Frequently Asked Questions

1. What is NB RAIL?

NB RAIL is the European Coordination group of Notified Bodies for Railway products and systems set up by the Commission according to Article 44 of the Interoperability Directive (EU) 2016/797. NB RAIL provides a forum for:

★ Sharing experiences and exchanging views on the conformity assessment procedures in order to understand better and apply more consistently the Interoperability Directives;

★ Drafting and issuing documents (recommendations for use, question and clarification, …) on matters relating to Railway Conformity Assessment;

★ Ensuring consistency with European standardisation work;

★ Drawing up reports on technical aspects of the assessment procedures;

★ Discussing Commission documents and other information relevant to Railway Interoperability;

★ Discussing questions and problems that arise from the practical application of the Interoperability Directives

All the Rail NoBos shall according to the ERA assessment scheme follow the activities and apply the documents of the coordination group of notified bodies.
NB-Rail Association AISBL is recognised representative body by ERA and supports the NB-Rail Coordination Group to interface with other stakeholders.

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3. What are Interoperability Directives?

The latest INTEROPERABILITY DIRECTIVE was adopted by the European Council and the Parliament on 11 May 2016.
The DIRECTIVE (EU) 2016/797 on the interoperability of the rail system within the Community repealed the directive 2008/57/EC, the Directive 2009/131/EC and the Directive 2011/18/EU.

4. Aims of the Interoperability Directives?

Interoperability is one of a number of European initiatives designed to promote the single market in the rail sector.
The INTEROPERABILITY DIRECTIVES are aimed at removing (mainly technical) barriers to the supply of equipment and the through-running of trains across Europe.
They provide for common technical standards (TSI's) to be applied across Europe's railways and establish a common European verification and authorisation process for placing new, upgraded and renewed infrastructure or rolling stock into service.
They also provide a process for placing certain rail components (known as interoperability constituents) onto the rail market.

5. How can Regulations help Technical Harmonisation?

The means by which the Regulations help deliver technical harmonisation can be summarised as follows:

- A series of mandatory "Essential Requirements" to which the rail system must comply and laid down in general terms by the INTEROPERABILITY DIRECTIVES
- The trans-European rail system is divided into "subsystems" each of which has to comply with the Essential Requirements, specified for that particular subsystem.
- Common characteristics of subsystems (including interfaces) for which the Essential Requirements must be met are set out in detail in Technical Specifications for Interoperability (TSI's). Compliance with the TSI's is mandatory and where the TSI's specifically mandate European standards, compliance with thoses standards also becomes mandatory.
- However there is scope to derogate from compliance with the TSI's, or part of them, under certain circumstances.
- In certain cases an existing national technical rule may be applied instead of aTSI to give effect to the Essential Requirements, so long as it has first been notified to the European Commission and to other Member States. This arises where a TSI has yet to be published, where there are gaps in a TSI or where a derogation from a TSI has been made.
- The TSI also define "Interoperability Constituents" related to each subsystem. The Interoperability Constituents are identifiable parts which must meet the Essential Requirements when placed on the market for use within the trans-European rail network.
- Details of how constituents can meet the Essential Requirements in practise are described in European standards.

6. If different applicable TSIs to the same subsystem have DIFFERENT CHAPTER 7 (IMPLEMENTATION), e.g with different validity periods, which one is valid?

Chapter 7 in each TSI is stand-alone, so the most restrictive validity period is valid.

7. Is it possible to issue an EC-CERTIFICATE if there is no valid TSI? Is it possible to issue an EC-CERTIFICATE if there are open points in a TSI, which require application of national rules? What would be the advantage on interoperability of such a certificate?

An EC-CERTIFICATE cannot be issued against a TSI which does not exist, because the NNTRs and the process to assess compliance to them are notified by the member state.

If there is any TSI for the constituent or subsystem, but it is not for the complete scope or has open points, an EC-CERTIFICATE is issued for the scope of the TSI(s) only, the remaining assessment and certification being in accordance with the notified process against the NNTRs.

The advantage of the EC-CERTIFICATE is that, for the scope of the certificate, no further assessment is required if the product is introduced into another member state.

8. Do the TSIs NOI, SRT and PRM require SEPARATE CERTIFICATES?

These subjects are "aspects" relating to one or more subsystems, so that, although each TSI lists the modules separately, the certification is for the subsystem, such as Rolling Stock. Hence a certificate issued for the Rolling Stock Subsystem can cover all TSIs applicable to that subsystem.

9. When MODULES SB AND SF are applied on an assessment of a series of vehicles, the Notified Body will have to issue a EC Certificate of Verification for each individual vehicle, and the contracting entity will have to issue an EC declaration of verification for each vehicle. When MODULES SB AND SD are applied, is then one EC Certificate of Verification issued, and one EC declaration of verification?

A single certificate is issued for a fleet of vehicles assessed using the SD MODULE whereas a certificate must be issued for each vehicle assessed using MODULE SF.

10. DIRECTIVE (EU) 2016/797repealed directives 2008/57/EC, 2009/131/EC and 2011/18/EU with effect from 16 June 2020. Are the certificates edited according to 2008/57/EC still valid after 16 June 2020?

Article 58 of Directive (EU) 2016/797 precises that: References to the repealed Directives shall be construed as references to these Directives. Conclusion is that the edited certificates according to 2008/57/EC are still valid after 16 June 2020 and that there is no need to edit new certificates mentioning (EU) 2016/797 in order to replace the old one mentioning Directive 2008/57/EC.

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12. Is it (according to TSI PRM) mandatory to install nursery facilities in trains, even when there is no toilet on board?

Only when the train is equipped with a universal toilet, it is mandatory to provide nursery facilities. Without a toilet, nursery facilities are not necessary.

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14. Do composite brake blocks to TSI WAG 2006/861/EC+2009/107/EC require any IC-Certificate?

No, if they are contained in appropriate ERA TD on ERA website. If they are not contained in this TD, they are an open point.

15. What is the definition of a -small crack- according to TSI WAG 2006/861/EC Ann.J.3?

This must be determined by the NoBo on a case by case basis. The decision must reflect all relevant parameters - welding, material, design, testing, standards, position of crack, crack propagation, maintenance and inspection provisions, etc.; as the NoBo consideres relevant.

16. Are cast iron brake blocks allowed to be applied on freight wagons which shall be certified according the TSI WAG 2006/861/EU & 2009/107/EC?

Cast iron brake blocks which are currently on the market produce rough wheel running surfaces. Therefore, with such blocks, the pass-by noise test which is defined in TSI CR NOISE 2011/229/EU will most likely not be passed. Therefore, current designs of cast iron brake blocks are today very unlikely to be acceptable. In case new brake block designs which would not roughen the wheel running surface and which are based on cast iron come to the market and are listed on an ERA TD (Technical Document), such blocks would be acceptable.

17. Can an EC-Certificate for a subsystem be issued for a single TSI?

An EC-Certificate is always issued for a subsystem with reference to the assessed TSI(s). It will depend on the scope of the project, if an EC-Certificate can be issued. In some cases a project includes only one TSI, in other cases a project will include more TSIs. If all relevant clauses of the relevant TSIs have been assessed in all relevant phases positively, then an EC-certificate can be issued. Be aware that an EC-certificate can also be issued in the case of a derogation that has been granted, partial application of TSI for upgrade or renewal, transitional period in TSI or specific cases.

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19. Do I have to apply a decision (amendment to an existing TSI) established under the 'omnibus procedure' even if I still apply the 'core' TSI?
Is the application of an Omnibus TSI amendment mandatory when the project has already started?

After the date of applicability stated in each Omnibus, the Omnibus must be considered as an integral part of the amended TSI. On the date (after applicability of the Omnibus) of placing on the market or requesting for APIS, the product has to be conforming to the requirements of the amended TSI (original TSI + Omnibus).

20. In which cases could the modules CA1, CA2 or CH be used for certification of the interoperability constituents wheelsets, wheels, axles, friction elements for wheel tread brakes in accordance to TSI WAG (EU) 321/2013?

The modules CA1, CA2 or CH may be used only in the case of products placed on the market, and therefore developed before the entry into force of the TSI WAG (EU) 321/2013. The assessment of these constituents in accordance with modules CA1, CA2 or CH requires a documented former design review and type examination that meets the requirements of the TSI WAG (EU) 321/2013. The corresponding relevant evidences must be demonstrated by the applicant to the NoBo. This is a general requirement; hence it is not relevant whether the constituent is a mature product widely used.

21. Shall the EC certificates of the ICs integrated into a subsystem be valid at the time of the certification of this subsystem?

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The EC certificates for ICs should be valid at the date of placing on the market of the ICs, not necessarily at the date of "installation" or integration into a subsystem. The authorising entity (ERA or NSA) is expected to consider as acceptable for authorisation purposes that an IC manufactured under the period of validity of the certificate is stored during a period of time and integrated into a subsystem after the expiry date of the certificate, because the IC was lawfully placed on the market.
As requirements in the TSIs evolve over time, it may happen that ICs lawfully placed on the market are not fully compatible with a subsystem compliant with the latest TSI in force. Therefore, the NoBo responsible for the assessment of that subsystem has the role of verifying the compatibility of the ICs with the subsystem.
If an IC is manufactured after the expiry date of the EC certificates, it shall be certified against the TSI in force, unless the TSI itself explicitly allows the use of a previous version of a TSI, or the subsystem benefits from the non-application of the latest TSI that impacts the concerned IC (see ERA-OPI-2016-3) or it is a modification due to obsolescence that does not require a new authorisation (see ERA-ADV-2017-03).

22. Is Loc&Pas TSI Reg. (EU) n°1302/2014 amended by Reg. (EU) 2016/919, Reg. (EU) 2018/868, Reg. (EU) 2019/776, Reg. (EU) 2020/387 and corrigendum OJ L10(16/01/2015) pg.45, mandatory for Infrastructure Inspection Vehicles?

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Clause 2.2.2 of TSI L&P defines two types of Special vehicles:
- On track Machines (OTMs) are vehicles specially designed for construction and maintenance of the track and infrastructure
- Infrastructure inspection vehicles are utilised to monitor the condition of the infrastructure.

Clause 7.1.1.3 of TSI L&P states that for OTMs application of TSI is not mandatory. A clear statement about Infrastructure Inspection Vehicle looks missing, however:

- ERA/GUI/07-2011/INT clearly states that for infrastructure inspection vehicles the application of TSI is not mandatory
- Commission Implementing Decision (EU) 2018/1614 defines a unique code (99) for special vehicles, as Vehicle Type, with no distinction between OTM and Infrastructure Inspection Vehicles

This means that clause 7.1.1.3, which state that for "mobile railway infrastructure construction and maintenance equipment" application of TSI Loc&Pas is not mandatory, includes infrastructure inspection vehicles even if they are not explicitly mentioned.

23. Is it allowed to use the published EN standard (as announced by the TSI) if the Applicant asks for it, instead of the TSI LOC&PAS 'state of the art' data in appendix E and F which has been copied from an old standard?

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There are some cases where the LOC&PAS TSI states that an EN standard is currently in the drafting process, namely:

LOC&PAS TSI Appendix E, Anthropometric measurements of the driver and Appendix F, Front visibility
"The following data represents the 'state of the art' and shall be used.
Note: they will be subject of an EN standard currently under drafting process".

The meaning of the note is not entirely clear. In addition, EN standard 16186-1:2014+A1:2018 Railway applications - Driver's cab Part 1: Anthropometric data and visibility has been published.

At STR060 it was decided that a new standard cannot change or add requirements of a TSI – see RFU-STR-088 and ERA-OPI-2016-3 and ERA-ADV-2017-03. Content of new standard can be used in addition, on a voluntarily basis; the important thing is that requirements of TSI (Annex E and F) remain unchanged. A voluntary standard can never replace mandatory references.

24. If the subsystem is divided into parts or checked at certain stages of the verification procedure, shall the Intermediate Statement of Verification (ISV) and the final verification certificate be based on the same form?

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When a NoBo carries out an overall verification assessment and some of the evidence of compliance is in the form of an ISV, it is permissible for the modules used for the ISV and the overall verification assessment to be different. In such circumstances, the NoBo shall be satisfied that the assessment work certified by the ISV also meets the requirements of the modules being used for the overall verification assessment.

Particular care shall be taken when integrating modules using Quality Management assessment and modules that are based on unit assessment. The interfaces between the various modules and the certificates issued should be very clearly explained in the NoBo-File or NoBo Conformity Assessment Report by the integrating NoBo.

According to (EU) 2016/797 annex IV clause 2.2.1 the scope of the ISV in relation to part or stage of a project must be defined by the applicant.

If the scope of a single TSI constitutes a part of a subsystem, then an ISV can be used to demonstrate compliance with that TSI.

25. Where a subsystem integrates an IC/ISV: Does the subsystem NoBo need to receive the full IC/ISV NoBo-Conformity Assessment Report / NoBo file and related documents?

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All information, as listed in RFU-STR-011, for NoBo conformity assessment reports on ICs must be available to the subsystem NoBo (refer to the modules decision 2010/713/EU), including cases where such information is contained in separate documents.

The subsystem NoBo needs access to all of this information to be able to complete the 'EC' Verification of the subsystem.

Yes, the subsystem NoBo has the right to receive the full report. The IC Conformity Assessment Report is an integral part of the certificate, see RFU-STR-001. Receiving only an extract of the IC Conformity Assessment Report (e. g. just one page) is not sufficient. The complete Conformity Assessment Report is needed to complete the 'EC' Verification of the subsystem. This also includes any document to which the IC Conformity Assessment Report refers to in the context of conditions and limits for use (e. g. SRACS from a Safety Case or installation manuals). This applies mutatis mutandis to ISVs.