national input would be needed for assessment of European projects. In other words, in the case of multi-national projects, conformity assessment should be carried out by a single conformity assessment body (only NoBo) with no DeBo involved. Similarly, one AsBo should be used for the final assessment they are responsible for. This would highly reduce the interfaces, assessment time and effort the applicant has to deal with during the authorisation process, while keeping the same level of requirements.

2. Revision of Module decision

Quality Management Systems (QMS) assessments mentioned in conformity assessment modules and which should be performed by a NoBo can find an alternative in IRIS certification® (ISO 22163) of the manufacturer and entities performing the required vehicle implementations (if separate). It would give the applicant the possibility to avoid repeating the same assessment for every project in conformity assessment module, while the same assessment may already have been performed for IRIS certification® (ISO 22163). In this case, an overall manufacturer QMS certification could be applied to declare conformity of a QMS for this manufacturer's products if the manufacturer can declare that the project works according to the processes that have been approved in the site audit. This possibility should also apply to the QMS approvals requested by national rules through designated bodies. An individual conformity assessment body product assessment for each individual product could still be performed as alternative. Essentially, one single proof of QMS approval must be sufficient.
Additionally, special attention should be paid to the validity of EC design/type examination certificates after small changes of an interoperability constituent (IC) or subsystem and on the validity of quality management approvals. In case of small changes (for example for error correction of the IC), renewing the quality management system (QMS) approvals on both ICs and subsystem levels is often not proportionate to the magnitude of changes. Implementation of the proposal above and allowing quality management approvals with IRIS certification® (ISO 22163) would solve this issue implicitly. Creation of a specific module (“SA”) that would allow self-declaration by the applicant for the on-board CCS subsystem would also help simplifying the CCS authorisation process.

The tables hereunder detail the different conformity assessment modules where QMS assessments are mentioned and where these QMS assessments which are carried out by conformity assessment bodies, can find an alternative in IRIS certification® (ISO 22163) of the manufacturer. In this case, overall manufacturer QMS certification can be applied as alternative. Once granted, this qualification of the manufacturer would be valid for three years, which is the IRIS audit validity period.

Modules for Conformity assessment of interoperability constituents		
Module	**Description**	**IRIS/ISO 22163 as alternative**
CA	Internal production control	Yes
CA1	Internal production control plus product verification by individual examination	Yes
CA2	Internal production control plus product verification at random intervals	Yes
CB	EC-type examination	No
CC	Conformity to type based on internal production control	Yes
CD	Conformity to type based on quality management system of the production process	Yes
CF	Conformity to type based on product verification	Yes
CH	Conformity based on full quality management system	For QMS part only
CH1	Conformity based on full quality management system plus design examination	For QMS part only
CV	Type validation by in-service experience (suitability for use	No

Modules for EC verification of subsystems		
Module	**Description**	**IRIS/ISO 22163 as alternative**
SB	EC-type examination	No
SD	EC verification based on quality management system of the production process	Yes
SF	EC verification based on product verification	Yes
SG	EC verification based on unit verification	For QMS part only
SH1	EC verification based on full quality management system plus design examination	For QMS part only

D. Improvement proposals specific to on-board Control Command and Signalling

1. On-board CCS retrofit should be exempt from the application of Rolling Stock related TSIs

Vehicle type authorisation requires application of the subsystem Rolling Stock TSIs, even for ERTMS retrofitting, despite the limited impact on the subsystem Rolling Stock. The requirements of the Rolling Stock-related TSIs that must be applied for a retrofit are not defined. This leads to project specific effortful analysis of the Rolling Stock TSIs with the bodies and persons involved and to formal demonstration of the identified requirements. From the experience of the suppliers the benefit of this activity is not proportionate to the effort required (complete project specific analysis of the TSI text, preparation of formal documentation and quality management approval for the Rolling Stock subsystem)
Therefore, the mandatory application of Rolling Stock-related TSIs should be eliminated. Applicants should only be required to apply the CCS TSI requirements related to the CCS on-board subsystem. As compensation for not applying the Rolling Stock TSI, the applicant shall create proof whether the entire vehicle type remains fit for purpose and whether safety is not adversely affected following the retrofit, which could in-turn be assessed by an Assessment Body.

Legislative text amendment proposal

COMMISSION REGULATION (EU) 1302/2014

Article 2
[…]
3. The TSI shall not apply to rolling stock subject to upgrading & renewal of the on-board CCS subsystem, unless otherwise specified in the TSI CCS ([1])

…

ANNEX
1.1 Technical Scope

[…]
Rolling Stock subject to upgrading & renewal of the on-board CCS subsystem are excluded from the scope of this TSI unless otherwise specified in the TSI CCS ([1]).

Legislative text amendment proposal

COMMISSION REGULATION (EU) 2023/1695 TSI CCS ([1])

ANNEX

[…]

4.2.21 Upgrading & renewal of the on-board CCS subsystem of Rolling Stock

For Rolling Stock subject to upgrading & renewal of the on-board CCS subsystem, TSI LOC & PAS does not apply, unless otherwise specified in other sections of this TSI.

Independently of the application of the TSI LOC & PAS it shall be demonstrated that the overall safety level of the Rolling Stock subsystem has not been adversely affected by the upgrading & renewal of the on-board CCS subsystem. Therefore, changes made on the Rolling Stock subsystem shall be managed according to the risk management process set out in Annex I to the Implementing Regulation (EU) No 402/2013, as referred to in Article 6(1)(a) of Directive (EU) 2016/798.

[1] Commission Implementing Regulation (EU) 2023/1695 of 10 August 2023 on the technical specification for interoperability relating to the control-command and signalling subsystems of the rail system in the European Union and repealing Regulation (EU) 2016/919 (JO L 222, 8.9.2023, p. 380).

Additionally, the correct application of the risk management process as set out in Annex 1 to Implementing Regulation (EU) No 402/2013, as well as the appropriateness of the results from this application, shall be independently assessed by a CSM assessment body according to Article 6 of that Regulation. The appointed CSM assessment body shall be accredited or recognised according to the requirements in Annex II to Implementing Regulation (EU) No 402/2013 in the field of 'Rolling Stock' sub-system, as listed in item 5 'classification' of ERADIS database entry for Assessment Bodies.

2. On-board Sub-system CCS EC verification should not require a Notified Body

Unlike the Rolling Stock sub-system, interoperability constituent (IC) is crucial for the CCS sub-system. The functional requirements of the CCS TSI (primarily as per Annex A) are implemented at the product/IC level, such as the ETCS on-board or radio-related ICs. Suppliers aim to reuse the same product (same software/hardware version) of the products/ICs for various vehicle types.
Suppliers carefully process all necessary requirements during the product/IC development phase. The integration of ICs into the specific application environment (the vehicle) is based on the product's/IC's documentation (such as installation manuals) and safety-related application conditions (SRACs). These requirements are then validated through the RAMS process of the specific application and ultimately in the specific application safety case (SASC).
From the perspective of UNIFE/UNISIG, there is no added value in the verification of the sub-system by the Notified Body. The assessment of the integration of ICs in the on-board CCS sub-system should be limited to the Safety Assessment Body as per CSM or the CENELEC RAMS standards (e.g. EN50129) to ensure safe integration.
In addition, UNIFE/UNISIG proposes that integration of non-safety-related ICs into the vehicle does not require third party assessment at all, when they carry an EC declaration of conformity.
The requirement could be enforced by changing Section 6 of the CCS TSI accordingly and create a specific module (SA) which would allow self-declaration by the applicant for the on-board CCS sub-system.

Legislative text amendment proposal

COMMISSION REGULATION (EU) 2023/1695 TSI CCS

ANNEX

[…]

6.3 Control-Command and Signalling Subsystems
6.3.1 Assessment procedures for Control-Command and Signalling Subsystems

[…]

~~At the request of the applicant the Notified Body shall carry out an 'EC' verification of a Control-Command and Signalling On-board or Trackside Subsystem in accordance with Annex IV to Directive (EU) 2016/797.~~

[…]

The assessment procedure shall be carried out using the modules specified in point 6.3.2 (Modules for Control-Command and Signalling Subsystems). At the request of the applicant the Notified Body shall carry out an 'EC' verification of a Control-Command and Signalling On-board or Trackside Subsystem in accordance with Annex IV to Directive (EU) 2016/797, if required by these modules.

The 'EC' declarations of verification for a Control-Command and Signalling On-board Subsystem and of a Control-Command and Signalling Trackside Subsystem~~, together with the certificates of conformity~~, shall be deemed sufficient to ensure that the subsystems are compatible under the conditions specified in this TSI.

6.3.2 Modules for Control-Command and Signalling Subsystems
6.3.2.1. On-board Subsystem

[…]

(3) the full quality management system with design examination procedure (Module SH1), or

(4) Internal verification (Module SA).

[…]

7.2.2 Changes to an existing On-Board subsystem

[…]

7.2.2.1 Rules to manage changes in on-board CCS subsystems

[…]
(2) The entity managing the change shall ~~inform a Notified Body of~~ record all changes affecting the conformity of the subsystem with the requirements of the relevant TSI(s) requiring new ~~checks~~ verification, in accordance with Articles 15 and 16 of Implementing Regulation (EU) 2018/545 and Decision 2010/713/EU and by application of modules SB, SD/SF, ~~or~~ SH1 or SA for the EC verification, and if relevant Article 15(5) of Directive (EU) 2016/797. This information shall be provided by the entity managing the change with corresponding references to the technical documentation relating to the existing 'EC' ~~certificate~~ declaration of verification.

(3) The entity managing the change has to justify and document that applicable requirements remain consistent at subsystem level~~, and this has to be assessed by a Notified Body~~.

[…]

(7) In order to establish the EC certificate of verification, the Notified Body may refer to:
a) the original EC certificate of verification for parts of the design that are unchanged or those that are changed but do not affect the conformity of the subsystem, as far as it is still valid;
b) amendments to the original EC certificate of verification for modified parts of the design that affect the conformity of the subsystem with the applicable TSI version used for the EC verification.

This does not apply if Module SA has been used for the EC verification.

(8) In any case, the entity managing the change shall ensure that the technical documentation which is relating to the EC ~~certificate~~ declaration of verification is updated accordingly.

(9) The updated technical documentation, ~~related to the EC certificate~~ is referred to in the technical file accompanying the EC declaration of verification issued by the entity managing the change for on-board subsystem declared as conformant to the modified type.

3. ETCS system compatibility (ESC)

There have been many complaints by sector stakeholders about ESC as being too costly and time consuming. Indeed, beside positive best practice examples, the practical implementation of the ESC process failed in some countries. Initial experience shows that the definition of ESC checks and types, the necessary processes and the stakeholders involved are handled very differently depending on the understanding and implementation by the infrastructure managers. The various implementations are strong cost drivers in the process leading up to vehicle commissioning. Furthermore, current practice severely restricts flexible use of rail vehicles as ESC checks and ESC types are constantly changing and evolving.

The main points for the reduction of effort in relation to ESC are the following:

- Harmonization of operational rules and trackside engineering.
- Stability of the ETCS specification.
- Elimination of the notified body assessments on ESC.
- Cross acceptance of ESC evidence across all vehicle types and of all subsequent product versions of the ETCS on-board.
- Reduction of diversity of the ESC processes among IMs and countries.

- Mitigation of poor availability of test laboratories or tracks for field tests through different approaches for collecting ESC evidence (field test, testing in IM or trackside supplier laboratory).
- Simplification of adding or removing ESC types for assignment to PAVA, Article 15 1c.

Legislative text amendment proposal

COMMISSION REGULATION (EU) 2023/1695 TSI CCS

ANNEX

4.2.17 ETCS and Radio System Compatibility

[…]

4.2.17.1 ETCS System Compatibility

ETCS System Compatibility (ESC) is the recording of technical compatibility between ETCS on-board interoperabilty constituent and the trackside parts ETCS of the CCS subsystems within an area of use.

[…]

~~(4) The ESC Interoperability Constituent Statement shall include the reference to the NoBo assessment Report according to 6.2.4.3 (ETCS and radio system compatibility checks for Interoperability Constituent).~~

~~The ESC of the specific on-board CCS subsystem with respect to one or more ESC Type(s) is laid down in the ESC Statement. The template provided in Appendix C.1 or C.5 shall be used.~~

~~At subsystem level, the ESC Statement shall also include the summary of the ESC Check Report and shall demonstrate the fulfilment of the required ESC checks (for each ESC Type included in the Statement) published in the Agency ESC/RSC technical document in addition to already provided ESC interoperability constituent statements.~~

~~The ESC Statement shall also include the full list of ESC Interoperability Constituent statements taken into account in the assessment (if any), the conditions (if any) with respect to the different ESC Types and the NoBo Assessment Report according to 6.3.3.1 (ETCS and radio system compatibility checks).~~

4.2.17.2 Requirements for ETCS System Compatibility

[…]

~~The Entity in charge of ESC demonstration shall define a representative configuration of the ETCS on-board subsystem.~~

~~The ESC Statement shall be produced by the Entity applying for ESC Demonstration.~~

~~The Entity applying for ESC Demonstration shall have the ESC check report for the Interoperability Constituent or Subsystem assessed by a Notified Body according with points 6.2.4.3 (ETCS and radio system compatibility checks for Interoperability Constituent) or 6.3.3.1 (ETCS and radio system compatibility checks).~~

If ~~a Check Report or~~ an ESC Interoperability Constituent Statement ~~referred to in the ESC Statement~~ contains Conditions, all Conditions shall be recorded, reflecting the status and if agreed how they are managed by the affected party (e.g. RU willing to demonstrate the compatibility with a route), and this responsibility shall be recorded ~~in the ESC Statement~~.

[…]

6.2.4.3 ETCS and radio system compatibility checks for Interoperability Constituents

Since the ESC/RSC checks are ~~not required~~ optional in Table 6.1.1, they are not required for issuing an interoperability constituent certificate.

It is the responsibility of the manufacturer of the interoperability constituent to record the results of the ESC/RSC checks appropriately with regard to correctness and completeness for transfer to the ERATV parameters.

~~If ESC/RSC checks are executed at Interoperability Constituent level, the task of the NoBo with regards to the ESC/RSC Interoperability Constituent statement(s) and associated report is to verify the correctness and completeness of the ESC/RSC check report for the Interoperability Constituent, according to the requirements in this point.~~

~~In line with the Directive (EU) 2016/797 the Notified Body performing this assessment may be a different one from the Notified Body performing the EC conformity or suitability procedure for the interoperability constituent.~~

~~Table 6.1.2~~

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