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0. DOCUMENT INFORMATION

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1. INTRODUCTION AND BACKGROUND

1.1. Mandate to the Agency

1.1.1. The Framework Mandate to the European Railway Agency, in Section 2.3.1, states that: *‘With respect to the time schedule of drafting or revising each TSI, the Agency shall regularly submit and publish on its website a general revision of the Implementation Guide published by the Commission in 2004 and intended to help the stakeholders in the application of the TSIs. The chapter related to the applicable standards in the Implementation Guide shall be updated and published at least annually’.*

1.2. Scope

1.2.1. This guide provides information on the application of Technical Specifications for Interoperability (TSIs); nevertheless, as these are to be considered as secondary legislation coming from Directives, it is also necessary to mention certain concepts and procedures referred to in Directive 2008/57/EC *on the interoperability of the rail system within the Community* (‘the Interoperability Directive’¹), which entered into force on 19 July 2008 and had to be transposed into national law by 19 July 2010. Even so, many of its provisions had already been present in the national legislation as they come from the former Interoperability Directives (96/48/EC and 2001/16/EC).

1.2.2. Furthermore, the guide aims at explaining how interoperability constituents and subsystems should be assessed with a view to meeting the essential requirements of the Interoperability Directive. References and procedures contained here concern the assessment of the conformity or the suitability for use of interoperability constituents as well as the ‘EC’ verification of structural subsystems regarding the TSIs in force. However, the placing of an interoperability constituent on the market or the placing in service of a subsystem in a Member State also requires the fulfilment of all the relevant EU legislation, national legislation and regulatory provisions which are compatible with EU legislation and are applied in a non-discriminatory manner. The scope of this guide does not include the authorisation for placing in service of vehicles ([chapter V], [Articles 21 to 26]). Finally, it is not intended to contain guidelines for designing or manufacturing railway equipment.

1.2.3. This guide does not contain any legally binding advice. It may serve as a clarification tool without however dictating in any way compulsory procedures to be followed, and without establishing any legally binding practice. The guide provides explanations on the provisions contained in the TSIs and should be helpful for understanding the approaches and rules described therein. So, it is intended to help minimise the number of applications of the safeguard clauses laid down in [Articles 14 and 19], particularly those originating from divergent interpretations of the Directive and the related TSIs.

1.2.4. The guide or its annexes gives examples of technical solutions. These examples should not be considered as ‘preferable’ solutions; any other solutions that meet requirements of the relevant TSIs are acceptable.

1.2.5. The guide should be read and used only in conjunction with the Interoperability Directive and the related TSI decisions and regulations in order to facilitate their application, but does not substitute for them.

¹ References to recitals, articles and chapters of Directive 2008/57/EC are written in square brackets.

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- 1.2.6. The guide has been prepared by the European Railway Agency (ERA) with the support of the representative bodies from the railway sector and the Coordination Group of the Notified Bodies – Rail (NB Rail). European Standardisation Organisations (ESOs) and national safety authorities (NSAs) have also had the opportunity to contribute and comment on the guide’s content. The guide has been presented to the Railway Interoperability and Safety Committee (RISC).
 - 1.2.7. The guide is publicly available and will be regularly updated to reflect progress with European standards and changes to the TSIs. The reader should refer to the ERA website for information about its latest available edition.

1.3. Target audience

- 1.3.1. The aim of this guide is to help the understanding, and so the application of the TSIs in force, by railway stakeholders. The Member States’ regulatory authorities and all the economic players and agents concerned, such as railway undertakings (RUs), infrastructure managers (IMs), manufacturers, maintenance service providers, trade associations, contracting entities and notified bodies (NoBos) are the target audience.

1.4. Content of the guide

- 1.4.1. In order to meet the audience’s needs as closely as possible, this guide aims to provide users with a complete overview of the TSIs’ content and to explain how to fulfil their requirements, managing them from a technical point of view (e.g. ‘open points’ and ‘specific cases’, use of conformity assessment modules, etc.). Accordingly, the guide consists of a general part giving the main explanations of concepts, roles and framework and guides specific for each TSI annexed to it.

principles and guidelines the Member States should take into account when authorising placing in service of structural subsystems and vehicles. The document is addressed to the Member States, but it is recommended reading for anyone wishing to understand the role of the TSI and 'EC' verification procedure in the process leading to the authorisation for placing in service.

2.2. Objectives of the Interoperability Directive

2.2.1. According to [Article 1], the Interoperability Directive framework is to be understood in a broader manner than that of the previous Directives:

1. *'This Directive sets out to establish the conditions to be met to achieve interoperability within the Community rail system in a manner compatible with the provisions of Directive 2004/49/EC. These conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of this system as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance.'*

2. *The pursuit of this objective must lead to the definition of an optimal level of technical harmonisation and make it possible to:*

(a) facilitate, improve and develop international rail transport services within the European Union and with third countries;

(b) contribute to the progressive creation of the internal market in equipment and services for the construction, renewal, upgrading and operation of the rail system within the Community;

(c) contribute to the interoperability of the rail system within the Community.'

2.2.2. The objectives of the Interoperability Directive should be understood as a part of the EU approach to improve the performance of rail transport, whose cornerstones are:

- open access in rail transport to favour competition and create incentives for product innovation and service quality;
- fostering the interoperability of the national networks (and hence international services) through technical harmonisation;
- developing an European rail network, by extending the Trans-European Network to the whole Community rail system;
- implementing a common rail safety approach to facilitate market access, while maintaining a reasonably high level of safety.

2.2.3. Finally, for the purpose of the Interoperability Directive, the terms 'Community' (which since the entry into force of the Lisbon Treaty should be read as 'European Union') or 'internal market' also indicate the territories of Liechtenstein, Iceland and Norway as part of the European Economic Area (EEA), according to the Decision of the Council and the Commission [19]. In practice, the geographical scope is composed of 27 states (i.e. all EU and EEA Member States, except Cyprus, Malta and Iceland, which do not have any railway infrastructure).

2.3. Geographical scope of the Interoperability Directive

2.3.1. The geographical scope of the Interoperability Directive has been extended from the TEN-T to the whole '[EU] rail system'. When transposing the Directive, the Member State may exclude:

- a) *'metros, trams and other light rail systems;*

- b) *networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;*
- c) *privately owned railway infrastructure and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its own freight operations;*
- d) *infrastructure and vehicles reserved for a strictly local, historical or touristic use.'*

2.3.2. The precise scope of application of the Interoperability Directive in each Member State is defined in the national legislation transposing it.

2.4. Geographical scope of TSIs

2.4.1. This extension of the scope of the Interoperability Directive does not mean an automatic extension of the scope of the TSIs. In fact, [Article 1(4)] states that *'[t]he scope of the TSIs shall be progressively extended (...) to the whole rail system (...).'*

2.4.2. The geographical scope of the TSIs will be extended by revising existing or adopting new TSIs. The geographical scope originally indicated in each TSI remains valid.

2.4.3. This means that the geographical scope of most of the existing TSIs is the trans-European high-speed and conventional rail system as defined in Annex I of the Interoperability Directive (or as it was formerly defined in Annex I of Directive 96/48/EC and Annex I of Directive 2001/16/EC), i.e. the railway lines of the trans-European transport network (TEN-T) and the vehicles likely to travel on it. The trans-European transport network is defined in [24] Decision 661/2010/EU, which replaced [25] Decision 1692/96/EC.

2.4.4. In 2010 ERA received a third mandate [40] with a view to extending TSIs scope to the whole rail system in the European Union and is carrying out a revision of TSIs *'with a view to covering the lines and rolling stock not yet covered'*.

2.4.5. A Member State may decide to apply a TSI or certain requirements of a TSI beyond the geographical scope defined in the TSI itself. In this case, it should be reflected in the national legislation. A Member State may notify the requirements of a TSI as national rule for the off-TEN part of the network according to [Article 17].

2.5. Technical scope of TSIs

2.5.1. According to [Article 5(2)] *'subsystems shall comply with the TSIs in force at the time of their placing in service, upgrading or renewal'*.

2.5.2. For structural subsystems, this means that any new subsystem that falls within the geographical scope of the TSIs should be in conformity with them.

2.5.3. Regarding the structural subsystems that undergo upgrading or renewal, [Article 20] should be taken into account. It states that the Member State should first *'decide whether (...) a new authorisation for placing in service (...) is needed'* and, if so, secondly, *'to what extent the TSIs need to be applied to the project'*. The Member States should take their decision *'taking account of the implementation strategy indicated in the applicable TSI'*.

2.5.4. For functional subsystems, which do not have a placing in service, the application of the TSIs requirements to the railway system is defined in the implementation strategy of the relevant TSI.

2.5.5. A Member State may decide to apply a TSI or certain requirements of a TSI beyond the technical scope defined in the TSIs themselves or in situations not defined in the Interoperability Directive. In this case, it should be reflected in the national legislation.

2.6. Derogations

- 2.6.1. In principle, the TSIs are being prepared taking into account different atypical situations that need particular treatment. These situations are normally addressed in Chapter 7 of the TSIs, which may include, inter alia, transitional periods and specific cases. But there may be some unexpected situations which have not been foreseen and addressed in the TSI. In such cases, where justified, a Member State may ask for derogation for certain TSIs or parts of TSIs.
- 2.6.2. As indicated above, a TSI is applicable to all new subsystems that fall within its geographical scope. In order not to apply a TSI, a project has to be granted a derogation according to [Article 9], which indicates the cases in which a derogation may be granted and the procedures to follow.
- 2.6.3. Derogations are granted by the European Commission upon application from the Member State concerned. If the organisation in charge of the project considers that derogation is necessary, it has to inform the authorities of the Member State in which the subsystem is to be placed in service so that the Member State may submit a derogation request to the Commission.
- 2.6.4. In particular, attention should be given to those cases falling under [Article 9(1)(a)], i.e. projects *'at an advanced stage of development or the subject of a contract in the course of performance when [the particular TSI is] published'*.
- 2.6.5. The Member States have to submit a list of such projects to the Commission within one year of entry into force of the TSI.

2.7. Main TSI-related provisions of the Interoperability Directive

The following articles of the Directive are of particular importance with regard to the TSIs.

Article 1(1): Interoperability conditions

'These (interoperability) conditions concern the design, the construction, placing in service, upgrading renewal, operation and maintenance of the parts of this system as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance'.

- [G 1] The TSIs were prepared with a view to allowing, in compliance with the essential requirements defined by the Directive, the safe and uninterrupted movement of interoperable trains. Therefore, they do not deal with, for example, the conditions relevant to comfort requirements, which are not an impediment to the free and safe movement of the trains, i.e. not related to the essential requirements and not relevant from the point of view of authorisation of placing in service of subsystems or right of placing on the market of interoperability constituents (Articles 4, 10 and 16 of the Interoperability Directive).
- [G 2] TSIs are only applicable to new, upgraded and renewed subsystems. TSIs are not a design handbook. They do not cover all the aspects of the system, but only those related to the essential requirements.

Article 2(a): 'Trans-European rail system'

'Trans-European rail system' means the 'trans-European conventional and high-speed rail systems as set out in Annex I, points 1 and 2 respectively, of the Directive'.

[G 3] Even though the directives on high-speed and conventional rail systems have been recast in one single document, and the scope of the Interoperability Directive has been extended to the whole EU railway system, the definition of the trans-European rail system [24] and its parts relating to high-speed and conventional rail are still important for the scope of application of the TSIs in force. The scope of these TSIs remains as indicated in each TSI.

Article 2(b): 'Interoperability'

'Interoperability' means the ability of the rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance. This ability depends on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements.'

[G 4] The Interoperability Directive and its related TSIs are designed to facilitate the 'optimal level of technical harmonisation' of the entire EU rail system with a view to improving its competitiveness, e.g. by lowering production, acceptance, operation and maintenance costs. The aim is, firstly, to facilitate international railway services and, secondly, to set up common EU-wide rules for conformity assessment and placing in service of infrastructure, fixed facilities and vehicles.

[G 5] In recent years, a number of new, high-speed trains have been brought into service on international routes. This has been achieved safely and with minimum disruption, but nearly all of these new trains achieved cross-border interoperability on a route-specific basis. In other words, these new trains relied on forms of interoperability that were not fully compliant with the Interoperability Directive and its related TSIs. Typically, the vehicles used on these international routes were specifically equipped for those routes with multiple control systems allowing it to switch rapidly from one control system to another, where necessary, for instance. Such specific solutions, which encompassed the rules of different states, entail additional production and conformity assessment costs.

Article 2(c): 'Vehicle'

'vehicle' means a railway vehicle that runs on its own wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems or parts of such subsystems'.

[G 6] As an example, a locomotive is normally composed of two subsystems:

- rolling stock and
- onboard control-command and signalling.

Article 2(e): 'Subsystems'

"Subsystems' means the result of the division of the rail system, as shown in Annex II [of the Interoperability Directive]. These subsystems, for which essential requirements must be laid down, may be structural or functional'.

[G 7] [Annex II] states that, for the purposes of the Interoperability Directive, the rail system may be broken down into:

- five structural subsystems:
 - infrastructure,
 - energy,

- trackside control-command and signalling,
- on board control-command and signalling and
- rolling stock;

(the former three subsystems may be called 'network-related subsystems', the latter two may be called 'vehicle-related subsystems')

- three functional subsystems:
 - operation and traffic management,
 - maintenance,
 - telematic applications for passenger and freight services.

[G 8] Furthermore, [Article 15(1)] states that '(...) each Member state shall authorise the placing in service of those structural subsystems constituting the rail system (...)'. For the functional subsystems there is no placing in service and, therefore, there is no EC declaration of verification, no EC verification procedure and no involvement of NoBos.

[G 9] The means by which structural and functional subsystems must achieve interoperability are set out in documents called 'technical specifications for interoperability' (TSIs), which are adopted by decisions or regulations of the European Commission and are therefore mandatory.

Article 2(f): 'Interoperability constituents'

'Interoperability constituent' means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly. The concept of a 'constituent' covers both tangible objects and intangible objects such as software'.

[G 10] The interoperability constituents and their interoperable characteristics are defined in the TSIs. One of the objectives is to create a European industrial market for railway products. To avoid an unnecessary repetition of assessment procedures and related costs, components or subassemblies of a subsystem necessary for interoperability, which are manufactured to an identical design as serial products, to be later sold in quantity and incorporated in subsystems, have been defined as interoperability constituents.

[G 11] Generally speaking, interoperability constituents have the following common points:

- the interoperability constituents' characteristics can be evaluated by reference to a European standard or another relevant document, independently of the subsystem in which the constituents will be integrated;
- interoperability constituents can be used in isolation as spare parts and placed on the European market by the manufacturer, before their integration into a subsystem;
- interoperability constituents are elements whose design can be developed and assessed individually.

[G 12] The conformity assessment of an interoperability constituent does not depend on whether it can be integrated into a subsystem. However, in any case, during the 'EC' verification procedure for a subsystem, it will be necessary to check whether interoperability constituents are used in their area of use, as intended in Chapter 5 of each TSI, and are properly integrated into the subsystem. The check of integration into the subsystem should

take into account restrictions and provisions indicated in the 'EC' declaration of conformity of the IC. In addition, the Interoperability Directive stresses the importance of constituents' conformity aimed at guaranteeing the interoperability of the system.

- [G 13] For the purposes of the Interoperability Directive (without prejudice to provisions of other regulations), manufacturers are not required 'to affix the CE marking to constituents' subject to its provisions. The manufacturer's declaration of conformity is sufficient ([recital (36)]). In fact, a 'CE' marking affixed to an IC or subsystem does not mean it complies with the Interoperability Directive and related TSIs; it is affixed as a result of the application of other European directive(s) on technical harmonisation. Evidence of compliance with the Interoperability Directive and the related TSIs must be sought in the relevant documentation.
- [G 14] CE marking has to be affixed on the ICs if so required by any other regulation applicable to this IC.

Article 5(2): 'Conformity of a subsystem with TSIs'

'The subsystems shall comply with the TSI in force at the time of their placing in service, upgrading or renewal, in accordance with 2008/57/EC Directive; this compliance shall be permanently maintained while each subsystem is in use.'

- [G 15] This article states the obligation of compliance with the TSIs only for those structural subsystems that have been placed in service (following their construction, upgrading or renewal) after the entering into force of these TSIs. The adoption of a TSI does not have a retroactive character. It does not impose an obligation to bring the existing structural subsystems into compliance with it, unless these subsystems are upgraded or renewed. In the cases of upgrading or renewal, [Article 20] applies.
- [G 16] A subsystem must be assessed against the applicable TSIs, even if those TSIs do not fully cover this subsystem. For instance, for a CR trainset, the SRT, NOI and PRM TSIs are applicable, even if the LOC & PAS TSI is not yet in force.
- [G 17] [Article 15(3)] and recital (40) refer to Articles 10 and 11 of the Safety Directive (for safety certificates for RUs and safety authorisations for IMs, respectively) in order to clarify the responsibilities of maintaining subsystems' compliance with the related TSIs during their use. In other words, maintaining subsystems' compliance with the related TSIs during their use falls under the responsibility of the RUs and IMs that operate these subsystems, and insofar as vehicles are concerned under the responsibility of the entity in charge of maintenance ('ECM'). In that field, the responsibility of the supplier is to provide the RU, IM and ECM with the relevant documentation (operation, maintenance and training documentation) so that they can carry out their own tasks. This maintaining compliance with TSIs concerns only those TSIs conformity to which was assessed and declared at the placing in service of the subsystem (i.e. structural subsystems placed in service before entry into force of a TSI do not need to be in compliance with this TSI).
- [G 18] Functional subsystems do not have a placing in service. The fulfilment of the TSI provisions relating to them has to be checked in the context of the granting and supervision of safety certificates and safety authorisations.

Article 5(7): 'Interoperable trains and trains not covered by TSIs'

'TSIs shall not be an impediment to decisions by the Member States concerning the use of infrastructures for the movement of vehicles not covered by the TSIs.'

- [G 19] As indicated above, there is no obligation to bring existing structural subsystems into conformity with the TSIs.
- [G 20] When drafting the TSIs, simultaneous circulation on the same infrastructure of both TSI-conform trains and other trains not covered by TSIs, whether passenger or freight, was considered. This situation did not require individual specifications for this type of mixed traffic, insofar as the specifications retained for the majority of the basic parameters of the network-related subsystems made it possible to adopt limit values compatible with the movement of other trains, without disturbing the circulation of TSI-conform trains. The choice of individual limit values remains, however, within the competence of the infrastructure manager who has to bear the economic impact and verify their compatibility with the TSIs' requirements.

Article 10(2): 'Placing on the market of interoperability constituents'

'Member States may not, in their territory and on the basis of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the rail system where they comply with the Directive. In particular, they may not require checks which have already been carried out as part of the procedure of 'EC' declaration of conformity or suitability for use, the components of which are set out in Annex IV'.

- [G 21] Annex IV of the Interoperability Directive defines three different categories of constituent:
- *'multiple-use constituents, that are not specific to the railway system and which may be used as such in other areas';*
 - *multiple-use constituents having specific characteristics, which are not, as such, specific to the railway system, but which must display specific performance levels when used for railway purposes';*
 - *specific constituents for railway applications.'*

For subsystems within the technical and geographical scope of the TSIs, the use of ICs covered by an EC declaration is mandatory, except if otherwise provided for in the applicable TSIs (e.g. for a transitional period).

- [G 22] TSIs set *'all the conditions with which an interoperability constituent must conform and the procedure to be followed in assessing conformity'* ([recital (15)]). In addition, *'when a TSI enters into force, a number of interoperability constituents are on the market. A transition period should be provided for so that these constituents can be integrated into a subsystem even if they do not strictly conform to that TSI'* ([recital (38)]).
- [G 23] In order to allow technological innovation, most of the TSIs in force include provisions for 'innovative solutions', which do not fulfil the requirements specified in the TSI or are not assessable as stated in the TSI. In such cases, the applicant has to state the deviations from the relevant parts of the TSI and submit them to the Commission for analysis. If the opinion of the Commission is favourable, a new specification and assessment procedure will be included in the TSI during its revision and use of the innovative solution may be allowed before its incorporation into the TSI.
- [G 24] According to Article 16 of the Safety Directive, the NSAs are responsible for supervising that the interoperability constituents placed on the market are in compliance with the TSIs.

Article 15: 'Placing in service of structural subsystems'

'...Each MS shall authorise the placing in service of those structural subsystems constituting the rail system which are located or operated in its territory.'

[G 25] To this end, Member States must in particular check:

- *'the technical compatibility of these subsystems with the system into which they are being integrated'* (Art.15(1));
- *'the safe integration of these subsystems in accordance with' the Safety Directive (Articles 4.3 and 6.3);*
- *their compliance 'with the relevant TSI provisions on operation and maintenance', if applicable.*

[G 26] *'The subsystem constituting the rail system should be subjected to a verification procedure. This verification must enable the authorities responsible for authorising their placing in service to be certain that, at the design, construction and putting in service stages, the result is in line with the regulations and technical and operational provisions in force. It must also enable manufacturers to be able to count upon equality of treatment whatever the country. It is therefore necessary to lay down one or more modules defining the principles and conditions applying to 'EC' verification of subsystems'* ([recital (39)]).

[G 27] In practice, for authorising a subsystem to be placed in service, the NSA has to check whether the following procedures have been carried out with a positive result:

- 'EC' verification,
- verification of conformity to applicable notified national rules (open points, specific cases, derogations),
- risk evaluation and assessment, if required according to Commission Regulation (EC) No 352/2009 (which can also mean an explicit requirement in the TSI).

[G 28] *'After a subsystem is placed in service, care should be taken to ensure that it is operated and maintained in accordance with the essential requirements relating to it'* ([recital (40)]). For this purpose, the Safety Directive defines the responsibilities of RUs and IMs regarding the subsystems they operate. The Member States have to check that these responsibilities are met when granting and supervising safety certificates and safety authorisations.

[G 29] In order to allow technological innovation, most of the TSIs in force include provisions for 'innovative solutions'.

Article 20: 'Placing in service of existing subsystems after renewal or upgrading'

'If a new authorisation is needed, the Member State shall decide to what extent the TSIs need to be applied to the project.'

[G 30] 'EC' verification to be carried out by a NoBo is limited to the parts or characteristics of the subsystem for which the TSIs have been applied.

[G 31] [Article 2(m)] defines 'upgrading' as 'any major modification work on a subsystem or part subsystem which improves the overall performance of the subsystem'. This definition is generally applicable to any kind of intentional change in the overall performance of a subsystem, for example:

- if a decision is taken to dismantle one track on a low traffic line, such dismantling would reduce the capacity of the line, but would make its operation and maintenance more cost efficient (i.e. would improve its performance);
- if a decision is taken to rebuild a flat wagon into a container carrying one, none of the two types has *a priori* a better performance, but the decision has certainly been taken with the intention of improving the performance in a particular business situation.

[G 32] In all such cases [Article 20] applies, and the Member State concerned has to *'decide to what extent the TSIs need to be applied'*.

[G 33] In certain cases TSIs include particular requirements regarding their application or renewal.

Chapter V: 'Vehicles'

[G 34] *'...as Directives 96/48/EC and 2001/16/EC dealt with new and upgraded subsystems and Directive 2004/49/EC focuses on in-use rolling stock, then all provisions concerning the procedure for placing in service of vehicles has been integrated in [Chapter V of the Interoperability] Directive' ([recital (41)](for both TSI conform and non-TSI conform vehicles, for parts of the network both covered by the geographical scope of the TSIs and not yet covered. These provisions take into account the new definition of vehicle (see comments on [Article 2(c)]).*

[G 35] Each of the subsystems that constitute a vehicle is subject to the relevant provisions of the Interoperability Directive and, as far as new, upgraded and renewed subsystems are concerned, is subject to the relevant TSIs.

[G 36] The process of authorisation for placing in service of vehicles is beyond the scope of the guide.

2.8. Structure and content of TSIs

2.8.1. [Article 5(3)] indicates the content of TSIs, to the extent necessary to achieve interoperability within the EU rail system.

Table 2: Content of TSIs

<p><i>'Each TSI shall:</i></p> <p><i>a) indicate its intended scope (part of network or vehicles referred to in Annex I [of the Interoperability Directive]; subsystem or part of subsystem referred to in Annex II [of the Interoperability Directive]);</i></p>	<p>This content is contained in Chapters 1 and 2 of the TSIs.</p>
<p><i>b) lay down essential requirements for each subsystem concerned and its interfaces vis-à-vis other subsystems;</i></p>	<p>The essential requirements are set out in general terms in Annex III of the Interoperability Directive; they are further elaborated upon for each subsystem in Chapter 3 of the TSIs.</p>

Table 2: Content of TSIs

<p>c) <i>establish the functional and technical specifications to be met by the subsystem and its interfaces vis-à-vis other subsystems. If need be, these specifications may vary according to the use of the subsystem, for example according to the categories of line, hub and/or vehicles provided for in Annex I [of the Interoperability Directive];</i></p>	<p>The subsystem-specific essential requirements are reflected in the technical parameters, interfaces and performance requirements set out for each subsystem in Chapter 4 of the TSIs.</p> <p>As an example of this variation of requirements, reference can be made to different categories of line, defined in the HS and CR Infrastructure TSI, different power supply systems in the HS and CR Energy TSI, etc.</p>
<p>d) <i>determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are necessary to achieve interoperability within the rail system.</i></p>	<p>Chapter 5 of the TSIs deals with constituents and interfaces covered by European specifications.</p> <p>Standards (voluntary or obligatory, see Section 3 of this guide) that ensure compliance with the essential requirements of the Interoperability Directive enable the fulfilment of the technical characteristics of the subsystems defined in Chapter 4 of the TSIs, and not directly the essential requirements of the Directive.</p>
<p>e) <i>state, in each case under consideration, which procedures are to be used in order to assess the conformity or the suitability for use of the interoperability constituents, on one hand, or the 'EC' verification of the subsystem, on the other hand. These procedures shall be based on the modules defined in Decision 93/465/EEC and its following amendments;</i></p>	<p>Chapter 6 of the TSIs. It should also be pointed out that this Decision was replaced by Decision 768/2008/EC. Furthermore, a specific Decision on railway modules has been adopted. TSIs adopted on or after adoption of this specific decision make reference to it. TSIs adopted before that date contain the description of the modules in each TSI itself.</p>
<p>f) <i>indicate the strategy for implementing the TSIs. In particular, it is necessary to specify the stages to be completed in order to make a gradual transition from the existing situation to the final situation in which compliance with the TSIs will be the norm;</i></p>	<p>Chapter 7 of the TSIs, which includes specific cases, also defines transitional periods for application of different provisions of the TSI and allowing for a certain time to place in service subsystems conform to the rules that were in force before the adoption of the TSI.</p>
<p>g) <i>indicate, for the staff concerned, the professional qualifications and health and safety conditions at work required for the operation and maintenance of the above subsystem, as well as for the implementation of the TSIs.</i></p>	<p>These points are described in Chapter 4, as part of the subsystem characterisation.</p>

2.8.2. [Article 5(6)] states that *'if certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI they shall be clearly identified in an annex as **open points**'*. The idea is that certain aspects are considered to be necessary for satisfying the essential requirements, but (due to their complexity or lack of time) it has not yet been possible to define an appropriate specification for the target system. In this case, a

TSI may be adopted with a view of closing the open point in further revisions. In the meantime, notified national rules apply for this open point.

2.8.3. These national rules for the open points and the bodies designated for the assessment of conformity to these rules have to be notified by the Member States to the Commission following the adoption of the TSI containing these open points.

2.9. Target system and specific cases

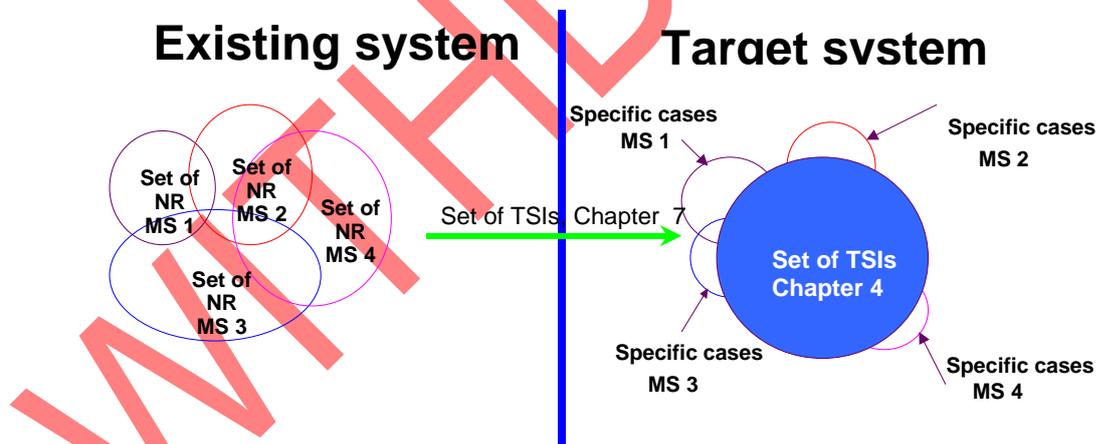
2.9.1. The objective of the TSI is to contribute to the achievement of the ‘*optimal level of technical harmonisation*’ by establishing a specification for a common target system (not to be confused with a ‘one-size-fits-all’ approach).

2.9.2. Depending on the particular situation of each Member State, the achievement of the target system may not be feasible (or require a long transitional period). Taking this into account, the TSIs ‘*shall retain (...) the compatibility of the existing rail system of each MS (...), provisions may be made for specific cases for each TSI...with regard to both network and vehicles...For each specific case, the TSIs shall stipulate the implementing rules (...)*’ ([Article 5(5)]).

2.9.3. These specific cases are classified according to two categories: the provisions apply either permanently (P cases), or temporarily (T cases).

2.9.4. Where the relevant TSI so requires, the Member States have to notify the Commission of the bodies designated for the assessment of conformity in the specific cases. As in the case of open points, the notification has to be made following the adoption of the TSI.

2.9.5. The diagram below illustrates the migration from the sets of national rules to the TSIs.



2.10. Errors in TSIs

2.10.1. The Interoperability Directive introduces the concepts of minor ([Article 7(2)]) and important or critical error ([Article 7(3)]).

2.10.2. Additionally, the ‘Framework Mandate to the Agency’ defines an error as critical when a subsystem or a constituent is prevented from:

- its completion or interoperable design,

- being assessed for its conformity,
- placed in service or on the market,
- being interoperable.

2.10.3. For all these reasons, as soon as a critical error has been identified, the Commission or ERA or a Member State has to be notified of it, so that the Railway Interoperability and Safety Committee (RISC) may be consulted, the Agency may be asked for a technical opinion and the procedure for the TSI amendment may be launched. Moreover, if a NoBo identifies such error/s, it may launch a question and clarification procedure through the NB Rail group.

2.10.4. When a deficiency is not critical, it may be considered as a minor error, which is also notified to the Commission or ERA or a Member State, but handled with less urgency; this case also includes translation errors.

2.10.5. The Agency shall publish a list of detected minor errors, including translation errors, on its website, pending revision of the relevant TSIs. The list shall also be transmitted to the RISC for information.

2.11. Technical opinions of the Agency

2.11.1. According to [Article 7(1)] of the Interoperability Directive, and as laid down by Articles 2(a) and 2(b) of Regulation (EC) No 881/2004, the European Commission may request a Technical Opinion (TO) from the Agency concerning, inter alia, deficiencies in TSIs (including cases where a requirement of the TSI is not clear and may lead to divergent interpretations). With reference to the latter, the impact of such deficiency on interoperability and on the interfaces with the TSI itself and with other TSIs has to be evaluated.

2.11.2. The TO has to provide a solution, assessing economic, interoperability and interface impacts accordingly, as well as compliance with the essential requirements and details for conformity assessment.

2.11.3. The Agency has to give its TO within two months (Article 10(2)(a) of Regulation (EC) No 881/2004). The TO has to be submitted to the RISC and, if adopted, has to be included in the revision of the relevant TSI. In the meantime (pending the revision of the TSI), it should be published by the Agency on its website and disseminated through the NSA Network. It may also be published on the NB Rail website.

2.11.4. According to [Article 7(2)], the Commission may recommend use of a TO. In this case, it should be used by the contracting entities or manufacturers to continue the subsystem/constituent design or by NoBos for conformity assessment.

2.11.5. The TO is not legally binding until it has become part of a TSI. If it has been used, this has to be clearly stated on both the 'EC' certificate and 'EC' declaration for the subsystem or constituent concerned.

2.12. The TSIs' state of play

2.12.1. The first group of TSIs for HS lines, concerning Infrastructure, Energy, Rolling Stock and Control-Command and Signalling structural subsystems as well as Operation and Maintenance functional subsystems was published in May 2002.

2.12.2. These and all of the TSIs adopted before 2009 were drafted on behalf of the European Commission by the joint representative body, later known as the European Association for Railway Interoperability (AEIF), consisting of IMs, RUs and rail industry representatives.

2.12.3. Once established, the European Railway Agency (ERA) took over the drafting of TSIs. Therefore, the Agency prepared the amendments of WAG and OPE TSI, adopted in 2009 and all the TSIs adopted from 2009 onwards. For a quick overview of the TSIs status a table is made available on the ERA website under Interoperability/TSIs.

2.13. Relevance of the TSIs to the subsystems defined in Annex II of the Interoperability Directive

2.13.1. [Article 5(1)] states that '*[w]here necessary, a subsystem may be covered by several TSIs and one TSI may cover several subsystems*'. In practice, this results in a type of matrix linking different subsystems to different TSIs. The following table shows which TSIs are applicable to which subsystem, and therefore have to be taken into account for conformity assessment of a particular subsystem (the draft TSIs are indicated for reference only).

Table 3: TSIs' scope v. subsystems

Applicable TSIs	Subsystem							
	Infrastructure	Energy	CCS on board	CCS trackside	Rolling Stock	Operation and Traffic Management	Maintenance	Telematic Applications
Dec 2008/217/EC HS INF TSI	X						X	
Dec 2011/275/EU CR INF TSI	X						X	
Dec 2008/284/EC HS ENE		X					X	
Dec 2011/274/EU CR ENE TSI		X					X	
Dec 2012/88/EU CCS TSI			X	X			X	
Dec 2008/232/EC HS RST TSI					X		X	
Dec 2006/861/EC CR WAG TSI					X		X	
Dec 2011/291/EU CR LOC&PAS TSI					X		X	
Dec 2011/229/EU RST Noise TSI					X		X	
Dec 2008/231/EC HS OPE TSI						X		
Dec 2011/314/EU CR OPE TSI						X		
Reg 62/2006/EC TAF TSI								X
Reg 454/2011/EU TAP TSI								X
Dec 2008/163/EC HS&CR SRT TSI	X	X	X	X	X	X	X	

Table 3: TSIs' scope v. subsystems

Dec 2008/164/EC HS&CR PRM TSI	X				X		X	
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2.13.2. The table above shows the subsystems as defined in Annex II of the Interoperability Directive. It does not mean that all the TSIs indicated for a given subsystem are applicable in all cases. For example, the HS RST TSI (Decision 2008/232/EC) is applicable to the Rolling Stock subsystem in general, but is not applicable to the Conventional Rolling Stock subsystem, and the HS&CR PRM TSI (Dec 2008/164/EC) is applicable to the Rolling Stock subsystem in general, but is not applicable to Freight Wagons.

2.14. Application of the different TSIs in practice

2.14.1. From a practical point of view, the projects do not necessarily correspond to one of the subsystems defined in the Interoperability Directive, but rather include several structural subsystems simultaneously. In addition, as indicated above, one subsystem may be (and generally is) covered by several TSIs. The following table (which is not exhaustive) gives an example of relevance of different TSIs in some practical cases.

Table 4: Application of each TSI in practice

Applicable TSIs	Case										
	HS Line	CR Electrified line	CR Non-electrified line	HS Trainset	CR Trainset	CR Trainset for occasional use on HS lines	HS Locomotive	CR Locomotive	CR Passenger coach	Freight wagon	Upgrading of CR line signalling system
Dec 2008/217/EC HS INF TSI	X										
Dec 2011/275/EU CR INF TSI		X	X								
Dec 2008/284/EC HS ENE	X										
Dec 2011/274/EU CR ENE TSI		X									
Dec 2012/88/EU CCS TSI	X	X	X	X	X	X	X	X			X
Dec 2008/232/EC HS RST TSI				X		X	X				
Dec 2006/861/EC CR WAG TSI										X	
Dec 2011/291/EU CR LOC&PAS TSI					X	X		X	X		
Dec 2011/229/EU RST NOI TSI					X	X		X	X	X	

Table 4: Application of each TSI in practice

Dec 2008/163/EC HS&CR SRT TSI	X	X	X	X	X	X	X	X	X		
Dec 2008/164/EC HS&CR PRM TSI	X	X	X	X	X	X			X		

2.14.2. The examples set out in the table should be understood as follows:

- A project for a new high-speed line includes the Infrastructure, Energy and CCS trackside subsystems. The TSIs relevant for each of these subsystems are:
 - Infrastructure: HS INF TSI, PRM TSI (if the line includes stations), SRT TSI (if the line includes tunnels)
 - Energy: HS ENE TSI, SRT TSI (if the line includes tunnels)
 - CCS trackside: CCS TSI, SRT TSI
- A project for a new conventional line includes the Infrastructure, Energy (if the line is electrified) and CCS trackside subsystems. The TSIs relevant for each of these subsystems are:
 - Infrastructure: CR INF TSI, PRM TSI (if the line includes stations), SRT TSI (if the line includes tunnels)
 - Energy: CR ENE TSI (if the line is electrified), SRT TSI (if the line includes tunnels; some parameters apply, even if the line is not electrified)
 - CCS trackside: CCS TSI, SRT TSI
- A new high-speed trainset includes the RST and CCS on board subsystems. The TSIs applicable to each of these subsystems are:
 - RST: HS RST TSI, PRM TSI, SRT TSI
 - CCS on board: CCS TSI
- A conventional locomotive includes subsystems RST and On board CCS. The TSIs applicable to each of these subsystems are:
 - RST: CR LOC&PAS TSI, SRT TSI, RST Noise TSI
 - CCS on board: CCS TSI

2.14.3. Consequently, in each of these cases, the 'EC' verification of each subsystem must include conformity to the TSIs that are relevant for it.

2.15. TSIs and other requirements

2.15.1. Applicable national rules

[G 37] A subsystem in conformity with all applicable TSIs, without open points, should be considered to satisfy the essential requirements of the Interoperability Directive. However, at present not all the aspects relating to the essential requirements are covered by the TSIs (i.e. the geographical scope of the TSIs does not cover the whole EU network, and there are open points). During this transitional period for the aspects not yet covered by the TSIs

in force, the national rules, notified by each Member State under [Article 17(3)] to the European Commission, apply on the territory of that Member State.

[G 38] These notified national rules apply as a reference for the verification of fulfilment of the essential requirements when (as stated in [Article 17(3)]):

- *'no relevant TSI exists, or*
- *a derogation has been notified (...)* or
- *a specific case requires the application of technical rules not included in the relevant TSI'*

or (as stated in [Article 20]) the TSIs are not fully applied for an upgrading or renewal of a subsystem.

[G 39] In addition to this general obligation regarding the notification of national rules, the legal acts adopting TSIs usually include more detailed requirements of the scope of the notifications required.

[G 40] The Member States also have to designate bodies in charge of assessment of conformity to these national rules, the so-called 'Designated Bodies'.

[G 41] National rules have to be considered as complementary to the current TSIs in order to ensure compliance with the essential requirements. The complete list of the references of these national rules has been published on the website on rail interoperability of the EC (see link on the ERA website, under registers\European Railway Agency Database for Interoperability and Safety – ERADIS).

[G 42] National rules may not contradict (this includes complementary rules as well) the relevant TSIs.

[G 43] If the TSI so requires, national rules have to be used for assessment of conformity in specific cases.

[G 44] Where necessary, a Member State may amend the rules it notified. Nevertheless, the list's purpose of ensuring a fair and non-discriminatory treatment of all stakeholders by making public the applicable national rules requires a certain stability.

[G 45] The need for such national rules will diminish as the TSIs are amended and developed, open points are closed and the scope is extended for the whole EU rail network.

[G 46] National rules will however remain applicable for derogations and partial application of TSIs in the case of upgrading or renewal.

2.15.2. Compliance with other regulations deriving from the Treaty

[G 47] All other directives covering the technical scope of the Interoperability Directive, including subsystems and interoperability constituents, shall remain applicable providing they do not relate to the essential requirements set out in the Interoperability Directive. Where appropriate, the provision of [Article 13(3)] shall apply: *'[w]here the interoperability constituents are the subject of other Community directives covering other aspects, the 'EC' declaration of conformity or suitability for use shall, in such instances, state that the interoperability constituents also meet the requirements of those other directives'*.

[G 48] The general principle is that the TSIs do not duplicate the requirements already covered by other EU regulations (electromagnetic compatibility (EMC), exhaust emissions, etc.). This does not mean that railway subsystems are exempt from the obligation of conformity to these other regulations.

[G 49] The following provisions apply:

- [Article 3(2)]: *'The provisions of this Directive shall apply without prejudice to other Community provisions. However, in the case of interoperability constituents, compliance with the essential requirements of this Directive may require the use of the individual European specifications drawn up for that purpose.'*
- Annex VI (2.1) of the Interoperability Directive: *"EC' verification is the procedure whereby a notified body checks and certifies that the subsystem:*
 - *complies with the relevant TSI(s);*
 - *complies with the other regulations deriving from the Treaty'*

[G 50] Besides the conformity to the TSIs, the manufacturer of an interoperability constituent is responsible for guaranteeing its conformity to the requirements of all other applicable legislation. To this end, and where necessary, the manufacturer must appoint bodies notified in accordance with those directives (see ERA website under interoperability/cooperation with organisations for the link to the list of bodies notified under the new approach directives). The NoBo appointed to assess the conformity of an interoperability constituent to the Interoperability Directive and the TSIs does not have to assess that constituent's conformity to other relevant directives. This assessment will be carried out either by the bodies notified to assess conformity under applicable directives or, if allowed by these directives, by the manufacturer itself. However, the same organisation may carry out an assessment of conformity to several directives, provided that it is notified for all of them.

[G 51] The case is different for a subsystem. The NoBo which performs the 'EC' verification must verify that the subsystem complies with:

- the TSIs, and that the interoperability constituents are provided with the 'EC' declaration of conformity in accordance with [Article 13], and
- any other applicable regulations deriving from the Treaty. For this purpose, the NoBo appointed to assess the conformity of the subsystem to the Interoperability Directive does not have to assess the conformity of the subsystem to other regulations. However, the NoBo must request evidence of conformity to all other applicable regulations from the applicant. The latter must provide such conformity evidence as is relevant, and the NoBo has to include it in the technical file.

[G 52] NB Rail maintains a list of other regulations deriving from the Treaty that are applicable for the subsystems, available on its website (see the above mentioned link on the ERA website). This list is not binding and there is no legal obligation for NB Rail to maintain such a list.

[G 53] In the case of conflict between essential requirements of the Interoperability Directive (or TSI requirements) and those of other legislation covering the same technical scope, the matter should be brought to the attention of the Commission, which will seek the best appropriate solution. A legal principle that may apply in this case is that sector-specific legislation prevails over horizontal legislation.

2.15.3. TSIs and other requirements – Summary

[G 54] The following table clarifies the combination of different requirements applicable to structural subsystems and assessment of conformity to them:

Table 5: Requirements applicable to structural subsystems and assessment of conformity to them

	Requirements	Conformity assessment carried out according to:	Body in charge of conformity assessment
Basic parameters & Interoperability Constituents	Chapters 4 and 5 of the TSI	Chapter 6 of the TSI	Notified Body of the Interoperability Directive
Specific cases	Chapter 7 of the TSI	Notification by MS	Designated Body
Open points	Notification by MS (national rules)	Notification by MS	Designated Body
Other regulations deriving from the Treaty	Other regulations	Other regulations	Notified Bodies under other regulations

[G 55] Generally speaking, the scope of notification of national rules and Designated Bodies (according to [Article 17]) has to correspond to the grey area of the chart above, while the white area of the chart is covered by EU legislation (TSIs and other regulations deriving from the Treaty). The specific cases stated in Chapter 7 of the TSIs may make reference to national rules, which then have to be notified by the Member States.

[G 56] In cases where derogation has been granted, the Designated Body is responsible for checking conformity to the notified national rules applied instead of the TSI(s).

[G 57] In cases of renewal or upgrading, the Designated Body is responsible for checking conformity to the notified national rules applied instead of the TSI(s).

2.16. Questions about TSIs

- 2.16.1. Formal interpretation of the legal text may only be given by the European Court of Justice.
- 2.16.2. For the Interoperability Directive and the TSIs to be totally effective, it is essential that all railway stakeholders in the EU share a common understanding and application of their content and requirements.
- 2.16.3. Many requests for clarification have been addressed to ERA by users along the way, and they are dealt with in this version of the guide. Nevertheless, users will probably still have questions, which will be collected and answered in further revisions.
- 2.16.4. Questions on the TSI may be sent to ERA; they will be collected as FAQ on the Agency website. These questions will be taken into account in further revisions of this guide and, where relevant, during the revision of the TSIs.

2.16.5. Furthermore, bodies notified under [Article 28] of the Interoperability Directive may refer to their coordination group, NB Rail, for any questions they may have regarding the assessment and verification procedures in relation to the implementation of the TSIs (see also Section 4.4).

WITHDRAWN

3. APPLICABLE STANDARDS AND OTHER DOCUMENTS

3.1. Overview

- 3.1.1. The TSIs are adopted by EC decisions or regulations, and are therefore mandatory. However, they do not normally prescribe a specific technical solution for meeting the requirements.
- 3.1.2. According to [Article 5(8)], the *'TSIs may make an explicit, clearly identified reference to European or international standards or specifications or technical documents published by the Agency'* or, in their absence, *'to other clearly identified normative documents'* (such as UIC leaflets, national standards, etc.), and compliance with these standards or specifications (or the relevant parts) or documents shall become mandatory. Only those (part(s) of) standards, specifications and documents that are strictly necessary to achieve the interoperability of the EU rail system are specifically referred to, and therefore mandated by, the TSIs.
- 3.1.3. However, several other standards and documents are also relevant to the TSIs, even though they are not referred to. Compliance with these standards or documents remains voluntary. Compliance with harmonised standards gives presumption of conformity to the corresponding essential requirements.
- 3.1.4. References to harmonised standards indicating the directives (new approach directives and directives based on the new approach) for which they give presumption of conformity are published in the Official Journal of the European Union (OJEU) and are also available on the website of Enterprise and Industry DG).
- 3.1.5. So it might also happen 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.
- 3.1.6. In practice, the standards and other documents relate to the technical requirements set out in Chapters 4 and 5 of each TSI (basic parameters, interfaces and performance requirements of each subsystem). These requirements, in turn, reflect the essential requirements of the Interoperability Directive and the subsystem-specific essential requirements set out in Chapter 3 of the TSIs.
- 3.1.7. The lists of standards and documents for each subsystem, both mandatory and voluntary, are included in the specific TSI guides (Annexes 1 of this guide).

3.2. Reference to European standards and other documents in the TSIs

- 3.2.1. References in the TSIs to existing standards or other documents may be either:
- 'strict' references – whereby the reference explicitly identifies a particular version of the document (e.g. with reference to the version number, date, etc.), or
 - 'slipping' references (i.e. with no explicit identification of a particular version of the document) – whereby the reference is to the version of the document in force at the time of adoption of the latest version of the TSI in question.
- 3.2.2. As far as possible, only strict references are made in the TSIs.
- 3.2.3. In both cases, the version of the standard (or document) referred to in a TSI is the binding one. If, after the adoption of a TSI, a new version of this standard (or document) is adopted,

it does not imply any change in the TSI, the 'old' version referred to in the TSI is still the binding one. That is, in both cases nothing actually 'slips'.

- 3.2.4. Where a TSI refers to a standard or document, the complete standard or document is mandatory. Where a TSI refers to a part of a standard or document, only the part referred to is mandatory.
- 3.2.5. Where a standard referred to in a TSI contains a reference to another standard, unless otherwise provided in the TSI, this second standard also becomes mandatory.
- 3.2.6. The TSIs make no reference to standards or other relevant documents whose application is not mandatory.

3.3. Technical documents of the Agency

- 3.3.1. It should be noted that 'technical document of the Agency' is not the same as 'technical opinion of the Agency', which is described in section 2.11.
- 3.3.2. A TSI may make reference to a technical document of the Agency in the same way as to a standard. In addition, the regulatory measure adopting the TSI may include provisions for the updating of a technical document by the Agency.

W I T H D R A W N

4. STAKEHOLDERS

4.1. Manufacturer of an interoperability constituent

- 4.1.1. The manufacturer of an interoperability constituent is the organisation responsible for the design and manufacture of the interoperability constituent (IC) covered by the Interoperability Directive and the related TSIs, with a view to placing it on the market on the EU territory on its own behalf.
- 4.1.2. In cases where a contracting entity (e.g. an RU or IM) is involved together with the supplier in the design of an IC, it should be clearly specified which party is considered to be the manufacturer. The associated obligations and responsibilities apply to the person who drew up the 'EC' declaration.
- 4.1.3. Whoever substantially modifies an IC, resulting in an 'as-new' IC (i.e. where the modifications could influence the characteristics of the basic parameters supported by the interoperability constituent), with a view to placing it on the market on the EU territory, becomes the manufacturer and must arrange for the appropriate conformity assessment.
- 4.1.4. An IM, RU, vehicle keeper, etc. may design and manufacture or modify an IC for their own use. In this case, they are considered to place this IC on the market and be its manufacturer.
- 4.1.5. The manufacturer bears responsibility for:
- the design and manufacture of the IC;
 - following the procedures for the certification of the conformity and suitability for use of the IC vis-à-vis the requirements laid down in the Interoperability Directive and related TSIs.
- 4.1.6. The manufacturer has sole and ultimate responsibility for the conformity of its IC to any applicable directives. It must understand both the design and manufacture of the IC, arrange, if required by the relevant TSI, for EC certification by (a) Notified Bodies(y) and issue an 'EC' declaration of conformity or suitability for use in respect of all applicable provisions and requirements of the relevant directives.
- 4.1.7. The manufacturer may subcontract certain operations – the IC design or manufacture, for instance – provided that it retains overall control and responsibility for the IC as a whole. By the same token, it may use ready-made items or components, whether or not 'CE' marked, to produce the IC without losing its status as manufacturer.
- 4.1.8. Annex IV of the Interoperability Directive defines the obligations incumbent upon the manufacturer with regard to the 'EC' declaration of conformity or suitability for use of an IC.
- 4.1.9. The manufacturer may be based in the Community or elsewhere. In either case, the manufacturer may appoint an authorised representative (see section 4.3) in the EU to act on its behalf in carrying out certain tasks required by the applicable directives, provided that they are specified in a mandate between the manufacturer and its authorised representative. However, a manufacturer established outside the EU is not obliged to have an authorised representative, although this may present some advantages.

4.2. Applicant for the 'EC' verification

- 4.2.1. The word 'applicant' is used in the Interoperability Directive in several articles and annexes. It does not refer in all cases to the same role and does not need to be the same organisation. For example:
- a rolling stock manufacturer may act as applicant for the 'EC' verification of the rolling stock subsystem ([Article 18]);
 - an onboard CCS manufacturer may act as applicant for the 'EC' verification of the onboard CCS subsystem ([Article 18]);
 - a leasing company may act as applicant for the first authorisation for placing in service of the vehicle ([Article 22]); and
 - a railway undertaking may act as applicant for an additional authorisation for placing in service in another Member State ([Article 23]).
- 4.2.2. The applicant for the 'EC' verification procedure *'may be the contracting entity or the manufacturer, or their authorised representative within the Community'*. Whichever organisation the applicant is, it is its obligation to establish the 'EC' declaration of verification. The applicant is therefore the entity responsible for the subsystem's fulfilment of the TSIs and other regulations deriving from the Treaty (requirements covered by an 'EC' declaration).
- 4.2.3. The applicant for the 'EC' verification is responsible for:
- the design, production and final testing of the subsystem. It is responsible for the subsystem's design and construction, even if elements of the subsystem were designed and built by different organisations;
 - arranging for the 'EC' verification to be carried out by a NoBo (see details in Annex 2 of this guide);
 - drawing up the 'EC' declaration of verification of the subsystem.
- 4.2.4. The applicant for the 'EC' verification may delegate or subcontract certain tasks relating to a subsystem (such as its design, construction or testing) but it retains overall control and responsibility for the subsystem as a whole and remains responsible for the 'EC' declaration of verification. Finally, the applicant who establishes the EC declaration of verification (after module SD or SF) must be the same as the one who got the EC type examination certificate".
- 4.2.5. In cases where certain parts or stages of the subsystem are covered by an intermediate statement of verification, the applicant, which draws up the 'EC' declaration of verification, may be different from the person/entity that drew up the declaration of intermediate verification.
- 4.2.6. Annexes V and VI of the Interoperability Directive define the obligations incumbent upon the applicant for authorisation for placing in service with regard to the 'EC' declaration of verification and the arrangements for holding this 'EC' declaration, together with the technical file accompanying it.
- 4.2.7. In cases of upgrading or renewal, it is the responsibility of the applicant for 'EC' verification to inform the NoBo of the decision taken by the Member State concerned regarding the extent of application of the TSIs. According to [Article 20(1)], *'the contracting entity or the*

manufacturer shall send the Member State concerned a file describing the project. The contracting entity and the manufacturer should agree on who sends the file. Normally, one of these two actors should be applicant for the 'EC' verification.

4.3. Authorised representative

- 4.3.1. According to definition R1(4) of Annex I of the Decision [22] on a common framework for the marketing of products, the authorised representative is *'any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified task'*.
- 4.3.2. In the context of the Interoperability Directive, it is an organisation expressly appointed by the manufacturer or by the contracting entity by a written mandate to act on his behalf in respect of certain manufacturer's or contracting entity's obligations. The extent to which the authorised representative may enter into commitments binding on the manufacturer or the contracting entity is determined in accordance with the mandate conferred on the authorised representative by the manufacturer or contracting entity.
- 4.3.3. As an example, the authorised representative may be appointed to request the conformity assessment on the EU territory, sign the 'EC' declaration of conformity or suitability for use or 'EC' declaration of verification, and hold these documents and the technical file (where applicable) at the disposal of the competent authorities during the lifetime of the IC or the subsystem.
- 4.3.4. A manufacturer's or contracting entity's authorised representative must be established within the EU.
- 4.3.5. Commercial representatives of a manufacturer (such as authorised distributors), whether or not established inside the EU, are not to be confused with an authorised representative within the meaning of the Interoperability Directive.
- 4.3.6. The authorised representative must respect the obligations incumbent upon the manufacturer or the contracting entity, such as the obligations with regard to assessment of conformity or suitability for use, 'EC' verification, 'EC' declaration of conformity or suitability for use, 'EC' declaration of verification or arrangements for holding the 'EC' declaration, together with the technical file, at the disposal of the competent authorities.
- 4.3.7. The authorised representative may be addressed by the authorities of the Member States instead of the manufacturer or the contracting entity with regard to the latter's obligations under the Interoperability Directive. The manufacturer or the contracting entity remains responsible for actions carried out by an authorised representative on its behalf.
- 4.3.8. The authorised representative may, at the same time, act as a subcontractor, importer or a person responsible for placing on the market.

4.4. Notified Bodies (NoBos)

- 4.4.1. A notified body (NoBo) is an organisation responsible for the third-party assessment of an IC or structural subsystem against the requirements of the relevant TSI. According to Articles 2(j), 13(2), 18 and 28 and Annex VI of the Interoperability Directive, the NoBos have the following tasks:

- to assess the conformity or suitability for use of the interoperability constituents;

- to undertake 'EC' verification of the subsystems;
- to draw up (compile) the technical file accompanying the 'EC' declaration of verification or intermediate statement of verification (ISV);
- to publish periodically information concerning
 - requests for 'EC' verification, ISV and assessment of conformity and/or suitability for use of ICs received,
 - 'EC' ISV certificates, 'EC' certificates of verification issued and 'EC' certificates of conformity and/or suitability for use issued or refused.

These tasks are in accordance with the 'global approach' principles, as explained in Annex 3 of this guide.

- 4.4.2. Furthermore, the *Guide to the implementation of directives based on the new approach and the global approach* (not yet updated according to the New Legislative Framework) is still relevant to the activities of NoBos, with the exception of the provisions dealing with the affixing of 'CE' markings on ICs and subsystems.
- 4.4.3. In accordance with the 'global approach' principles, the Interoperability Directive requires NoBos to closely cooperate with a view to coordinating their activities. For this purpose, a NoBo Coordination Group, NB Rail, has been set up to discuss any problems that may arise in relation to the assessment of the conformity or suitability for use of interoperability constituents and the 'EC' verification of subsystems, and to propose solutions to these problems ([Article 28(5)]). These solutions are formalised as 'Recommendations for Use' (RFU) or "Questions and clarifications" (Q&C). Q&Cs are submitted to the Commission for adoption. RFUs and Q&Cs do not supersede, but complement EU legislation by giving additional support and information to NoBos on technical issues. Once an RFU or a Q&C has been adopted, it is used by all the NoBos.
- 4.4.4. Information on RFUs and Q&C can be found on the NB Rail website (see link on the ERA website under interoperability/cooperation with organisations).
- 4.4.5. When notifying a body under the Interoperability Directive, the Member State notifying it should indicate the scope of competence of this NoBo:
- Procedure: assessment of conformity of ICs, assessment of suitability for use of ICs or 'EC' verification of subsystem;
 - Subsystems: energy, trackside control-command and signalling, onboard control-command and signalling, rolling stock or infrastructure;
 - TSI and revision of TSIs;
- 4.4.6. Annex VIII of the Interoperability Directive defines minimum criteria to be taken into account by the Member States when notifying bodies. These criteria are mostly related to competence and independence of both the business players (manufacturers, RUs, IMs, etc.) and the authorities authorising the placing in service.

4.5. Designated Bodies (DeBos)

- 4.5.1. A designated body is an organisation responsible for the third-party assessment of an IC or structural subsystem against the requirements of the relevant notified national rules (see section 2.15.1 for the cases where national rules apply).

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- 4.5.2. The organisation or organisations designated for the assessment of conformity to notified national rules can (and according to [recital (18)] should) be the same as the notified bodies. This, however, is not mandatory. In any case, if the same organisation is at the same time a 'designated body' and a 'notified body' and from a practical point of view can make the whole assessment in one single process, from the formal point of view it still acts with two different roles, and this should be reflected in the documents it establishes.
- 4.5.3. The tasks of the designated bodies regarding the verification of conformity to national rules are *mutatis mutandis* those of the notified bodies regarding the verification of conformity to the TSIs. There is however one significant difference – for the EC verification procedure, the applicant is free to appoint any competent NoBo (regardless of which Member States has notified it), while for the verification of conformity to national rules and specific cases the applicant is obliged to address the body designated by the Member State on whose territory the subsystem is intended to be placed in service.
- 4.5.4. The Interoperability Directive does not define the criteria the Member States must follow when designating these bodies. In this respect, Article 6(2) of the Decision [22] on a common framework for the marketing of products, may be mentioned as guidance. It states that *'[w]here Community harmonisation legislation provides for conformity assessment to be carried out by public authorities, the legislation shall provide that the conformity assessment bodies on which those authorities rely for technical assessments must comply with the same criteria as those set out in this Decision for notified bodies'*.

4.6. Applicant for an authorisation for placing in service of a subsystem

- 4.6.1. The applicant for an authorisation for placing in service of a subsystem may be different from the applicant for the 'EC' verification.
- 4.6.2. The applicant for authorisation for placing in service is explained in Section 8.1 of [43] the Recommendation on the authorisation for the placing in service of structural subsystems and vehicles. It is responsible for:
- ensuring that the subsystem has undergone the verification procedure and providing the NSA with the necessary evidence, including:
 - 'EC' verification;
 - verification of conformity to applicable national rules (open points, specific cases, derogations);
 - risk evaluation and assessment, if required according to Commission Regulation No 352/2009;
 - submitting an application for the authorisation for placing in service from the NSA of the Member State on whose territory the subsystem is intended to be located or operated.

4.7. National Safety Authorities (NSAs)

- 4.7.1. Regarding application of the TSIs, the main tasks of the NSAs are the following (all defined in Article 26 of the Safety Directive):
- *'authorising the placing in service of the structural subsystems (...)'*;
 - *'supervising that the interoperability constituents are in compliance with the essential requirements (...)'*;

- *'checking that conditions and requirements laid down in [safety certificates and safety authorisations] are met and that infrastructure managers and railway undertakings are operating under the requirements of the Community or national law'; this includes checking that TSIs requirements for the functional subsystems are met.*

WITHDRAWN

5. CONFORMITY ASSESSMENT

5.1. Conformity assessment procedures

5.1.1. Interoperability Constituents (ICs)

- [G 58] Before being placed on the market (see Section 6.1), an IC must carry an 'EC' declaration of conformity and, where required, an 'EC' declaration of suitability for use. These declarations are issued by the manufacturer of the IC or its authorised representative following certification by a NoBo, where appropriate.
- [G 59] With respect to the Interoperability Directive the general definition of 'conformity assessment' (see definitions in Table 7) should be understood for the ICs as the process demonstrating whether requirements specified in the relevant TSI relating to an interoperability constituent have been fulfilled.
- [G 60] Other characteristics of an IC may be defined in a contractual way between the manufacturer and the purchaser, providing they do not contradict the requirements of TSIs. A NoBo does not need to assess these characteristics in the framework of interoperability.
- [G 61] The 'EC' declaration of conformity or suitability for use of an IC must precisely identify the product it was drawn up for.
- [G 62] A new conformity assessment and a new 'EC' declaration of conformity are necessary for an existing IC (before it has been integrated into a subsystem) when
- it is substantially modified (i.e. where the modifications could influence the characteristics of the basic parameters); or if
 - it is intended to be used in a new area of use.
- [G 63] In the cases stated above, a new 'EC' declaration of suitability for use is also necessary if this declaration is required for the IC by the relevant TSI.
- [G 64] The entity placing the IC on the market on the EU territory must keep at the disposal of the competent national authority the 'EC' declaration/s of conformity and 'EC' declaration/s of suitability for use and the technical documentation for a period defined in the relevant TSI; where the TSI does not define this period is 10 years from the date on which the last IC was manufactured. This applies for ICs manufactured in the EU as well as those imported from a third country. If this obligation has not been met by the manufacturer or its authorised representative in the EU, it is incumbent on whoever placed the IC on the EU market (importer or any other person).
- [G 65] In practice, interoperability constituents are usually manufactured in serial production on the basis of the same design or type, and may be incorporated into different subsystems. With this in mind, an 'EC' declaration of conformity and/or suitability for use is issued before the incorporation of the IC into a subsystem, and is not usually related to a specific project or subsystem.
- [G 66] An IC carrying an 'EC' declaration of conformity and/or suitability for use can be incorporated into a subsystem without further assessment of its conformity. Subsequent 'EC' verification of the subsystem (see section 5.3.3 below) has to include a verification of whether the IC has been integrated correctly and is compatible with other ICs in that subsystem (in particular, the 'EC' verification process must include a check that ICs are used in their relevant area of use).

- [G 67] When an IC forms part of another IC (for example, the 'sleeper' IC is part of the 'switch' IC), it is the responsibility of each respective manufacturer to provide the appropriate verification and 'EC' declaration. Thus, in the above example, the manufacturer of the sleeper has a responsibility to provide the 'EC' declaration of the sleeper to the manufacturer of the switch.
- [G 68] An application for the conformity assessment of a constituent may be made at any time. However, unless the relevant TSI provides otherwise, the 'EC' certificate for the subsystem incorporating this IC may only be established after all relevant 'EC' declarations of conformity and suitability for use have been established.
- [G 69] If the IC is assessed at the same time as the subsystem and placed on the EU market through the placing in service of this subsystem, a specific 'EC' declaration of conformity is still required for the IC, unless the relevant TSI provides otherwise (e.g. for a transitional period). The placing on the market of an IC cannot be covered by the 'EC' declaration of verification of the subsystem in which the IC is integrated. From the formal point of view, the process of conformity assessment of the IC is separate from the verification process of the subsystem.
- [G 70] In particular situations (where the obligations relating to the 'EC' declaration of conformity or suitability for use has not been met by the manufacturer or its authorised representative), it is possible for the organisation that uses ICs (e.g. a vehicle manufacturer that incorporates ICs in a vehicle, a civil works contractor that uses ICs for the infrastructure, or the contracting entity) to issue an 'EC' declaration of conformity or suitability for use for an IC in place of the manufacturer. In this case, the organisation has to arrange for the EC conformity assessment, and will be considered to be the entity that placed this IC on the market ([Article 13(4)]).
- [G 71] The 'EC' declaration of conformity and 'EC' declaration of suitability for use must be registered at the European Railway Agency database, ERADIS.

5.1.2. Subsystems

- [G 72] Before seeking authorisation from a Member State to place a subsystem in service, the following steps must take place:
- 'EC' verification of the subsystem by a NoBo (Annex VI of the Interoperability Directive); and establishment by this NoBo of the 'EC' verification certificate;
 - establishment of an 'EC' declaration of verification for the subsystem by the applicant for the 'EC' verification;
 - verification of conformity to notified national rules by a designated body, where necessary;
 - a Common Safety Method (CSM) risk assessment, where necessary

This guide does not cover the complete process – it is limited to conformity to the TSIs.

- [G 73] An 'EC' declaration of verification is needed for any new and, if the Member State so requires, upgraded or renewed structural subsystems. If a project includes more than one of the structural subsystems defined in Annex II of the Interoperability Directive (e.g. a vehicle may include a rolling stock subsystem and an onboard CCS subsystem; a railway line includes an infrastructure subsystem and usually energy and trackside CCS subsystems), then several 'EC' declarations of verification are needed, one for each structural subsystem.

- [G 74] In the case of serial production (e.g. for rolling stock), each unit must be covered by an 'EC' declaration of verification. This may be done by means of an individual declaration for each unit or listing several units in one declaration.
- [G 75] If only certain parts or certain stages of the subsystem are covered, and they meet the requirements of the relevant TSI(s), the NoBo issues an Intermediate Statement of Verification (ISV), in compliance with [Article 18(4)].
- [G 76] In the case of an ISV procedure, the applicant draws up an 'EC' declaration of intermediate subsystem conformity.

5.2. Conformity assessment modules

- [G 77] The procedures for conformity and suitability for use assessment and 'EC' verification are based on the use of modules.
- [G 78] TSIs adopted before 2010 include a description of conformity assessment modules in each TSI. TSIs adopted in 2010 refer to a separate Commission decision on conformity assessment modules, and thus do not contain the description of modules themselves. This decision includes a correlation table of 'old' and 'new' modules in an annex.
- [G 79] Both 'old' and 'new' modules are based on generic modules as defined by Decisions^o[26] concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, and^o[22] on a common framework for the marketing of products respectively. However, due to specific requirements in the railway sector, they have been adapted (e.g. separate modules for ICs and subsystems have been created^o[42]).
- [G 80] Further details (including tasks of the manufacturers, applicants for the 'EC' verification and NoBo) are given in Annex 2 of this guide.

5.3. Choice of modules

5.3.1. Interoperability constituent assessment

- [G 81] It is up to the manufacturer of the IC to choose, from the modules indicated in the TSI for a particular IC, those that best suit its production process.
- [G 82] The degree of involvement required of a NoBo in the IC assessment procedure is different for each module.
- [G 83] Generally, the TSI allow a choice of at least two modules for the conformity assessment of an IC: one module for manufacturers without a quality management system (QMS) and one module for manufacturers with a QMS. In the latter case, a formal certification of a quality management system (e.g. EN ISO 9001) by an accredited certification body has to be taken into account by the NoBo when these certifications apply to the IC. If there is no certified QMS, the NoBo has to assess the QMS implemented for the design and/or the manufacture of the IC.
- [G 84] In the case of a certified QMS, the assessment by a NoBo does not cover general requirements of the QMS, but only the application of this QMS to the particular IC.
- [G 85] CA and CC modules (a CC module can only be used in a CB+CC combination) do not require involvement of a NoBo in the conformity assessment, or the issue of a certificate by a NoBo.

- [G 86] CD modules (a CD module can only be used in a CB+CD combination) and CH and CH1 modules require a QMS.
- [G 87] Where a manufacturer does not have a QMS, only CA, CA1, CA2, CB, CC and CF modules (CC and CF modules can only be used in CB+CC and CB+CF combinations, respectively) can be used for assessing an IC.
- [G 88] For certain ICs, the TSIs do not require a conformity assessment by a NoBo (CA module) or do not require a conformity assessment by a NoBo in the production stage (CC module). In these cases, the IC is not covered by an 'EC' certificate of conformity. However, the manufacturer is responsible for the issue an 'EC' declaration of conformity for all the ICs manufactured.

5.3.2. Interoperability constituent suitability for use assessment

- [G 89] The suitability for use procedure applies to constituents that need a validation by in-service experience. It is specified, in particular, for constituents of a new design or which are used in a new area of use.
- [G 90] Where the suitability for use procedure is required by the TSI, the CV module is to be applied. In this case, it is always complementary to the conformity assessment CB or CH1 modules.
- [G 91] The suitability for use assessment procedure normally implies use of the constituent in service, integrated representatively into the subsystem over a specific operational time or running distance.
- [G 92] If the relevant TSI indicates such possibility, the suitability for use can be assessed by simulation methods (such as on a test bench or a test circuit). The conditions of acceptance are specified in the TSI.

5.3.3. 'EC' verification of subsystems

- [G 93] It is up to the applicant to choose, from the modules indicated in the TSI for the subsystem concerned, those that best suit the process of design, production and final testing of the subsystem.
- [G 94] For the assessment of subsystems, the 'EC' verification procedure has in all the cases to be carried out by a NoBo, and an 'EC' verification certificate has to be established.
- [G 95] SD and SH1 modules require the applicant to operate a QMS.
- [G 96] To use the SD module, the applicant must operate a QMS for the production and final testing of the subsystem.
- [G 97] To use the SH1 module, the applicant must operate a QMS for the design, production and final testing of the subsystem.
- [G 98] If several partners are involved in a project, for using a QMS-based module, the relevant tasks of all the partners involved in the design, manufacture, installation and final testing (e.g. both infrastructure manager and suppliers, if they are involved) have to be covered by the QMS.
- [G 99] Where an applicant does not have a QMS, only the SB+SF or SG modules can be used for the 'EC' verification of the subsystems.
- [G 100] The applicant who establishes the EC declaration of verification (after module SD or SF) must be the same as the one who got the EC type examination certificate.

[G 101] The applicant establishes the EC declaration of verification under his sole responsibility. That is, independently from any contractual arrangements, the applicant takes complete responsibility for the product including its design, which is covered by Module SB. In other words, if a subsystem does not meet the requirements of the TSIs, the applicant cannot say that he only manufactured what was on the drawings and is not responsible for the design.

[G 102] If an applicant in possession of an EC type examination certificate (applicant X), wishes to licence the design of his product to someone else (applicant Y), it can be done as follows:

- applicant X makes all relevant documentation of type examination available to applicant Y;
- applicant Y applies for his own EC type examination certificate and includes this documentation in his application as *“results of tests carried out by the appropriate testing body of the applicant, or by another testing body on his behalf and under his responsibility”* (section 3 in the description of module SB).

After applicant Y has got his EC type examination certificate, he can verify conformity of his products to his type (module SD or SF).

5.4. Assessments applicable to certain stages

5.4.1. The TSIs specify to which stages (overall design, production or final testing) the assessments of conformity apply, and by which specific assessment methods (design review, type test, manufacturing process review, validation of in-service experience, etc.) they have to be carried out. The choice of the modules depends on those stages.

5.4.2. For some basic parameters, only design characteristics (such as dimension requirements ensuring compatibility) are essential. In those cases, the conformity assessment is focused on a design review of the IC or the subsystem.

5.4.3. Where a design review is required in the TSI or in the module chosen by the applicant, this design review must either

- be performed by a NoBo, according to a documented process, or
- be part of a QMS

5.4.4. The NoBo has to assess the implementation of the design review, in accordance with the procedure defined by the conformity assessment module chosen by the applicant. If it is part of a QMS certified by an independent third party, the NoBo has to take this certification into account for the assessment of the implementation of the design review.

5.4.5. The applicant may arrange for verification by a NoBo limited to a certain stage. In this case, the NoBo issues an EC ISV certificate and, based on this, the applicant issues an EC ISV declaration (Annex VI of the Interoperability Directive).

5.4.6. Any NoBo in charge of further stages of ‘EC’ verification has to take the EC ISV certificate as evidence of conformity of the stage covered by it.

5.5. Cases not covered by ‘EC’ verification

5.5.1. An ‘EC’ verification procedure, which is carried out by a NoBo, does not include verification of conformity in the following cases:

- national rules apply for an open point;

- a specific case applies instead of a clause of Chapter 4 of the TSI;
- national rules apply instead of a requirement of a TSI following a derogation;
- national rules apply instead of a requirement of a TSIs in a case of renewal or upgrading.

5.5.2. In these cases, the 'EC' verification certificate and 'EC' declaration of verification must clearly identify parts of the relevant TSIs to which conformity has not been assessed.

5.5.3. Parts or aspects of the subsystem not covered by the 'EC' verification have to be assessed by a DeBo against applicable national rules.

5.6. Assessments in the case of renewal or upgrading

5.6.1. In these cases, [Article 20] applies. The following situations may be distinguished:

- renewal or upgrading of an existing subsystem (or series of subsystems) in conformity with the TSIs in force at the moment of renewal or upgrading;
- renewal or upgrading of an existing subsystem (or series of subsystems) not in conformity with the TSIs in force at the moment of renewal or upgrading, but in conformity with earlier versions of the TSIs (i.e. in conformity with the TSIs in force at the moment when it (or they) were originally placed in service);
- renewal or upgrading of an existing subsystem (or series of subsystems) not in conformity with any version of the TSIs.

5.6.2. In the latter two cases, the extent of application of the TSIs in force has to be decided by the Member State on whose territory the subsystem is intended to be placed in service after its renewal or upgrading.

5.6.3. In this respect, the particularity of the situation of subsystems that constitute a vehicle should be mentioned. These subsystems are subject to authorisation for placing in service by the NSA of all the Member States on whose territory the vehicle is intended to be operated. The decision on the extent of application of the TSIs should be taken by the Member State in which the first authorisation for placing in service after upgrading or renewal is sought. Regarding the additional authorisations, the scope of related verifications has to be limited according to the provisions of [Articles 23 or 25].

5.6.4. In the case of renewal or upgrading of existing subsystems in conformity with the TSIs in force at the moment of renewal or upgrading, full application of the TSIs should not present any problem.

5.6.5. The terms 'renewal' and 'upgrading' refer to existing subsystems. In the context of [Article 20] they do not refer to modifications of a certified type or design with a view to producing new subsystems.

6. TSI APPLICATION THROUGHOUT THE LIFECYCLE OF RAILWAY SYSTEM ELEMENTS

6.1. Placing on the market of an interoperability constituent

6.1.1. [Article 10] states that *'Member States shall take all necessary steps to ensure that interoperability constituents:*

- *are placed on the market only if they enable interoperability to be achieved within the rail system while at the same time meeting the essential requirements;*
- *are used in their area of use as intended and are suitably installed and maintained.'*

6.1.2. These provisions shall not obstruct the placing on the market of these constituents for other applications.'

6.1.3. The placing of an IC on the market is the initial action, which typically takes place when the constituent leaves the manufacturing stage, of making this constituent available for the first time on the EU territory, with a view to its distribution or use in the EU. The concept of placing on the market refers to each individual IC, not to a type of constituent, and regardless of being manufactured as an individual unit or in series.

6.1.4. An IC can be made available (i.e. placed on the market) either for payment or free of charge, typically by physical handover or by transfer of ownership from the manufacturer, the manufacturer's authorised representative or the importer established in the EU to the distributors or directly to the final users, regardless of the legal instrument upon which the transfer is based (sale, loan, hire, leasing or any other type of legal instrument).

6.1.5. An IC must comply with the applicable directives and the TSIs when placed on the market. As the concept of placing on the market refers to each individual IC, the manufacturer must ensure that every such IC complies with the Interoperability Directive, the related TSIs and other applicable directives at its placing on the market.

6.1.6. If a manufacturer, his authorised representative in the EU or the importer offers an IC covered by the Interoperability Directive and the related TSIs in a catalogue, it is deemed not to have been placed on the market until it is actually made available for the first time. Therefore if an IC offered in a catalogue is not in full conformity with the provisions of the Interoperability Directive and the related TSIs, this fact should be clearly advertised in the catalogue.

6.1.7. When the IC is placed on the market, it has to be covered by an 'EC' declaration. An 'EC' declaration may cover one single component or a series of identical components, In either case, the component or components covered by the 'EC' declaration have to be clearly identified in it, e.g. by serial numbers.

6.1.8. Placing on the market is considered not to take place where the product is:

- transferred from a manufacturer in a third country to an authorised representative in the EU whom the manufacturer has engaged to ensure that the IC complies with the Interoperability Directive and the related TSIs;
- imported into the EU for the purpose of re-export, that is, under processing arrangements;
- manufactured in the EU for export to a third country;

- displayed at trade fairs or exhibitions. In this case, it may not be in full conformity with the provisions of the Interoperability Directive and the related TSIs, but this fact should be clearly advertised next to the IC being exhibited.

6.2. Lifecycle of subsystems

[G 103] The lifecycle of a subsystem has the following stages:

- design,
- production,
- final testing,
- placing in service,
- operation and maintenance and
- end of life

[G 104] The lifecycle of a subsystem may include several renewals or upgradings.

[G 105] As indicated in [Article 5(2)] *'[s]ubsystems shall comply with the TSIs in force at the time of their placing in service, upgrading or renewal, in accordance with [the Interoperability] Directive; this compliance shall be permanently maintained while each subsystem is in use'*.

[G 106] At the moment of placing a subsystem in service, the responsibility for compliance with the TSIs lies with the organisation that established the 'EC' declaration of verification. Moreover, this conformity to the TSIs has to be checked and certified by a NoBo.

[G 107] After a subsystem has been placed in service, the responsibility for compliance with the TSIs lies, according to [Article 15(3)], with the RU or IM that operate the subsystem and, according to Article 14a of the Safety Directive, with the ECM as far maintenance of vehicles is concerned.

[G 108] Annex 4 of this guide provides some practical examples illustrated with flowcharts.

6.2.1. Design, production and final testing of a subsystem

[G 109] As indicated in [Article 18(2)], the involvement of the NoBos starts at the design stage and finishes immediately before the placing in service of a subsystem. It has to be noted that for certain aspects a NoBo may not be able to perform the checks if it has not been involved from the very beginning of the production stage and, in any case, a late involvement of a NoBo may lead to a delay in the 'EC' verification and consequently in the authorisation for placing in service.

[G 110] As result of the 'EC' verification, the NoBo establishes an 'EC' certificate of verification.

[G 111] The NoBo is also responsible for compiling the technical file accompanying the 'EC' declaration of verification ([Article 18(3)]). This file has to include among other documents *'all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance'*.

[G 112] The technical file has to include the results of verification by the designated bodies of conformity to the applicable notified national rules and, when required according to Commission Regulation (EC) No 352/2009, the report relating to the CSM on risk

assessment referred to in Article 6(3) of Directive 2004/49/EC (according to sections 2.4 and 3.3 of Annex VI of the Interoperability Directive).

6.2.2. Placing in service of a subsystem

[G 113] [Article 15(1)] states that '(...) each Member State shall authorise the placing in service of those structural subsystems constituting the rail system which are located or operated in its territory.

To this end, Member States shall take all appropriate steps to ensure that these subsystems may be placed into service only if they are designed, constructed, installed in such a way as to meet the essential requirements concerning them when integrated into the rail system.'

This includes, but is not limited to, conformity to the relevant TSIs. It also includes conformity to applicable notified national rules and safe integration of these subsystems.

[G 114] In accordance with [Article 18], the contracting entity or the manufacturer, or their authorised representative within the EU, establishes the 'EC' declaration of verification on the basis of an 'EC' verification certificate delivered by a NoBo and the technical file accompanying the certificate.

[G 115] Once the verification procedure has been completed, the NSA of the Member State in which the subsystem is intended to be placed in service should authorise the placing in service of the subsystem.

[G 116] The obligation for a subsystem to conform with a particular TSI begins with its first placing in service after the entry into force of this TSI if the scope (both geographical and technical) of this TSI includes this particular subsystem. After that, this conformity must be verified at each subsequent placing in service. In addition, this compliance shall be permanently maintained while each subsystem is in use.

6.2.3. Renewal or upgrading of a subsystem

[G 117] In the event of renewal or upgrading, as a first step, the contracting entity or the manufacturer has to submit a file describing the project to the Member State concerned. Based on the file, and taking into account the implementation strategy in Chapter 7 of the applicable TSI, the Member State has to decide whether the extent of the work means that a new authorisation for placing in service within the meaning of the Interoperability Directive is needed.

[G 118] Such authorisation for placing in service is necessary whenever the level of safety may be adversely affected by the work envisaged.

[G 119] If a new authorisation is required, the Member State has to decide to what extent the TSIs need to be applied to the project. In particular it can specify, where appropriate, the characteristics of the subsystem that have to be submitted to a new design examination and/or type test, the parts of the TSIs that have to be complied with, or parts of the subsystem that have to comply with the TSIs.

6.2.4. Operation and maintenance of a subsystem

[G 120] For subsystems that were placed in service, upgraded or renewed before entry into force of the relevant TSIs, in the case of maintenance-related replacement, application of these TSIs is voluntary.

- *****
- [G 121] For a subsystem that was placed in service, upgraded or renewed after entry into force of the relevant TSIs, conformity to these TSIs has to be maintained during the lifetime of this subsystem, including any maintenance-related replacement. This includes the use of ICs covered by an 'EC' declaration.
 - [G 122] To fulfil such requirement a measure repealing a TSI usually contains an article stating that the provisions of the repealed TSI continue to apply in relation to maintenance of projects authorised in accordance with this TSI.
 - [G 123] This option allows NoBos to issue an EC certificates complying with (a) repealed TSI/s, in particular for an interoperability constituent for a subsystem authorised in accordance with this TSI.
 - [G 124] Apart from the compliance of the rolling stock with the provisions of the Interoperability Directive, an RU must also obtain a safety certificate in each of the Member States in which it operates, and an IM must obtain a safety authorisation, in accordance with Articles 10 and 11 of the Safety Directive, respectively.
 - [G 125] There is no NoBo involvement in the operation and maintenance stage of a subsystem.

6.3. Placing in service of a vehicle

- 6.3.1. According to [Article 21(1)] of the Interoperability Directive, *'[b]efore being used on a network, a vehicle shall be authorised to be placed in service by the national safety authority which is competent for this network, unless otherwise provided...'*
- 6.3.2. A vehicle may be composed of one or more subsystems.
- 6.3.3. All provisions relating to authorisations of placing in service of vehicles (both existing and new) have been included in the Interoperability Directive.
- 6.3.4. An important difference between the subsystems that compose a network (infrastructure and fixed facilities) and subsystems that compose a vehicle is that the former receive only one authorisation for placing in service (granted by the NSA of the Member State in which the network is located), while the latter (unless otherwise provided in [Chapter V]) need to be authorised in every Member State in which the vehicle is intended to be used.
- 6.3.5. For vehicles, the Interoperability Directive establishes difference between the *'first authorisation for placing in service'* (i.e. authorisation in the first Member State in which the vehicle is intended to be placed in service) and *'additional authorisations for placing in service'* (i.e. authorisations in other Member States in which the vehicle is intended to be operated).
- 6.3.6. The principle is that the checks carried out for the authorisation in one Member State should not be repeated for the authorisations in any other Member State. In particular, 'EC' verification needs to be carried out for the first authorisation for placing in service, and is also valid for the additional authorisation.

7. LIST OF ANNEXES

1. Specific guides for different TSIs (including lists of applicable standards and other documents)
2. Conformity assessment and 'EC' verification
3. The European framework
4. Examples of application of TSIs at different stages

(See the Agency website for the latest available versions of the annexes, useful Internet links and addresses and frequently asked questions.)

WITHDRAWN

REFERENCE DOCUMENTS

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[1]	Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways	L 237, 24.8.1991	Directive 2007/58/EC L 315, 3.12.2007	--
[2]	Council Directive 95/18/EC of 19 June 1995 on the licensing of railway undertakings	L 143, 27.6.1995	Directive 2004/49/EC L 220, 21.6.2004	--
[3]	Council Directive 95/19/EC of 19 June 1995 on the allocation of railway infrastructure capacity and the charging of infrastructure fees	L 143, 27.6.1995	Directive 2001/14/EC (repeal) L 75, 15.3.2001	--
[4]	Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system	L 235, 17.9.1996	Directive 2008/57/EC (repeal) L 191, 18.7.2008	--
[5]	Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations	L 24, 21.7.1998	Directive 2006/96/EC L 363, 20.12.2006	--
[6]	Directive 2001/12/EC of the European Parliament and of the Council of 26 February 2001 amending Council Directive 91/440/EEC on the development of the Community's railways	L 75, 15.3.2001	Corrigendum, L 334, 18.12.2001	--
[7]	Directive 2001/13/EC of the European Parliament and of the Council of 26 February 2001 amending Council Directive 95/18/EC on the licensing of railway undertakings	L 75, 15.3.2001	–	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[8]	Directive 2001/14/EC of the European Parliament and of the Council of 26 February 2001 on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification	L 75, 15.3.2001	Directive 2007/58/EC L 315, 3.12.2007	--
[9]	Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system	L 110, 20.4.2001	Directive 2008/57/EC (repeal) L 191, 18.7.2008	--
[10]	Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors	L 134, 30.4.2004	Regulation (EC) No 1251/2011 L 319 43 2.12.2011	--
[11]	Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending 95/18/EC and 2001/14/EC	L 164, 30.4.2004	Directive 2009/149/EC L 313, 28.11.2009	--
[12]	Directive 2004/50/EC of the European Parliament and of the Council of 29 April 2004 amending Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system	L 164, 30.4.2004	Directive 2008/57/EC (repeal) L 191, 18.7.2008	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[13]	Directive 2004/51/EC of the European Parliament and of the Council of 29 April 2004 amending Council Directive 91/440/EEC on the development of the Community's railways	L 164, 30.4.2004	Corrigendum L 164, 30.4.2004	--
[14]	Directive 2007/32/EC amending Annex VI to Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and Annex VI to Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system	L 141, 2.6.2007	Directive 2008/57/EC (repeal) L 191, 18.7.2008	--
[15]	Directive 2007/58/EC of the European Parliament and of the Council of 23 October 2007 amending Council Directive 91/440/EEC on the development of the Community's railways and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure	L 315, 3.12.2007	–	--
[16]	Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community	L 315, 3.12.2007	–	--
[17]	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	L 191, 18.7.2008	Directive 2009/131/EC L 273, 17.10.2009 Directive 2011/18/EU L 57, 2.3.2011	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[18]	Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations	L 315, 3.12.2007	–	--
[19]	Decision 94/1/EC of the Council and the Commission of 13 December 1993 on the conclusion of the Agreement on the European Economic Area between the European Communities, their Member States and the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation	L 1, 3.1.1994	–	--
[20]	Regulation (EC) No 881/2004 establishing a European Railway Agency (Agency Regulation)	L 220, 21.6.2004	Regulation (EC) No 1335/2008 L 354, 31.12.2008	--
[21]	Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission	L 184, 17.7.1999	Regulation (EU) N°182/2011 L 55, 28.2.2011	--
[22]	Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC	L 218, 13.8.2008	–	--
[23]	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93	L 218, 13.8.2008	–	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[24]	Decision No 661/2010/EU of the European Parliament and of the Council of 7 July 2010 on Union guidelines for the development of the trans-European transport network	L 286, 4.11.2010	–	--
[25]	Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the trans-European transport network	L 228, 9.9.1996	Decision No 661/2010/EU (repeal) L 286, 4.11.2010	--
[26]	Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking	L 220, 30.8.1993	Decision 768/2008/EC (repeal) L 218, 13.8.2008	--
[27]	Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity to the rules on product safety in the case of products imported from third countries	L 40, 17.2.1993	Regulation (EC) No 765/2008 (repeal) L 218, 13.8.2008	--
[28]	Commission Decision 2006/679/EC TSI relating to the CCS subsystem of the trans-European conventional rail system	L 284, 16.10.2006	Repeal: Decision 2012/88/EU L 51, 25.1.2012 Amendment: Decision 2012/463/EU L 217, 14.8.2012	--
[29]	Commission Decision 2006/860/EC TSI relating to the CCS subsystem of the trans-European HS rail system	L 342, 07.12.2006	Repeal: Decision 2012/88/EU L 51, 25.1.2012 Amendment: Decision 2012/463/EU L 217, 14.8.2012	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[30]	Commission Decision 2006/861/EC TSI relating to the 'Rolling stock – Freight Wagons' subsystem of the trans-European conventional rail system	L 344, 8.12.2006	Amendment: Decision 2009/107/EC L 45, 14.2.2009 Decision 2012/464/EU L 217, 14.8.2012	--
[31]	Commission Decision 2006/920/EC TSI relating to the Operation subsystem of the trans-European conventional rail system	L 359, 18.12.2006	Repeal: Decision 2011/314/EU L 144, 31. 5.2011	--
[32]	Commission Decision 2011/229/EU TSI 'Rolling stock – Noise'	L 99, 13.4.2011	Decision 2012/464/EU L 217, 14.8.2012	--
[33]	Commission Regulation (EC) No 62/2006 TSI 'Telematic Applications for Freight'	L 13, 18.1.2006	Commission Regulation (EU) 328/2012 L 106, 17.4.2012	--
[34]	Commission Decision 2008/217/EC TSI relating to the Infrastructure subsystem of the trans-European HS rail system	L 77, 19.3.2008	Amendment: Decision 2012/464/EU L 217, 14.8.2012	--
[35]	Commission Decision 2008/163/EC TSI SRT trans-European HS and conventional rail system	L 64, 07.3.2008	Amendment: Decision 2011/291/EU L 139, 26.5.2011 Decision 2012/464/EU L 217, 14.8.2012	--
[36]	Commission Decision 2008/164/EC TSI PRM trans-European HS and conventional rail system	L 64, 07.3.2008	Amendment: Decision 2012/464/EU L 217, 14.8.2012	--
[37]	Commission Decision 2008/231/EC TSI Operation trans-European HS rail system	L 84, 26.3.2008	Amendment: Decision 2010/640/EU L 280, 26.10.2010 Decision 2012/464/EU L 217, 14.8.2012	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[38]	Commission Decision 2008/232/EC TSI Rolling stock trans-European HS rail system	L 84, 26.3.2008	Amendment: Decision 2012/464/EU L 217, 14.8.2012	--
[39]	Commission Decision 2008/284/EC TSI Energy trans-European HS rail system	L 104, 14.04.2008	Amendment: Decision 2012/464/EU L 217, 14.8.2012	--
[40]	Commission decision C(2010)2576 concerning a mandate to the Agency to develop and review TSIs with a view to extending their scope to the whole rail system in the European Union			
[41]	Commission Decision 2010/640/EU of 21 October 2010 amending Decisions 2006/920/EC and 2008/231/EC concerning the technical specifications of interoperability relating to the subsystem 'Traffic Operation and Management' of the trans-European conventional and high-speed rail systems	L 280, 26.10.2010	Decision 2011/314/EU L 144, 31.5.2011	--
[42]	Commission Decision 2010/713/EU of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council	L 319, 4.12.2010	--	--
[43]	Commission Recommendation 2011/217/EU of 29 March 2011 on the authorisation for the placing in service of structural subsystems and vehicles under Directive 2008/57/EC of the European Parliament and of the Council	L 95, 8.4.2011	--	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[44]	Framework Mandate to the European Railway Agency for the Performance of Certain Activities under Directives 96/48/EC and 2001/16/EC – COM(2007)3371	Not applicable	–	--
[45]	Commission Decision 2011/274/EU of 26 April 2011 concerning a technical specification for interoperability relating to the energy subsystem of the trans-European conventional rail system	L 126, 14.5.2011	Decision 2012/464/EU L 217, 30, 14.8.2012	--
[46]	Commission Decision 2011/275/EU of 26 April 2011 concerning a technical specification for interoperability relating to the infrastructure subsystem of the trans-European conventional rail system	L126, 14.5.2011	Decision 2012/464/EU L 217, 14.8.2012	--
[47]	Commission Decision 2011/291/EU of 26 April 2011 concerning a technical specification for interoperability relating to the rolling stock subsystem – ‘Locomotives and passenger rolling stock’-of the trans-European conventional rail system	L 139, 26.5.2011	Decision 2012/464/EU L 217,14.08.2012	--
[48]	Commission Decision 2011/314/EU of 12 May 2011 concerning the technical specification for interoperability relating to the ‘Operation and traffic management’ subsystem of the trans-European conventional rail system	L 144, 31.5.2011	Amendment: Decision 2012/464/EU L 217, 14.8.2012	--
[49]	Commission Regulation (EU) 454/2011 of 5 May 2011 on the technical specification for interoperability relating to the subsystem ‘telematics applications for passenger services’ of the trans-European rail system	L 123, 12.5.2011	Regulation (EU) 665/2012 L 194, 1, 21.7.2012	--

Table 6: Reference documents

Ref.	Document reference	Official Journal	Last modification/ amendment	Version
[50]	Commission Directive 2009/131/EC of 16 October 2009 amending Annex VII to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community	L 273, 17.10.2009	--	--
[51]	Commission Directive 2011/18/EU of 1 March 2011 amending Annexes II, V and VI to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community	L 57, 2.3.2011	--	--
[52]	Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers	L 55, 28.2.2011	--	--
[53]	Commission decision of 25 January 2012 on the technical specification for interoperability relating to the control-command and signalling subsystems of the trans-European rail system	Decision 2012/88/EU L 51, 1, 25.1.2012	--	--

DEFINITIONS AND ABBREVIATIONS

Definitions

- [G 126] The following table provides list of terms used in this guide, and their definitions.
- [G 127] Some of these terms have already been defined in the relevant legal texts; in these cases they are given in italics and in quotation marks, and the source of the definition is indicated. These definitions are binding.
- [G 128] Some of the terms are not defined in the legal texts; in these cases, the definitions have been taken from standards or guides or worked out by the team that drafted this guide. These definitions are not binding.

Table 7: Definitions

Term	Definition/source
Acts of the Agency	Any document issued by the European Railway Agency according to Article 2(a) of Regulation (EC) No 881/2004.
Area of use	Design characteristic of subsystem(s) into which the interoperability constituent is intended to be incorporated.
Basic parameter	<i>'any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs'</i> ([Article 2(k)])
Conformity	Fulfilment of specified requirements by a product, process, service, system, person or body (interpretation of Article R1(12) of Annex 1 of Decision 768/2008/EC).
Conformity assessment	<i>'the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled'</i> (Article R1(12) of Annex 1 of Decision 768/2008/EC)
Conformity assessment body	<i>'a body that performs conformity assessment activities including calibration, testing, certification and inspection'</i> (Article R1(13) of Annex 1 of Decision 768/2008/EC); in the case of the Interoperability Directive, a notified body is a conformity assessment body regarding the TSIs and a designated body is a conformity assessment body regarding the notified national rules.
CSM assessment body	<i>'independent and competent person, organisation or entity which undertakes investigation to arrive at a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements'</i> (Article 3(14) of Commission Regulation (EC) No 352/2009)
Contracting entity	<i>'any entity, whether public or private, which orders the design and/or construction or the renewal or upgrading of a subsystem. This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for carrying out a project'</i> ([Article 2(r)])
Derogation	Exemption from all or part of TSI requirements granted according to [Article 9].

Table 7: Definitions

Term	Definition/source
Design examination	assessment of the design of a product by examination of the design methods, the design tools and the design results, taking into account, if appropriate, the results of tests and reviews and validation by in service experience (procedure within CH1 module for interoperability constituents or SH1 module for subsystems)
Designated body (DeBo)	Body designated by a Member State for the assessment of conformity of subsystems to notified national technical rules according to [Article 17 or 20]
Essential requirements	<i>all the conditions set out in Annex III which must be met by the rail system, the subsystems, and the interoperability constituents, including interfaces</i> ([Article 2(g)])
European specification	<i>'a common technical specification, a European technical approval or a national standard transposing a European Standard, as defined in Annex XXI to Directive 2004/17/EC'</i> ([Article 2(h)])
Existing rail system	<i>'the structure composed of lines and fixed installations of the existing, rail system plus the vehicles of all categories and origin travelling on that infrastructure'</i> ([Article 2(o)])
Harmonised standard	<i>'any European standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of the rules on Information Society services in connection with a mandate by the Commission drawn up in accordance with the procedure referred to in Article 6(3) of that Directive, which, by itself or together with other standards, provides a solution as regards compliance with a legal provision'</i> ([Article 2(u)])
Infrastructure manager (IM)	<i>'any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or part thereof, as defined in Article 3 of Directive 91/440/EEC, which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings'</i> (Article 3(b) of the Safety Directive)
Innovative solution	Technical solution that meets the essential requirements of the Interoperability Directive and other regulations deriving from the Treaty, but does not meet some of the requirements specified in the relevant TSIs and/or is not assessable as stated in these TSIs.

Table 7: Definitions

Term	Definition/source
National safety authority (NSA)	<i>'national body entrusted with the tasks regarding railway safety in accordance with [the Safety] Directive or any binational body entrusted by Member States with these tasks in order to ensure a unified safety regime for specialised cross-border infrastructures'</i> (Article 3(g) of the Safety Directive)
Notified body (NoBo)	<i>'[a body] which [is] responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the 'EC' procedure for verification of the subsystems'</i> ([Article 2(j)])
Open point	Any technical aspects corresponding to the essential requirements that could not be explicitly covered in a TSI and clearly identified in an annex to the TSI according to [Article 5(6)].
Placing in service	<i>'all the operations by which a subsystem or a vehicle is put into its design operating state'</i> ([Article 2(q)])
Placing on the market	<i>'the first making available of a product on the Community market'</i> (Article R1(2) of Annex 1 of Decision 768/2008/EC), where <i>'making available on the market'</i> means <i>'any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge'</i> (Article R1(1) of Annex 1 of Decision 768/2008/EC)
Project at an advanced stage of development	<i>'any project whose planning/construction stage has reached a point where a change in the technical specifications would be unacceptable to the Member State concerned. Such an impediment may be legal, contractual, economic, financial, social or environmental in nature and must be duly substantiated'</i> ([Article 2(t)])
Railway undertaking (RU)	<i>'railway undertaking as defined in Directive 2001/14/EC, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only'</i> (Article 3 (c) of the Safety Directive)
Regulatory domain	Product requirements and all actions and activities to comply with, to verify and to attest these requirements, legally required by the state or by a state authority.
Renewal	<i>'any major substitution work on a subsystem or part subsystem, which does not change the overall performance of the subsystem'</i> ([Article 2(n)])

Table 7: Definitions

Term	Definition/source
Specific case	<i>'any part of the rail system which needs special provisions in the TSIs, either temporary or definitive, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system. This may include, in particular, railway lines and networks isolated from the rest of the Community, the loading gauge, the track gauge or space between the tracks and vehicles strictly intended for local, regional or historical use, as well as vehicles originating from or destined for third countries'</i> ([Article 2(l)])
Substitution in the framework of maintenance	<i>'any replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance.</i> ([Article 2(p)])
Technical opinion (TO)	act of the Agency issued in accordance with Article 2 of the Agency Regulation
Type examination	EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instruments that apply to it. (Procedure within the CB and SB modules in TSIs, also provided for in European Parliament and Council Decision 768/2008/EC.)
Upgrading	<i>'any major modification work on a subsystem or part subsystem, which improves the overall performance of the subsystem'</i> ([Article 2 (m)])
Voluntary domain	Product requirements and all actions and activities to comply with, to verify and to attest these requirements, which are required by the customer on a contractual base, but are not required by the state or by a state authority.

Abbreviations

Table 8: Abbreviations

ABBREVIATION	FULL TEXT
AEIF	European Association for Railway Interoperability (Association Européenne pour l'Interopérabilité Ferroviaire)
CCS	Command Control and Signalling
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CR	Conventional Rail
CSM	Common Safety Methods
DeBo	Designated Body
ECM	Entity in Charge of Maintenance
EEA	European Economic Area
EIM	European Infrastructure Managers
EMC	Electromagnetic Compatibility
ENE	Energy
EPTTOLA	European Passenger Train and Traction Operating Lessors Association
ERA	European Railway Agency also called 'the Agency'
ERADIS	Interoperability database of European Railway Agency Database of Interoperability and Safety
ERTMS	European Rail Traffic Management System
ESO	European Standardisation Organisation
ETCS	European Train Control System
ETSI	European Telecommunications Standards Institute
EU	European Union
GSM-R	Global System for Mobile Communications – Railway
HS	High Speed

Table 8: Abbreviations

ABBREVIATION	FULL TEXT
IC	Interoperability Constituent
IEC	International Electrotechnical Commission
IM	Infrastructure Manager
INF	Infrastructure
ISO	International Organisation for Standardisation
ISV	Intermediate Statement Verification
LOC&PAS	Locomotives and Passenger Rolling Stock
MS	EU or EEA Member State
NB Rail	Coordination group of NoBos for railway products and systems
NoBo	Notified Body
NSA	National Safety Authority
PRM	Persons with Reduced Mobility
OJ	Official Journal of the European Union
OPE	Operation and Traffic Management
Q&C	Questions and clarifications
QMS	Quality Management System
RFU	Recommendation for Use
RISC	Railway Interoperability and Safety Committee
RST	Rolling Stock
RU	Railway Undertaking
SRT	Safety in Railway Tunnels
TAF	Telematic Applications for Freight Services
TAP	Telematic Applications for Passenger Services
TEN-T	Trans-European Network for Transport
TO	Technical Opinion

Table 8: Abbreviations

ABBREVIATION	FULL TEXT
TSI	Technical Specifications for Interoperability
UIC	International Union of Railways (Union Internationale des Chemins de fer)
UIP	International Union of Private Wagons Owners (Union Internationale d'associations de Propriétaires de wagons de particuliers)
UIRR	International Union of Combined Road-Rail Transport Companies (Union Internationale des opérateurs de transport combiné Rail-Route)
UITP	International Association of Public Transport (Union Internationale des Transports Publics)
UNIFE	Union of the European Railway Industries (Union des Industries Ferroviaires Européennes)
WAG	Freight Wagons

DRAFT