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TECHNICAL ADVICE

ERA/ADV/2017-3

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

THE EUROPEAN COMMISSION

Regarding

Certification according to withdrawn TSIs

Disclaimer:

The present document is a non-legally binding advice of the European Union Agency for Railways. It does not represent the view of other EU institutions and bodies, and is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

1. General context

1.1. Introduction

1.1.1. *In its letter referenced as 'Ares(2017)5411444', dated 7th November 2017, addressed to the European Union Agency for Railways ("the Agency"), the European Commission requested the Agency to provide additional advice regarding the technical opinion ERA/OPI/2016-3 that answered a request put forward by NB Rail (ref. NB-Rail QC-STR-009) concerning certifications according to withdrawn Technical Specifications for Interoperability.*

1.1.2. *The advice requested has the objective of answering a question raised by Germany during the 79th meeting of the Railway Interoperability and Safety Committee (RISC 79), as captured in the point 14 of the minutes of the meeting:*

“ 14. The Agency's Opinions and Advices

14.1. Technical Opinion regarding question of NB-Rail QC-STR-009 concerning the certification according to withdrawn TSIs (revised).

[...]

Very brief exchange of comments took place, in particular concerning technical opinion regarding certification according to withdrawn TSIs (NB-Rail QC-STR-009). DE reminded RISC of their proposal sent to COM to include the cases where modifications are needed in relation with obsolescence and error-corrections. JPC-R supported DE. DG MOVE answered that this would need further analysis and proposed, due to the fact that the sector urgently needs the current opinion, to treat these issues in a separate opinion.“

1.1.3. *In addition, UNISIG submitted a letter both to the Head of Unit of DG MOVE C4 and to the Executive Director of the European Union Agency for Railways, dated on 14th of November 2017, expressing their concerns on the possible interpretation of the opinion ERA/OPI/2016-3 as implying that, even in case of small error corrections, the latest TSI CCS is to be applied and not the one applied for the first authorisation. According to UNISIG, this is quite the opposite of common practice and against an efficient approval process required for ETCS in case of critical error corrections.*

2. Legal background

- 2.1.1. *Article 41 of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004¹ (Agency Regulation) provides the Commission with the possibility to request advice from the Agency “in matters requiring specific knowledge”.*
- 2.1.2. *The Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system² (Interoperability Directive) sets out the principles concerning the assessment of conformity for constituents and of subsystems, together with the principles governing the authorisation of subsystems and the treatment of modifications.*
- 2.1.3. *The Commission Recommendation 2014/897/EU 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 Council³(DV 29bis) refers to the situations related to management of modifications on subsystems already placed in service.*
- 2.1.4. *The Commission Decision 2010/713/EU of 9 November 2010 on modules for the procedures of 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 Council⁴ refers to the obligation to inform the notified body of the relevant modifications of Interoperability Constituents and Subsystems, and the obligation of the notified body to compile the technical file accompanying a certificate.*

3. Analysis

3.1. Modifications in relation with obsolescence

- 3.1.1. *According to the Interoperability Directive, the “EC declaration of verification” of a Subsystem must include in the Technical File accompanying it the documentation on maintenance relevant for the subsystem concerned. In addition, in article 15, it is stated that the “EC declaration” must contain all the elements relating the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.*
- 3.1.2. *In some occasions, for example, due to evolution in the market or modifications performed by the suppliers, some of the elements needed to maintain the Subsystems that are already authorised may not be available any longer.*
- 3.1.3. *The Interoperability Directive defines actions considered as “substitution in the framework of maintenance” as the replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance. There is no mention to the need to reassess the Subsystem after one of these actions.*
- 3.1.4. *The principle 110 in Recommendation DV29bis clearly indicates that for the changes that do not introduce a deviation from the technical file accompanying the “EC declaration of verification” there is no need to perform any additional verification by the assessment body, the Member State does not need to be informed, and the initial “EC declaration of verification” remains valid and unchanged.*
- 3.1.5. *The Interoperability Directive also defines “renewal” as any major modification work on a Subsystem or part of it which results in a change in the technical file accompanying the “EC declaration of verification”, and which improves the overall performance of the Subsystem. According to its article 15, if the renewal of a Subsystem results in an amendment to the technical file, affecting the validity of the verification procedures already carried out, the applicant shall assess the need for a new “EC declaration of verification”.*

- 3.1.6. *The same principles apply by analogy to the “EC certificates of conformity” of Interoperability Constituents. The Decision 2010/713/EU on modules for the procedures for assessment of conformity, provides details on the obligation of the entity requesting the assessment to inform the Notified Body of all modifications that may affect the conformity or the conditions of validity of the certificate. This obligation is both for the modules used for assessment of ICs and Subsystems. Depending on the nature of the modifications, these may require additional approval in the form of an addition to the original EC certificate.*
- 3.1.7. *The principle 110 in Recommendation DV29bis indicates that for the changes that introduce a deviation from the technical file accompanying the “EC declaration of verification” which require new checks (and therefore, require verification according to the applicable conformity assessment modules) but do not have any impact on the basic design characteristics of the Subsystem, the technical file accompanying the “EC declaration of verification” needs to be updated (and communicated to the authorities by the entity who requested the authorisation); the relevant information should be made available upon request by the National Safety Authority.*
- 3.1.8. *If the modifications introduced are not impacting the basic characteristics of the Subsystem, there is no need to issue a new certificate, and therefore, no need to consider a new authorization by the National Safety Authority.*
- 3.1.9. *If the modifications introduced are impacting the basic characteristics of the Subsystem, according to the Interoperability Directive, the TSIs shall indicate the provisions applicable to the existing Subsystems and vehicles, and the modification work which requires an application for new authorization. The National Safety Authority (alone or in close cooperation with the Agency, if it applies) shall decide whether a new authorisation for placing in service is needed or not.*
- 3.1.10. *The principle 112 in Recommendation DV29bis states that the modification should always be considered by reference to the subsystem or vehicle at the moment of authorisation.*
- 3.1.11. *The principle 115 in Recommendation DV29bis reminds both railway undertakings and infrastructure managers that, concerning any changes to the maintenance of a subsystem or vehicle, they should assess using their SMS whether the change introduced is significant and, if it is significant, ensure that the systems of maintenance of ECMs and SMS of the railway undertaking and infrastructure manager are appropriately adapted.*
- 3.2. Modifications in relation with error correction**
- 3.2.1. *In the Interoperability Directive, there is no difference in the handling of modifications depending on the cause of the modification. Error correction is one of the reasons for the introduction of modifications in ICs or Subsystems.*
- 3.2.2. *Although an IC or Subsystem may hold a certificate issued by an assessment body, an error may not have been detected during the assessment activity. In particular, software issues are much more difficult to detect due to the different combination of situations that may change the response of the system.*
- 3.2.3. *The correction of these errors may affect or not the conformity to the TSI requirements and specifications.*
- 3.2.3.1. *For example, errors discovered in the implementation of requirements that are additional to those in the TSI may be corrected without impacting the implementation of the TSI requirements. When those errors are corrected, no new certificate has to be issued.*

- 3.2.3.2. *For errors discovered in the implementation of TSI requirements after a certificate has been issued, if they are not corrected, the original certificate will have to be amended to reflect the existing deviation/limitation. If they are corrected, the original certificate that was issued will not have to be amended, as it will reflect accurately the fact that now compliance to the TSI requirements is really established.*
- 3.2.3.3. *If the correction of errors leads to further changes, then this has to be treated as any other modification.*

4. The advice

- 4.1.1. *The handling of modifications (due to the obsolescence of parts for an Interoperability Constituent or Subsystem, due to an error correction or due to any other reason) is covered in the Interoperability Directive and explained in the Recommendation DV29 bis.*
- 4.1.2. *When the modification does not impact the basic characteristics, as it could be the case when correcting errors of an IC or Subsystem previously undetected, no recertification is needed; the technical file accompanying the certificate has to be updated with the corresponding elements and this shall have no impact on the authorisation of the Subsystem. The TSI that was used for the original certification continues to be the reference*
- 4.1.3. *In case the obsolescence of a component requires modification to an IC or Subsystem, the technical file accompanying the certificate has to be updated; the NoBo shall assess if a new certificate is needed. If a new certificate is needed, the Authorizing Entity shall identify if a new authorisation is also needed. The TSI that was used for the original certification continues to be the reference if a new authorisation is not needed.*
- 4.1.4. *The Agency opinion ERA/OPI/2016-3 has to be read together with Recommendation DV 29bis to understand in which cases a modification may require a new certification and the applicability of the correct TSI version.*

Valenciennes, 16.01.2018


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Executive Director

ANNEX 1

Letter from DG MOVE reference Ares(2017)5411444, dated 07/11/2017 [move.ddg2.c.4(2017)5952872].

UNISIG letter to the Head of Unit of DG MOVE C4 and to the Executive Director of the European Union Agency for Railways, dated on 14th of November 2017.