

Moving Europe towards a sustainable and safe railway system without frontiers.

Guide for the application of the Technical Specifications for Interoperability (TSIs)

In accordance with Article 19(3) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016

Released by European Union Agency for Railways

This guide does not contain any legally binding advice. It may serve as a clarification tool without however dictating in any manner 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. However, it does not substitute for them.

The guide is publicly available and it will be regularly updated to reflect progress with European standards and changes to the TSIs.

The reader should refer to the website of the European Union Agency for Railways for information about its latest available edition.

Document History

<i>Version date</i>	<i>Section number</i>	<i>Modification description</i>
Version 1.0 20/12/2023	All	First publication of this upgraded guide considering the new requirements from the 4th Railway Package and the adoption of the TSI package 2023

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1. SCOPE AND CONTENT OF THIS GUIDE

Scope

According to Article 19(3) “Technical support in the field of railway interoperability” of the Agency Regulation 2016/796/EU, the European Union Agency for Railways may issue guidelines and other non-binding documents to facilitate the implementation of railway interoperability legislation.

This version of the application guide GUI/TSI/2022 replaces the former guide ERA/GUI/07-2011/INT Version 1.02 from 30/11/2012. It considers the new requirements from the 4th Railway Package as stipulated in Regulation (EU) 2016/796 (the Agency Regulation), Directive (EU) 2016/797 (the Interoperability Directive) and Directive (EU) 2016/798 (the Safety Directive).

The specific application guides for the application of the specific TSIs are an Annex to this “Guide for the Application of TSIs”.

Guidance is of voluntary application. It does not mandate any requirement in addition to those set out in the specific TSIs.

Guidance is given by means of further explanatory text and where relevant by reference to standards that are means of demonstrating compliance with the TSIs.

1.1. Reference Documents

<i>DOCUMENT REFERENCE</i>	<i>TITLE</i>	<i>LATEST ISSUE</i>
[1] (EU) 2016/796	Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004	L 138, 26.5.2016, p. 1-43
[2] (EU) 2016/797	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union	L 138, 26.5.2016, p. 44-101
[3] (EU) 2016/798	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety	L 138, 26.5.2016, p. 102-149
[4] 2012/34/EU	Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area	L 343, 14.12.2012, p. 32-77
[5] 2010/713/EU	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, p. 1-52
[6] 768/2008/EC	Decision 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	L 218, 13.8.2008, p. 82-128

	93/465/EEC	
[7] (EU) 2018/545	Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council	L 90, 6.4.2018, p. 66–104
[8] (EU) 402/2013	Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 Text with EEA relevance	L 121, 3.5.2013, p. 8–25
[9] (EU) 2017/1474	Commission Delegated Decision (EU) 2017/1474 of 8 June 2017 supplementing Directive (EU) 2016/797 of the European Parliament and of the Council with regard to specific objectives for the drafting, adoption and review of technical specifications for interoperability	L 210, 15.8.2017, p. 5-15
[10] (EU) 2020/424	Commission Implementing Regulation (EU) 2020/424 of 19 March 2020 on submitting information to the Commission as regards non-application of technical specifications for interoperability in accordance with Directive (EU) 2016/797	L 84, 20.3.2020, p. 20-23
[11] (EU) 2019/250	Commission Implementing Regulation (EU) 2019/250 on the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011	OJ L 42, 13.2.2019, p. 9–24

Table 1 – Reference Documents

In addition, the TSI chronology table is available here: <https://www.era.europa.eu/system/files/2022-10/TSIs%20chronology%20table.pdf>

1.2. Definitions & Abbreviations

The definitions and abbreviations defined below cover this application guide and Specific application guides of the different TSIs.

<i>TERM</i>	<i>DEFINITION/SOURCE</i>
Acts issued by the Agency	They are those listed in Article 4 of Regulation (EU) 2016/796 of the European Parliament and of the Council (Agency Regulation)

<i>TERM</i>	<i>DEFINITION/SOURCE</i>
Basic parameter	Any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs (Article 2(12) of Directive (EU) 2016/797)
Basic design characteristics	Parameters that are used to identify the vehicle type as specified in the issued vehicle type authorisation and recorded in the European Register of Authorised Types of Vehicles ('ERATV') (Article 2(2) of Regulation (EU) 2018/545)
Conformity assessment	Process demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled (Article 2(41) of Directive (EU) 2016/797)
Conformity assessment body	Body that has been notified or designated to be responsible for conformity assessment activities, including calibration, testing, certification and inspection; a conformity assessment body is classified as a 'notified body' following notification by a Member State; a conformity assessment body is classified as a 'designated body' following designation by a Member State (Article 2(42) of Directive (EU) 2016/797)
Contracting entity	Public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem (Article 2(20) of Directive (EU) 2016/797)
European Register of Authorised Types of Vehicles (ERATV)	Register of types of vehicles authorised by the Member States for placing in service. It contains the technical characteristics of vehicles' types as defined in the relevant TSIs, the manufacturer's name, dates, references and Member States granting authorisations, restrictions and withdrawals (Article 48 of Directive (EU) 2016/797)
Existing rail system	Infrastructure composed of lines and fixed installations of the existing, rail network as well as the vehicles of all categories and origin travelling on that infrastructure (Article 2(16) of Directive (EU) 2016/797)
Harmonised standard	European standard adopted on the basis of a request made by the Commission for the application of Union harmonising legislation (Article 2(1)(c) of Regulation (EU) No 1025/2012)
Infrastructure Manager	Any body or firm responsible for the operation, maintenance and renewal of railway infrastructure on a network, as well as responsible for participating in its development as determined by the Member State within the framework of its general policy on development and financing of infrastructure (Article 3(2) of Directive 2012/34/EU amended by Directive (EU) 2016/2370)
Non-application of a TSI	Certain circumstance, by which projects can be exempted from having to comply with all or part of a TSI or TSIs (Article 7 of Directive (EU) 2016/797)
Open point	Certain technical aspect corresponding to the essential requirements, which cannot be explicitly covered in a TSI (Article 4(6) of Directive (EU) 2016/797)
Placing in service	All the operations by which a subsystem is put into its operational service (Article 2(19) of Directive (EU) 2016/797)
Placing on the market	First making available on the Union's market of an interoperability constituent, subsystem or vehicle ready to function in its design operating state (Article 2(35) of Directive (EU) 2016/797)

<i>TERM</i>	<i>DEFINITION/SOURCE</i>
Project at an advanced stage of development	Any project the planning or construction stage of which has reached a point where a change in the technical specifications may compromise the viability of the project as planned (Article 2(23) of Directive (EU) 2016/797)
Railway Undertaking	Railway undertaking as defined in point (1) of Article 3 of Directive 2012/34/EU, 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 is to ensure traction; this also includes undertakings which provide traction only (Article 2(45) of Directive (EU) 2016/797)
Register of infrastructure (RINF)	Register of infrastructure indicates the main features of fixed installations, covered by the subsystems: infrastructure, energy and parts of control-command and signalling. It publishes performance and technical characteristics mainly related to interfaces with rolling stock and operation (Article 49 of Directive (EU) 2016/797)
Renewal	Any major substitution work on a subsystem or part of it, which does not change the overall performance of the subsystem. (Article 2(15) of Directive (EU) 2016/797)
Specific case	Any part of the rail system which needs special provisions in the TSIs, either temporary or permanent, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system, in particular railway lines and networks isolated from the rest of the Union, 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 (Article 2(13) of Directive (EU) 2016/797)
Substitution in the framework of maintenance	Any replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance (Article 2(17) of Directive (EU) 2016/797)
Upgrading	Any major modification work on a subsystem or part of it which results in a change in the technical file accompanying the 'EC' declaration of verification, if that technical file exists, and which improves the overall performance of the subsystem (Article 2(14) of Directive (EU) 2016/797)

Table 2 – Definitions

<i>ABBREVIATION</i>	<i>FULL TEXT</i>
AC	Alternating Current
ATO	Automatic train operation
CCS	Command Control and Signalling (TSI)
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CSM	Common Safety Method
CST	Common Safety Target

<i>ABBREVIATION</i>	<i>FULL TEXT</i>
DC	Direct Current
DeBo	Designated Body
EC	European Commission
ECM	Entity in Charge of Maintenance
EEA	European Economic Area
EMC	Electro Magnetic Compatibility
EN	European standard
ENE	Energy (TSI)
ERA	European Union Agency for Railways also called “the Agency”
ERADIS	Interoperability and Safety database managed by the European Union Agency for railways
ERATV	European Register of Authorised Types of Vehicles
ERTMS	European Rail Traffic Management System
ETCS	European Train Control System
ESO	European Standardisation Organisation
EU	European Union
IC	Interoperability Constituent
IEC	International Electrotechnical Commission
IM	Infrastructure Manager
INF	Infrastructure (TSI)
IOD	Interoperability Directive
ISO	International Organisation for Standardisation
ISV	Intermediate Statement of Verification
IU	Influencing Unit
LOC&PAS	Locomotive and passenger rolling stock (TSI)
MS	EU or EEA Member State
NB-Rail	Coordination group of notified bodies for railway products and systems
NoBo	Notified Body
NOI	Noise (TSI)
NSA	National Safety Authority
NSR	National Safety Rule
NR	National Rule
OCL	Overhead Contact Line

<i>ABBREVIATION</i>	<i>FULL TEXT</i>
OJ/OJEU	Official Journal of the European Union
OPE	Operation and Traffic Management
OTIF	Organisation intergouvernementale pour les Transports Internationaux Ferroviaires
PRM	Person with Disabilities or Person with Reduced Mobility (TSI)
PRR	Passenger Rights Regulation
QMS	Quality Management System
RCC	Route Compatibility Check
RFU	Recommendation for Use
RINF	Register of Infrastructure
RISC	Railway Interoperability and Safety Committee
RSD	Railway Safety Directive
RST	Rolling Stock
RU	Railway Undertaking
SRT	Safety in Railway Tunnels (TSI)
SS	Subsystem
TAF	Telematics Applications for Freight Service (TSI)
TAP	Telematics Applications for Passenger Service (TSI)
TR	Technical Report
TS	Technical Specification
TSI	Technical Specification for Interoperability
UIC	International Union of Railways (Union Internationale des Chemins de Fer)
WAG	Freight wagon (TSI)
WG	Working Group
WP	Working Party

Table 3 – Abbreviations

2. TECHNICAL SPECIFICATIONS FOR INTEROPERABILITY

2.1. Structure and content of the TSIs

[Article 4(3)] of (EU) 2016/797 indicates the content of the TSIs, to the extent necessary to achieve interoperability within the EU rail system.

<i>Text of the Interoperability Directive</i>	<i>Content of the TSIs</i>
<i>Each TSI shall:</i>	This scope & content is contained in Chapters 1 and 2 of the TSIs.

<i>Text of the Interoperability Directive</i>	<i>Content of the TSIs</i>
<i>(a) indicate its intended scope (part of network or vehicles referred to in Annex I; subsystem or part of subsystem referred to in Annex II);</i>	
<i>(b) lay down essential requirements for each subsystem concerned and its interfaces in relation to other subsystems;</i>	The essential requirements that are set out in general terms in Annex III of the Interoperability Directive are further elaborated upon for each subsystem in Chapter 3 of the TSIs.
<i>(c) establish the functional and technical specifications to be met by the subsystem and its interfaces in relation to other subsystems. If necessary, 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;</i>	The functional and technical specifications of the subsystem(s) and the interfaces to other subsystems are set out for each subsystem in Chapter 4 of the TSIs.
<i>(d) determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are necessary to achieve interoperability within the Union rail system;</i>	The list of interoperable constituents and interfaces including applicable specifications are set out for each subsystem in chapter 5 of the TSIs.
<i>(e) 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 the one hand, or the 'EC' verification of the subsystems, on the other. Those procedures shall be based on the modules defined in Commission Decision 2010/713/EU;</i>	<p>The assessment of conformity and/or suitability for use of the interoperable constituents and the verification of the subsystems is set out in Chapter 6 of the TSIs.</p> <p>The EC verification procedure is based on module decision 2010/713/EU. The choice of module(s) is specified in chapter 6 of the TSIs.</p>
<i>(f) indicate the strategy for the application of the TSI. In particular, it is necessary to specify the stages to be completed, taking into account the estimated costs and benefits and the expected repercussions for the stakeholders affected in order to make a gradual transition from the existing situation to the final situation in which compliance with the TSI shall be the norm. Where coordinated implementation of the TSI is necessary, such as along a corridor or between infrastructure managers and railway undertakings, the strategy may include proposals for staged completion;</i>	Chapter 7 of the TSIs provides rules for TSIs implementation, which includes specific cases and also defines transitional periods for the application of different provisions of the TSI(s).
<i>(g) 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 application of the TSIs;</i>	The professional qualifications and health and safety conditions at work for the staff concerned are set out in Chapter 4 of the TSIs.

<i>Text of the Interoperability Directive</i>	<i>Content of the TSIs</i>
<i>(h) indicate the provisions applicable to the existing subsystems and vehicles, in particular in the event of upgrading and renewal and, in such cases, the modification work which requires an application for a new authorisation;</i>	The provisions applicable to the existing subsystems and vehicles, also those related to upgrading or and renewing are defined in in Chapter 7 of the TSIs.
<i>(i) indicate the parameters of the vehicles and fixed subsystems to be checked by the railway undertaking and the procedures to be applied to check those parameters after the delivery of the vehicle authorisation for placing on the market and before the first use of the vehicle to ensure compatibility between vehicles and the routes on which they are to be operated.</i>	The route compatibility checks to be performed by railway undertaking are set out in chapter 4 and Appendix D1 of the TSI OPE

Table 4 – Content of TSIs

[Article 4(6)] of (EU) 2016/797 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 to the TSI as open points’*. The idea is to identify and list certain aspects, which are considered necessary for satisfying the essential requirements, but for which no appropriate specification for the target system is defined yet. 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.

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

2.2. Target railway system and specific cases

The objective of the TSIs is to contribute to the achievement of the *‘optimal level of technical harmonisation’* by establishing a specification for a common target system. (Recital 3 of (EU) 2016/797)

Depending on the 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, in an appropriate manner, the compatibility of the existing rail system of each Member State. For that purpose, specific cases for each TSI may be provided for, with regard to both network and vehicles, and in particular for the loading gauge, the track gauge or space between the tracks and vehicles originating from or destined for third countries. For each specific case, the TSIs shall stipulate the implementing rules’* ([Article 4(5)] of (EU) 2016/797).

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

The technical rules related to the specific cases are:

- either defined in the chapter 7 of the TSIs, in this case the assessment of conformity is performed by the Notified Body, or
- when not specified in the TSIs, in the notified national rules in accordance with Article 13 of Directive (EU) 2016/797. In this case the assessment of conformity is performed by the Designated Body. The national rules for the related specific cases and the bodies designated for the assessment of

conformity to these rules shall be notified by the Member States to the Commission following the adoption of the TSIs.

The Figure 1 below illustrates the migration from the sets of national rules to the TSIs.

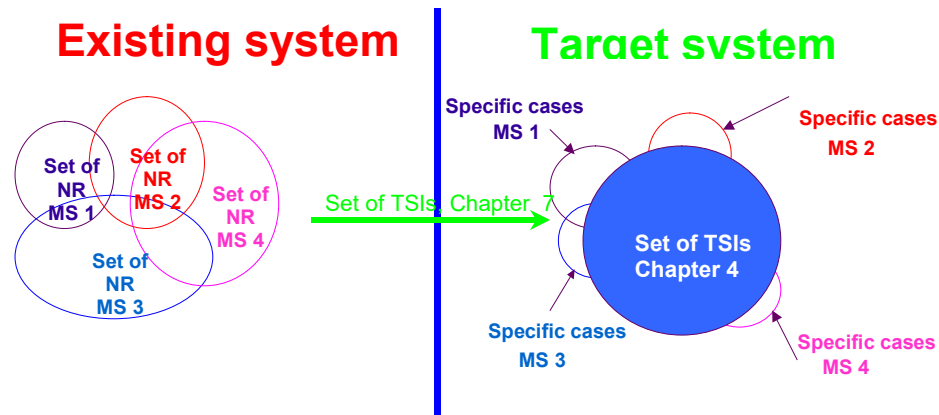


Figure 1 – Migration to the target system

2.3. Deficiencies in the TSIs

Deficiencies in TSIs are textual errors, omissions, mistakes in translation or in technical content, or other inconsistencies as referred to in Article 6 of Directive (EU) 2016/797.

TSIs deficiencies are classified in the following categories:

1. Typographical errors (spelling, typing errors, computing errors, text with no sense, formatting, missing words, missing figures) as well as evident translation mistakes (i.e. easily detectable in a translated version without doubts by comparison with the original English version).
2. Substantial linguistic and translation deficiencies which may affect the content of the TSI.
3. Technical deficiencies, which need to be analysed by the Agency experts.
4. Critical errors.
5. Critical errors which must be urgently corrected.

Depending on the category of deficiency:

- The Agency can perform a simple check or deliver an Agency opinion that constitutes an acceptable means of compliance.
- The Railway Interoperability and Safety Committee (RISC) is either simply informed or asked to approve the technical opinion. In the latter case, the opinion of the RISC is recorded in the minutes of the corresponding RISC meeting.
- Depending on the importance and urgency of the correction, the legal act implementing the amendment can be included in an ongoing revision.
- Category 1 errors (typographical errors) may be corrected by a corrigendum published on the Official Journal of the European Union (normally within a few weeks).

When deficiencies are discovered in the TSIs, the Agency may be asked to issue an opinion which, under certain conditions, might be published and used by all stakeholders (including industry and notified bodies) as an acceptable means of compliance pending the revision of the TSIs concerned.

The deficiencies in TSIs that have already been adopted are published in the Official Journal of the European Union. The deficiencies in the TSIs which are still in the process of being drafted by the Agency or are in any following approval step cannot be found in the Official Journal of the European Union. However, an updated list of TSI deficiencies is provided regularly for the RISC meetings.

Any member of the network of representative bodies referred to in Article 38(4) of Regulation (EU) 2016/796 may make the Commission aware of possible TSI deficiencies (Article 6(4) of (EU) 2016/797).

The identified deficiencies are listed in the "Deficiency table", published on the ERA Website.

<https://www.era.europa.eu/system/files/2023-02/TSI%20deficiencies.pdf>

The table is containing mainly the following information: the proposed amendment, the category of deficiency, the date when the deficiency was published on the ERA Website and the references to a potential ERA Recommendation and/or Agency Opinion.

The deficiencies in TSIs should be considered during the process for requirements capture (see Article 13 of regulation 2018/545). The management of deficiencies in the TSIs concern the correction of the content of the TSIs as specified in Article 5(1) of Directive 2016/797. It does not concern the evolution of the technical documents published by the Agency and referred to in the TSIs. Similarly, this document does not cover the Change Control Management for the ERTMS specifications and documents listed in the TSI on control-command and signalling.

Concerning differences between translated versions of TSIs: when a mistake of translation is a critical error, it will be addressed in a formal process involving an opinion of the Agency, European Commission agreement and approval by the Railway Interoperability and Safety Committee (RISC). In considering its opinion the Agency will not use the English version as the base reference because all the different language versions of the TSIs have the same status.

The NSAs for the area of use shall share with the Agency and all other NSAs all information resulting from return of experience related to technical and operational matters that may be relevant for the issuing of a vehicle type authorisation and/or vehicle authorisation for placing on the market, such as deficiencies in a TSI in accordance with Article 6 of Directive (EU) 2016/797 (Article 7(4(c)) of (EU) 2018/545).

2.4. Non-Application of TSIs

The **basic principle is that TSIs apply** to the subsystems, vehicles or networks, for which they were designed, starting from the day the TSI has entered into force (or once transition periods have expired).

Non-applications of TSIs are exceptional measures. Therefore, non-application decisions have to follow a procedure involving the Member State(s) and the Commission, except for Article 7.1(b)-non-applications of Directive (EU) 2016/797.

Non-applications can only be granted for a defined scope. In particular, they must be issued in relation to subsystems defined in relation to identifiable vehicles or infrastructure, a number of vehicles or a defined network, in order to ensure compatibility with the non-application cases (Directive (EU) 2016/797 Article 7.1(a) – (e)). An open-ended vehicle type for an undefined number of vehicles cannot be subject of a non-application decision.

Non-applications are granted based on reasons (exhaustive list in Directive (EU) 2016/797 Article 7.1). Based on the information provided by an applicant for a request for non-application, non-application decisions by MS – after verification with the Commission - confirm **that all reasons for the non-application are met**.

The most frequent non-applications require an assessment of the **lack of economic viability** (Directive (EU) 2016/797 article 7.1.a and c). Such an assessment can only be performed in respect of a clearly defined project and in respect of distinct list of subsystems, vehicles or networks.

2.5. Agency opinions and advices

According to Article 4(c) of the Agency Regulation (EU) 2016/796, the Agency may issue opinions to the Commission and to the authorities concerned in the Member States.

The Agency shall issue opinions at the request of the Commission as well:

The Table 5 below provides an overview of opinion/advice that can be issued

Type of act	Opinion	Opinion	Opinion	Opinion	Opinion	Opinion	Technical Advice
Legal base	Art. 10(2) AR	Art. 42 AR	Art. 19(1)(d) AR	Art. 10(1) AR	Art. 25/26 AR	TSIs and deficiencies in TSIs	Art. 41
Scope	legal changes	railway projects	acceptable means of compliance	any RSD / IOD issue	national rules	innov. sol./ error correction	any technical issue
Requested by	EC	EC	EC	Regulatory Body	Agency	EC	EC
Deadline	2 months (+ x mths if EC agrees)	2 months (+ x mths if EC agrees)	2 months (+ x mths if EC agrees)	2 months (+ x mths, if RB agrees)	1 month if Agency maintains its negative assessment	2 months (+ x mths if EC agrees)	-
Impact Assessment	YES	YES	YES	YES	YES	YES	If considered Necessary
External consultation	NSA/NIB/RB/OTIF	-	OTIF	-	-	OTIF	-
Adoption	Exec. Dir.	Exec. Dir.	Exec. Dir.	Exec. Dir.	Exec. Dir.	Exec. Dir.	Exec. Dir.
RISC	-	-	informed by EC	-	-	-	-
Publication	YES	YES	YES	YES	NO	YES	Upon decision

Table 5 – Agency opinions and advice

2.6. Relevance of the TSIs to the subsystems defined in Annex II of the Interoperability Directive (EU) 2016/797

According to Article 4(1) of the Interoperability Directive (EU) 2016/797, each of the subsystems defined in Annex II shall be covered by one TSI. Where necessary, a subsystem may be covered by several TSIs and one TSI may cover several subsystems. In practice, this results in a type of matrix linking different subsystems to different TSIs. Table 6 shows the subsystems as defined in Annex II of the Interoperability Directive (EU)

2016/797. It indicates which TSIs are applicable to which subsystem, and therefore shall be considered for conformity assessment¹ of a particular subsystem.

Applicable TSIs	Subsystem							
	Infrastructure	Energy	CCS on board	CCS trackside	Rolling Stock	Operation and Traffic Management	Maintenance	Telematic Applications
Reg 454/2011/EU TAP TSI								X
Reg (EU) 321/2013 WAG TSI					X		X	
Reg (EU) 1299/2014 INF TSI	X						X	
Reg (EU) 1300/2014 PRM TSI	X				X	X		
Reg (EU) 1301/2014 ENE TSI		X					X	
Reg (EU) 1302/2014 LOC & PAS TSI					X		X	
Reg (EU) 1303/2014 SRT TSI	X	X	X	X	X	X		
Reg (EU) 1304/2014 RST Noise TSI					X		X	
Reg (EU) 1305/2014 TAF TSI								X
Reg (EU) 2016/919 CCS TSI			X	X			X	
Com. Impl. Reg (EU) 2019/773 OPE TSI						X		

Table 6 – Applicability of TSIs to subsystems

An overview of the dates of application and the entry into force of the different Structural & Functional TSIs and their amendments by year is available in the "TSI chronology table", published on the ERA Website.

(<https://www.era.europa.eu/system/files/2022-10/TSIs%20chronology%20table.pdf>)

¹ Conformity assessment here relates to Commission Decision 2010/713/EU [5] and doesn't cover the TSIs TAF, TAP and OPE

2.7. TSIs versus other requirements

2.7.1. National rules and, where relevant, acceptable national means of compliance in the field of interoperability

For structural subsystems which are covered by TSIs, in some cases national rules (and where relevant acceptable national means of compliance) may also apply to these subsystems.

There are two categories of national rules:

- Existing national rules (see Article 13(2) of Directive (EU) 2016/797), which are limited to:
 - Where the TSIs do not cover(..) aspects corresponding to the essential requirements, including open points,
 - Specific cases listed but not described in TSIs,
 - Ensure technical compatibility with existing network,
 - Case where non-application of one or more TSIs or parts of them,
 - Networks and Vehicles not covered by TSIs,
 - Urgent temporary preventive measure (..) following an accident.
- New national rules may only be adopted (see Article 14(4) of Directive(EU) 2016/797) :
 - when a TSI does not fully meet the essential requirements;
 - as an urgent preventive measure, in particular following an accident.

From 16 June 2019 and pending the Single Rule Database (SRD), Reference Document Database (RDD) is the reference for Applicants, NSAs and the Agency in terms of applicable National rules for Vehicle Authorisation: (https://www.era.europa.eu/registers_en#rdd)

National Rules related to fixed installation are notified in the Single Rules Database: (https://www.era.europa.eu/registers_en#srd)

Figure 2 below presents the contents of the Single Rule Database (SRD):



Figure 2 – Content of the SRD database

When the evaluation of National Rules leads to a negative assessment, the Agency addresses to the relevant MSs an Agency opinion in accordance with articles 25 and 26 of ERA regulation.

In accordance with Article 15(8) of Directive (EU) 2016/797, Member States designate the bodies responsible for carrying out the verification procedure in respect of national rules.

The list of the Designated Bodies can be found in the Reference Document Database: (<http://rdd.era.europa.eu/rdd/ReportsManagementPage.aspx#>)

2.7.2. National rules in the field of safety

The OPE TSI is a functional TSI and national safety rules for operational activities are covered by EU Directive 2016/798.

There are two categories of national rules:

- Existing national rules are limited to:
 - Open points and areas for national rules as identified in OPE TSI Appendix I,
 - Cases not covered in the TSI (see EU Directive 2016/798 Art 8 (1 and 2),
 - Specific cases described in TSI,
 - Urgent temporary preventive measure following an accident.
- New national rules may only be adopted:
 - For cases not covered in the TSIs and CSMs (see EU Directive 2016/798 Art 8 (3),
 - Where an already notified rule needs to be revised,
 - As an urgent preventive measure, in particular following an accident.

National rules notified by 15 June 2016 pursuant to Directive 2004/49/EC shall apply if they:

- a) fall into one of the types identified under Annex II; and
- b) comply with Union law, including in particular TSIs, CSTs and CSMs; and
- c) would not result in arbitrary discrimination or a disguised restriction on rail transport operation between Member States. (Article 8(1) of (EU) 2016/798).

By 16 June 2018, Member States shall review the national rules referred to in paragraph 1 and repeal:

- a) any national rule which was not notified, or which does not meet the criteria specified in paragraph 1;
- b) any national rule which has been made redundant by Union law, including in particular TSIs, CSTs and CSMs.

To that end, Member States may use the rule management tool referred to in Article 27(4) of Regulation (EU) 2016/796 and may request Agency to examine specific rules against the criteria specified in this paragraph. (Article 8(2) of (EU) 2016/798).

Member States may lay down new national rules pursuant to this Directive only in the following cases:

- a) where rules concerning existing safety methods are not covered by a CSM;
- b) where operating rules of the railway network are not yet covered by TSIs;
- c) as an urgent preventive measure, in particular following an accident or an incident;
- d) where an already notified rule needs to be revised;
- e) where rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, physical and psychological fitness and vocational training are not yet covered by a TSI or by Directive 2007/59/EC of the European Parliament and of the Council (Article 8(3) of (EU) 2016/798).

Member States shall notify to the Agency and to the Commission the national rules adopted. They shall use the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796 (Article 8(7) of (EU) 2016/798).

Member States shall submit the draft of a new national rule to the Agency and the Commission for consideration in due time and within the deadlines referred to in Article 25(1) of Regulation (EU) 2016/796, before the expected introduction into the national legal system of the proposed new rule, providing justification for its introduction, through the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796. Member States shall ensure that the draft is sufficiently developed to allow the Agency to carry out its examination in accordance with Article 25(2) of Regulation (EU) 2016/796. (Article 8(4) of (EU) 2016/798).

Since November 2020, SRD has replaced NOTIF-IT in the notification of new Safety National Rules. NOTIF-IT is no longer accessible. The Agency, in concertation with the Member States, is currently re-assessing these rules and will transfer them into the Single Rules Database (SRD):

(https://www.era.europa.eu/domains/registers/srd_en)

The Agency may by means of technical opinion define acceptable means of compliance, which shall be presumed to ensure compliance with specific requirements of OPE TSI, and ensure safety in accordance with Directive (EU) 2016/798.

Acceptable means of compliance with OPE TSI are published on the Agency website:

(https://www.era.europa.eu/domains/technical-specifications-interoperability/operation-and-traffic-management-tsi_en)

2.7.3. Compliance with other regulations deriving from the Treaty

In accordance with Annex IV of Directive (EU) 2016/797, the technical file accompanying the ‘EC’ declaration of verification of the subsystem should contain, among other elements, *‘certificates of verification issued in accordance with other legal acts of the Union’*. The Applicant is responsible to ensure that the subsystem complies with all relevant Union law. Under the “relevant Union law”, some are not railway specific, but must be respected in any case (e.g. REACH Regulation (EC) 1907/2006, EMC Directive 2014/30/EU, non-road mobile machinery emissions Regulation (EU) 2016/1628, etc.).

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.

For the purpose of this Directive, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI). This is without prejudice to the obligations of the applicant to comply with the other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules (Annex IV, Article 2.1. of Directive (EU) 2016/797).

For vehicle authorisation, please refer to the ERA website where provisions are defined in Regulation 2018/545, clarification and guidance are provided in the application guide and the clarification note : [Applications for Vehicle \(type\) Authorisations \(VAs\) | European Union Agency for Railways \(europa.eu\)](#)

The applicant shall establish the ‘EC’ declaration of verification of a subsystem. The applicant shall declare on his sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule (Article 15(2) of Directive (EU) 2016/797).

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.

2.7.4. *Monitoring other regulations impacting the railway system*

As far as possible, the Agency monitors and analyses the EU developments in regulation and legislation that may be relevant for the railway system and have an impact on TSIs or on other regulatory documents.

For example, the Cyber Resilience Act will impact all subsystems and may require the inclusion of some requirements in several TSIs.

Pending the adoption of the Act and the subsequent discussions in one or several ERA Working Parties, the following document is an interesting source of information and guidance:

CLC/TS 50701:2023 “Railway applications – Cybersecurity”

It contains several key aspects related to cyber security and is helpful for starting to consider these issues in railway applications.

2.8. Questions about TSIs

Formal interpretation of the legal text may only be given by the European Court of Justice.

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.

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.

Questions on the TSI may be sent to ERA through ERA website contact form : [Contact Us · Customer Self-Service \(powerappsportals.com\)](#)

They will be collected as FAQ on the Agency website and considered in further revisions of this guide and, where relevant, during the revision process of the TSIs.

Furthermore, bodies notified under Article 37 of (EU) 2016/797 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. NB Rail is publishing regularly on their website Recommendations For Use (RFUs) [A RFU shall ensure a uniform application of the current technical provisions of the applicable legislation as established by the European Commissions by clarification, but it cannot alter any mandatory content of this applicable legislation] and Questions & Clarification (Q&C) to the European Commission.

http://nb-rail.eu/co/co_docs_en.html

3. APPLICABLE STANDARDS AND OTHER DOCUMENTS

3.1. Overview

TSIs are adopted by EC regulations and are therefore mandatory.

According to [Article 4(8) of Directive (EU) 2016/797, the ‘TSIs may make an explicit, clearly identified reference to European or international standards or specifications or technical documents published by the

Agency'. In their absence, they may refer 'to other clearly identified normative documents' (such as UIC leaflets, national standards, etc.): 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.

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 as described in Regulation (EU) 1025/2012 gives presumption of conformity to the corresponding essential requirements.

References to harmonised standards, indicating the Directives (new approach Directives and Directives based on the new approach) and the TSI clauses 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). This relationship is detailed in annex ZA or ZZ of the harmonised standard.

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). Consequently, 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.

In practice, the standards and other documents relate to the technical requirements set out in 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.

The list of harmonised standards is published in the Official Journal of the European Union:

<https://eur-lex.europa.eu/oj/direct-access.html>

The list is accessible on the European Commission website:

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/rail-system-interoperability_en

The application guide of each TSI may also refer to harmonized standards giving presumption of conformity to TSI requirements. Application of these standards remains voluntary. If a new revision of a harmonised standard is published in the Official Journal of the European Union, this version can also be used considering its annex ZA/ZZ.

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

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.

To ensure certainty, as far as possible, only strict references are made in the TSIs.

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 until the TSI is updated.

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.

Where a standard(or document) or a part of a standard (or document) referred to in a TSI contains a reference to another standard, which is needed to apply the quoted parts of the referred standard, unless otherwise provided in the TSI, this second standard also becomes mandatory.

3.3. Technical documents of the Agency

It should be noted that a ‘technical document of the Agency’ is not the same as an ‘Agency opinion’, which is described in section 2.4.

A TSI may reference 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.

4. CONFORMITY ASSESSMENT – STRUCTURAL TSIs

Each conformity assessment body shall be responsible for compiling the documents and producing all necessary reports related to its conformity assessments performed.

4.1. Conformity assessment procedures

4.1.1. Interoperability constituents

Before being placed on the market (see Section 5.1), 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.

With respect to the Interoperability Directive (EU) 2016/797, the general definition of ‘conformity assessment’ (see definitions in Table 2) should be understood for the ICs as the process demonstrating whether requirements specified in the relevant TSI related to an interoperability constituent have been fulfilled.

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.

The ‘EC’ declaration of conformity or suitability for use of an IC must precisely identify the product it was drawn up for.

In theory, interoperability constituents are manufactured in serial production based on the same design or type and may be incorporated into different subsystems. This means that 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.

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 4.1.2 below) include a verification of whether the IC has been integrated correctly (in particular, the ‘EC’ verification process must include a check that ICs are used in their relevant area of use).

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 must only be

established at the same time or after all relevant 'EC' declarations of conformity and suitability for use have been established.

If the IC is assessed at the same time as the subsystem and placed on the EU market through the placing in service or placing on the market 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 a formal point of view, the process of conformity assessment of the IC is separate from the verification process of the subsystem.

Provisions related to templates for 'EC' declarations and certificates for railway interoperability constituents are defined in Regulation 2019/250.

The Agency has set up the European Railway Agency Database of Interoperability and Safety (ERADIS) to store certificates and declarations. This register must be used by:

- Manufacturers of interoperability constituents to submit the EC declarations; and
- Notified Bodies to submit EC certificates.

It is accessible via:

(https://www.era.europa.eu/domains/register/eradis_en)

4.1.2. Subsystems

Before the applicant submits a request for authorisation of the placing in service of fixed installations (Energy, Infrastructure and trackside Control-Command and Signalling subsystems) to the National Safety Authority (NSA), the following steps must have taken place:

- 'EC' verification of the subsystem(s) by a NoBo (Annex IV of the Interoperability Directive (EU) 2016/797); and establishment by this NoBo of the 'EC' verification certificate(s);
- establishment of (the) 'EC' declaration(s) of verification for the subsystem(s) by the applicant for the 'EC' verification;
- evidence of the technical compatibility of the subsystems with the system into which they are being integrated, established on the basis of the relevant TSIs, national rules and registers;
- evidence of the safe integration of the subsystems, established on the basis of the relevant TSIs, national rules, and the common safety methods ('CSMs').

Only in the case of trackside control-command and signalling subsystems involving European Train Control System (ETCS) and/or Global System for Mobile Communications — Railway (GSM-R) equipment, the positive decision of the Agency is also required ([Article 18(4) of Directive (EU) 2016/797]).

In accordance with Article 20 of Directive (EU) 2016/797, an applicant can place mobile subsystems on the market based on the 'EC' declaration of verification, only if they are designed, constructed and installed in such a way as to meet the essential requirements.

An 'EC' declaration of verification for a subsystem is needed for any new subsystem. An 'EC' declaration of verification for a subsystem is necessary as well if a change is made to the subsystem and the applicant has assessed that the change implies a new 'EC' declaration of verification for a subsystem. If a project includes more than one of the structural subsystems defined in Annex II of the Interoperability Directive (EU) 2016/797 (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. In case of change of subsystem, see provisions defined in TSIs, regulation 2019/250 and for vehicle authorisation regulation 2018/545.

Intermediate Statement of Verification (ISV): an ISV can be issued by a NoBo against relevant TSIs covering part of a subsystem or part of the verification procedure (design, production or testing).

The verifications should be done only for the following stages of the EC verification procedure:

- overall design (e.g. SB design/type examination);
- production: manufacturing, constituent assembly and overall adjustment (e.g. SD); and/ or
- final testing (e.g. SD).

An ISV can be delivered only if all the relevant TSI requirements are demonstrated (including type tests if necessary, e.g. for SB). Some parts of a subsystem are covered by TSI requirements that can be demonstrated without a need to carry out dynamic tests on a network, and can be covered by ISV(s) (e.g. gauge Commission Regulation (EU) 1302/2014 4.2.3.1 or vehicle structure strength Commission Regulation (EU) 1302/2014 4.2.2.4)

ISV(s) are not to be used as a substitute of the EC certificate of verification. When the NoBo responsible for the subsystem uses ISV(s), it is permissible for the modules used for the ISV(s) and the overall verification assessment to be different

Applicant

- decides if there is a need of division of the subsystem into parts; and
- specifies for which parts of the subsystem or part of the verification procedure (as defined in the assessment modules) there is a need to have an ISV from the NoBo.

NoBo (ISV)

- performs the necessary assessments according to the division of the subsystem or part of the verification made by the applicant; and
- issues ISVs.

NoBo (subsystem)

- where ISV(s) have been issued, takes them into account before issuing its certificate of verification;
- verifies that the ISV(s) cover correctly the relevant requirements of the TSIs;
- checks all aspects that are not covered by the ISV(s); and
- checks the final testing of the subsystem as a whole.

The template to be used for issuing ISV is to be in accordance with Regulation 2019/250.

4.2. Conformity assessment modules

The procedures for conformity and suitability for use assessment and 'EC' verification are based on the use of modules that are defined in commission decision 2010/713/EU.

Chapter 6 of the TSIs specifies the EC verification modules that are to be chosen by the Applicant of the subsystem or the manufacturer of the IC.

Some modules can be used only in combination with others. Modules may involve a Notified Body or not (self-assessment modules CA, CC for Interoperability Constituents).

Example of module choice for the IC coupler defined in LOC&PAS TSI 1302/2014:

Point	Constituents to be assessed	Module CA	Module CA1 or CA2	Module CB + CC	Module CB + CD	Module CB + CF	Module CH	Module CH1
5.3.1	Automatic centre buffer coupler		X (*)		X	X	X (*)	X
5.3.2	Manual end coupling		X (*)		X	X	X (*)	X

Table 7 – Example of modules for the IC ‘coupler’

Example of a module choice for the Rolling Stock subsystem defined in the LOC&PAS TSI 1302/2014:

Module SB	EC-Type Examination
Module SD	EC verification based on quality management system of the production process
Module SF	EC verification based on product verification
Module SH1	EC verification based on full quality management system plus design examination

Table 8 – Example of modules for the Rolling Stock subsystem

For the Rolling Stock subsystem, the Applicant chooses one combination of modules: (SB+SD) or (SB+SF) or (SH1). The assessment is done according to the combination of modules chosen.

Further details (including tasks of the manufacturers, applicants for the ‘EC’ verification and NoBo) are given in the document “Guide for Conformity assessment and EC verification” available on ERA website:

https://www.era.europa.eu/system/files/2022-11/iu_tsi_guide_annex02_en.pdf

4.3. Assessments applicable to certain stages

The TSI assessment basis for a ‘EC type or design examination’ is defined in each TSI (ex. appendix H of LOC&PAS TSI). 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 Applicant is responsible for:

- the choice the EC verification modules to use;
- the identification of the evidence to be delivered to demonstrate the compliance of the subsystem with the TSIs;
- the establishment of the technical documentation to be used to assess the conformity of the subsystem with the TSIs; and
- the establishment of the relevant declarations for the subsystem(s).

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.

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.

The NoBo shall 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 must take this certification into account for the assessment of the implementation of the design review.

ANNEXES

Specific application guides of the different TSIs:

(https://www.era.europa.eu/domains/technical-specifications-interoperability_en)

Guide for Conformity assessment and EC verification (EN):

Note: that guide still needs to be updated and adapted to the 4th Railway Package.