

**OPINION**

*ERA/OPI/2014-10*

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**OF THE EUROPEAN RAILWAY AGENCY**

FOR

*EUROPEAN COMMISSION*

REGARDING

*QUESTION AND CLARIFICATION NB RAIL - QC-STR-007*

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The present document is a non-legally binding opinion of the European Railway Agency. 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. In its letter referenced as MOVE B2/AA/fz Ares(2014)4206707 and dated 15<sup>th</sup> December 2014 addressed to the European Railway Agency ("ERA"), the European Commission ("EC") requested ERA to "evaluat[e], technical opinion, draft answer to QC-STR-007 from NB-Rail". In the same request, the EC asks "ERA to ensure dialog with NB-Rail to understand their concerns and therefore provide an appropriate answer".
2. The QC-STR-007 raises the issue of the updates of mandatory European standards quoted in the TSIs and their relations with the list of harmonised standards published by the EC in the Official Journal of the European Union.

The question raised by NB-Rail is the following:

*"The industry has approached NB Rail with a concern that the inability to update Mandatory Standards as quoted in the TSIs will lead to significant economic burden at design, production and authorisation of railway products. Can an applicant and a NoBo assume that the publication of an updated reference of a Harmonised Standard may replace a reference to a previous version of the same standard as quoted in the TSI?"*

3. The text of the NB-Rail Q-C contains also three suggested solutions:
  - Solution 1) *Yes, the list of harmonised standards relating to 2008/57/EC is published in the Official Journal of the European Union and is an official legally binding document. Therefore it changes and updates the referenced standards given in the TSIs.*
  - Solution 2) *No, the referenced standards given in the TSIs cannot be changed by Official Journal of the European Union (OJEU) (e.g. "2013/C 345/03" or a later version of this list) and therefore the direct reference to standards remains unchanged until next "Omnibus procedure" or new revision of TSI is published.*
  - Solution 3) *The referenced standard as well as the replaced standard are both considered to be applicable upon the choice of the applicant.*
4. Furthermore the document QC-STR-007 from NB-Rail contains a note referring to the list of harmonised standards published in the OJEU:

*"Harmonised standards give presumption of conformity with the essential requirements according to the directives for which they are published. The current list of harmonised standards relating to 2008/57/EC is published in the Official Journal of the European Union (OJEU) (e.g. "2013/C 345/03" or a*



later version of this list). Some standards in this list are marked as 'no longer giving presumption of conformity' (see note 2.1 in the document), but remain quoted in the TSIs which is seen as a contradiction by industry." In a dialogue between ERA and NB-Rail-chairman on 12 March 2015, NB-Rail expressed its wish that ERA includes this note in its technical opinion.

## 2 Legal Background

1. Article 2(1)(c) of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation<sup>1</sup>, provides definitions for the terms "standard", "European standard" and "harmonised standard":
  - 1.1. "Standards" are defined as technical specifications, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory.
  - 1.2. "European standards" are "standards" adopted by the European standardisation organisations (ESOs) listed in Annex I of Regulation (EU) No 1025/2012 (i.e. CEN, CENELEC, ETSI).
  - 1.3. "Harmonised standards" are "European standards" adopted by the European Commission for the application of the Union harmonisation legislation.
2. Regulation (EU) No 1025/2012 on European standardisation also provides that "*Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union*" (article 10(6)). Therefore, the process of identifying a European standard as "harmonized" (as defined by art 2(1)(c) of Regulation (EU) 1025/2012) shall start only after the publication of the corresponding "Union harmonisation legislation"<sup>2</sup> (ref. art 10(5) and 10(6) of the Regulation (EU) 1025/2012).
3. Article 5(8) of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community<sup>3</sup> (the "Interoperability Directive") provides that "*TSIs may make an explicit, clearly identified reference to European or international standards or specifications or technical documents published by the Agency where this is strictly*

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<sup>1</sup> "amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council" (OJEU, L 316, 14.11.2012, p. 12).

<sup>2</sup> Clause "4.1.2.2. Role of harmonised standards" of the Blue Guide 2014 provides description of this process. Blue Guide 2014 available at EC website at this link: <http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?id=7326>

<sup>3</sup> OJ L 191, 18.7.2008, p.1.



*necessary in order to achieve the objective of this Directive. In such case, these standards or specifications (or the relevant parts) or technical documents shall be regarded as annexes to the TSI concerned and shall become mandatory from the moment the TSI is applicable. ...”.*

4. The Interoperability Directive defines a “*harmonised standard*” as “*any European standard adopted by one of the European standardisation bodies [...]which, by itself or together with other standards, provides a solution as regards compliance with a legal provision*” (article 2(u)).
5. 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 Council<sup>4</sup> contains useful clarifications concerning the use of European standards and harmonized standards in TSIs.

### **3 Analysis**

1. Technical specifications for interoperability (“TSIs”), including the standards or parts of standards they refer to, are adopted by the Commission through Commission Decisions or Commission Regulations which are binding on the Member States of the EU (Directive 2008/57/EC, art 5(8)) and need therefore to be legitimated by the applicable legislative process. Any change of the references to standards in the TSIs must therefore be considered as a change of EU law and the update of the respective reference in the TSI requires again this legitimation.
2. However, to facilitate the update of references in TSIs the so called “*omnibus procedure*” has been developed and introduced. This procedure provides the possibility to amend several TSIs simultaneously in order to correct deficiencies in the TSIs previously addressed by ERA Technical Opinions, as well as to correct several other minor identified deficiencies for which alone an amendment of the TSIs would not be proportionate. Therefore it is also used for correcting and updating references to standards in the TSIs.
3. The contradiction perceived by the industry and reflected in a note in the document QC-STR-007 refers to cases of harmonised standards for which a new version of the standard has been included in the list of harmonised standards and the “old” version is listed in the column titled “Reference of superseded standard”. The column “Date of cessation of presumption of conformity of superseded standard” gives information about the date on which the superseded harmonised standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation.

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<sup>4</sup> OJEU L 355, 12.12.2014, p. 59.



4. The list of “EU harmonised standards” published in the Official Journal of the European Union (OJEU) 2013 C345 03 “Information and Notice” shall be considered as one of the complementary specification which could facilitate the industry in using the European standards in applying the TSIs. Manufacturers, other economic operators, or conformity assessment bodies are free to choose another technical solution to demonstrate compliance with the mandatory legal requirements. These specifications should remain as complementary to the TSIs (ref. Commission recommendation 2014/897/EU, point 30).
5. Additionally, there might be cases of superseded harmonised standards marked as “no longer giving presumption of conformity”, which nevertheless remain quoted in the TSIs. This is possible, due to the fact that *“the same standard can be (in full or in part) at the same time harmonised (i.e. voluntary and giving presumption of conformity) and mandatory (i.e. referred to as such in the TSI). As a consequence, the standard will appear in the list of the harmonised standards published on the OJEU as well as in the list of mandatory standards referred to in the TSIs”* (TSI Application Guide. General Part, ERA/GUI/07-2011/INT, section 3.1.5.). This indicates two different applications of the same standard in the technical regulation in EU (Commission Recommendation 2014/897/EU, point 31).
6. The publication of updated lists of harmonised standards is subject to the procedure according to Regulation (EU) N° 1025/2012 (ref. art 10(6)) and the updating of the references to standards in the TSI falls under Art. 6 and Art. 7 of the Directive 2008/57/EC without a direct link between the two procedures. However, should the reference to a superseded harmonised standard in the TSI result in an important or critical error in the TSI, the procedure for important or critical errors in TSIs described in Art 7.3 of Directive 2008/57/EC applies.

#### 4 Opinion

The Agency is of the opinion that:

1. The standards referred to in TSIs are not changed by an updated version of standards listed in the Official Journal of the European Union (OJEU). The direct reference to standards remains unchanged and the quoted standard in the TSI remains valid for the purposes of the TSI.
2. NB-Rail proposed solution 2) meets the main concept of the ERA opinion.

Valenciennes, 10.04.2015

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Executive Director

