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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-711

Issue 01
Date 06/03/2024

TITLE

DEFINITION OF NoBos CONFORMITY ASSESSMENT SCOPE

ORIGINATOR

RINA, ARSENAL RACE

SUBJECT RELATED TO

IOD (EU) 2016/797, all TSIs from
09/2023 on

AMENDMENT RECORD:
06/03/2024: FIRST ISSUE.

DESCRIPTION AND BACKGROUND EXPLANATION

Scope:

This RFU deals with the definition of the conformity assessment activities of Notified Bodies (NoBo) given in the IODs and in the different TSIs. Conformity assessment activities by NoBos include the EC verification of subsystems and the assessment of conformity or suitability for use of interoperability constituents.

This RFU deals only with the requirements that are applicable to the NoBos. Sometimes responsibilities of other bodies are also mentioned, so to clarify the boundaries of the scope of the NoBo to parts where other bodies are responsible.

Background Explanation:

The IOD and TSIs contains many requirements for various different actors. Many requirements have to be assessed by NoBos within the conformity assessment process. However, some requirements have to be considered by other actors such as the applicants, Designates Bodies (DeBo), Assessment Bodies (AsBo) or NSAs/ERA.

Legal background:

The definition of the work for the NoBos is given in the following articles of IOD (EU) 2016/797:

- Art. 10.2 for interoperability constituents (IC)
- Art. 15.1 and 15.3 and Annex IV, 2. for subsystems

The definition of the work for the DeBos is given in the following articles of IOD (EU) 2016/797:

- Art. 15.8 and Annex IV, 3. for subsystems

Following these articles, it is clear that the national rules have to be assessed by the DeBo. Article 13.2 of IOD (EU) 2016/797 defines for which cases national rules apply.

Note: When reading Art. 4 of TSI INF (EU) No. 1299/2014 and TSI ENE (EU) No. 1301/2014 (in the original version without amendment (EU) 2019/776) it could be understood that DeBos have to assess all specific cases. However, this is not the case;

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with the legal basis from the IODs (as explained above), it is clear that only those specific cases that require national rules not included in the TSI have to be assessed by a DeBo. The TSI amendment (EU) 2019/776 clarifies this by rewording the Article 4. It states that the DeBo carries out conformity assessment for the national rules relating to the specific cases only. The same understanding and concept have to be used for all TSIs.

RFU PROPOSAL

NoBo scope of work is defined by:

- the relevant TSI(s) that apply to a product, and
- the module/modules chosen by the client amongst those which are allowed in the relevant TSI(s).

The following text is focusing only on TSI requirements which apply to NoBos. Other requirements (e.g. from Modules Decision) shall be also taken into account, but they are not mentioned in this RFU.

Each external document (or part thereof) referred in a TSI becomes automatically part of the TSI, and by consequence its application is mandatory.

The TSI contains also many explanations, definitions and requirements that have to be assessed by other actors. However, the NoBo still has to know them and – especially for explanations and definitions – apply them correctly. In the following, only those parts that form directly a requirement to be assessed by a NoBo are identified.

In detail, the requirements of the subsystems and interoperability constituents to be assessed by the NoBo are defined as follows:

- a) for all subsystems: chapter 4 based on the assessment tables provided in Annexes of each TSI or chapter 6 (TSI CCS only), see letter e) below. That means, if a requirement from TSI chapter 4 is not included in this assessment table, then this requirement does not have to be assessed by a NoBo. Requirements which shall be assessed by a NoBo are:

- i. including subchapter 4.2 “Functional and technical specifications of the subsystem(s)”.

Note: if the requirements of one subsystem necessitate values from another subsystem, then these values have to be provided by the applicant to the NoBo. The NoBo is not required to re-assess the correctness of such values obtained from the applicant. However, if the NoBo identifies that a value appears to be non-plausible, then it is highly recommended that the NoBo informs the applicant about this finding.

- ii. excluding subchapter 4.3 “Functional and technical specifications of the interfaces to other Subsystems”

Note: The interfaces to other subsystems are designed in a way that the requirement for one subsystem can be assessed independently from the

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requirement of the other subsystem. Therefore, the respective requirement within the subsystem under assessment is checked, while the referenced requirement of the other subsystem is not assessed. Consequently, the subchapter 4.3 does not include any requirements to be assessed by the NoBo.

- iii. excluding subchapters on “professional competencies/qualifications”, “health and safety conditions”, “registers” and “route compatibility checks before the use of authorised vehicles”
- iv. for subchapters on “maintenance rules” and “operating rules”: these elements shall be assessed by the NoBo as far as detailed requirements are contained in chapter 6 and/or tables in Annexes of a TSI (see e) below)
- b) chapter 5 for ICs based on the assessment tables provided in Annexes of each TSI or chapter 6 (TSI CCS only), see letter e) below:
- c) chapter 6 for the assessment procedures in combination with chapter 4 and 5. This includes all requirements in chapter 6 that are linked to requirements of chapter 4 that are part of the tables (see letter e) below) as well as all requirements that are related (generic and/or specific topics) to EC verification of subsystems and the conformity or suitability for use assessment of interoperability constituents.
- d) chapter 7 for implementation
 - i. including those specific cases, where no national rules are needed
 - ii. excluding those specific cases that requires the application of national technical rules not included in the relevant TSI
 - iii. including those requirements which need an assessment for mutual recognition (e.g. chapter 7.1.2 of TSI WAG)
- e) annexes of each TSI (different numbering in each TSI)
 - i. In each TSI (except for TSI CCS) an annex for the assessment of ICs (if existing) and subsystem(s) is present. This annex defines in a table, which requirements of chapter 4 (for subsystem) or of chapter 5 (for IC) have to be assessed in which phases by a NoBo. These tables form the basis for the assessment scope of the NoBo.
 - ii. In TSI CCS the conformity assessment requirements are provided in chapter 6 (instead of an Annex as for other TSIs)
- f) TSI may contain optional requirements (e.g. specific environmental conditions, Annex C of TSI WAG). Only if the applicant demands such option, the NoBo shall assess these options.

The chapters 1 and 2 of the TSIs contain definitions and include the technical and geographical scope of each TSI as well as the definition of the subsystem and have to be applied by all the actors. The correct matching of the object under assessment to

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the definitions in chapters 1 and 2 taken by the applicant shall be assessed by the NoBo in connection with the relevant items of chapters 4, 5 and 6 as appropriate.

Chapter 3 of the TSIs (Essential Requirements) does not form a part of assessment by a NoBo. Chapter 3 is for information purpose only and links the requirements of the TSI to the essential requirements as defined by the IOD.

For more information on this topic, please refer to RFU-STR-088.

Chapter 7 (in addition to the aspects mentioned in section d) above) of TSIs contains rules for implementation and assessment procedures which have to applied by all the actors.

THIS RFU WAS AGREED ON

PLENARY MEETING 70

THIS RFU ENTERS INTO FORCE ON

DATE OF PUBLICATION: 13/03/2024

FROM THIS DATE ON, THIS RFU CAN BE APPLIED.

RFU APPLICATION IS MANDATORY STARTING FROM

13/03/2024

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

NONE

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