OCORA

Open CCS On-board Reference Architecture

Acceptance of Global Standards

Overview

Document ID: OCORA-BWS09-010

Version: 3.01

Date: 24.06.2022

Revision history

Version	Change Description	Initial	Date of change
0.00	▪ First clean version based on work conduct for Delta and 27/04/21 meeting	HAK	27/04/2021
0.01	▪ Comments DB + SBB taken into account	HAK	07/05/2021
0.02	▪ SNCF extended review	HAK	21/05/2021
0.023	▪ SNCF corrections on AMOC + figure 4 + NS comments	HAK	26/05/2021
0.024	▪ Editorials comments from SNCF DB and SBB	HAK	02/06/2021
0.03	▪ Final Draft from BWS09	HAK	08/06/2021
1.00	Official version for OCORA Delta Release	HAK	26/06/2021
1.1	▪ No modification from Delta to Release 1.0	HAK	10/11/2021
2.00	Official version for OCORA Release 1.0	HAK	23/11/2021
3.01	Decoupled document from a specific OCORA release	RM	24/06/2022
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References

Reader's note: please be aware that the numbers in square brackets, e.g. [1], as per the list of referenced documents below, is used throughout this document to indicate the references to external documents. Wherever a reference to a TSI-CCS SUBSET is used, the SUBSET is referenced directly (e.g. SUBSET-026). OCORA always reference to the latest available official version of the SUBSET, unless indicated differently.

[1]   OCORA-BWS01-010 – Release Notes

[2]   OCORA-BWS01-020 – Glossary

[3]   OCORA-BWS01-030 – Question and Answers

[4]   OCORA-BWS01-040 – Feedback Form

[5]   OCORA-BWS03-010 – Introduction to OCORA

[6]   OCORA-BWS04-010 – Problem Statements

The following references are used in the documents on Acceptance of Global Standards:

[7]   OCORA-BWS01-010-Delta – Release Notes

[8]   CLC/TR 50506-2: 2009 Railway applications - Communication, signalling and processing systems - Application Guide for EN 50129 - Part 2: Safety assurance

[9]   EN 50126-1:2017 – Railway Applications – The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 1: Generic RAMS Process

[10]   EN 50126-2:2017 – Railway Applications – The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety

[11]   EN 50128:2011 – Railway Applications – Communication, signalling and processing systems — Software for railway control and protection systems. New version developed by SC 9XA/WG 18, the evolutions don't interfere with the content of this document

[12]   EN 50657:2017 – Railways Applications – Rolling stock applications – Software on Board Rolling Stock

[13]   EN 50129:2018 – Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling

[14]   EN 50159:2010 – Railway applications - Communication, signalling and processing systems - Safety-related communication in transmission systems

[15]   IEC 61508:2010 – Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems Part 1 to 7

[16]   TSI CCS: COMMISSION REGULATION (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union, amended by Commission Implementing Regulations (EU) 2019/776 of 16 May 2019, (EU) 2020/387 of 9 March 2020 as regards the extension of the area of use and transition phases, (EU) 2020/420 of 16 March 2020 correcting the German language version

[17]   COMMISSION IMPLEMENTING DECISION (EU) 2020/453 of 27 March 2020 on the harmonised standards for railway products drafted in support of Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community

[18]   Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation

[19]   ICT (Information and Communication Technologies) Rolling Plan for Standardization of ICT 2020

[20]   Interoperability Directive (EU) 2016/797 Directive (EU) 2016/797 of 11 May 2016 on the interoperability of the rail system within the European Union

[21]   Directive (EU) 2016/798 of 11 May 2016 on railway safety

[22] CLC/TC9X/sec1221/INF Harmonised standards in the Rail sector: Clarification of the definition, fundamental question to handle and way to proceed when drafting the Annex ZA/ZZ Edition 1 – august 2020

[23] RFU-STR-016 Issue 1 on 14/06/2018 RECOMMENDATION FOR USE from NBRail, ACCEPTANCE OF ASSESSMENT REPORTS ON SAFETY PREPARED BY OTHER PARTIES

[24] IEC/TR 61511-4:2020   Functional safety - Safety instrumented systems for the process industry sector - Part 4: Explanation and rationale for changes in IEC 61511-1 from Edition 1 to Edition 2

[25] IEC Safety and functional safety https://www.iec.ch/safety

[26] IEC Functional safety - An introduction to Functional safety and the IEC 61508 series. https://www.iec.ch/resource-centre/functional-safety-essential-overall-safety

[27] ISO/IEC Guide 51:2014 - Safety aspects — Guidelines for their inclusion in standards

[28] IEC GUIDE 104:2019 -The preparation of safety publications and the use of basic safety publications and group safety publications

[29] SFR GRB fact sheet 4/7/2020

[30] CENELEC TR 50506-1 Application Guide for EN 50129 - Part 1: Cross-acceptance, approved by CENELEC on 2007-01-16.

[31] Frankfurt Agreement between IEC and CENELEC
 https://ftp.cencenelec.eu/CENELEC/Guides/CLC/13_CENELECGuide13.pdf

[32] Vienna Agreement between CEN and ISO
(https://isotc.iso.org/livelink/livelink/fetch/2000/2122/3146825/4229629/4230450/4230458/01__Agreement_on_Technical_Cooperation_between_ISO_and_CEN_(Vienna_Agreement).pdf?nodeid=4230688&vernum=-2)

Management Summary

This document aims to explore the strategy to be considered for improving competition and increasing economy of scale through the mean of re-using off-the-shelves components (COTS) designed for other sectors of activities and which have been produced using alternative largely applied and well-recognized standards from another sector of activities (Global Standards as defined here). Different approaches are considered with respect to the fact that an EU railway legislation is already referencing or not a standard.

When an alternative standard exists and has been adopted by a European or International standardisation body without being referenced in the TSI, a first step could be through the issuing of Acceptable Means of Compliance" (AMOC) in order to define ways of establishing compliance with the essential requirements. The AMOC would then define at the EU level the alternative standards to be used. A second step could be through the creation of an Annex Zx for this alternative global standard.

When a legally binding referenced standard exists in the EU legislation, a Cross-Acceptance guideline would then be required. This Cross-Acceptance guideline concerns the supplementary requirements/conditions to fulfil in order to accept the Cross-Acceptance of a Non-Railway Component which was originally developed and approved with an alternative Global Standard, meaning that this alternative standard is comparable in terms of requirements with the referenced Standard.

1 Introduction

1.1 Purpose of the document

This overview on Acceptance of global standards aims to provide the reader:

- A general overview on standardization and the definitions and terms used by OCORA on that respect
- The problem description with respect to the standardization
- The approach suggested with respect to a standardization strategy

This document is addressed to experts in the CCS domain and to any other person, interested in the OCORA concepts for on-board CCS. The reader is invited to provide feedback to the OCORA collaboration and can, therefore, engage in shaping OCORA. Feedback to this document and to any other OCORA documentation can be given by using the feedback form [4].

If you are a railway undertaking, you may find useful information to compile tenders for OCORA compliant CCS building blocks, for tendering complete on-board CCS system, or also for on-board CCS replacements for functional upgrades or for life-cycle reasons.

If you are an organization interested in developing on-board CCS building blocks according to the OCORA standard, information provided in this document can be used as input for your development.

1.2 Applicability of the document

The document is currently considered informative but may become a reference at a later stage for OCORA compliant on-board CCS solutions. Subsequent releases of this document will be developed based on a modular and iterative approach, evolving within the progress of the OCORA collaboration.

1.3   Context of the document

This document is published as part of the OCORA Release R1, together with the documents listed in the release notes [1]. Before reading this document, it is recommended to read the Release Notes [1]. If you are interested in the context and the motivation that drives OCORA we recommend to read the Introduction to OCORA [5], and the Problem Statements [6]. The reader should also be aware of the Glossary [2] and the Question and Answers [3].

2 Definitions and used terminology

The following definitions are taken from [17], [18], [19] and [22]:

A 'standard' is a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, except when referenced in a Technical Specification for Interoperability, or any other regulatory or legislative text (e.g. national rule, law, …).

A 'European standard' means a standard adopted and published by a European standardisation organisation (CEN, CENELEC or ETSI).

A 'harmonised standard' is a European standard published upon request of the European Commission, to support the application of Union harmonisation legislation. The application of all or part of its contents can be mandatory (referenced standard) or voluntary (standard listed in the Official Journal of the EU in the New Legislative Framework).

In this document, a 'referenced standard' is a standard or a part of a standard referenced in a Technical Specification for Interoperability (TSI). Furthermore, article 4.8 of Directive (EU) 2016/797 (c.f. [20]) sets out that other normative documents, such as specifications or technical documents can also be referenced in a Technical Specification for Interoperability (TSI). When referenced, their nature changes from voluntary to mandatory.

An 'International standard' is a standard developed and adopted by an international standardisation body (ISO, IEC or ITU).

In this document, we will define as 'Global Standard' a well-proven and largely-applied standard adopted by an international body or a European standardization organization in a different domain than the railway sector

'Presumption of conformity' The presumption of conformity is a concept that is widely used in the context of the European "New Approach" for better regulation. The presumption of conformity allows a manufacturer who has complied with a harmonised standard listed in the OJEU to legally assume he has met the requirements of the directive (or TSI) covered by that standard, as described in its Annex ZA/ZZ (c.f. [22]).

'AMOC' stands for "Acceptable Means Of Compliance", which is a document whose application is not mandatory, but provides an assumption of conformity to a regulatory text. In other words, if you prove conformity to an AMOC, you are considered conform to the legal requirement that is covered by this AMOC (e.g. application of EN 50126 provides assumption of conformity to CSM-RA). If you decide not to apply the AMOC, you have to prove full conformity to the legal text

Non-Railway Component: A part of or a single building block that originates from a non-railway domain. In this document, a Non-Railway Component can be integrated into the (CCS) on-board or (CCS) trackside system

Demonstration of Equivalence: Is the activity carried by the applicant of an authorization (to be placed on the market or to be placed in service). This demonstration can be based on a Cross-Acceptance between standards. This demonstration will then be proposed to the authorizing entity (NSAs or the relevant Agencies).

Cross-Acceptance [of a product, system or process]: is 'an aspect of the technical and legal process principally aimed at establishing the fastest route to the deployment of Product, System or Process in a target (new) context or **environment**. The Product, System or Process considered for cross-acceptance is generally assumed to satisfy the qualifications for reliability, tolerable safety and environmental performance in their native (original) context or environment' (c.f. [30]).

In this document, 'Cross-Acceptance' is understood as the fact that equivalence between two requirements of two different standards is recognized once for all and has not to be re-demonstrated each time. Cross-acceptance also includes cases where a re-demonstration is required, but only on particular issues.

ANNEX ZA/ZZ of standards and the Official Journal of the European Union

The listing of a European standard in the OJEU requires a positive assessment of the Harmonized Standard Consultant and a corresponding positive statement of the EC desk officer. Furthermore, it is required that the listed standard contains an Annex Zx (Annexes ZA generally refer to CEN standards whereas annexes ZZ refer to CENELEC Standards) detailing to which requirements of the directive (or TSI) it provides presumption of conformity.

Application Guides

For sake of clarity, the TSIs are also "accompanied" by application guides (AGs), written and published by the European Union Agency for Railways (ERA). These AGs provide guidance on how to fulfil the requirements listed in the TSI in detail. In order to achieve this, the AGs indicate which harmonised standards can be used to provide Presumption of Conformity, and how. Such references in the ERA AGs do, however, not have any legal standing. The legal certainty provided by the Presumption of Conformity comes from the combination of Annex ZA/ZZ AND the listing in the OJEU, hence their importance (c.f. [22]).

'RASCOP': Rail Standardisation Coordination Platform for Europe

RASCOP members, under the chairmanship of DG-MOVE: railway associations: EIM, CER, UNIFE, UITP, UIC, UIP, ERFFA, UIRR Chairs of CEN, CENELEC and ETSI Railway Technical Committees, European Union Agency for Railways, SFR officers, CEN-CENELEC Management Centre (CCMC), Shift2Rail Joint Undertaking (S2R)

RASCOP is a platform established by the European Commission contributing to streamlining the European standardization landscape with the EC and stakeholders.

The RASCOP primary objective is that the right documents are developed, in the right place, by the right actors, taking into account the European legal framework, the needs of the various stakeholder and the future developments of the railway system.

A secondary objective of RASCOP is to feed the reflexion among the stakeholders in the railway field on the relation between European and international standards and to foster the promotion of European Standards and TSIs outside of the EU.

'SFR': Sector Forum Rail (previously named JPCR, for Joint Programming Committee for Railways)

SFR Members: railway associations: EIM, CER, UNIFE, UITP, UIP, ERFA, UIC. Chairs of CEN, CENELEC and ETSI Railway Technical Committees, CEN-CENELEC Management Centre (CCMC)

SFR, as a joint co-ordination group of CEN, CENELEC and ETSI with participation of railway stakeholder organizations and in liaison with the EC and the Agency, has the mission to coordinate, plan, promote and facilitate the production and use of European standards for the benefit of the European sector

3 Problem description

3.1 General view on referenced standards

Today most of the Standards used in railways are specific to the railway domain and may be Referenced Standards.

However, non-railway standards which may provide the same level of quality and safety are globally accepted in other domains, are regularly applied in safety critical branches of industry including the transportation industry and are tolerant to the application of state of art technologies. Therefore, there is ample technical and economic justification to ease the use of Non-Railway Components compliant with globally accepted industry standards that ensure at least an equivalent RAMS level.

Since alternative standards that are widely used in substantially bigger markets (e.g. petrochemical industry, aviation and automotive) are also rigorous with the fit for use testing, they could viably permit the use of products from these bigger markets. Non-Railway Components especially designed for safety applications are generally certified against standards providing access to bigger markets and not against railway standards. This is for instance the case in markets for (safe) microprocessors, complete programmable logic controller and telecommunication related commodities in general where the railway sector is just a niche in a huge global market for industry and automotive.

It would be possible to address the problem in two ways:

➢ Open the option to apply well-proven and largely-applied standards as an alternative to railway-specific mandatory standards: it will speed up the introduction of new technologies in the railway industry.

➢ Facilitate the Cross-Acceptance against railway standards of off-the-shelf components already compliant with well-proven and largely-applied standards: it will enable the swift introduction and use in the railway domain of off the shelve products to the benefit of the European railway community.

This document aims first to explore those two possible ways of the problem statement in a general overview which is not specific to Control Command and Signalling.

The analysis addressing the specific case **of the safety standards referenced in the CCS TSI is conducted in a subsequent document, OCORA-BWS09-020-Delta.**

3.2 New challenge: introduction of innovation

Automation, digitalization and virtualization of functions require acceleration and simplification of the process of certification and safety demonstration of both individual Non-Railway Component and of the whole system composed of those individual Non-Railway Components.

When applied to future innovations that are envisaged for the rolling stocks and infrastructure, the main concerns are:

➢ For certification: How to certify Non-Railway Components for the railway domain?

   o e.g. a Computing Platform or a fail-safe GNSS-based localisation, which are already used in safety applications outside the railway sector

➢ For lifecycle management: How to make possible to add, in the global architecture, off-the-shelf component compliant with either railway standards or other standards

Facilitating the use of Non-Railway Components may help enhancing the ability to manage systems over the life cycle, improving user satisfaction, protecting IT investments, maximizing return on investment and reducing life cycle costs. The installed base for products will be enlarged because suppliers from different sectors of activity can dynamize the market. Supply chain integration will be facilitated.

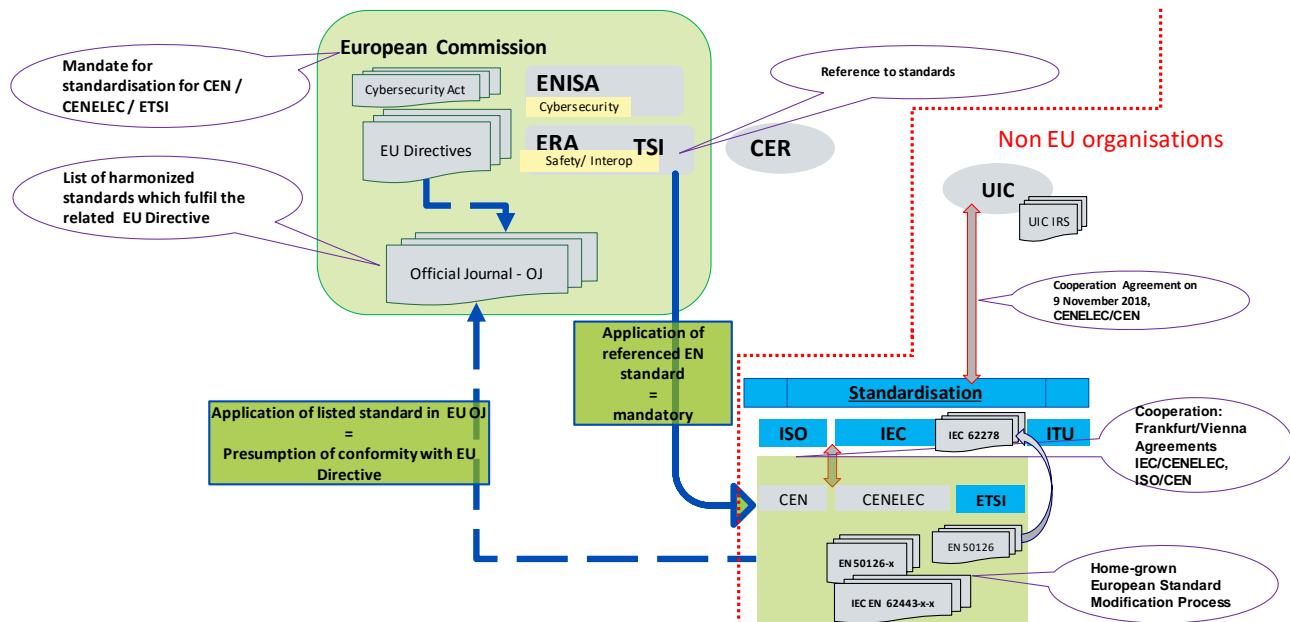# 4 The role of the European Agency for Railways and the European Commission in Standardisation

Figure 1　　Standardisation and regulation

The standardization ecosystem within Europe is based on the following steps:

a) The need for a new standard (or update of an existing standard), which can occur from 2 possible ways:

- o Technical committees within the European standardisation organisations (CEN, CENELEC, ETSI) identify the request for publication/update of a standard submitted by National Committees

- o The European Commission identifies the need for a standardisation project and defines this request by sending a standardisation request to a European standardisation body (CEN, CENELEC, ETSI). This is based on a mandate from the Commission toward a given standardisation body technical committee.

b) Based on Agreements, the European standardisation bodies work together with the international standardisation bodies

- o IEC – CENELEC cooperation based on Frankfurt Agreement [31]

- o ISO – CEN cooperation based on Vienna Agreement [32]

The agreements between ISO / IEC and CEN / CENELEC aim to avoid the duplication of work and reduce time when preparing standards. They follow the principle:

New standardisation projects shall be addressed on international level. Only in case there is no need for international standardisation, a project can be started on European level. This principle is applied for CEN and CENELEC projects. ETSI is organized differently.

In most technical committees at CEN / CENELEC it is agreed to follow a parallel vote process. This means that standards for vote at International level, will be circulated at European level at the same time.

ERA is willing to establish liaisons with technical committees beyond the European area. The liaison with ISO TC269 is established and a liaison with IEC TC9 is underway. These liaisons enable the chance to implement on IEC / ISO standards annexes related to European directives and European regulations, especially TSI documents produced under ERA responsibility.

5 First thoughts towards a standardization strategy

The CEN/CENELEC Management Centre (CCMC) identifies in document [22] some key questions to be addressed by any standardization working group when dealing with a work item:
1. Does this standard have a necessity to be destined for harmonisation?
2. Is there any specific sense and added value to consider this standard as a needed and appropriate support to a specific part of the legislation?
3. Does the standard (or part of it) requires a mandatory application and should thus be integrated in the legislation or should it stay voluntary?

OCORA identifies the following additional questions to address in order to foster innovation and accelerate the certification process:

Could other largely-applied and widely-used standards be considered as an alternative for this work item?
  a. If so, what are the benefits and drawbacks for the railway sector in using those alternative standards?
  b. What are the interfaces and interaction with other railway/non-railway standards?

Additionally, in a more generic view, it would be necessary to answer to the following question:

Is it possible to establish a railway-specific Annex Zx for a Global Standard?

Figure 2 depicts the overview towards the acceptance of global standards.

Figure 2   Standardization and regulation hierarchy: Overview toward Acceptance of Global Standards
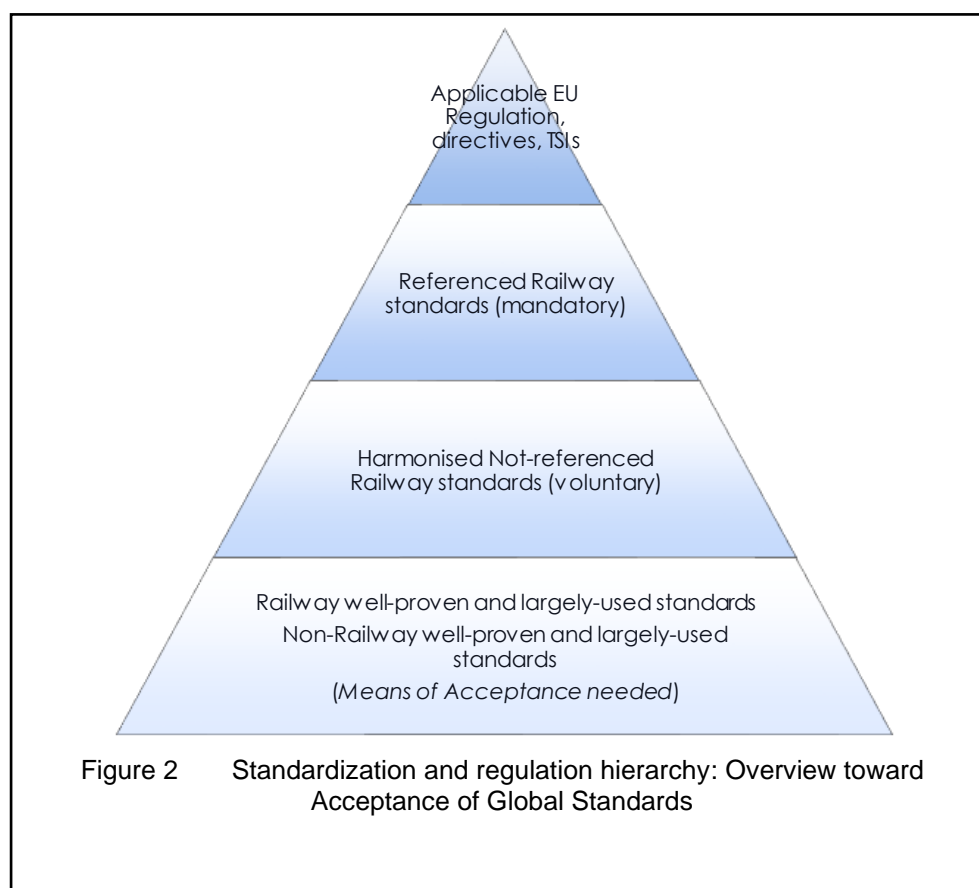
5.1 Pros and Cons: voluntary versus mandatory standards and revised version of standards

Today, "the application of a TSI-referenced standard remains mandatory even though a revised version of the same standard might be listed in the OJEU as harmonised standard. For fulfilling the requirements of the TSI, there is currently no free choice of the version of the standards in this respect" (c.f. [29]). The European legislation is referencing European Standards from CEN, CENELEC or ETSI or other normative documents as parts of the TSI requirements. Such standards, produced originally by the rail sector on a voluntary basis, have thus become "mandatory" into the regulatory domain. Today, over 160 European standards are referenced in this way in the TSIs. Several drawbacks have become obvious, particularly due to the fact that the referenced standards evolve over time thus becoming unaligned with the TSIs. Changes brought in each TSI require to assess the evolutions in the referenced standards. This increases the regulatory gap that must be considered when adapting an existing product to a new regulatory framework.

Tomorrow, "the possibility to use also revised versions of referenced standards is foreseen to be achieved by future amendments of the TSI. These amendments will only concern the TSI Annex listing the referenced standards. The amendment will be designed in a way that will leave the applicant the choice between the older or the newer version of the standard, provided the newer version is still considered to fulfil the needs of the Directive or related TSI" (c.f. [29]). Flexibility in the application of the revised version of standards or the previous version would allow a smooth transition and reduce legal uncertainty. This flexibility is possible as long as no incompatible specifications are introduced in the revised version of the standards.

As stated in the Interoperability directive[1], removal of the reference to standards where not "strictly necessary could be an additional step to consider in the context of the European "New Approach" for better regulation and reducing the complexity of maintaining the alignment of the references between standards and legislation. In that case, only the proper and correct expression of the strictly necessary essential requirements should be maintained in the legislation in the TSIs, while the detailed specifications corresponding to those requirements should be expressed in the standards. The advantage of this approach would be to have coherence between the work conducted for EU standardization on one hand and the European legislation on the other hand.

5.2 How to introduce other standards to boost innovation?

In order to boost innovation, OCORA is investigating a third approach to consider largely used and well-proven Standards (including. Global Standards coming for other sectors) as an identified alternative to provide presumption of conformity with the EU legislation or to be used as an alternative to an existing referenced standard with potential mitigations in case of gaps between those standards.

Two specific orientations are possible depending on the existence or not of referenced standards in the TSIs.

Regarding the first orientation: when no referenced standards exist in the regulatory framework

➢ A first step would be by means of Acceptable Means of Compliance (AMOC). The directive (EU) 797-2016 introduced the notion of AMOC "Acceptable Means Of Compliance" as non-binding opinions issued by the Agency to define ways of establishing compliance with the essential requirements. The AMOC would then define at the EU level alternative standards. This step, if adopted by the Agency,

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[1] *The Interoperability Directive Article 4.8 mentions 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 necessary** in order to achieve the objectives of this Directive."*

could be a quick and efficient mean to boost innovation. It is a first step toward the presumption of conformity of a given Global Standard, or even a railway standard.

➢ A second step would be to allow this standard to provide Presumption of Conformity: Such alternative standard could be allowed <u>by means of an Annex Zx</u> (or equivalent) detailing to which requirements of the TSIs (or Directive) presumption of conformity is provided for. It has to be noted that if the Global Standard is already adopted as an EN standard, this step is necessary. The creation of this opportunity requires that:
  • an EC mandate identifies this alternative standard and provide the essential requirements it should fulfil
  • the Annex Zx redaction must be undertaken.

Such acceptance of Global Standards would additionally require a positive assessment of the HAS Consultant and of the EC desk officer. The maintenance process of this standard could then be an opportunity to create this Annex Zx.

A possible drawback of this orientation may be the time before the recognition of an alternative Global Standard could effectively occur.

The second orientation: when standards are referenced in the TSI

The approach for this orientation, is through the introduction of Cross-Acceptance guidelines in the legal framework, or in the standardization framework, or if duly justified, in the application guide of a TSI. This Cross-Acceptance guideline concerns the supplementary requirements/conditions to fulfil in order to accept the Cross-Acceptance of a Non-Railway Component which was originally developed and approved with an alternative Standard, meaning that this alternative standard is comparable in terms of requirements. The demonstration of fulfilment may be given by complementary assessment or evaluation or analysis or audit.

5.3   What are the benefits and drawbacks in maintaining "bridges" between EU railway standards and global standards?

Where will the centre of gravity of standardization stand tomorrow? Observers of the Technological world may recognize for many reasons a shift from European to International as the results of globalization and the digital revolution.

The benefit of creating bridges between EU railway domain and alternative Global Standards would be to reduce the need (and cost) for re-certification under the EU legislation and simplify the use of existing Non-Railway Components. Reciprocally, another benefit of such gateways, especially for the railway supply industry, would be to foster the capturing of new market shares in other industrial sector, on the basis of railway-specified components and products.

The drawback lies in the necessity to continue to maintain a periodic assessment of this other alternative standard against the directive (or TSI) evolution, and/or the existing referenced standard, and/or this alternative standard.

Therefore, we propose to limit this effort to identified Global Standards, i.e. well-proven and largely-applied standards adopted by an international body or a European standardization organization in a different domain than the railway sector.

6   Next steps and conclusions

The proposed next steps in terms of methodologies for Acceptance of Global Standard Workstream are:

  • To offer through this document a global overview of the objectives on the Acceptance of Global standards

- To focus on the CCS safety and RAMS and apply the Acceptance of Global Standards on the IEC 61508 to provide the preliminary elements for a cross-acceptance in safety and RAMS

- Then, to develop a guideline for Cross-Acceptance in the frame of a Non-Railway Component developed and approved under the global standards IEC 61508-x as an alternative to the referenced CENELEC 50126/8/9 in the CCS TSI.

Innovation take-off in railway industry could be enhanced by multiple ways:

- By opening the opportunity to find "bridges" between well-recognized standards and railway-specific standards in order to diversify the supply of components and expand the market to other sectors.

- By simplifying the recertification of equipment already certified with well-proven standards from other sectors such as aeronautics and space when applicable.

- By better highlighting and isolating in EU railway standards the railway-specific parts from the non-railway specific parts, so that they can be easily applied for certification.

Recognizing:

- the limited size of overall EU railway market volumes,

- the fierce competition between railway, automotive and aviation sectors,

it is of paramount importance that the European railway sector carefully address its standardisation strategy to foster innovation and boost its market share. In order to do so our objectives are defined as:

➢ Facilitate, for the railway industry, the use of off-the-shelf components compliant with well-proven and largely-applied standards

➢ Reduce the time necessary to introduce new technologies in the railway industry

➢ Allow for safety-related electronic systems, the use of well-proven and largely-applied standards

➢ And ensure the safety levels required by CSM are still reached

OCORA collaboration is therefore proposing to further study this item with European organizations (CER, EIM, CENELEC, CEN, JPCR, NBRAIL, ERA, UNIFE, …).