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RECOMMENDATION FOR USE

NB-RAIL COORDINATION GROUP

Administrative Decision according to Interoperability Directive
(EU) 2016/797 art. 30.6



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RFU-STR-088

Issue 02

Date 02/03/2021

TITLE

Scope of Conformity Assessment Requirements for the Conformity Assessment by NoBos

ORIGINATOR

NB-Rail STR SG

SUBJECT RELATED TO

Directive (EU) 2016/797
Decision 2010/713/EU
(with references to
Regulation (EC) No 765/2008
Decision No 768/2008/EC)

AMENDMENT RECORD

ISSUE 02: AMENDED ACCORDING 4RP LEGAL FRAMEWORK

DESCRIPTION AND BACKGROUND EXPLANATION

1) Introduction

The legal provisions relating to NoBo conformity assessment activities are often considered to be complex and complicated. Therefore different interpretations have been developed over time. To avoid any contradictions in approach and clarify the situation, this RFU summarises the relevant issues and arguments for **Conformity Assessment Requirements**.

In the framework of the EC verification process according to Directive (EU) 2016/797 various Conformity Assessment Requirements for the object of conformity assessment (Subsystem or IC) are established. Each Conformity Assessment Requirements can be assigned to one of the following scopes of requirements:

Scope 1) Essential Requirement (as defined in the Article 2 (9) and in the Annex III of Directive (EU) 2016/797)

Example of scope 1) The Subsystem Locomotive Type xyz including all its parts, interfaces as well as it's operational and maintenance and decommissioning provisions shall be meeting the Essential Requirement 'Safety'.

Conformity Assessment Requirements of this scope are not detailed enough for the practical conformity assessment and require further detailing via:

- Either Scope 2
- Or Scope 3 in combination with Scope 4.



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Scope 2) TSI text on basic Parameters formulated as **directly assessable Conformity Assessment Requirement**

Example of Scope 2) The height of an automatic centre buffer coupler above rail of its coupling centre line shall be 1 025 mm + 15 mm /- 5 mm (measured with new wheels in load condition 'design mass in working order').

Scope 3) TSI text on basic Parameters **not** formulated as **directly assessable Conformity Assessment Requirement**

Example of Scope3) The bearing condition shall be evaluated either by monitoring its temperature, or its dynamic frequencies or some other suitable bearing condition characteristic.

Scope 4) Requirements contained within

- a) (parts of) harmonised standards and/or
- b) Alternative Solutions

as **selected/defined by the Applicant** in order to establish from the related TSI text on basic parameters under scope 3) an **assessable Conformity Assessment Requirement**

2)Mandatory References from a TSI to External Documents

According to (EU) 2016/797 Art. 4(8) TSIs may establish a reference to other documents which 'shall be regarded as annexes to the TSI concerned and shall become **mandatory** from the moment the TSI is applicable'.

This is a frequently used variation on the aforementioned Scopes 2 or 3.

Where a TSI refers to an external document (e.g. a standard, an ERA Technical Document, a legal document) such a referenced document becomes mandatory for Applicants and NoBos while they apply that TSI.

Each of the Conformity Assessment Requirements contained in the external document **must be considered itself to be falling under Scope 2 or Scope 3.**

A Mandatory Reference may be to the full external document or a certain part of it.

Such a reference may be to a certain defined version/ revision/ status of the external document (which may be a historic version/ revision/ status).



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In this case exactly that defined version/ revision/ status is mandatory and must be applied by Applicants and NoBos.

Where no reference to a specific version/ revision/ status is provided, that version which was valid at the time of adoption of a TSI shall be taken (usually contained in the heading of a TSI).

Note: Care must be taken, when the document to which a Mandatory Reference applies is published in a new release:

*a) Where a Mandatory Reference **points to a standard**, and this standard has already been published in a new release, this new release of the standard may only be used,*

- *if a revision of that TSI permits the application of the new release of that standard. (Even if this new release is already published in the list of harmonised standards in the Official Journal of the European Union for 'voluntary' application, then still the quoted standard in the TSI stays mandatory!)*
- *if an ERA Opinion defines that a certain Mandatory Reference to the old release of a standard shall be replaced by a Mandatory Reference to the new release of that standard (refer to Art.6 of (EU) 2016/797).*

*b) Where a Mandatory Reference **points to a legal document**, usually a new release of the legal document defines that all references to the old release must be construed as a reference to the new release.*

In general: Where a new release of a Mandatory Reference document is not in conflict with the previous release, the new release may be used as 'voluntary' Alternative Solution in addition to the old release.

3) Coverage of TSIs:

TSIs contain Conformity Assessment Requirements for Subsystems and the Basic Parameters which relate to these Subsystems.

Article 2 of the Directive (EU) 2016/797 defines that:

- 'Subsystems' means the structural or functional parts of the Union rail system", as set out in its Annex II" (Art.2.(5))
- 'Basic Parameter' means any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs." (Art. 2. (12))

For each Basic Parameter the TSIs - via Scope 2 & 3 (see section 1 of this RFU) - provide requirements for the object of conformity assessment (subsystem or IC).



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Besides, according to Article 4(1) of this Directive, *“each of the subsystems defined in Annex II shall be covered by one TSI. Where necessary, a subsystem may be covered by several TSIs and one TSI may cover several subsystems”*.

The TSI defines for each requirement, whether it shall be assessed by either a NoBo, a DeBo or the Applicant. (In some cases a TSI may permit for certain defined requirements (e.g. TSI-CSM scope) that the assessment may be performed by an AsBo instead of the NoBo. Refer to RFU-STR-706 for this case.

Only where a TSI requires Basic Parameters to be assessed by a NoBo, these shall be subject to NoBo assessment.

4)Standards:

Standards contain Conformity Assessment Requirements. As mentioned in section 1) of this RFU, there is a relation between TSIs and Standards.

The use of the term ‘Standard’ and related definitions such as ‘European standard, harmonised standard’ are defined by Regulation (EU) 1025/2012 Art. 2:

‘**standard**’ means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

‘**international standard**’ means a standard adopted by an international standardisation body (e.g. ISO or IEC);

‘**European standard**’ means a standard adopted by a European standardisation organisation (e.g. CEN or CENELEC);

‘**harmonised standard**’ means a ‘European standard’ adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;

‘**national standard**’ means a standard adopted by a national standardisation body.

This is further defined in several EU legal documents:

(EU) 1025/2012 ‘whereas’ (5) defines that: **European standards** play a very important role within the internal market, for instance through the use of **harmonised standards** in the **presumption of conformity** of products to be made available on the market with the **Essential Requirements** relating to those products laid down in the relevant Union harmonisation legislation.



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(EU) 1025/2012 defines in Art.10(6) further: Where a **harmonised standard** satisfies the [Conformity Assessment] requirements which it aims to cover and which are set out in the corresponding **Union harmonisation legislation** [e.g. (EU) 2016/797], the Commission shall **publish a reference of such harmonised standard** without delay **in the Official Journal of the European Union** or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation.

The IOD (EU) 2016/797 in 'whereas' (61) relates to this principle: This Directive should be limited to establishing the interoperability requirements for interoperability constituents and subsystems. In order to facilitate compliance with those **requirements [=Conformity Assessment Requirements]**, it is necessary to provide for a presumption of conformity for interoperability constituents and subsystems which are in conformity with **harmonised standards** that are adopted in accordance with Regulation (EU) No 1025/2012 for the purpose of expressing detailed technical specifications relating to those requirements.

This is further contained in IOD (EU) 2016/797 Art.17 (**Presumption of conformity**): Interoperability constituents and subsystems which are in conformity with **harmonised standards or parts thereof**, the references of which have been **published in the Official Journal of the European Union**, shall be **presumed to be in conformity** with the **Essential Requirements** covered by those **standards or parts thereof**.

At the time of writing of this RFU, COMMISSION IMPLEMENTING DECISION (EU) 2020/453 contains the current list of **harmonised standards** for application with IOD (EU) 2016/797.

Note: The reference to 2008/57/EC contained in this list shall via (EU) 2016/797 Art.57&58 taken as a reference to (EU) 2016/797.

Updated versions of this list are from time to time published in the Official Journal of the European Union.

A link to this list is provided via: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

Note: GRB fact sheet '202007 SFR GRB Fact Sheet_Standardisation Ref & Harmon Standards' can enhance the comprehension of the full picture of this topic <http://grbrail.eu/index.php/joint-letters-position-papers#>.

It is very important to note, that the list of harmonised standards in the Official Journal of the EU can not be used as an argument to modify on project level (e.g. by



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Applicant or by the NoBo) any Mandatory Reference document contained in a TSI.
Where a conflict arises, the Mandatory Reference in the TSI takes precedence.

*Only if the new release of such a harmonised standard is **not in conflict with the Mandatory Reference** previous release, the new release may be used as 'voluntary' Alternative Solution in addition to the old release. The Applicant has in any situation to demonstrate the conformity of the subsystem or IC with the Mandatory Reference as contained in the TSI (refer also to section on Mandatory Reference in this RFU).*

5)Alternative Solutions:

According to Module Decision 2010/713/EC, the applicant shall lodge with the NoBo the set of 'solutions adopted to meet the requirements of the relevant TSI(s) where harmonised standards have not been applied. In the event of partly applied harmonised standards, the parts shall be specified which have been applied'.

The selection of a Standard from a list of harmonised standards published in the Official Journal remains for the Applicant **voluntary**.

Note: Harmonised standards which are published in the Official Journal can be regarded as a proposed solution.

To distinct the used harmonised standards from the 'mandatory references', they are often named 'voluntary standards'.

'Voluntary' does not indicate, that they may simply not applied.

The term 'voluntary' is in this context indicating, that the application of this standard gives direct **presumption of conformity**, but it's application is voluntary in the sense, that an **Alternative Solution** to the standard is equally acceptable, **if equivalency** with the (part of) standard it replaces **can be demonstrated** by the Applicant:

Other **Alternative Solution** are permitted under demonstration of their

- **equivalence to harmonised standards** and
- **compatibility with the TSI requirements** and
- **compatibility with the Essential Requirements**

by the Applicant (refer to each of the modules within Module Decision 2010/713/EC).



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Further guidance on this principle to replace harmonised standards by Alternative Solutions may be taken from several sections of the COMMISSION NOTICE 'The Blue Guide' on the implementation of EU products rules 2016 (Text with EEA relevance) (2016/C 272/01)), e.g. section 4.1.3. <https://ec.europa.eu/docsroom/documents/18027/attachments/1/translations>

Should the lists of Standards not define any (part of) Standard which may be applied in connection with a given Scope 3) TSI basic Parameter, the Applicant may directly proceed to define an Alternative Solution detailing the Conformity Assessment Requirements. In this situation, the Applicant shall justify to itself the applicability of the Alternative Solution against the Scope 3) TSI basic Parameter.

An **Alternative Solution may also be** a code of practice or similar document not contained in the lists, e.g. an EN, ISO, prEN, historic EN or ISO standard, a UIC or ERRI leaflet, a National Rule or an ERA Technical Document, ERA Advise, other ERA documents not quoted in a TSI (e.g. ERA guidance & contained lists of standards), etc.

A **project specific Alternative Solution may also be developed** (e.g. based on risk identification and risk assessment) and validated by the Applicant, provided the Applicant may justify this to itself to be equivalent with a standard from the published lists.

In no case, an Alternative Solution may oppose or diverge from requirements of a TSI or another EU legal document.

Note: It should be understood by all stakeholders, that the application of Alternative Solutions requires typically more effort – caused e.g. by demonstration the equivalency and its subsequent more complex assessment by the NoBo - than a direct application of a (part of) Standard from the published lists.

Applying a (part of) Standard from the lists may be considered as a preferred solution from an EU common market point of view.

However, an Alternative Solution remains always available to the Applicant in relation to Scope 4 Conformity Assessment Requirements.

6)RFUs of NB-Rail:

The application of RFUs is mandatory for NoBos (as they form administrative decisions according to Interoperability Directive (EU) 2016/797 art. 30.6).



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RFUs may contain requirements for the EC conformity assessment process/ method or they may include clarifications on requirements for the object of conformity assessment (Subsystem or IC).

Note: The primary objectives of an RFU are to clarify and standardise towards a single pan-European approach among all NoBos.

7) ERA Opinions:

ERA may from time to time provide Opinions (previously also called Technical Opinions (TOs)) in accordance with (EU) 2016/797 Art. 6(2&3).

Where ERA has published on their webpage

https://www.era.europa.eu/library/opinions-and-technical-advice_en

they shall constitute 'acceptable means of compliance' and may therefore be used for the conformity assessment of Subsystems or ICs, pending the 'adoption' of a revised TSI.

8) Selection of Conformity Assessment Requirements:

Based on the explanations in (EU) 2016/797 Annex IV (1) defines: "EC" verification' means a procedure carried out by the applicant within the meaning of Article 15 to demonstrate that the requirements [=these include the **Conformity Assessment Requirements**] of the relevant Union law and any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.

(EU) 2016/797 Art.15(2) defines further: The applicant shall establish the 'EC' declaration of verification of a subsystem. The applicant shall declare on his sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements [=these include the **Conformity Assessment Requirements**] of relevant Union law and any relevant national rule.

In relation to the Conformity Assessment Requirements of Scope 4 it is understood, **the Applicant has to choose/determine these Requirements as part of its product design activities under its sole responsibility**. A NoBo who would "support" an Applicant at this part of the design activities, would perform consultancy in the meaning of ISO 17065. Such consultancy is prohibited (refer to ERA Assessment Scheme and ISO17065) for NoBos.



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Note: This does not preclude

- *the possibility of exchange of information (e.g. explanations of findings or clarifying requirements, choice of standards) between the certification body and its clients and*
- *the use, installing and maintaining of certified products which are necessary for the operations of the certification body.*

Refer to Note 1 to clause 4.2.6 of ISO/IEC 17065:2012 and EA-2/20 G: 2020 'Consultancy, and the Independence of Conformity Assessment Bodies'.

https://european-accreditation.org/wp-content/uploads/2020/04/EA-2-20_Consultancy_rev00_April-2020.pdf

9) Definition of Assessment Scope for NoBos:

9.1) NoBos are not obliged to assess a Subsystem/IC directly against all essential requirements of Directive (EU) 2016/797 (refer section 1 of this RFU, Scope 1):

Conformity assessment of **full compliance with all Essential Requirements** is the responsibility of the Applicant (in co-operation with the manufacturer(s)). In addition (EU) 2016/797 provides for the involvement of a NoBo, a DeBo or accredited in-house conformity assessment body in certain situations.

It can be taken from the EU Blue Guide (2016/C 272/01) section 5, that in the (EU) 2016/797 the NoBo and DeBo have been introduced to perform the conformity assessments in such cases, where there is a specific need for third party level trust in competent, independent and impartial assessment results.

The results of the required conformity-assessment activities are a prerequisite for the Applicant's EC Declaration in the context of (EU) 2016/797 (refer to Art.9&10, Art 15 (in connection with Art. 18 or 21) and Annex IV).

In this context the assessment of NoBos is limited to the assessment of the Essential Requirements **through**

- those Conformity Assessment Requirements contained in the applicable TSIs only (**Scopes 2 and 3**) or
- as **chosen/determined by the Applicant** as necessary supporting Conformity Assessment Requirement (**Scope 4**).



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Note: This differs from the 'standard' task for Notified Bodies to the "New Approach" within Decision No 768/2008/EC (see R18 and the 'standard' Modules) to assess directly against the Essential Requirements (Scope 1) in combination with the supporting Conformity Assessment Requirement (Scope 4) as chosen/determined by the Applicant.

This is caused by certain distinctly different provisions in (EU) 2016/797:

- *Directive (EU) 2016/797 was made only 'in the spirit of' the new approach, and includes specific definitions and solutions.*
- *Directive (EU) 2016/797 (Art.1) establishes the conditions to be met to achieve interoperability within the Union rail system in a manner compatible with Directive (EU) 2016/798 and, therefore is interfacing with the latter Directive, for instance, in relation to a.o. technical compatibility, safe operation, maintenance and decommissioning. This results in large areas of safety aspects not being subject to NoBo assessment, as these safety aspects are subject to the related provisions under Directive (EU) 2016/798.*
- *Directive (EU) 2016/797 defines TSIs as an additional layer of more detailed Conformity Assessment Requirements between the Essential Requirements and the Harmonised Standards*
- *Decision 2010/713/EU defines specific assessment Modules for Conformity Assessment, different from the 'standard' modules of Decision No 768/2008/EC.*
- *A TSI may define in Section 6 specific methods for the conformity assessment activities.*

9.2) NoBos are obliged to assess a Subsystem/IC against TSI text on basic Parameters formulated as directly assessable requirement (refer section 1 of this RFU, Scope 2):

This also applies to Mandatory References contained in the TSIs, where they include Scope 2 requirements.

9.3) NoBos are obliged to assess a Subsystem/IC against TSI text on basic Parameters NOT formulated as directly assessable requirement (refer section 1 of this RFU, Scope 3):

In this case conformity assessment of these requirements must be done in combination with further and more specific requirements as chosen/determined by the Applicant under Scope 4) below.



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This also applies to mandatory references contained in the TSIs, where they include Scope 3 requirements.

9.4) NoBos are obliged to assess a Subsystem/IC against Requirements contained within Alternative Solutions - as chosen/determined by the Applicant and related to the TSI text on basic Parameters under Scope 3 (refer section 1 of this RFU, Scope 4):

(EU) 2016/797 and Decision 2010/713/EU requires either the application of 'Harmonised Standards' (refer to section 3 of this RFU) or Alternative Solutions consistent with the TSI Requirements (refer to section 8 (in connection with section 5) of this RFU).

The NoBo must assess the object of conformity assessment (subsystem or IC) against the TSI Requirements in combination with the Alternative Solutions as chosen/defined by the Applicant. (refer to section 8 of this RFU)

For clarity: The Applicant is **not required to demonstrate to the satisfaction of the NoBo** that their chosen/determined set of proposed Alternative Solutions, or indeed any individual Alternative Solution, comply with the Essential Requirement of Directive (EU) 2016/797. This is part of the Applicant's activities when preparing the EC Declaration, as explained above in this RFU. It remains the duty of the NoBo to ensure compliance with TSI parameters.

*Note: Where during the conformity assessment, a NoBo considers by judgement of their experts, that an Applicant may have made an unsuitable/ inconsistent/ implausible choice/determination of a certain Scope 4 Conformity Assessment Requirements, it is **highly recommended that the NoBo communicates this finding to the Applicant without delay.***

*This shall enable the Applicant to review the situation (especially for safety related aspects), but **the NoBo cannot demand a modification by the Applicant or block the conformity assessment** where an Applicant does not react to such an information in a particular way.*

It is also highly recommended that the NoBo retains a record on such a communication and the associated answers of the Applicant.

Due to the confidentiality requirements of ISO17065 (which apply via the ERA Assessment Scheme, Technical document MNB - Assessment scheme 000MRA1044 ver 1.1) the NoBo shall only communicate in this regard with its client.



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10) Additional Information:

Often a single TSI section/ functional description (of a Parameter) as worded in a TSI may contain a large number of **individual requirements**. These may relate individually to scope 2) or scope 3).

It is recommended, that when the NoBo uses checklists, it identifies the individual Conformity Assessment Requirements as separate CL points and in case of Scope 3) requirements, assigns the related detailed Scope 4) Conformity Assessment Requirements clearly (e.g. (part of) a harmonised standard and/or an Alternative Solution).

Note: For **any individual requirements** under Scope 3), a related (part of) harmonised standard **and/or** Alternative Solution must be provided to the NoBo by the Applicant (refer to section 5 of this RFU).

All (parts of) harmonised Standards or Alternative Solutions used for assessment under scope 4) must be listed in the NoBo File under section 5.4 and 6(2).

If only parts of a Standard were chosen/defined by the Applicant as relevant and were thus to be applied during the conformity assessment, these parts must likewise be indicated in the NoBo File under section 5.4 and 6(2).

RFU PROPOSAL

NoBos are **not obliged** to assess a Subsystem/IC against:

- All **Essential Requirements** of Directive (EU) 2016/797 (**Scope 1**).

NoBos are **obliged** to assess a Subsystem/IC against:

- TSI text on basic Parameters formulated as **directly assessable requirement (Scope 2)**.
- TSI text on basic Parameters **not** formulated as **directly assessable requirement (Scope 3)**. **In this case** assessment must be done in combination with further and more specific requirements defined under scope 4).
- Requirements contained within (parts of) **harmonised standards** and/or **Alternative Solutions, (Scope 4) - as chosen/determined by the Applicant** and related to the TSI text on parameters under scope 3)



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NoBos may not advise/consult/require an Applicant at the choice/determination of Scope 4 Conformity Assessment Requirements.

Note: The DESCRIPTION AND BACKGROUND EXPLANATION sections of this RFU summarises conditions on the definition and assessment of these harmonised standards and Alternative Solutions by the Applicant.

THIS RFU WAS AGREED ON

PLENARY MEETING 61

THIS RFU ENTERS INTO FORCE ON

02/03/2021 (DATE OF PUBLICATION)

FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.

RFU APPLICATION IS MANDATORY STARTING FROM

02/03/2021

AT THIS DATE ANY PREVIOUS VERSIONS (OR, ALTERNATIVELY, VERSION XX) OF THIS RFU WILL BE WITHDRAWN.

RFUs SHALL BE APPLIED BY ALL NOBOS. PLEASE REFER TO RFU-STR-702, CHAPTER 3 OF THE SECTION "DESCRIPTION AND BACKGROUND EXPLANATION", FOR THE LEGAL BASIS SUPPORTING THIS OBLIGATION.

ERA COMMENTS

PM 61 – 25/02/2021: NO COMMENTS - OR SPECIFY IF ANY

ERA DISCLAIMER WILL BE INCLUDED