

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

Guide

Guidelines for the practical arrangements for the vehicle authorisation process

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The present document is a non-legally binding guidance of the European Union Agency for Railways. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

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0. Summary table

This table gives an overview of the different practical cases that are expected to be experienced by the applicants and summarises their link to the authorisation cases found in the Regulation (EU) 2018/545. It also provides, for each case, information to applicants about the need to submit an application for authorisation via the OSS, the tasks that need to be performed and the documentation to be included in the file accompanying the application. The cases are also identified in the flowchart for substage 1-1 (see section 4).

This synthesis table should be seen as giving a consolidated overview of the process and an introduction to the practical arrangements for vehicle authorisation (Regulation and guidelines) for prospective applicants. The table has been drafted in collaboration with the Group of Representative Bodies (GRB) with the aim of providing a 'quick start' entry point for applicants to the practical arrangements.

It should be noted that the table gives a legally non-binding overview for the different cases. The legally binding provisions are to be found in the Directive (EU) 2016/797 and in the Regulation (EU) 2018/545. Supportive references and remarks have been made in the table to assist applicants in finding the related content of the Directive and the Regulation (including guidelines).

Table 0: Summary table

Table case	Description of the case	Authorisation case	Submit an application?	Include requirements capture evidence in the application? (5)	Involve NoBo and/or DeBo?	Involve an AsBo? (3)	Include technical files accompanying the EC DoFV in the application?	Include the EC DoFV in the application?	Include the (risk) declaration in the application? (3)	Remarks - Specific Requests	Outcome
1a	Vehicle type authorisation (for a new vehicle type) ID article 21(1) & 24; AG 3.2.2.16 & 3.3.2.1	First authorisation IR article 14(1)(a)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	The applicant may choose to authorise the new type without an authorisation for placing on the market of the first vehicle at the same time. AG 3.2.2.16	Vehicle type authorisation IR article 48 AG 3.8.2
1b	Vehicle authorisation for placing on the market (for the first vehicle of a type) ID article 21(1) & 24; AG 3.2.2.16 & 3.3.2.1									An application for authorisation for placing on the market for the first vehicle of a type will result in both the vehicle type authorisation and the authorisation for placing on the market of for the first vehicle. This is done in a single application. ID article 24(2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3
1c	Vehicle type authorisation and vehicle authorisation for placing on the market in conformity to a type ID article 21(1) & 24; AG 3.2.2.15, 3.2.2.16, 3.3.2.1 & 3.3.2.6	First authorisation & authorisation in conformity to type IR articles 14(1)(a), 14(1)(e) & 14(3)	Yes	Yes The process for requirements capture should also cover the manufacturing phase (conformity to type), but this evidence is not required in the application	Yes	Yes	Yes	Yes	Yes	Evidence to provide for the placing on the market in conformity to type: declaration of conformity to type (and associated documentation) and decisions for non-application of TSIs. IR annex I §18.3 & 18.4. AG 3.11.1.5	Vehicle type authorisation and vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3
2a	Authorisation in conformity to a type (delivery of a series of vehicles) ID article 25; AG 3.2.2.15 & 3.3.2.6	Authorisation in conformity to type IR article 14(1)(e)	Yes	No (5) The process for requirements capture should also cover the manufacturing phase, but this evidence is not required in the application	Yes Manufacturing phase to be under the surveillance of Conformity Assessment Body(es) 2010/713/EU	No As long as the aspects related to safety and safe integration between subsystems for the manufacturing phase were already covered by the requirements capture related to the vehicle type / type authorisation and there are no changes in the manufacturing process	No	Yes The EC DoV(s) are part of the associated documentation to the declaration of conformity to type	No The proposer needs to establish a risk declaration covering the manufacturing phase	Evidence to provide: declaration of conformity to type (and associated documentation) and decisions for non-application of TSIs. IR annex I §18.3 & 18.4; AG 3.11.1.5	Vehicle authorisation for placing on the market IR article 49 AG 3.8.3
2b	Changes to an already authorised vehicle to bring it in conformity to another type variant or Ext AoU version ID article 25; AG 3.2.2.15 & 3.3.4.3									Evidence to provide: declaration of conformity to type (and associated documentation) and decisions for non-application of TSIs. IR annex I §18.3 & 18.4; AG 3.11.1.5. All variants/versions should derive from a common parent type. Bringing a vehicle in conformity to a vehicle type version created following a 15(1)(c) change does not require an authorisation for placing on the market. AG 3.3.4.2	
3	Changes in the TSI or National rules pursuant to ID article 24(3) which does not require a change in the vehicle type ID article 24(3); AG 3.3.2.2 & 3.3.5.1	Renewed vehicle type authorisation IR article 14(1)(b)	Yes	No (5)	Yes	Depends on the nature of the changed rules (3) (4)	Yes	Yes	Yes (4) If an AsBo is involved, the proposer needs to establish a risk declaration	Scope of the evidence to be included in the file accompanying the application for authorisation limited to the changed rules. ID article 24(3) The renewal of vehicle type authorisation only requires verification of the changed parameters for which the new rule renders the existing vehicle type invalid.	Vehicle type authorisation IR article 48 AG 3.8.2
4	Extended area of use without a change in the vehicle and/or vehicle type ID article 21(13); AG 3.3.2.3 & 3.6.2.1	Extended area of use IR article 14(1)(c)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	The checks to be performed by the authorising entity for an authorisation extending the area of use of a vehicle type should be limited to checking that the original vehicle type authorisation still is valid and the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out at the first authorisation should not be repeated. AG 3.3.2.3 For the extension of the area of use of vehicles authorized under Directive 2008/57/EC or in operation before 19 July 2010, the particular rules in the applicable TSIs apply: • 7.1.4 of Regulation (EU) 2014/1302 (LOC&PAS TSI) • 7.2.2.4 of Regulation (EU) 2013/321 (WAG TSI) The particular rules in chapter 7.4.2.3 of CCS TSI always apply in case of extension of the area of use. Possibility for the holder to choose to ask for a new type or to create a new version of the existing type. IR article 14(2); AG 3.3.2.3	Vehicle type authorisation and/or vehicle authorisation for placing on the market covering the extended area of use IR articles 48 & 49 AG 3.8.2 & 3.8.3
5a (8)	Extended area of use including a change in the vehicle and/or vehicle type which requires a new authorisation ID article 21(13); AG 3.3.2.5 & 3.6.2.1 Entity managing the change = holder	New authorisation and extended area of use IR articles 14(1)(c), 14(1)(d) & 14(2) & 14(3)	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	This is effectively a combination of cases 4 and 6. The application for the combined new and extended area of use authorisation could be sent at the same time in a single OSS application. IR article 14(3); AG 3.3.2.5 Possibility for the holder to choose to ask for a new type or to create a new variant of the existing type. IR article 14(2); AG 3.3.2.3 & 3.3.2.4	Vehicle type authorisation and/or vehicle authorisation for placing on the market, covering the changes and the extended area of use IR articles 48 & 49 AG 3.8.2 & 3.8.3
5b (8)	Extended area of use including a change in the vehicle and/or vehicle type which requires a new authorisation ID article 21(13); AG 3.3.2.5 & 3.6.2.1 Entity managing the change ≠ holder	New authorisation and extended area of use IR articles 14(1)(c), 14(1)(d), 14(2), 14(3) & 15(4)								This is effectively a combination of cases 4 and 7. The application for the combined new and extended area of use authorisation could be sent at the same time in a single OSS application. IR article 14(3); AG 3.3.2.5 Creation of a new vehicle type by the new holder. IR article 15(4); AG 3.3.3.3	
6	Change to the basic design characteristics or vehicle's safety level beyond the criteria of ID article 21(12): • parameters outside range in the TSIs • the overall safety level of the vehicle may be adversely affected • requested by the relevant TSI ID article 21(12); IR article 15(1)(d); AG 3.3.3.2 & 3.3.2.4 Entity managing the change = holder	New authorisation IR articles 14(1)(d), 14(2) & 14(3)	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Possibility for the holder to choose to ask for a new type or to create a new variant of the existing type. IR article 14(2); AG 3.3.2.4 The issued type authorisation will cover the whole vehicle type, but the extent of the assessments will be limited to the changes and the interfaces with the unchanged parts. Aspects not impacted by the changes are covered by the existing authorisation.	Vehicle type authorisation and/or vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3
7	Change to the basic design characteristics or vehicle's safety level beyond the criteria of ID article 21(12): • parameters outside range in the TSIs • the overall safety level of the vehicle may be adversely affected • requested by the relevant TSI ID article 21(12); IR article 15(1)(d) AG 3.3.3.2 & 3.3.2.4 Entity managing the change ≠ holder	New authorisation IR articles 14(1)(d), 15(1)(d), 15(4) & 16(3)	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Creation of a new vehicle type by the new holder. IR article 15(4); AG 3.3.3.3 The issued type authorisation will cover the whole vehicle type, but the extent of the assessments will be limited to the changes and the interfaces with the unchanged parts. Aspects not impacted by the changes are covered by the existing authorisation. ID Annex IV 2.3.3 The applicant can request in the same application through the OSS the authorisation of a variant of the new vehicle type that will be authorized as a result of the change.	Vehicle type authorisation and/or vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3

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Table case	Description of the case	Authorisation case	Submit an application?	Include requirements capture evidence in the application? (5)	Involve NoBo and/or DeBo?	Involve an AsBo? (3)	Include technical files accompanying the EC DoFV in the application?	Include the EC DoFV in the application?	Include the (risk) declaration in the application? (3)	Remarks - Specific Requests	Outcome
8	Change to the basic design characteristics or vehicle's safety level not beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters within range in the TSIs the overall safety level of the vehicle may not be adversely affected not requested by the relevant TSI ID article 21(12); IR article 15(1)(c) AG 3.3.3.2.3 Entity managing the change = holder	N/A IR article 15(1)(c), 15(2)	No	N/A (5)	Yes (1)	Yes (6) (9)	N/A (1)	N/A (2)	N/A (7)	Type holder will keep available the relevant information upon request of the authorising entity, NSAs, the Agency or MSs. ID Annex IV §2.6; IR article 15(2). The holder must request the creation of a new vehicle type version or a new version of a vehicle type variant and provide the relevant information to the authorising entity. The authorising entity shall register in ERATV the new version of the vehicle type or the new version of the vehicle type variant. IR article 15(3); AG 3.8.4.1.1. https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2676 Applicant may want an AsBo to provide a judgement that change is not beyond criteria, however this is not mandatory.	The authorising entity shall register in ERATV the new version of the vehicle type or the new version of the vehicle type variant, using the information provided by the holder of the vehicle type authorisation IR article 15(3)
9a	Change to the basic design characteristics or vehicle's safety level not beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters within range in the TSIs the overall safety level of the vehicle may not be adversely affected not requested by the relevant TSI ID article 21(12); IR articles 15(1)(c) & 16; AG 3.3.3.2.3 Entity managing the change ≠ holder Change to vehicle(s) only AG 3.3.4.1	N/A IR article 16(4) Unless requested by the authorising entity within 4 months of notification of changes	No Entity managing the change must submit a notification	N/A (5)	Yes (1)	Yes (6) (9)	N/A (1)	N/A (2)	N/A (7)	The entity managing the change must notify the changes to the authorising entity. The change can be implemented immediately, and the modified vehicles can be used without having to wait for an answer of the authorising entity. This may apply to a vehicle or a number of identical vehicles. The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information (see case 7). When ERA is the authorising entity, notification to be made following the process described in ERA website: https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=948	Reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information
		New authorisation IR articles 14(1)(d) & 16(4) If requested by the authorising entity within 4 months of notification of changes	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	The entity managing the change must notify the changes to the authorising entity. This may apply to a vehicle or a number of identical vehicles. Creation of a new vehicle type by the new holder. IR article 15(4); AG 3.3.3.3.	
9b	Change to the basic design characteristics or vehicle's safety level not beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters within range in the TSIs the overall safety level of the vehicle may not be adversely affected not requested by the relevant TSI ID article 21(12); IR article 15(1)(c) AG 3.3.3.2, 3.3.2.4 & 3.3.3.3 Entity managing the change ≠ holder Change to vehicle type only and/or vehicle type and vehicle(s)	New authorisation (IR articles 14(1)(d), 15(4)(d))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	This is effectively case 7. Creation of a new vehicle type by the new holder. IR article 15(4); AG 3.3.3.3	Vehicle type authorisation and/or vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3
10	Change that introduces deviation from the technical file but does not trigger the criteria of ID article 21(12) IR articles 15(1)(b) & 16(2) AG 3.3.3.2.2 Entity managing the change = holder	N/A IR article 15(1)(b)	No	N/A (5)	Yes In case of impact on conformity assessments already performed and need for new checks and verifications AG 3.3.3.2.2	Yes (6) (9)	N/A	N/A (2)	N/A (7)	Type holder will keep available the relevant information upon request of the authorising entity, NSAs, the Agency MSs. ID Annex IV §2.6; IR article 15(2). When new conformity assessments are needed, the holder shall request an update of the references to the EC type or design examination certificates in ERATV https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2675 Already authorized vehicles do not need to be re-authorized. Newly built vehicles incorporating the 15(1)(b) change shall be authorized in conformity to the updated type (case 2a).	The authorising entity shall update the concerned ERATV entry with the references to the new EC type or design examination certificates
11a	Change that introduces deviation from the technical file but does not trigger the criteria of ID article 21(12) IR articles 15(1)(b) & 16(2) AG 3.3.3.2.2 Entity managing the change ≠ holder Change to vehicle(s) only AG 3.3.4.1	N/A IR article 16(4) Unless requested by the authorising entity within 4 months of notification of changes	No	N/A (5)	Yes (1)	Yes (6) (9)	N/A	N/A (2)	N/A (7)	The entity managing the change must notify the changes to the authorising entity. The change can be implemented immediately and the modified vehicles can be used without having to wait for an answer of the authorising entity. This may apply to a vehicle or a number of identical vehicles. The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information (see case 7). When ERA is the authorising entity, notification to be made following the process described in ERA website https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=948	Reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information
		New authorisation IR articles 14(1)(d) & 16(4) If requested by the authorising entity within 4 months of notification of changes	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	The entity managing the change must notify the changes to the authorising entity. This may apply to a vehicle or a number of identical vehicles. Creation of a new vehicle type by the new holder. IR article 15(4); AG 3.3.3.3	Vehicle type authorisation and/or vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3

Table 0: Summary table

Table case	Description of the case	Authorisation case	Submit an application?	Include requirements capture evidence in the application? (5)	Involve NoBo and/or DeBo?	Involve an AsBo? (3)	Include technical files accompanying the EC DoFV in the application?	Include the EC DoFV in the application?	Include the (risk) declaration in the application? (3)	Remarks - Specific Requests	Outcome
11b	Change that introduces deviation from the technical file but does not trigger the criteria of ID article 21(12)) IR articles 15(1)(b) & 16(2) AG 3.3.3.2.2 & 3.3.3.3 Entity managing the change ≠ holder Change to vehicle type only and/or vehicle type and vehicle(s)	New authorisation IR articles 14(1)(d), 15(4)(d)	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Creation of a new vehicle type by the new holder. IR article 15(4); AG 3.3.3.3	Vehicle type authorisation and/or vehicle authorisation for placing on the market IR articles 48 & 49 AG 3.8.2 & 3.8.3
12	Change to an authorised vehicle type or vehicle that does not introduce a deviation from the technical files IR article 15(1)(a) AG 3.3.3.2.1	N/A	No	N/A (5)	No	No	N/A	N/A	N/A	Need to update configuration management of the vehicle and/or vehicle type	N/A
13	Changes to an already authorised vehicle which are linked to substitution in the framework of maintenance with no change to design/functions IR article 16(1)	N/A	No	N/A (5)	No	No	N/A	N/A	N/A	Need to update configuration management of the vehicle	N/A
14 (8)	If tests are necessary on the network to obtain evidence of technical compatibility and safe integration of subsystems, and/or technical compatibility with the network ID article 21(3) & 21(5) IR article 19 AG 3.3.7	N/A Temporary authorisation to use the vehicle for tests on the network issued by the NSA when it is required and specified in the national legal framework of the MS.	No		Depending on the national legal framework of the MS					Should be covered by the Safety Management System of the RU that will operate the test vehicle(s) to perform a risk assessment. AG 3.3.7.2 & 3.3.7.3	Temporary authorisation issued by the NSA

Legend:
 ID - Interoperability Directive (EU) 2016/797
 IR - Implementing Regulation (EU) 2018/545
 AG - Guidelines for the practical arrangements for the vehicle authorisation process
 AsBo – Assessment body (CSM RA)
 CSM RA – Implementing Regulation (EU) 402/2013

- Notes :**
- (1) Only the changes and their interfaces with the unchanged parts are to be subjected to the EC verification procedure, covered by the requirements capture process and assessed by the authorising entity and the NSAs for the area of use (where applicable), according to ID Annex IV §2.3.3
 - (2) Applicant to decide if there is a need to establish a new or an updated declaration, according to ID article 15(5)
 - (3) AsBo shall be involved in:
 - assessing the requirements capture process for the essential requirement safety and the safe integration between subsystems
 - when the nature of the changes require the application of the CSM RA for a significant change
 - when the mandatory rules explicitly require the application of the CSM RA
 - (4) The changes and/or the changed rules may require the application of the risk assessment process set out in CSM RA. In this case, there is a need for involving an AsBo and the proposer shall establish a risk declaration following article 16 of the CSM RA. This will depend on the nature of the change and the changed rules.
 - (5) The requirements capture process should be performed always, no matter of the authorisation case or the category of the change. However, depending on the case, the documentation related to the requirements capture process performed by the applicant does not need to be submitted to the authorising entity (i.e., there is no application for authorisation nor a 16(4) notification, see section 3.3.1.6)
 - (6) AsBo to assess requirements capture (confirmation that the process followed by the applicant is enough to ensure that the changes do not have the potential to affect adversely safety, see section 3.3.2.4)
 - (7) The proposer may need to establish a (risk) declaration as a result of the requirements capture process for the essential requirement safety and the safe integration between subsystems
 - (8) Not covered in flowchart for substage 1-1
 - (9) Involvement of the AsBo for the assessment of the requirements capture process related to safety and safe integration not needed if it can be demonstrated in a simple manner that the nature of the change does not have the potential to impact safety adversely (see section 3.3.1.7)

1. Introduction

1.1. Legal base

The Agency has a general obligation to provide technical support in the field of railway interoperability, according to articles 4(i) and 19(3) of Regulation (EU) 2016/796. This includes that the Agency may issue guidelines to facilitate the implementation of railway interoperability legislation. In addition, Article 8(1) of the Regulation (EU) 2018/545 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation specifies that:

‘The Agency shall set up, publish and keep up to date guidelines describing and explaining the requirements set out in this Regulation, and make them available to the public free of charge, in all the official languages of the Union. The guidelines shall also include model templates that may be used by the authorising entity and the NSAs for the area of use for the exchange and recording of information and model templates for the application that may be used by the applicant.’

1.2. Scope

All vehicles to which Directive (EU) 2016/797 applies, as specified in Article 1 of the Directive, are included in the scope of Regulation (EU) 2018/545 and are therefore also included in the scope of the “Guidelines for the practical arrangements for the vehicle authorisation process” (VA guidelines).

1.3. Objectives

This document is intended to provide guidance for authorising entities, NSAs for the area of use, holders of the vehicle type authorisation, entities managing change, applicants and other concerned parties for the application of the vehicle authorisation process specified in Regulation (EU) 2018/545 as laid down in Article 21 and 24 of Directive (EU) 2016/797. The VA guidelines aims to support a consistent implementation of the railway vehicle authorisation and railway vehicle type authorisation process.

In order to facilitate the reading of the VA guidelines the structure of the information has been based on the structure of Regulation (EU) 2018/545 and the text of the regulation has been included with the following legend:

Legend:

Yellow shaded text with a frame corresponds to the proposed text for the Regulation (EU) 2018/545 referred to in Article 21(9) of the recast interoperability directive (EU) 2016/797.

Normal text corresponds to the non-legislative acts supporting the Regulation (EU) 2018/545.

Links to webpages have been introduced where appropriate to facilitate for the reader. However, it should be recognised that it has only been introduced for informative purposes, as it could be subject to change at any time.

1.4. Management of the document

It is envisaged to regularly review and when necessary, update and/ or amend the VA guidelines according to the experience gained in the implementation of the vehicle authorisation process according to the Regulation (EU) 2018/545.

Users, being any stakeholders or national safety authorities, can introduce requests for changes to the “Guidelines for the practical arrangements for the vehicle authorisation process” using the ‘Comment sheet’ provided in section 5 of this document, and sending it to VAFeedback@era.europa.eu. The Agency can also propose a revision on its own initiative.

The change requests will be reviewed by the Agency and incorporated, where relevant, in the list of changes for the next version of the VA guidelines. The Agency will provide an answer to the requestor via email.

This version of the document takes into account the legal text in force at the date of drafting and publication, and the corresponding guidelines issued by the Agency. However, the TSIs (and the corresponding application guides) are undergoing revision, and several aspects of this guideline will be impacted both by the adopted legal texts and the revised application guides. It is foreseen to update this guideline as soon as the legal texts and/or the application guides are available.

2. References, definitions and abbreviations

2.1. Reference Documents

Table 1 : Table of Reference Documents¹

[Ref.]	Title	Reference	Version / date
[1]	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	(EU) 2016/796	11-05-2016
[2]	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 (recast)	(EU) 2016/797	11-05-2016
[3]	DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety (recast)	(EU) 2016/798	11-05-2016
[4]	COMMISSION IMPLEMENTING REGULATION on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	(EU) 402/2013	30-04-2013
[5]	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 (Recast)	2008/57/EC	17-06-2008
[6]	COMMISSION IMPLEMENTING DECISION of 4 October 2011 on the European register of authorised types of railway vehicles (2011/665/EU)	2011/665/EU	04-10-2011
[7]	COMMISSION REGULATION (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem 'rolling stock — freight wagons' of the rail system in the European Union and repealing Decision 2006/861/EC	(EU) 321/2013	13-03-2013
[8]	ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary	ISO 9000:2015	2015
[9]	COMMISSION REGULATION (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock — locomotives and passenger rolling stock' subsystem of the rail system in the European Union	(EU) 1302/2014	18-11-2014
[10]	COMMISSION IMPLEMENTING DECISION (EU) 2015/2299 of 17 November 2015 amending Decision 2009/965/EC as regards an updated list of parameters to be used for classifying national rules	(EU) 2015/2299	17-11-2015
[11]	COMMISSION REGULATION (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union	(EU) 2015/995	08-06-2015
[12]	COMMISSION REGULATION (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union	(EU) 2016/919	27-05-2016
[13]	COMMISSION DECISION 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 (2010/713/EU)	2010/713/EU	09-11-2010
[14]	COMMISSION DECISION of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (2007/756/EC)	2007/756/EC	09-11-2007
[15]	COMMISSION NOTICE The 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01)	2016/C 272/01	26-07-2016

¹ The dates/versions indicated in the table are the latest ones at the date of drafting of this document; the applicable versions are always the ones legally in force

Table 1 : Table of Reference Documents¹

	[Ref.] Title	Reference	Version / date
[16]	ISO/IEC 17000:2004 Conformity assessment -- Vocabulary and general principles	ISO/IEC 17000:2004	2004
[17]	ISO 9001:2015 Quality management systems -- Requirements	ISO 9001/2015	2015
[18]	The Luxembourg Protocol to the Convention on International Interests in Mobile Equipment on Matters specific to Railway Rolling Stock, adopted in Luxembourg on 23 February 2007	-	23-02-2007
[19]	COMMISSION IMPLEMENTING REGULATION (EU) 2018/545 of 4 April 2018 on 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	(EU) 2018/545	04-04-2018
[20]	COMMISSION DELEGATED REGULATION (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012	(EU) 2018/761	16-02-2018
[21]	COMMISSION IMPLEMENTING REGULATION (EU) 2019/250 of 12 February 2019 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	(EU) 2019/250	12-02-2019
[22]	COMMISSION IMPLEMENTING REGULATION (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU	(EU) 2019/773	16-05-2019
[23]	COMMISSION IMPLEMENTING REGULATION (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474	(EU) 2019/776	16-05-2019
[24]	COMMISSION IMPLEMENTING REGULATION (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases	(EU) 2020/387	09-03-2020
[25]	COMMISSION IMPLEMENTING REGULATION (EU) 2020/420 of 16 March 2020 correcting the German language version of Regulation (EU) 2016/919 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union	(EU) 2020/420	16-03-2020
[26]	COMMISSION IMPLEMENTING REGULATION (EU) 2020/779 of 12 June 2020 amending Implementing Regulation (EU) 2019/250 as regards the dates of application following the extension of the transposition deadline of Directive (EU) 2016/797 of the European Parliament and of the Council	(EU) 2020/779	12-06-2020
[27]	DIRECTIVE (EU) 2020/700 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 May 2020 amending Directives (EU) 2016/797 and (EU) 2016/798, as regards the extension of their transposition periods	(EU) 2020/700	25-05-2020
[28]	COMMISSION IMPLEMENTING REGULATION (EU) 2020/781 of 12 June 2020 amending Implementing Regulation (EU) 2018/545 as regards the dates of application and certain transitional provisions following the extension of the transposition deadline of Directive (EU) 2016/797 of the European Parliament and of the Council	(EU) 2020/781	12-06-2020

Table 1 : Table of Reference Documents¹

	[Ref.] Title	Reference	Version / date
[29]	COMMISSION IMPLEMENTING DECISION (EU) 2018/1614 of 25 October 2018 laying down specifications for the vehicle registers referred to in Article 47 of Directive (EU) 2016/797 of the European Parliament and of the Council and amending and repealing Commission Decision 2007/756/EC	(EU) 2018/1614	25-10-2018
[30]	DECISION NO 1/2013 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE of 6 December 2013 amending Annex 1 to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road.	2013/804/EU	24-12-2013
[31]	DECISION NO 2/2019 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE of 13 December 2019 on transitory measures to maintain smooth rail traffic between Switzerland and the European Union	2020/40	13-12-2019
[32]	DECISION NO 1/2020 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE of 19 June 2020 aligning Decision No 2/2019 with the dates of transposition, postponed due to the COVID-19 pandemic, of Directives (EU) 2016/797 and (EU) 2016/798 of the European Parliament and of the Council	2020/896	19-06-2020
[33]	DECISION NO 2/2020 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE of 11 December 2020 amending Annex 1 to the Agreement between the European Community and the Swiss Confederation on the Carriage of Goods and Passengers by Rail and Road and Decision No 2/2019 of the Committee on transitory measures to maintain smooth rail traffic between Switzerland and the European Union	2021/35	11-12-2020
[34]	DECISION NO 2/2021 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE of 17 December 2021 amending Annex 1 to the Agreement between the European Community and the Swiss Confederation on the Carriage of Goods and Passengers by Rail and Road and Decision No 2/2019 of the Committee on transitory measures to maintain smooth rail traffic between Switzerland and the European Union	2022/38	17-12-2021
[35]	DECISION NO 1/2022 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE of 21 December 2022 amending Annex 1 to the Agreement between the European Community and the Swiss Confederation on the Carriage of Goods and Passengers by Rail and Road and Decision No 2/2019 of the Committee	2023/143	21-12-2022
[36]	COMMISSION NOTICE The 'Blue Guide' on the implementation of EU products rules 2022 (2022/C 247/02)	2022/C 247/01	29-06-2022
[37]	COMMISSION IMPLEMENTING REGULATION (EU) 2023/1694 of 10 August 2023 amending Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1300/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1304/2014 and Implementing Regulation (EU) 2019/777	(EU) 2023/1694	08-09-2023
[38]	COMMISSION IMPLEMENTING REGULATION (EU) 2023/1695 of 10 August 2023 on the technical specification for interoperability relating to the control-command and signalling subsystems of the rail system in the European Union and repealing Regulation (EU) 2016/919	(EU) 2023/1695	08-09-2023
[39]	COMMISSION IMPLEMENTING DECISION (EU) 2023/1696 of 10 August 2023 amending Implementing Decision 2011/665/EU as regards the specification for the European register of authorised types of vehicles referred to in Article 48 of Directive (EU) 2016/797 of the European Parliament and of the Council (notified under document C(2023) 5020)	(EU) 2023/1696	08-09-2023
[40]	Guide for the application of the Technical Specifications for Interoperability (TSIs)	GUI/TSI/2023	20-12-2023
[41]	Guide for the application of the WAG TSI	GUI/WAG TSI/2023	08-12-2023
[42]	Guide for the application of the LOC&PAS TSI (Commission Regulation (EU) No 1302/2014 of 18 November 2014 and amended by the Commission Implementing Regulation (EU) 2019/776)	GUI/LOC&PAS/2023	n.a.

2.2. Definitions and abbreviations

The general terms and abbreviations used in the present document can be found in a standard dictionary. Specific terms and abbreviations are either defined below or can be found in section 3.2.2.

Table 2 : Table of Terms

Term	Definition
Agency	The European Railway Agency (ERA) such as established by the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European railway agency, as last amended by Regulation (EC) No 1335/2008 [2].
Commission	The European Commission, in particular DG MOVE
Heavy rail infrastructure	Heavy rail infrastructure, by opposition to "light rail infrastructure", is formed of any part of the infrastructure included in Union's network, which falls in the scope defined in Article 1(3) of Directive (EU) 2016/797, i.e. any infrastructure not used by metros, not functionally separate from the rest of the Union rail system and not exclusively used by trams and light rail vehicles as defined in Article 2 (29) of Directive (EU) 2016/797. Article 2 of Directive (EU) 2016/797 defines light rail vehicles according to technical criteria regarding crashworthiness and strength of vehicle.
One-stop shop	'one-stop shop' means the information and communications system operated by the Agency as referred to in Article 12 of Regulation (EU) 2016/796. The one-stop shop constitutes: <ul style="list-style-type: none"> › A single entry point through which the applicant should submit its application and the file accompanying the application for vehicle type authorisation, vehicle authorisations for placing on the market and single safety certificates; › A common information-exchange platform, providing the Agency and national safety authorities with information about all applications for authorisations and single safety certificates, the stages of these procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal; › A common information-exchange platform, providing the Agency and national safety authorities with information about requests for approvals by the Agency in accordance with Article 19 of Directive (EU) 2016/797 and applications for authorisations 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 stages of these procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal; and › An early-warning system able to identify at an early stage the needs for coordination between decisions to be taken by national safety authorities and the Agency in the case of different applications requesting similar authorisations or single safety certificates.
Technical file	Technical file that accompanies the EC declaration(s) of verification, described in §2.4 of Annex IV of Directive (EU) 2016/797.
Union law	The Union law is the system of European laws operating within the MSs of the European Union. The Union law is published in the Official Journal of the European Union and can be accessed free of charge through EUR-Lex (https://eur-lex.europa.eu/homepage.html), and it is published daily in the 24 official EU languages.
Validation	According to ISO 9000/2015 validation is: <i>"The confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled."</i> It should be noted that: <ul style="list-style-type: none"> › The objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculation or reviewing documents. › The word "validated" is used to designate the corresponding status. › The use conditions for validation can be real or simulated. Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is established. Validation can be carried out under realistic use conditions or within a simulated use environment. There are several ways to confirm that the requirements which define an intended use or application have been met. For example, tests, calculations, simulations.
VA guidelines	Guidelines for the practical arrangements for the vehicle authorisation process, pursuant to Article 8(1) of Regulation (EU) 2018/545

Table 3 : Table of Abbreviations

Term	Definition
AsBo	Assessment body under Regulation (EU) 402/2013
CCS	Control Command and Signalling
CfU	Conditions for use of the vehicle and other restrictions
CSM	Common Safety Method
CSM RA	Commission Implementing Regulation (EU) 402/2013
DeBo	Designated Body
DoV	Declaration of Verification

Table 3 : Table of Abbreviations

Term	Definition
ERADIS	European Railway Agency Database of Interoperability and Safety
ERATV	European Register of Authorised Types of Vehicles
ERTMS	European Railway Traffic Management System
ETCS	European Train Control System
EU	European Union
EVN	European Vehicle Number
GSM-R	Global System for Mobile Communications – Railway
IC	Interoperability Constituent
ICT	Community/Switzerland Inland Transport Committee
IM	Infrastructure Manager
ID	Identification
ISV	Intermediate Statement of Verification
LTA	Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road (also known as Land Transport Agreement)
MS	Member State
NoBo	Notified Body
NSA	National Safety Authority
NVR	National Vehicle Register
OSS	One-Stop Shop
OTM	On Track Machine
QMS	Quality Management System
RDD	Reference Document Database
RFU	Recommendation for Use
RINF	Register of Infrastructure
RU	Railway Undertaking
SMS	Safety Management System
SRD	Single Rules Database
TEN	Trans-European Network
TSI	Technical Specification for Interoperability
(TSI) CCS	Technical Specification for Interoperability relating to the subsystem 'control-command and signalling'
(TSI) LOC&PAS	Technical Specification for Interoperability relating to the 'rolling stock — locomotives and passenger rolling stock' subsystem
(TSI) OPE	Technical Specification for Interoperability relating to the 'operation and traffic management' subsystem
(TSI) WAG	Technical Specification for Interoperability relating to the subsystem 'rolling stock — freight wagons'
URVIS	Unique Rail Vehicle Identification System

3. Content of the practical arrangements

3.1. Recitals

3.1.1. Regulation (EU) 2018/545

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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⁽¹⁾, and in particular Article 21(9) thereof,

Whereas:

(1) The practical arrangements for the vehicle authorisation process referred to in Directive (EU) 2016/797 should reduce the complexity, length and cost of the vehicle authorisation process, provide uniform conditions for harmonising the vehicle type authorisation and/or vehicle authorisation for placing on the market in the Union and foster collaboration among all the parties involved in the vehicle authorisation process. In order to reduce length and cost of the vehicle authorisation process, the timeframes should practically be kept as short as possible.

(2) Taking into account the experience gained by national safety authorities ('NSAs') in the authorisation process and in the preparation of the cooperation agreements referred to in Article 21(14) of Directive (EU) 2016/797, early contact with the applicant in the form of coordination ("pre-engagement") is recognised as good practice to facilitate the development of the relationship between the parties involved in the vehicle authorisation process. Such pre-engagement should be offered before an application for a vehicle type authorisation and/or vehicle authorisation for placing on the market is submitted, with the aim of enabling the authorising entity and the concerned NSAs for the area of use to become familiar with the project. In order for the applicant to be aware of what to expect, that pre-engagement should clarify to the applicant the applicable rules, provide the applicant with the details of the vehicle authorisation process, including the process of decision-making, and verify that the applicant has received sufficient information. The applicant is responsible for ensuring that all the requirements are met when submitting its application for vehicle type authorisation and/or vehicle authorisation for placing on the market. In performing its duties, it is assisted by other entities such as conformity assessment bodies, suppliers and service providers.

(3) With a view to providing economies of scale and reducing administrative burden, vehicle type authorisation should enable the applicant to produce a number of vehicles of the same design and facilitate their authorisation. The vehicle type identifies the design that will be applied to all vehicles corresponding to that type. Every new vehicle type should follow the process of authorisation and a new type should only be created if it is authorised.

(4) The concepts of variant and version of a vehicle type should be introduced in order to provide the possibility of identifying options for configuration or changes during the life cycle of the vehicle within an existing type, the difference between variants and versions being that variants require an authorisation while versions do not.

(5) In order to ensure that the vehicle type continues to meet the requirements over time and that any changes to the design that affects the basic design characteristics are reflected as new variants and/or versions of the vehicle type, the process of configuration management of the vehicle type, should be used. The entity responsible for the configuration management of the vehicle type is the applicant that received the vehicle type authorisation.

(1) 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 (recast) (OJ L 138, 26.5.2016, P. 44 -101)

(6) As far as vehicles are concerned, it is necessary to have a configuration management process limited to changes that are not managed through the configuration management process of an authorised vehicle type.

(7) The European Union Agency for Railways (the 'Agency') should set up guidelines describing, and where necessary, explaining the requirements set out in this Regulation. The guidelines should be updated, published and made available to the public free of charge. With the aim of harmonising the approach to the exchange and recording of information through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council⁽¹⁾, the guidelines should also include model templates set up by the Agency in cooperation with the NSAs.

(8) The Agency and the NSAs should implement internal arrangements or procedures to ensure that the requirements of the vehicle authorisation process are fulfilled.

(9) Considering that return of experience is recognised as a good practise, the NSAs and the Agency should be encouraged to share any related relevant information. With a view to provide such service, the Agency should establish a protocol and procedures for the recording and exchange of information among the Agency and NSAs.

(10) To avoid any duplication of assessment and to reduce the administrative burden and cost for the applicant, the Agency and the NSAs should take into account the cooperation agreements and multilateral agreements concluded pursuant to Article 21(14) and (15) of Directive (EU) 2016/797, where relevant.

(11) The Agency and the NSAs should register all relevant information and the documented reasons for the decision in the one-stop shop, in order to justify the decisions at each stage of the vehicle authorisation process. If the Agency and the NSAs have their own information management systems for the purposes of the assessment, they should ensure that all relevant information is transferred to the one-stop shop for the same reasons. In order to facilitate the communication between the interested parties, the guidelines of the Agency and the NSAs should provide practical arrangements for those communications which are not relevant for the decision making process and which therefore do not need to be submitted through the one-stop-shop.

(12) Where the intended area of use for the vehicle type is limited to a network or networks within one Member State, the authorisation is valid without extension of the area of use for vehicles travelling to stations in neighbouring Member States with similar network characteristics, when those stations are close to the border. In such a case, the applicant may submit their application for a vehicle type authorisation and/or vehicle authorisation for placing on the market to the Agency or the NSA. Where the Agency acts as the authorising entity it is to consult the relevant NSAs in accordance with Article 21(8) of Directive (EU) 2016/797 and take into account the relevant cross-border agreements.

(13) Where the Agency acts as the authorising entity, the applicant should, without prejudice to the provisions of point 2.6 of Annex IV to Directive (EU) 2016/797, have the right to submit its application to the Agency in one of the official languages of the Union. During the course of the assessment, the NSAs should have the right to address documents pertaining to the assessment to the Agency in a language of its Member State, without any obligation to translate them.

(14) The Agency and the NSAs should develop internal arrangements or procedures for managing the issuing of vehicle type authorisations and/or vehicle authorisations for placing on the market with a view to reducing the administrative burden and costs for the applicant. In that respect, the applicant should have the possibility to submit copies of documents in the application file. The original documents should be available for verification by the Agency and the NSAs following the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market.

(1) 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 (OJ L 138, 26.5.2016, p. 1)

(15) It is necessary to harmonise the categorisation of issues in the assessment process to ensure that the applicant understands the severity of any issues raised by the Agency or by a NSA. That categorisation is particularly important when several NSAs are involved in the process. In order to facilitate the vehicle authorisation process and to reduce administrative burden in cases where there are no applicable national rules, the Agency's consultation with the concerned NSAs for the area of use should be limited to the check of the correct specification of the area use for the Member State concerned. In cases where the technical specifications for interoperability ("TSIs") contain specific provisions, the area of use should be able to cover the whole Union network and the checks performed by the Agency should be sufficient.

(16) Vehicles and vehicle types are to remain authorised in accordance with Article 54(2) of Directive (EU) 2016/797 without prejudice to Article 21(12) and 24(3) of that Directive. In the case of renewal or upgrading of those vehicles, the provisions of this Regulation are to apply in accordance with article 21(12) of Directive (EU) 2016/797.

(17) According to Article 54(4) of Directive (EU) 2016/797, the new vehicle authorisation regime is to start from 16 June 2019. However, Member States have the possibility to notify the Agency and the Commission pursuant to Article 57(2) of that Directive that they have extended the transposition period and may in consequence continue to issue vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with Directive 2008/57/EC of the European Parliament and of the Council⁽¹⁾ until 16 June 2020. Between 16 June 2019 and 15 June 2020, two different legal regimes where the authorising entities are different could coexist. It is therefore necessary to clarify how the new regime should apply in addition to the old one where the intended area of use includes one or more of those Member States.

(18) Where a NSA recognises that it will not be able to issue a vehicle type authorisation/vehicle authorisation for placing in service in accordance with Directive 2008/57/EC before either 16 June 2019, or 16 June 2020 in respect of those Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797, the Agency, when acting as authorising entity, should accept the results of the assessment of the NSA in order to avoid any duplication of assessment and additional burden and any delay for the applicant.

(19) In order to facilitate the placing on the market of the vehicles and to reduce administrative burdens, a vehicle type authorisation and/or vehicle authorisation for placing on the market issued by the Agency should be recognised as equivalent to vehicle type authorisation referred to Article 26 of Directive 2008/57/EC and vehicle authorisation for placing in service referred to in Articles 22 and 24 of Directive 2008/57/EC.

(20) TSIs in accordance with Article 4(3)(f) of Directive (EU) 2016/797, as well as national rules, should foresee a gradual transition, in particular taking into account projects at an advanced stage of development as defined in Article 2(23) of Directive (EU) 2016/797.

(21) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 21 of Council Directive 96/48/EC⁽²⁾.

(1) 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 (OJ L 191, 18.7.2008, p. 1)

(2) Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system (OJ L 235, 17.9.1996, p. 6).

3.1.2. Regulation (EU) 2020/781

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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⁽¹⁾, and in particular Article 21(9) thereof,

Whereas:

(1) Directive (EU) 2016/797 was amended by Directive (EU) 2020/700⁽²⁾ in order to give Member States the possibility to extend the deadline to bring into force the national laws, regulations and administrative provisions necessary to comply with the provisions referred to in Article 57(1) Directive (EU) 2016/797.

(2) The assessment of applications for a vehicle type authorisation or a vehicle authorisation for placing on the market in accordance with Directive 2008/57/EC of the European Parliament and of the Council⁽³⁾, for which the relevant authorisations had to be issued before 16 June 2020, might be delayed because of the COVID-19 outbreak. Therefore, in the Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and where Directive (EU) 2016/797 is to apply from 16 June 2020, the national safety authority ('NSA') should, at the request of the applicant, continue the assessment beyond that date. The NSA should finalise that assessment and issue the authorisation before 30 October 2020.

(3) With regard to Member States that have notified the European Union Agency for Railways ('the Agency') and the Commission of their intention to extend the transposition period of Directive (EU) 2016/797 in accordance with Article 57(2a) thereof, the application of certain provisions of Commission Implementing Regulation (EU) 2018/545⁽⁴⁾ should be postponed and apply from 31 October 2020. Transitional provisions set out in Implementing Regulation (EU) 2018/545 should also be adapted.

(4) Applicants may have compiled applications in accordance with Commission Implementing Regulation (EU) 2018/545 in view to the current application deadline. For the purposes of both Directive 2008/57/EC and Directive (EU) 2016/797, vehicles are to comply with technical specifications for interoperability and relevant national rules and meet the essential requirements. Applications drawn up in accordance with Implementing Regulation (EU) 2018/545 should include all the necessary evidence for either the placing in service of vehicles under Directive 2008/57/EC or the placing on the market of vehicles under Directive (EU) 2016/797. Therefore, applicants should be allowed to submit, to national safety authorities in Member States that have notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797, applications which list evidence in accordance with Commission Implementing Regulation (EU) 2018/545. National safety authorities should accept those applications without requiring a revised application.

(5) Implementing Regulation (EU) 2018/545 should therefore be amended accordingly

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 51(1) of Directive (EU) 2016/797.

(7) In order to ensure that the measures provided for in this Regulation are effective, this Regulation should enter into force on the day following that of its publication in the Official Journal of the European Union,

(1) OJ L 138, 26.5.2016, p. 44.

(2) Directive (EU) 2020/700 of the European Parliament and of the Council of 25 May 2020 amending Directives (EU) 2016/797 and (EU) 2016/798, as regards the extension of their transposition periods (OJ L 165, 27.5.2020, p. 27).

(3) 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 (OJ L 191, 18.7.2008, p. 1).

(4) 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 (OJ L 90, 6.4.2018, p. 66).

3.2. Chapter 1 - General provisions

3.2.1. Article 1: Subject matter and scope

1. This Regulation lays down requirements to be complied with by:
 - (a) the applicant, when submitting, through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council, an application for vehicle type authorisation and/or vehicle authorisation for placing on the market;
 - (b) the Agency and the NSAs, when processing an application for vehicle type authorisation and/or vehicle authorisation for placing on the market and in relation to pre-engagement;
 - (c) the authorising entity, when deciding on the issuing of vehicle type authorisations or vehicle authorisations for placing on the market.
 - (d) the infrastructure managers, when providing conditions for the carrying out of tests in their network(s) and providing information for the vehicle authorisation regarding the area of use.
2. This Regulation shall apply without prejudice to Article 21(16) and (17) of Directive (EU) 2016/797.

The practical arrangements set out in the document aim to put in place and maintain an effective and efficient process with the various entities collaborating in order to:

- › Take decisions on the issuing of vehicle authorisations;
- › Harmonise the practices of the entities issuing vehicle authorisations across the EU (irrespective of the area of use); and
- › Bring more consistency and transparency for the applicant, in particular when the process involves an authorising entity and one or more NSAs for the area of use.

The practical arrangements set out in Regulation (EU) 2018/545 should apply for vehicle type authorisation/ authorisation for placing on the market of vehicles intended to be operated in the Union rail system as defined by Article 2 of Directive (EU) 2016/797.

This should apply without prejudice of the potential exclusion by MSs as mentioned in Article 1(4) (a) of Directive (EU) 2016/797.

Access to ports and terminals are in the scope of Directive (EU) 2016/797 (as they were in the Directive 2008/57/EC). Authorisation for placing on the market according to Directive (EU) 2016/797, especially Article 21, applies also on these parts of the network. This applies without prejudice of the potential exclusion by MSs as mentioned in Article 1(4) (a) of Directive (EU) 2016/797.

3.2.2. Article 2: Definitions

For the purposes of this Regulation, the following definitions shall apply:

3.2.2.1. (1) Authorising entity

(1) 'authorising entity' means the entity that issues the vehicle type authorisation and/or vehicle authorisation for placing on the market;

The role of authorising entity is performed by:

- › The Agency in the case of vehicle type authorisation and/ or vehicle authorisation for placing on the market to be issued for an area of use covering one or more MSs; or
- › The NSA in the case of vehicle type authorisation and/ or vehicle authorisation for placing on the market to be issued for an area of use limited to the network(s) within one MS and where the applicant has requested this in accordance with Article 21(8) of Directive (EU) 2016/797.

In the case of vehicle type authorisation and/ or vehicle authorisation for placing on the market in respect of vehicles having an area of use covering more than one MS it is the Agency that should have the role of the authorising entity.

In cases where, following an extension of the area of use to another MS pursuant to Article 14(1)(c) of Regulation (EU) 2018/545, the vehicles will not be operated anymore in the original area of use, they still remain authorised there, hence the final area of use in which they are authorised covers networks in more than one MS and the Agency shall be the authorising entity. See also section 3.3.2.3.4 for more information on changes (rather than extension) of the area of use.

If a wagon to be authorised is compliant with section 7.1.2 of WAG TSI, the assessments of the Agency acting as authorising entity, when the applicant has applied for an authorisation with an area of use covering more than one MS, will cover the additional conditions that the wagon should meet and no involvement of the NSAs for the area of use should be necessary (no applicable national rules). For such cases, the involvement of the NSAs for the area of use (that will be notified of the application and will have access to the file accompanying the application in the OSS) should focus on providing information from return of experience that may be relevant for the issuing of the authorisation, in accordance with Article 7(4) of Regulation (EU) 2018/545.

3.2.2.2. (2) Basic design characteristics

(2) 'basic design characteristics' means the 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 Vehicle Types ('ERATV').

Further guidance about basic design characteristics and basic parameters can be found in the guidelines for the application of the TSIs.

3.2.2.3. (3) Configuration management

(3) 'configuration management' means a systematic organisational, technical and administrative process put in place throughout the lifecycle of a vehicle and/or vehicle type to ensure that the consistency of the documentation and the traceability of the changes are established and maintained so that:

- (a) requirements from relevant Union law and national rules are met;
- (b) changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;
- (c) information and data is kept current and accurate;
- (d) relevant parties are informed of changes, as required;

3.2.2.3.1. Configuration management of a vehicle

The scope of the configuration management for a vehicle is limited to the changes specified in Article 16 of Regulation (EU) 2018/545. The keeper of the vehicle or the entity entrusted by that keeper should be responsible for the configuration management of the vehicle, this should apply without prejudice to the responsibilities assigned to the:

- › Entity in charge of maintenance for the vehicle; and
- › RU using the vehicle.

3.2.2.3.2. Configuration management of a vehicle type

The configuration management of a vehicle type refers to establishing and maintaining (throughout the life of the vehicle type) a file containing all details of the vehicle type (drawings, calculations etc.), covering the evolution over time (changes in the legal framework, changes in the vehicle type etc.).

More precisely, the configuration management of the vehicle type covers aspects such as:

- › Monitoring of changes in the legal framework and impact on the vehicle type (TSIs, national rules, other applicable EU law, etc);
- › Keeping up to date the documentation that forms the basis of the vehicle type authorisation in case of changes in the legal framework and/or changes to the vehicle type that do not require a new authorisation (i.e., categories 15(1)(a), (b) or (c) of Regulation (EU) 2018/545), e.g.:
 - EC DoVs and accompanying technical files (including EC declarations of conformity for ICs)
 - EC certificates and accompanying files (when the involvement of a NoBo is needed)
 - Evidence related to requirements capture
- › Inform the NoBos that performed the conformity assessment of the changes on the vehicle type that have an impact on compliance with the TSIs;
- › Categorisation of changes to the vehicle type according to article 15(1) of Regulation (EU) 2018/545;
- › Request the necessary updates of the concerned ERATV entry in case of changes to the vehicle type that do not require a new authorisation (including compilation of versions, when the holder decides to request it, see section 3.8.4.2);
- › Etc.

3.2.2.4. (4) Date of receipt of the application

(4) 'date of receipt of the application' means:

- (a) where the Agency acts as the authorising entity, the first working day common to the Agency and to the NSAs concerned with the intended area of use following the acknowledgement of receipt of the application;
- (b) where a NSA acts as the authorising entity, the first working day in the Member State concerned following the acknowledgement of receipt of the application;

3.2.2.5. (5) Entity managing the change

(5) 'entity managing the change' means the holder of the vehicle type authorisation, the keeper or the entity entrusted by them.

The roles of entity managing the change for a vehicle type and entity managing the change for a vehicle conforming to that type can be played by different companies. As a result, the configurations they are responsible for managing are different as well:

- › Configuration management of the vehicle type, when the entity managing the change is the holder of the vehicle type authorisation, or
- › Configuration management of the vehicles when the keeper is the entity managing the change.

In case of changes pursuant to Article 16(4), see section 3.3.4.4, the entity managing the change is also responsible for the submission of the notification and the accompanying file.

3.2.2.6. (6) Holder of the vehicle type authorisation

(6) 'holder of the vehicle type authorisation' means the natural or legal person that has applied for and received the vehicle type authorisation, or its legal successor;

For any given vehicle type, there can only be one holder of a vehicle type authorisation under Directive (EU) 2016/797 and Regulation (EU) 2018/545. However, two series of vehicles of the same design could have two different applicants for authorisation for placing the (individual) vehicles on the market. When this

authorisation is not requested in conformity to an authorised vehicle type, it will lead to two different vehicle types, although each vehicle type will have the same basic design characteristics.

Please note that for vehicle types authorised under Directive 2008/57/EC, there can be more than one holder of the vehicle type authorisation (see section 3.2.2.6.3).

When several companies are cooperating in the development of a new vehicle type, it is possible that each company becomes the holder of a vehicle type authorisation. To do so, each company should submit an application for authorisation through the OSS, which will result in an issued vehicle type authorisation and an ERATV entry per application.

3.2.2.6.1. Legal successor

For the purposes of Regulation (EU) 2018/545, the legal successor should be considered as the natural or legal person that lawfully obtained from the previous holder of the vehicle type authorisation their assets, rights and obligations related to the authorised vehicle type as a result of the cessation of activities of the previous holder of the type authorisation due to but not limited to merger, acquisition, division etc.

3.2.2.6.2. Transfer of the holdership of a vehicle type authorisation

The definition of a holder clearly establishes that the holdership may be only obtained through (i) application and reception of the vehicle type authorisation or (ii) legal succession, therefore the actual holder of a vehicle type authorisation may not transfer its role to another party under private contracts or other arrangements.

If a company ceases to exist due to circumstances such as merger or division and this company was a holder of vehicle authorisation then this should be treated as an asset of the company and the legal successor becomes the holder of the vehicle type authorisation. How assets of a company are dealt with in the event that a company ceases to exist is normally regulated in national legislation.

3.2.2.6.3. Holder of the vehicle type authorisation for vehicle types authorised under previous regimes

For vehicle types authorised before the relevant date (see section 3.2.2.17), the holder of the vehicle type authorisation can be established on the basis of:

- › Who is registered as the authorisation holder in ERATV (vehicle type authorisations issued under Directive 2008/57/EC). For cases where there is more than one authorisation holder (e.g., in case of first authorisation and additional authorisation in other MSs), both are considered holders of the vehicle type authorisation;
- › Who is identified as the holder in an issued vehicle type authorisation, or

If there is no ERATV entry (vehicle placed on the market before Directive 2008/57/EU or in operation before 19 July 2010) nor a vehicle type authorisation, there is no holder of the vehicle type authorisation; in order to establish a holdership, there is a need to perform a change falling under Article 15(4) of Regulation (EU) 2018/545. The entity managing the change will become the holder of the new vehicle type that will be authorised and registered in ERATV when the relevant vehicle type authorisation is issued.

3.2.2.7. (7) Justified doubt

(7) 'justified doubt' means an issue classified as 'type 4' according to Article 41(1)(d), with a justification and supporting evidence, raised by the authorising entity and/or the NSAs for the area of use concerning the information provided by the applicant in its application;

A justified doubt:

- › Is an issue classified as a ‘type 4’, as specified in Article 41(1)(d) of Regulation (EU) 2018/545, where there is a justification with supporting evidence;
- › Raises a serious concern on the content of the application file;
- › Is considered to have the potential to result in the rejection of the application unless the applicant agrees to provide further information as specified in Article 42 of Regulation (EU) 2018/545; and
- › Gives the possibility to suspend the assessment and to extend the time frame, as specified in Article 34(6) of Regulation (EU) 2018/545.

For further information about issues to be classified as ‘justified doubt’, see section 3.7.11.

3.2.2.8. (8) National safety authority for the area of use or NSA for the area of use

- (8) ‘national safety authority for the area of use’ or ‘NSA for the area of use’ means the national safety authority when it performs one or more of the following tasks:
- (a) the assessments specified in Article 21(5)(b) of Directive (EU) 2016/797;
 - (b) the consultations requested in Article 21(8) of Directive (EU) 2016/797;
 - (c) issues the temporary authorisations, when required, for using the vehicle for tests on the network and takes measures to ensure that the tests on the network can take place as specified in Article 21(3) of Directive (EU) 2016/797;

If there are no national rules to be applied, there is no need to involve the NSAs for the area of use, other than to assess that the area of use for the concerned MS is correctly specified and/or report return of experience to be taken into account, see section 3.7.8.3.

The NSAs for the area of use will be notified by the OSS in any case and will have access to the file accompanying the application, but no assessment in the sense of Article 40 of Regulation (EU) 2018/545 (see section 3.7.9 is expected from them).

There is a need to differentiate between cases where it is clear that no national rules apply (e.g., wagons conforming to section 7.1.2 of WAG TSI), and cases where there is a change to an already authorised vehicle that has an impact on the compliance with national rules.

- › In the first case, there are no assessments to be performed by the NSAs for the area of use. The Agency will deliver an authorisation after performing the assessments described in Annex II of Regulation (EU) 2018/545.
- › In the second case, while the applicant is responsible for ensuring that all requirements are met before submitting an application for authorisation, including the evaluation of national rules which may be directly and indirectly impacted by the changes, the NSAs for the area of use shall assess if the national rules identified are correct (point 3 of Annex III of Regulation (EU) 2018/545). From this point of view, NSAs for the area of use are entitled to raise issues when there are doubts concerning the national rules that need to be re-evaluated as a result of the change.

However, the NSAs for the area of use should not require the fulfilment of national rules which are not in the scope of the change or are not notified (i.e., published in RDD), nor request statements from third parties confirming that the national rules applied are the correct ones.

In the case of a vehicle that is to be authorised for an area of use covering only one MS, the NSA of the concerned MS can be the authorising entity if the applicant chooses this. However, the role of authorising entity is a different role as compared to that of the NSA for the area but in the case where the NSA is the authorising entity the roles are performed by the same entity.

The NSAs also have the responsibility to issue the temporary authorisation to use the vehicle for tests on the network when it is required by the national legal framework of the MS, see section 3.3.7.

3.2.2.9. (9) Pre-engagement

(9) 'pre-engagement' means a procedural stage preceding the submission of an application for authorisation performed upon request of the applicant;

3.2.2.10. (10) Pre-engagement baseline

(10)'pre-engagement baseline' means the opinion of the authorising entity and of the concerned NSAs for the area of use on the pre-engagement file;

3.2.2.11. (11) Requirements capture

(11)'requirements capture' means the process of identification, assignment, implementation and validation of requirements performed by the applicant in order to ensure that relevant Union and national requirements are complied with. Requirements capture may be integrated in the product development processes;

See section 3.3.1.

3.2.2.12. (12) Safe integration

(12)'safe integration' means the fulfilment of the essential requirement on safety as specified in Annex III of Directive (EU) 2016/797 when combining parts into its integral whole, such as a vehicle or a subsystem as well as between the vehicle and the network, with regards to the technical compatibility;

In the framework of vehicle type authorisation and/ or vehicle authorisation for placing on the market, the term 'safe integration' can be used to cover:

- › Safe integration between the elements composing the mobile subsystem. This is fully in the scope of the TSIs covering a subsystem. Where there are no explicit technical rules covering this matter, the TSIs may adopt a risk based approach and require the application of CSM RA specifying to which acceptable level the risk should be controlled;
- › Safe integration between mobile subsystems that constitute a vehicle; and
- › Safe integration for the network-vehicle interface with regards to technical compatibility.

Further information about the concept of safe integration can be found in the clarification note ERA120/063, available at the website of the Agency:

https://www.era.europa.eu/domains/common-safety-methods/risk-evaluation-assessment-csm_en

3.2.2.12.1. Safe integration between mobile subsystems

The interfaces between subsystems within vehicles should be specified in the TSIs and/ or national rules but as this is not always considered necessary to achieve the objectives of Directive (EU) 2016/797, not all interfaces are fully covered by TSIs and/ or national rules.

By properly controlling the identified risks related to the integration between mobile subsystems using the harmonised risk assessment process specified in CSM RA , as prescribed in Article 21(3) of Directive (EU) 2016/797, in conjunction with the application of existing technical requirements, the safe integration between mobile subsystems can be ensured.

3.2.2.12.2. Safe integration for the network-vehicle interface, with regards to technical compatibility

Each side of the network-vehicle interface is managed by different actors therefore a harmonised approach is required and the interface parameters should be specified in the TSIs and/ or national rules; this means that the technical compatibility at the network-vehicle interface should be ensured

by the application of the relevant requirements (TSIs and/ or national rules). However, there is the need to have a systematic approach (i.e., requirements capture) to analyse the interface network-vehicle to identify further harmonisation (rules) for technical compatibility and safe integration for each project, with the objective of identifying whether the existing rules are enough or not, and if there is a need for additional requirements (or modification of the existing ones), follow the process for dealing with deficiencies in the TSIs and/ or national rules.

3.2.2.13. (13) Vehicle type variant

(13) 'vehicle type variant' means an option for the configuration of a vehicle type that is established during a first authorisation of the vehicle type in accordance with Article 24(1) or changes within an existing vehicle type during its life cycle that require a new authorisation of the vehicle type in accordance with Articles 24(1) and 21(12) of Directive (EU) 2016/797;

Vehicle type variants are different options for a design covered by a vehicle type (i.e., if the holder of the vehicle type authorisation wants to add a vehicle type variant to an already authorised vehicle type it has to apply for a new authorisation).

It is not possible to create a variant from an existing variant or version of a vehicle type, even if the entity managing the change is the holder of the vehicle type authorisation. For such cases, a new type shall be authorised, using the authorisation case referred to in Article 14(1)(d) – new authorisation.

3.2.2.14. (14) Vehicle type version

(14) 'vehicle type version' means an option for the configuration of a vehicle type or type variant or changes within an existing type or type variant during its life cycle, created to reflect changes to the basic design characteristics that do not require a new authorisation of the vehicle type in accordance with Articles 24(1) and 21(12) of Directive (EU) 2016/797;

Vehicle type versions are configurations or modifications that constitute a change to the basic design characteristics of the vehicle type or vehicle type variant below the threshold for a new authorisation laid down in the TSIs according to Articles 24(1) and 21(12) of Directive (EU) 2016/797.

It is not possible to create a version from an existing version of a vehicle type, even if the entity managing the change is the holder of the vehicle type authorisation. For such cases, a new type shall be authorised, using the authorisation case referred to in Article 14(1)(d) – new authorisation.

When the applicant for an extension of an area of use of an already authorised vehicle type is the holder of the vehicle type authorisation, it can decide whether the result will be a new type, a vehicle type version or a version of a variant of a vehicle type. It is not possible to authorise a variant of a vehicle type following an extension of the area of use due to the definition of vehicle type variant in article 2(13) of Regulation (EU) 2018/545: variants can only be the result of authorisation cases first or new (pursuant to articles 14(1)(a) and 14(1)(d) of Regulation (EU) 2018/545).

When the applicant for an extension of the area of use is not the holder of the vehicle type authorisation, the result should be a new type, pursuant to Article 14(2) of Regulation (EU) 2018/545.

3.2.2.15. (15) Vehicle authorisation for placing on the market

(15) 'vehicle authorisation for placing on the market' means the decision issued by the authorising entity based on a reasonable assurance that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle have fulfilled their respective obligations and responsibilities in order to ensure conformity with essential requirements of the applicable legislation or to ensure conformity with the authorised type enabling that the vehicle may be placed on the market and may be used safely in the area of use according to the conditions for use and other restrictions, when applicable, specified in the vehicle authorisation and in the vehicle type authorisation;

Authorising entities can issue, upon request of the applicant, the authorisation to a series of vehicles (set of identical vehicles) on the basis of a declaration of conformity to a vehicle type pursuant to Article 14(1)(e) of Regulation (EU) 2018/545 – authorisation in conformity to type – . An applicant can also submit an application for authorisation for placing on the market in conformity to an already authorised type for a single vehicle.

When the applicant requests for a vehicle to be authorised for placing on the market for authorisation cases referred to in Articles 14(1)(a) – first authorisation – , (c) – extended area of use – and/or (d) – new authorisation –, there is no need to provide a declaration of conformity to a vehicle type.

An applicant can combine in a single application through the OSS an application for a first authorisation pursuant to Article 14(1)(a), including a first vehicle conforming to that type as mentioned in the paragraph above, and an application for authorisation for placing on the market of a single vehicle or a series of identical vehicles, pursuant to Article 14(3)(b).

3.2.2.16. (16) Vehicle type authorisation

(16) ‘vehicle type authorisation’ means the decision issued by the authorising entity based on reasonable assurance that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle type have fulfilled their obligations and responsibilities in order to ensure conformity with the essential requirements of the applicable legislation enabling that a vehicle manufactured according to this design may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions for use of the vehicle and other restrictions, when applicable, specified in the vehicle type authorisation and to be applied to all vehicle authorised in conformity to this type;

The vehicle type authorisation can take place either:

- › at the same time as the first vehicle of that vehicle type is authorised for placing on the market, or
- › without a vehicle of that vehicle type being authorised for placing on the market if the applicant’s request is limited to the authorisation of a vehicle type.

When authorising a vehicle type, a vehicle of that vehicle type may be used for the verification and validation of the conformity with the essential requirements of the applicable legislation. That vehicle does not have to be authorised for placing on the market. It is the choice of the applicant in its request if the vehicle used for verification and validation of the vehicle type should be authorised for placing on the market or not.

The concept of vehicle type applies to a vehicle as a whole not to a specific subsystem. A vehicle may contain more than one subsystem, in which case, the characteristics of a vehicle type is the combination of characteristics of subsystems and their interaction with each other when integrated together in a vehicle.

From a vehicle type, it is possible to create variants of it or versions of it. From a variant of a vehicle type, it is also possible to create a versions of such variant. It is not possible though to create variants of a variant of a vehicle type, versions of a version of a vehicle type, or variants of a version of a vehicle type. This is summarized in the following schematic:

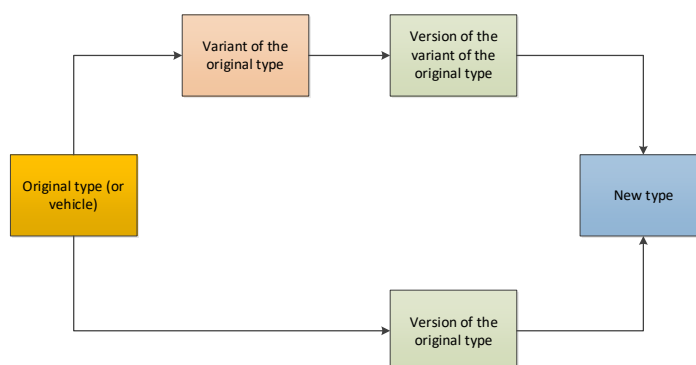


Figure 1: Type, variant and version

3.2.2.17. (17) Relevant date

(17)“relevant date” means 16 June 2019 as regards those Member States that have not notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 that they have extended the transposition period of that Directive. It means 16 June 2020 as regards those Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 that they have extended the transposition period of that Directive and that have not notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797. It means 31 October 2020 as regards those Member States that have notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797 that they have further extended the transposition period of that Directive.

3.2.3. Article 3: Responsibilities of the applicant

The applicant shall submit its application for vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with the provisions of this Regulation.

It is the responsibility of the applicant to ensure that the relevant requirements from applicable legislation are identified and met when submitting its application for vehicle type authorisation and/or vehicle authorisation for placing on the market

For the definition of ‘applicant’ see Article 2(22) of Directive (EU) 2016/797. This definition contains three different applicants:

- › The first part of the definition refers to the applicant for authorisation:
 - Authorisation for the placing in service of fixed installations as specified in Article 18 of Directive (EU) 2016/797;
 - Vehicle authorisation for placing on the market as specified in Article 21 of Directive (EU) 2016/797, or
 - Vehicle type authorisation as specified in Article 24 of Directive (EU) 2016/797).

For vehicle and/or vehicle type authorisation purposes, it is a natural or legal person requesting an authorisation, be it a RU, an IM or any other person or legal entity, such as a manufacturer, an owner or a keeper. It can be the manufacturer of the vehicles, the manufacturer of (one of) the mobile subsystems, a RU (operator), a leasing company etc.

- › The second part of the definition refers to the applicant that places the mobile subsystems on the market and establishes the EC Declaration for Verification for subsystems as specified in Article 15 of Directive (EU) 2016/797; it can be a contracting entity or a manufacturer, or its authorised representatives. This role is normally played by the manufacturer of the mobile subsystem. Within a vehicle type, there can be two different applicants for placing on the market of the mobile subsystems: one for RST, another one for CCS.
- › The third part of the definition refers to the applicant requesting Agency approval of trackside ERTMS as specified in Article 19 of Directive (EU) 2016/797.

It follows then that the role of applicant for placing on the market of the subsystems and applicant for authorisation can be played by different companies, who then have different rights and responsibilities. For example:

- › Role A: applicant for vehicle type authorisation through the OSS
- › Role B: applicant for placing on the market of RST subsystem (manufacturer), establishing the EC DoV for the mobile subsystem
- › Role C: applicant for placing on the market of CCS subsystem (manufacturer), establishing the EC DoV for the mobile subsystem

- › Role D: applicant for vehicle authorisation for placing on the market through the OSS, establishing the EC declaration of conformity to type
- › Role E: manufacturer of the vehicles
- › Role F: RU that will operate the vehicle
- › Role G: entity managing the change

The following scenarios are found often (not exhaustive list)

- › Roles A, B, C, D and E played by the same company, who becomes the holder of the vehicle type authorisation following a first authorisation and then produces vehicles in conformity to the type and applies for the authorisation for placing on the market of the vehicles; role F is played by another company that will operate the vehicles
- › Roles A, B, C and E played by the same company, who becomes the holder of the vehicle type authorisation following a first authorisation and then manufactures vehicles in conformity to the type.

However, role D is played by another company (submitting the application for vehicle authorisation for placing on the market through the OSS), that will also be the operator of the vehicles (RU)

- › Roles A, B, D and E played by the same company, who manufactures the vehicles, integrates CCS subsystem placed on the market by another company, becomes the holder of the vehicle type authorisation following a first authorisation and then produces vehicles in conformity to the type and applies for the authorisation for placing on the market of the vehicles.

Role C is played by another company (supplier of CCS subsystem).

Finally, role F is played by a company that will operate the authorised vehicles.

- › All roles are played by the same company, a RU that makes changes to vehicles already authorised and in operation, becomes the holder of the vehicle type authorisation following a new authorisation, implements the changes in all vehicles, placing the modified mobile subsystems into the market (establishing the EC DoV(s) of the modified subsystems), and applies for the authorisation for placing on the market of the modified vehicles
- › Roles A, B, D, E, F and G are played by the same company, a RU that wants to modify vehicles already authorised and in operation, becomes the holder of the vehicle type authorisation following a new authorisation, subcontracts the implementation of the changes in the CCS subsystem to the company that originally manufactured it, and applies for the authorisation for placing on the market of the modified vehicles .

Role C is played by another company (original supplier of CCS subsystem).

The ‘applicant’ referred to in Regulation (EU) 2018/545 is the applicant for authorisation for vehicle authorisation for placing on the market as defined in Article 2(22) of Directive (EU) 2016/797, as specified in Article 21 of Directive (EU) 2016/797 and/ or for vehicle type authorisation as specified in Article 24 of Directive (EU) 2016/797.

The ‘applicant’ referred to in Regulation (EU) 2018/545 (applicant for vehicle type authorisation and/or vehicle authorisation for placing on the market) must be the ‘proposer’ referred to in the fourth bullet point of Article 3(11) ⁽²⁾ of CSM RA when there is a need to apply the risk management and/or risk assessment process described in the regulation. This article states that the ‘proposer’ is “an applicant for an authorisation for the placing in service of structural sub-systems”, taking into account the fact that under Directive (EU)

² According to Article 3(11) of CSM RA, ‘proposer’ means one of the following:

- (a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC;
- (b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive 2004/49/EC;
- (c) a contracting entity or a manufacturer which invites a notified body to apply the ‘EC’ verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;
- (d) an applicant for an authorisation for the placing in service of structural sub-systems

2016/797, mobile sub-systems are not anymore authorised but placed on the market. It should be noted that the use of the methodology described in Annex I of CSM RA for the requirements capture process of the essential requirement “safety” and for the safe integration between subsystems is mandatory. For this reason, when there is a need to submit an application through the OSS, the ‘applicant’ for a vehicle type authorisation and/ or vehicle authorisation for placing on the market will also be the ‘proposer’.

When the entity managing the change concludes that there is no need to apply for a vehicle type authorisation, there will be no ‘applicant’ (in the sense of Regulation (EU) 2018/545) and the entity managing the change will be the ‘proposer’.

3.2.3.1. Responsibilities of the ‘applicant’ referred to in Regulation (EU) 2018/545

The applicant for vehicle type authorisation and/ or vehicle authorisation for placing on the market takes the responsibility for the vehicle type and/ or vehicle as a whole (vehicle types/ vehicles can be composed of several subsystems) to ensure that the relevant Union (including essential requirements laid down in Annex III of Directive (EU) 2016/797) and national requirements are identified and complied with. However, other actors (conformity assessment bodies, applicant(s) for the purpose of Article 15 of Directive (EU) 2016/797 etc.) remain responsible for their respective parts, see Article 4 of Directive (EU) 2016/798.

In case of changes to an already authorised vehicle type and/ or vehicle, the applicant for the new authorisation is responsible for the changed parts (and the interfaces with the unchanged parts) and the new vehicle type as a whole. However, the existing holder of the vehicle type authorisation is still responsible for the unchanged parts and the new applicant is responsible for the changes it introduces and the interfaces with the unchanged parts. See section 3.2.5 for further details.

3.2.3.2. Responsibilities of the applicant for the purpose of Article 15 of Directive (EU) 2016/797

The applicant for the purpose of Article 15 of Directive (EU) 2016/797 performs the EC verification procedure and establishes the EC DoV for a subsystem and is responsible that the subsystem meets all requirements of the relevant Union law and any relevant national rules. In the case of mobile subsystems, it takes the responsibility that those mobile subsystem(s) it has placed on the market meet the essential requirements laid down in Annex III of Directive (EU) 2016/797.

There is no requirement for authorisation for placing on the market for mobile subsystems. Mobile subsystems are placed on the market by the applicant as specified in Article 20 of Directive (EU) 2016/797.

3.2.4. Article 4: Responsibilities of the authorising entity

1. The authorising entity shall issue vehicle type authorisations and/or vehicle authorisations for placing on the market ('the authorisations') in accordance with Articles 21, 24 and 25 of Directive (EU) 2016/797 and with the provisions of this Regulation.
2. For the purposes of issuing or refusing an authorisation, the authorising entity shall:
 - (a) Coordinate the assignment of the tasks to the relevant parties and the setting up of coordination arrangements between them;
 - (b) Undertake an assessment of the application file to reach the reasonable assurance that the vehicle type and/or vehicle conforms to the applicable laws;
 - (c) Compile any supporting documentation, the results of all relevant assessments and the documented reasons for its decision to issue or refuse the authorisation, in accordance with this Regulation.
3. In case the Agency is the authorising entity, it shall coordinate the activities of the NSAs for the area of use related to vehicle type authorisation and/or vehicle authorisation for placing on the market.
4. The authorising entity shall provide pre-engagement at the request of the applicant.

5. The authorising entity shall carry out its tasks in an open, non-discriminatory, transparent way and shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for any decision.
6. The authorising entity shall establish internal arrangements or procedures for managing the issuing of a vehicle type authorisation and/or a vehicle authorisation for placing on the market. Those arrangements or procedures shall take into account the agreements referred to in Article 21(14) of Directive (EU) 2016/797 and where relevant, multilateral agreements as referred to in Article 21(15) of Directive (EU) 2016/797.
7. Where the applicant indicates under Article 5(2) that the validity of the type authorisation has been affected the authorising entity shall update the ERATV accordingly.
8. Where the applicant indicates in its application that the intended area of use of the vehicle(s) or the vehicle type includes stations in neighbouring Member States with similar network characteristics, when those stations are close to the border, the authorising entity shall:
 - (a) receive confirmation from the NSAs of the neighbouring Member States that the relevant notified national rules and the obligations pertaining to the relevant cross-border agreements are met, before issuing the vehicle type authorisation and/or vehicle authorisation; and
 - (b) specify in the issued authorisation that the vehicle type authorisation and/or vehicle authorisation is also valid to such stations without an extension of the area of use.

All NSAs for the area of use and authorisation entities, should take into account the information 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 resulting from the return of experience shared pursuant to Article 7(4) of Regulation (EU) 2018/545. When such information is subject to a Joint Network Secretariat (JNS) procedure, the authorising entity and/ or the NSAs for the area of use should take into account the outcomes of the JNS procedure.

Such information could be used by the authorising entity and/ or the NSAs for the area of use in the course of an assessment of an application. It should be used also by the authorising entity during the pre-engagement stage of an application to inform the applicant about the identified risk(s), allowing to anticipate its consideration in term of design and/ or area of use for instance.

3.2.5. Article 5: Responsibilities of the holder of the vehicle type authorisation

1. The holder of the vehicle type authorisation shall be responsible for the configuration management of the vehicle type and the accompanying file for the decision issued in accordance with Article 46.
2. Without prejudice of Articles 53 and 54, the holder of the vehicle type authorisation, as part of the configuration management of the vehicle type, shall inform the authorising entity that issued the vehicle type authorisation about any changes in Union law that affect the validity of the type authorisation.

In addition to being responsible for the configuration management of the vehicle type (see section 3.2.2.3.2), the holder of the vehicle type authorisation is the applicant that received the vehicle type authorisation. Due to this, it has also the responsibilities specified for the applicant, see section 3.2.3.

In the event of a change where there is a new applicant that becomes the holder for a new vehicle type based on an existing vehicle type:

- › The new holder of the vehicle type authorisation is primarily responsible for the changed parts but also for the new vehicle type as a whole (not only for the changes). From that moment, it can make changes to the new vehicle type, within the scope of the configuration management of this new type, including changes on those parts that were not in the scope of the new authorisation;

- › The initial holder of the vehicle type authorisation remains liable for the unchanged parts; the new holder of the vehicle type authorisation is liable for the changes it introduces and the interfaces with the unchanged parts , and
- › The new holder of the vehicle type authorisation is solely responsible for the configuration management of the new vehicle type, including the creation of new types, variants or versions deriving from the vehicle type authorised after the change.

The monitoring of that the entity managing the change/ the potential applicant/ the applicant has correctly applied the provisions of Regulation (EU) 2018/545 for the management of changes and the configuration management of the vehicle type and/ or vehicles (right categorisation of the change, right decision on whether a new authorisation is required according to the criteria specified in Article 21(12) of Directive (EU) 2016/797, correct use of CSM RA etc.) can be performed, directly or indirectly, by the NSAs through controls during their supervision activities.

In the absence of a vehicle type authorisation, there is no holder of the vehicle type authorisation and no need to perform the configuration management of the vehicle type.

3.2.6. Article 6: Responsibilities of the infrastructure manager

1. In the area of use, the infrastructure manager's responsibilities in the framework of vehicle type authorisation and/or vehicle authorisation for placing on the market, based on the information provided by the applicant according to Article 18, shall be limited to the identification and provision of the following:
 - (a) operational conditions to be applied for the use of the vehicle for tests on the network;
 - (b) necessary measures to be taken on the infrastructure side to ensure safe and reliable operation during the tests on the network;
 - (c) necessary measures in the infrastructure installations to perform the tests on the network.
2. The concerned infrastructure managers for the area of use shall:
 - (a) support the applicant for the conditions to use the vehicle for tests on the network;
 - (b) provide information on the infrastructure in a non-discriminatory way for using the vehicle for tests on the network;
 - (c) identify and provide conditions and measures to use the vehicle for tests on the network within the given timeframe specified in Article 21(3) and 21(5) of Directive (EU) 2016/797 based on the information provided by the applicant;
 - (d) by agreement with the applicant, participate in the pre-engagement.

The Regulation (EU) 2018/545 specifies the responsibilities and requirements to be complied with by the IM in the framework of the railway vehicle authorisation and railway vehicle type authorisation process. The IM has no other role, in this context, and should not impose any technical requirements on the design of a vehicle, provide statements or evaluations concerning the technical compatibility of the vehicle and/or vehicle type with the networks or request that the applicant performs tests on the network, see also section 3.3.7.

An applicant can decide to involve the IM during the authorisation process (e.g., to anticipate issues that can appear for route compatibility checks) but this is not always applicable and is subject to applicant's request/ need. The route compatibility check referred to in Article 23(1)(b) of Directive (EU) 2016/797 regarding the checks to be performed by a RU before the use of authorised vehicles is not part of the authorisation process.

The role of the IM in the framework of the vehicle authorisation for placing on the market and vehicle type authorisation process is focused on providing the necessary elements to allow the applicant to conduct the tests on the network that are necessary to complete the assessment of the requirements:

- › Provide information on the infrastructure which is needed to perform the conformity assessments (e.g., track geometry for running dynamics tests);
- › Provide track access for tests on the network (allocation of capacity to actually perform the tests on the network);
- › Provide, where necessary, and based on the information provided by the applicant (namely test specifications, sequence of tests on the network, etc.), the additional operational conditions for the vehicle to be applied during the tests on the network. This includes conditions and restrictions for use during the tests due to the fact that not all systems of the test vehicle may have been fully verified and validated when the tests on the network begin (e.g., avoid operation in degraded modes of the traction system such as a reduced number of converters);
- › This will also have an impact on the allocation of capacity and slots (e.g., it may be necessary to restrict the circulation of trains on the adjacent track, or to block a given section of the line in which the tests on the network are being conducted); and
- › Take the necessary measures on the infrastructure side to allow the applicant to conduct the tests on the network that are needed for the conformity assessments (e.g. changes in the voltage in the catenary, permission to over speed in certain sections of the test line, etc.), taking into account aspects such as safety and capacity restrictions, limit excessive wear or damage to the infrastructure, etc.

Please note that the IM can have distinct roles (and therefore different responsibilities) based on its various interests:

- › Applicant for the purpose of Article 21 and 24 of Directive (EU) 2016/797 for its own vehicles.
- › Operator of its own mobile railway infrastructure construction and maintenance equipment.
- › Keeper for the purpose of Article 2(21) of Directive (EU) 2016/797.

3.2.7. Article 7: Responsibilities of the NSAs for the area of use

1. For the purposes of issuing a vehicle type authorisation and/or a vehicle authorisation for placing on the market, the NSAs for the area of use shall be responsible
 - (a) for their part of the assessment in accordance with Article 40;
 - (b) for issuing an assessment file to the authorising entity pursuant to Article 40(6).
2. In undertaking its responsibilities, the NSAs for the area of use shall carry out its tasks in an open, non-discriminatory, transparent way and shall exercise professional judgment, be impartial, proportionate, and provide documented reasons for conclusions reached.
3. The concerned NSAs for the area of use shall provide pre-engagement at the request of the applicant.
4. 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:
 - (a) information received pursuant to Article 4(5)(b) of Directive (EU) 2016/798;
 - (b) non-compliance with essential requirements that may lead to amendment or revocation of an authorisation in accordance with Article 26 of Directive (EU) 2016/797;
 - (c) deficiencies in a TSI in accordance with Article 6 of Directive (EU) 2016/797.
5. The NSAs for the area of use shall establish internal arrangements or procedures for managing the issuing of a vehicle type authorisation and/or a vehicle authorisation for placing on the market. Those arrangements or procedures shall take into account the agreements referred to in Article 21(14) of

Directive (EU) 2016/797 and where relevant, multilateral agreements as referred to in Article 21(15) of Directive (EU) 2016/797.

6. The NSAs for the area of use shall set up, publish and keep up to date guidelines describing their language policy, communication provisions and the process for temporary authorisation when required according to the national legal framework and make them available to the public free of charge.

Further information on the scope of the assessments to be performed by the NSAs for the area of use in the framework of an application for authorisation can be found in section 3.7.9.

3.2.7.1.1. Information received pursuant to Article 4(5)(b) of Directive (EU) 2016/798

As provided by Article 7(4) of Regulation (EU) 2018/545 the NSAs for the area of use shall share with the Agency and all other NSAs all relevant 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, i.e. information that can be used by the authorising entity and/ or the NSAs for the area of use to raise issues according to Article 41 of Regulation (EU) 2018/545.

The origin of information resulting from return of experience are mostly the activities performed by the NSAs, in particular the supervision carried out following Article 17 of Directive (EU) 2016/798 and Commission Delegated Regulation (EU) 2018/761 on CSM on supervision. In the course of these activities, an NSA might detect itself, or be made aware by a RU, or any other relevant actor, of relevant technical and/ or operational matters.

Return of experience also covers information and knowledge concerning the performance of already authorised vehicle types and their component systems in order to guide the assessment of applications.

The use by NSAs of information and knowledge gained from supervisory activities provides a means for evaluating the effectiveness of the applicant's processes for the design, manufacture, verification and validation of the vehicle type/ vehicle.

Vehicle manufacturers, the principal applicants for vehicle type authorisation/ vehicle authorisation for placing on the market, are not a primary focus for NSA supervisory activities. However, it is likely that supervisory activities relating to RUs will provide the NSA with knowledge about the vehicles operated by the RUs that is relevant to the assessment of applications for vehicle type authorisation/ vehicle authorisation for placing on the market. Of particular interest will be reactive activities arising from problems with vehicles, such as accidents, incidents or significant disruption to service.

The return of experience may relate to existing vehicles using the same platform as that being used for the application being assessed, or it may relate to systems that are in use on existing vehicles. Although vehicles may be assembled by different manufacturers, many of the systems on them will be from the same supplier. Understanding common themes will provide grounds for prioritising the elements considered as part of the assessment of the application. These common themes may also concern the interaction of the vehicle with the infrastructure.

The listed information in Article 7(4) of Regulation (EU) 2018/545 only represents some typical type of information to be shared and does not form an exhaustive list. Other relevant information might exist and should also be subject to those recording and exchanging provisions

The information could also be relevant for other actors, such as potential applicants, manufacturers, and conformity assessment bodies. In such cases, if the NSA for the area of use or any other NSA or the Agency as authorising entity decides so, the information should be communicated also to those other actors. To this end, the NSA for the area of use, or any other NSA or the Agency as authorising entity deciding to share the information with other actors should ensure that the confidentiality of

information is safeguarded by removing any reference to individual, company name and/ or by using a generic denomination of a product/ part.

Regarding information received pursuant to Article 4(5)(b) of Directive (EU) 2016/798, a voluntary tool called the Safety Alert IT system (SAIT) has been developed and implemented by the Agency to cover these exchanges of information between operational actors only (operational actors being RUs, IMs and all other actors having a potential impact on the safe operation of the Union rail system, including manufacturers, maintenance suppliers, keepers, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers), therefore excluding NSAs and the Agency. The communication by operational actors of such information to the NSAs and the Agency therefore follows another protocol, which is currently mostly informal.

3.2.7.1.2. *Non-compliance with essential requirements or deficiencies in TSIs*

Regarding information received about non-compliance with essential requirements or deficiencies in a TSI (Article 7(4)(b) and (c) of Regulation (EU) 2018/545), the protocols and procedures provided by Article 11, 16 and 26 of Directive (EU) 2016/797 and Article 6 of Directive (EU) 2016/797 respectively should be followed by the NSAs for the area of use. These protocols and procedures cover the requirement to record and exchange such information with the other NSAs and the Agency.

3.2.8. Article 8: Responsibilities of the Agency

1. The Agency shall set up, publish and keep up to date guidelines describing and explaining the requirements set out in this Regulation, and make them available to the public free of charge, in all the official languages of the Union. The guidelines shall also include model templates that may be used by the authorising entity and the NSAs for the area of use for the exchange and recording of information and model templates for the application that may be used by the applicant.
2. The Agency shall establish a protocol and procedures for the recording and exchange of information referred to in Article 7(4). Other affected or concerned parties may have access to relevant information, provided that the confidentiality of information is safeguarded.

3.2.8.1. Protocol for recording and exchange of information

The Agency gathers information relevant for authorisation purposes from NSAs by means of:

- › Periodical meetings with NSAs in the framework of delivering vehicle authorisations;
- › Safety Information System (SIS), accessible only to authorising entities;
- › Ad-hoc exchanges (e.g., letters sent to the Agency by NSAs)

The future Information Sharing System (ISS) will also be the tool to collect return of experience pursuant to Article 7(4) and 8(2) of Regulation (EU) 2018/545.

Meanwhile, the process for collecting return of experience is described on the website of the Agency:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=3044

3.2.8.2. VA Toolbox

The Agency has developed a toolbox that meant to provide in a single place a simple access to relevant information and tools on vehicle authorisation. It is accessible to applicants and authorising entities (ERA, NSAs). It should also help stakeholders to be aware of all available documentation (guidance, clarification notes, FAQs etc.). It is hosted in the SharePoint environment of the Agency:

<https://eraeuropaeu.sharepoint.com/sites/VATool/SitePages/Vehicle-Authorisation-ToolBox.aspx>

This tool is provided free of charge to Applicants and NSAs staff that have an OSS account. The parts of the tool that can be accessed depends on the role of the user (e.g., users with role “Applicant” will not have access to documents to be used by authorising entities and NSAs for the area of use only, users with role “NSA” will not have access to internal documents to be used by Agency staff only).

The use of the tool is voluntary. Registered users of OSS have access to the tool without the need of any further action. Users that do not have an OSS account or cannot access the tool even if registered in OSS, can request access by using the following Contact Us webform, selecting the topic “VA Toolbox”:

<https://srm-portal.powerappsportals.com/contact-us/>

3.2.9. Article 9: Use of an authorised vehicle

After performing the checks referred to in Article 23 of Directive (EU) 2016/797, a railway undertaking or an infrastructure manager may use a vehicle in the area of use, according to the conditions for use of the vehicle and other restrictions specified in the vehicle type authorisation and/or the authorisation for placing on the market.

Checks before use of an authorised vehicle should be limited to those checks specified in Article 23 of Directive (EU) 2016/797. The RU or IM that intends to use the vehicle shall be responsible for performing the compatibility check between the vehicle(s) and the intended routes and also to perform the compatibility check between trains and routes, covering the elements set out in TSI OPE (clause 4.2.2.5 and Appendix D.1 of Regulation (EU) 2019/773).

This route compatibility check should be based on the data collected in RINF and the vehicle data specified in the issued vehicle type authorisation (and the concerned ERATV entry), in the full accompanying file for the decision issued in accordance with Article 46 of Regulation (EU) 2018/545, including the conditions of use and other restrictions, by means of parameters and procedures described in the relevant TSI OPE (pursuant to Article 4(3)(i) of Directive (EU) 2016/797). RINF contains a tool that facilitates the route compatibility check:

<https://data-interop.era.europa.eu/route-compatibility>

In the case where the data in RINF is incomplete, the relevant information on the infrastructure, including any temporary restrictions, should be supplied by the IM free of charge and within a reasonable time.

The compatibility of a vehicle with the network(s) in the area of use is checked at the vehicle authorisation level on the basis of TSIs, national rules and the relevant CSM, which is why a vehicle is authorised for a certain area of use. These checks should not be repeated by the RU or the IM intending to use the vehicle as part of the compatibility check between the vehicle(s) and the intended routes, as the area of use of the vehicle is defined in the issued authorisation. Specificities for a given line section are identified in RINF (or provided by the IM when RINF does not exist or is incomplete, free of charge and within a reasonable time).

When tests on the network are necessary to perform compatibility checks with the route the RU or the IM that intends to use the vehicle should lodge a request to the concerned IM. The procedure to perform such tests on the network should be described and communicated by the IM. These tests on the network should take place within three months of the request and the RU or the IM that intends to use the vehicle and the concerned IM should cooperate to execute them. These tests on the network should be:

- › Seen as an exception and only take place when strictly necessary to perform the route compatibility check, the technical compatibility of the vehicle with the network has already been demonstrated within the vehicle authorisation process; and
- › Should not repeat tests on the network that have already been performed during the vehicle authorisation process.

It is recommended that the applicant involves the concerned IM at an early stage of the vehicle authorisation process in order to identify the need for such future tests on the network and any other potential issues that can impact the checks before the use of the vehicle by future RU(s) as referred to in Article 23 of Directive 2016/797. This is left to the discretion of the applicant.

The RU or IM that intends to use the vehicle should also check that the vehicle is properly integrated in the composition of the train where it is intended to operate. This check involves using the SMS set out in Article 9 of Directive (EU) 2016/798 and in Commission Regulation (EU) 2019/773 (for full operational compatibility i.e., for train composition, braking performance etc.).

3.2.10. Article 10: Language

1. Where the vehicle type authorisation and/or vehicle authorisation for placing on the market is to be issued in accordance with the provisions of Article 21(5) to (7) of Directive (EU) 2016/797, the applicant shall:
 - (a) submit the application and the file accompanying the application in one of the official languages of the Union;
 - (b) translate parts of the file accompanying the application upon request, in accordance with point 2.6 of Annex IV to Directive (EU) 2016/797. In this case, the language to be used is determined by the NSA and indicated in the guidelines referred to in Article 7(6).
2. Any decision concerning the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market taken by the Agency, including the documented reasons for the decision and where applicable, the issued vehicle type authorisation and/or vehicle authorisation for placing on the market shall be provided in the language referred to in point (a) of paragraph 1.

The application and the file accompanying the application will be submitted by the applicant in one of the official languages of the Union. The concerned NSAs for the area of use can request that the applicant translates parts of the file accompanying the application in accordance with point 2.6 of Annex IV of Directive (EU) 2016/797. The language to be used when determined by the concerned NSAs for the area of use should be indicated in the guidelines referred to in Article 7(6) of Regulation (EU) 2018/545. A patchwork approach mixing different languages of the Union when not required by the concerned NSAs for the area of use should be avoided.

To reduce the need for translation and to facilitate exchanges during the assessment it is recommended to use English or a commonly agreed language for the assessment (exchange of comments/ request for information/ issues) of the application. The choice of language for the assessment should take into account:

- › The language used for the application (i.e., if it is possible to use this language as the language for assessment then the need for translation can be reduced);
- › The language competency (i.e., competence in the language at a level which is appropriate for the full understanding of the file) of the applicant and of the members of the assessment team (including NSAs for the area of use), and
- › The legal requirements applicable in the concerned MSs (as described in the relevant guidelines).

When applicable, the choice of language for the assessment should be made during pre-engagement. When there is no pre-engagement, the language regime should be agreed between the parties soon after the submission of the application through the OSS.

Concerning the outcomes of the vehicle authorisation process:

- › Authorising entity's assessment report as specified in Article 39(5) of Regulation (EU) 2018/545: English or the commonly agreed language.
- › Assessment reports from the concerned NSAs for area of use as specified in Article 40(6) of Regulation (EU) 2018/545: NSA's language, English or the commonly agreed language, if permitted by the national legal framework of the MS as indicated in the guidelines referred to in Article 7(6) of Regulation (EU) 2018/545.
- › Authorising entity's file for the conclusion of the assessment including documented reasons for the decision as specified in Article 45 of Regulation (EU) 2018/545: commonly agreed language or the official language of the Union used by the applicant for its application.
- › Authorising entity's decision to issue the authorisation or to refuse the application as specified in Article 46 of Regulation (EU) 2018/545: commonly agreed language or the official language of the Union specified by the applicant in the OSS application.

- › The issued vehicle type authorisation and/ or vehicle authorisation for placing on the market as specified in Articles 47 and 48 of Regulation (EU) 2018/545: commonly agreed language or the official language of the Union specified by the applicant in the OSS application.

3.2.11. Article 11: Vehicle authorisation process for tram-trains on the Single European Railway Area

1. For the purpose of a tram-train vehicle type authorisation and/or a tram-train vehicle authorisation for placing on the market intended to be operated in the Union rail system, without prejudice to Article 1 of Directive (EU) 2016/797, and when no technical specification for interoperability ('TSI') applies to the concerned tram-train vehicle or tram-train vehicle type as described by the Article 1(5)(b) of Directive (EU) 2016/797, Member States may use a procedure provided for in its national legal framework regarding the tram-train vehicle type authorisation and/or tram-train vehicle authorisation for placing on the market. In such a case, the applicant shall refer to the national framework of the Member State concerned regarding the procedure to follow for the tram-train vehicle type authorisation and/or tram-train vehicle authorisation for placing on the market.
2. In case of a tram-train vehicle type authorisation and/or a tram-train vehicle authorisation for placing on the market intended to be operated in the Union rail system for cross-border operation, and when no TSI applies to the concerned tram-train vehicle type, the applicant shall apply to the authorising entities designated by the Member States involved, which shall cooperate with a view to issuing a tram-train vehicle type authorisation and/or a tram-train vehicle authorisation for placing on the market.
3. In other cases, a tram-train vehicle and tram-train vehicle type in the scope of Directive (EU) 2016/797 shall be authorised according to the procedure set out in this Regulation.

Tram-train is a concept which allows for a combined operation on both light-rail infrastructure and heavy-rail infrastructure, as defined by Article 2 of Directive (EU) 2016/797.

A “tram-train vehicle type” is in the scope of the directive (“case of an authorisation of tram-train vehicle type on heavy rail” as expected in the issue description above) when:

- › It is a tram-train vehicle type which does not fulfil the criteria for “light rail” (Directive (EU) 2016/797 Article 1(3) and 2(18));
- › It is a tram-train vehicle type with an area of use including “heavy rail infrastructure” (not limited to a “transit to be effected on confined and limited section of heavy rail for connectivity purpose only”); and
- › Not functionally separate from the rest of the Union rail system and intended only for the operation of local, urban or suburban passenger services.

When one of the criteria is not fulfilled, it means that the “tram train vehicle type” concerned is not in the scope of Directive (EU) 2016/797. In this case, authorisation of these vehicles are subject to purely national procedures, which may request the (partial or total) application of some TSIs.

MSs may exclude from the scope of the Directive (EU) 2016/797:

- › Light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and
- › Vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

3.2.12. Article 12: Cross-border agreements

1. The NSAs shall make publicly available on their website the procedure to be followed regarding cross-border agreements for the authorisation to cover stations in the neighbouring Member States, pursuant to Article 21(8) of Directive (EU) 2016/797, in particular:
 - (a) any existing cross-border agreements between NSAs that may have to be used;
 - (b) the procedure to be followed where such cross-border arrangements do not exist.
2. For a cross-border agreement on the process to issue an authorisation to cover stations in the neighbouring Member States, pursuant to Article 21(8) of Directive (EU) 2016/797, the NSAs shall specify the procedure to be applied, and shall at least provide the following details:
 - (a) the procedural stages;
 - (b) the timeframes;
 - (c) the technical and geographical scope;
 - (d) the roles and tasks of the parties involved; and
 - (e) the practical arrangements for the consultation with the relevant parties.

When the area of use is limited to a network or networks within a MS, the national safety authority of that MS is allowed to act as an authorising entity and issue authorisations. According to Article 21(8) of Directive (EU) 2016/797, authorisations issued by NSAs when the area of use covers only 1 MS shall also be valid for stations close to the border in neighbouring MSs, following consultation with the competent NSAs. This consultation may be carried out on a case-by-case basis or set out in a wider cross-border agreement between national safety authorities.

When the Agency is the authorising entity, provisions of Article 21(8) of Directive (EU) 2016/797 do not apply. However, when the applicant includes neighbouring stations in the application for authorisation, the consultation process with the NSAs of the neighbouring MSs where the stations close to the border are located will take place within the OSS and will be coordinated by the Agency. If the results of the consultation are positive, the authorisation issued by the Agency will include the neighbouring stations requested by the applicant.

When there is a need to operate to neighbouring stations not explicitly covered in the issued authorisation, the consultation between NSAs should be triggered by the RU. When there are applicable cross-border agreements between the concerned NSAs or the procedure when there are no cross-border agreements is followed successfully (e.g., case by case agreement), there is no need to submit a new application nor to update the existing application and/or authorisation.

In the absence of a framework agreement between NSAs, and when it is not possible to conclude a case specific agreement following the consultation referred to in the Directive, the neighbouring stations shall be considered as part of the area of use, and the NSAs concerned shall be considered as NSA for the area of use (instead of NSA of a neighbouring member state) and provide an assessment report pursuant to Article 40 of Regulation (EU) 2018/545.

The OSS facilitates the consultation process, allowing applicants to indicate which NSAs are part of the area of use and which NSAs relate to the MSs of the neighbouring stations, while allowing communication between all NSAs within the OSS and providing access to the file accompanying the application to all NSAs.

To anticipate the need for an application for an extension of the area of use when there are no applicable cross-border agreements, applicants are kindly advised to check the status and applicability of the agreements with the concerned NSAs for the area of use before applying through the OSS.

The NSAs have the obligation, pursuant to Article 12(2) of Regulation 2018/545, to specify the procedure to be applied for neighbouring stations. The information concerning cross-border agreements and neighbouring stations that is officially communicated to the Agency by NSAs will be made available through the VA Toolbox:

<https://eraeuropa.eu.sharepoint.com/sites/VATool/SitePages/Cross-Border.aspx>

3.3. Chapter 2 - Stage 1: preparation of the application

For description of the process, see the flowchart for Stage 1 in section 4.

3.3.1. Article 13: Requirements capture

1. In accordance with the overall objective of managing and mitigating all the identified risks to an acceptable level, the applicant shall, before submitting an application, undertake a requirements capture process which shall ensure that all the necessary requirements covering the design of the vehicle for its life cycle have been:
 - (a) identified properly;
 - (b) assigned to functions or subsystems or are addressed through conditions for use or other restrictions; and
 - (c) implemented and validated.
2. The requirements capture performed by the applicant shall in particular cover the following requirements:
 - (a) essential requirements for subsystems referred to in Article 3 and specified in Annex III to Directive (EU) 2016/797;
 - (b) technical compatibility of the subsystems within the vehicle;
 - (c) safe integration of the subsystems within the vehicle;
 - (d) technical compatibility of the vehicle with the network in the area of use.
3. The risk management process set out in Annex I to Regulation (EU) 402/2013¹ shall be used by the applicant as the methodology for requirements capture as regards the essential requirements "safety" related to the vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules.

¹Commission 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 (OJ L 121, 3.5.2013, p. 8)

Further guidance on the process for requirements capture in the framework of vehicle and/or vehicle type authorisation can be found in the clarification note ERA1209/146, available at the website of the Agency:

https://www.era.europa.eu/domains/applicants/applications-vehicle-type-authorisations_en

The AsBo cooperation group managed by the Agency has also issued several RFUs, covering the following topics:

- › RFU no.1 Working method of the AsBo
- › RFU no.3 AsBo technical knowledge and competence requirements for the different areas
- › RFU no.8 Hiring-in experts and sub-contracting by the AsBo – Mutual recognition
- › RFU no.11 Tracking (identification, recording and closing) of issues and non-compliances by the AsBo

These RFUs (and new ones to come) can be found in the following Agency website:

https://www.era.europa.eu/domains/common-safety-methods/risk-evaluation-assessment-csm_en

In the following sections, you will find a summary of some key messages from the clarification note mentioned above.

3.3.1.1. Why it is necessary to perform the requirements capture

Requirements capture (and management) is the application of a systematic process for the identification, implementation, verification and validation of requirements, and the management of risks. This is to ensure, as far as is reasonably practicable, that when designing, manufacturing and testing a vehicle all considerations have been accounted for, and the vehicle or vehicle type meets the essential requirements.

The structured and systematic management of the applicable requirements for a project is a widespread practice in the industry since decades. This activity takes different names depending on the company (e.g., requirements management, system engineering, functional safety engineering etc.) being in all cases a structured, systematic and top-down approach/process for the specification and management of the implementation of the applicable requirements. It may be covered by a specific procedure or spread between different existing (and complementary) procedures. In the end, the objective is to have process(es) to ensure that all applicable requirements are properly considered and managed, and that nothing is left apart or forgotten.

The requirement capture activity requires that the applicant or the entity managing the change (and its suppliers) proactively define the applicable requirements early in the project and formalize their traceability (produce documentary evidence) throughout the life cycle of the project, with the involvement of the different actors that take part in the development of the product.

Now, under Article 13 of Regulation (EU) 2018/545, having this process developed, documented and implemented becomes mandatory for companies submitting applications for authorisation or managing changes to already authorised vehicles and/or vehicle types. It is also mandatory to include the evidence of the application of this process in the file accompanying an application for authorisation.

3.3.1.2. What is requirements capture?

Requirements capture is the process by which requirements applicable to a vehicle are systematically identified, implemented and validated, alongside with documenting all steps or the process and providing the necessary traceability.

The following diagram provides a simple overview of a requirements capture process. The concept of design, implementation and validation of requirements is central to requirements capture and management, which includes traceability to support the validation process.

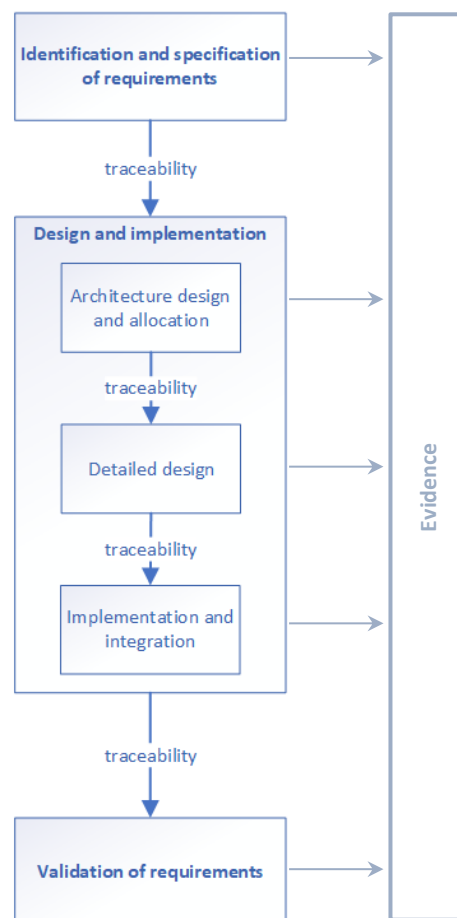


Figure 2: An outline of the requirements capture process

In addition to the concept of validation, to demonstrate that requirements have been fulfilled, the topics of design decomposition (allocation of requirements to components, functions, systems etc.), verification and integration, to show how requirements are addressed throughout the development life cycle to ensure that they are fulfilled, are key elements of a robust requirements capture process. Underlying all those concepts there are the general requirements of providing traceability and generating documentary evidence, which are necessary to support the system development process.

The requirements capture should start at an early stage of the process of design and development of the vehicle. This is the only way to ensure a proper management of requirements and risks. For the purposes of vehicle authorisation, the requirements capture process finishes at the point at which a vehicle or vehicle type is authorised. The holder of the vehicle type authorisation is responsible for the configuration management of the vehicle type from that moment onwards.

The concept of “requirements capture” includes both the systematic capture (identification) and the management (implementation, verification and validation) of all applicable requirements through the entire development process (e.g., V-Cycle of EN 50126-1, from step 1 to 10, see Figure 3), It also includes producing the necessary documentary evidence.

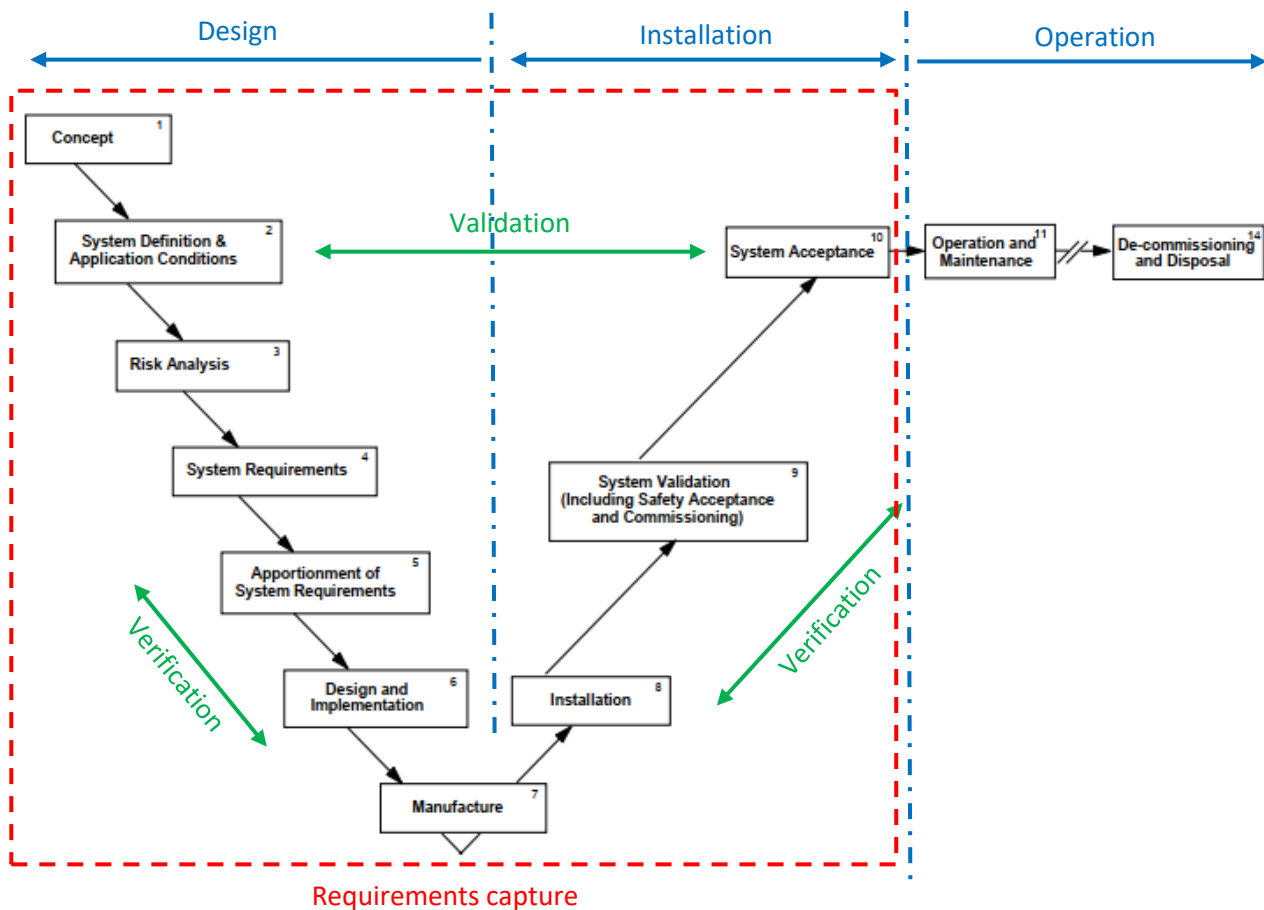


Figure 3: V-Cycle EN 50126-1

The requirements capture is therefore not limited to:

- › the identification of the requirements; it also covers the implementation, verification, and validation, and producing the necessary evidence
- › the mandatory rules (legal requirements), such as TSIs, national rules, other Union legislation; it also covers requirements which are necessary to meet the essential requirements

It should be noticed that in EN 50126-1 validation is defined as “confirmation, through the provision of objective evidence, that the requirements for an intended use of application have been fulfilled”. Requirements which have been identified, are then developed into a design, and implemented, to later on be validated.

3.3.1.3. Scope of the requirements capture

A requirements management process should cover all requirements that a vehicle type needs to fulfil, no matter where the requirements come from:

- › requirements that can be found in mandatory laws (TSIs, national rules, other EU legislation), hence legally enforceable;
- › contractual requirements;
- › requirements that are necessary to control hazards and associated risks;
- › requirements adopted on a voluntary basis, such as standards, codes of practice or company specifications (design codes, guidelines);
- › etc.

Figure 4 gives an overview of the potential sources of requirements for the requirements management process, also making a difference between the sources that are mandatory and shall be fulfilled (legally enforceable requirements, such as TSIs or notified national rules), and those that are either voluntarily adopted by the applicant or entity managing the change, or imposed to the applicant or entity managing the change by means of contractual arrangements, that may be in addition necessary to meet other legal obligations, e.g. fulfil the essential requirements (e.g., safety).

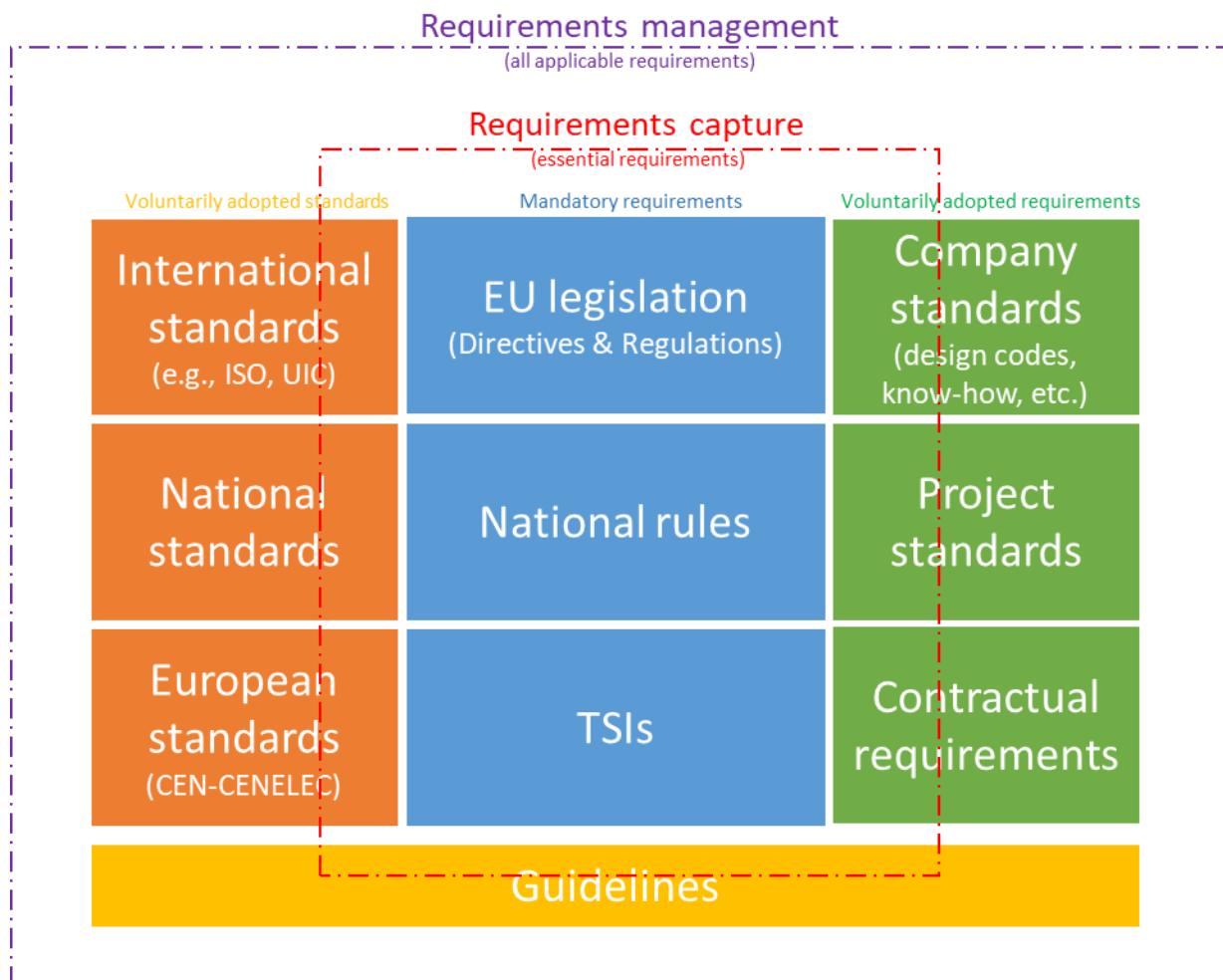


Figure 4: Sources and scope of requirements for vehicle authorisation

Some requirements are not relevant for the authorisation process because they are not related to the essential requirements laid down in Annex III of Directive (EU) 2016/797, even if they need to be complied with for other reasons (e.g., contractual requirements). Some other, while not mandatory, may trigger the need to fulfil other requirements which are mandatory (e.g., a customer may require in the contract that the vehicle is fitted with a playground area for kids with toys, which is not compulsory; however, such toys shall

fulfil Directive 2009/48/EC on the safety of toys). Similarly, some non-mandatory requirements may have an impact on mandatory requirements already applicable to railway vehicles (following the example of the toys, the fire safety requirements for the vehicle).

Another example of a requirement that could be voluntarily adopted to meet essential requirements is the cybersecurity standard IEC 62443-3-3, that would reduce risk of cyberattacks to trains that may result in a safety issue (e.g., train not braking due to an attack that prevents the correct functioning of the on-board signalling system).

For vehicle authorisation purposes, the requirements to be considered in the requirements management process are those that need to be fulfilled in order to meet the essential requirements, no matter if they derive from mandatory rules or not. The essential requirements are defined in Annex III of Directive (EU) 2016/797: safety, reliability/availability, health, environmental protection, technical compatibility, and accessibility.

The voluntary requirements which are not necessary to meet an essential requirement, while being normally in the scope of the requirements management process (after all, they are requirements that the applicant or the entity managing the change has decided to fulfil), are out of the scope of the authorisation process and the requirements capture process; meeting them remains within the responsibility of the manufacturer and its suppliers and customers.

In the end, the requirements management process put in place by the applicant or the entity managing the change should cover all requirements. However, the independent assessment of the requirements capture process required by the Regulation (EU) 2018/545 should focus on how the process is applied to the requirements that are necessary to fulfil the essential requirements of Directive (EU) 2016/797.

In other words, “requirements capture” refers to a process by which requirements applicable to a vehicle are systematically identified, implemented and validated, alongside with documenting all steps of the process and providing the necessary traceability, albeit limited to the essential requirements laid down in Annex III of Directive (EU) 2016/797. “Requirements management” also refers to a process of identification, implementation and validation (including the necessary traceability and documentation) of requirements but covering all requirements that need to be complied with independently of the source of the requirement or its nature. From this point of view, the requirements covered by “requirements capture” are a subset of the requirements to be covered by “requirements management”.

It should be noted that the scope of the requirements capture process is not limited to identifying the applicable TSIs is neither enough nor identifying the different standards quoted by the TSIs. The level of detail and the granularity in the identification of the requirements shall be enough to allow the allocation of requirements to functions, components, systems, subsystems etc., and the subsequent implementation, verification and validation. In many cases, it will be necessary to break down high level requirement (such as TSI or a EN standard) into smaller requirements that will be managed independently. Section 3.11.4 of this document contains a conceptual example on which are the main aspects to consider for the management of the requirements (requirements matrix).

3.3.1.4. Other applicable legislation of the Union

The applicant for placing on the market of a mobile subsystem, based on its knowledge and experience, and considering the characteristics of the subsystem, is the sole responsible for the identification of the applicable Union law and for ensuring that the law(s) is actually fulfilled.

Before placing a mobile subsystem on the market, the applicant shall take any necessary measure to ensure that the subsystem complies with the relevant Union law and national rules. The Union law includes Directives, Technical Specifications for Interoperability (TSIs), but also any other applicable Union law, that, not being railway specific, shall also be complied with.

As a result, the applicant for placing on the market the mobile subsystem shall issue an EC DoV, where it shall declare that the subsystem complies with the relevant Union law and any relevant national rule. In other words, the EC DoV shall contain the references to the Union law that the subsystem complies with, and the references to the outcomes required by such law (e.g., certificates, reports, etc.).

Similarly, the applicant for vehicle and/or vehicle type authorisation, or the entity managing the change, is responsible for ensuring that all applicable requirements, including other legislation of the Union, are met at vehicle level.

Notwithstanding the above, it should be noted that the following EU laws may be applicable to railway vehicles, depending on vehicle characteristics:

- › Simple pressure vessels directive 2014/29/EU;
- › Electromagnetic compatibility directive 2014/30/EU;
- › Emissions from non-road mobile machinery regulation (NRMM) (EU) 2016/1628;
- › Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (REACH), EC 1907/2006;
- › Machinery Directive 2006/42/EC;
- › Regulations concerning the international carriage of dangerous goods by rail (RID), and
- › Radio Equipment Directive (RED) 2014/53/EU.

Further information concerning Union law that may be applicable to railways can be found in the following website of the European Commission:

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en

The Agency has also developed an informative list of Union law that may be applicable to railways. This list includes information as well about the evidence of the fulfilment of the concerned Union law that should be included in the file accompanying the application through the OSS. The list can be found in the website of the Agency ([link](#)), in the section “Related documents” of the following webpage:

https://www.era.europa.eu/domains/applicants/applications-vehicle-type-authorisations_en

See also section 2.7.3 and 2.7.4 of the guide for the application of the TSIs, available on the website of the Agency:

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

3.3.1.5. Roles and responsibilities in the framework of the requirements capture process

- › The **applicant** for vehicle and/or vehicle type authorisation or the **entity managing a change** in case of modifications, have the legal duty to:
 - Undertake a process to identify and manage hazards, associated risks and requirements with the objective to ensure that the vehicle and/or vehicle type concerned meets the applicable legislation (including other EU legislation that not being railway specific is still applicable to railways) and the essential requirements described in Annex III of Directive (EU) 2016/797 (requirements capture).
 - Document the requirements capture process (description of the process), its implementation in the concerned project and produces the necessary evidence of the application of the process for the concerned project;
 - Hire an AsBo for an independent assessment of the requirements capture process (for aspects related to safety and safe integration between subsystems) and its application;
 - Establish a declaration that all risks and requirements have been effectively managed, and
 - Include the evidence above in the file accompanying the application for authorisation when required by the legal texts.

Applicants or entities managing changes can subcontract the workload for both the development and implementation of the process, and its application for a particular project. However, applicants or entities managing changes cannot delegate their responsibility and remain responsible for ensuring that there is a proper requirements capture in place, that the process is applied to the concerned project and that the related documentary evidence is produced.

Similarly, applicants or entities managing changes are the sole responsible for establishing a declaration concerning the undertaken requirements capture; the issuing of this declaration cannot be subcontracted or delegated.

- › The **AsBo** has the duty to assess the requirements capture process for aspects related to safety and safe integration between subsystems (upon request of the applicant, it can also cover other essential requirements), and produce an assessment report summarizing the results of the assessment. In particular, it shall evaluate whether the process in place is robust enough to allow for a proper management of the requirements or not, and the appropriateness of the results of the application of the process to the project under assessment.

Defining the requirements capture process, applying it to a project, producing the relevant documentation and/or provide advice or solutions that could compromise its independence are tasks which are out of the scope of the independent assessment to be performed by the AsBo.

The involvement of the AsBo for the independent assessment of the requirements capture process should start as early as possible in the project; a late intervention of the AsBo may lead to a late identification of non-compliances which could be difficult to solve when the project is at advanced stage of development. It may also lead, during the authorisation process, to further enquiries by the authorising entity and/or the NSAs for the area of use regarding the assessments performed by the AsBo related to activities that took place before its appointment.

Compared to the conformity assessments for a TSI performed by a NoBo, which aims at checking that all the requirements of the TSIs are met, the independent assessment by an AsBo of the requirements capture process is more about checking the process put in place by the applicant or the entity managing the change to manage all requirements (and risks).

The CSM RA and the Regulation (EU) 2018/545 do not require that the AsBo performs a complete and thorough assessment of all the identified requirements, nor that it reviews thoroughly all the outputs of the assessments performed by other conformity assessment bodies, namely NoBos and DeBos, or the risk assessment performed by the applicant or the entity managing the change. Furthermore, Article 6(3) of CSM RA requires the avoidance of duplication of work between those different conformity assessment bodies.

The role of the AsBo should be systemic, focusing its assessment on:

- the process for the requirements capture, in order to ensure that the process is robust enough to allow for a proper identification and management of the requirements;
- the suitability of the results of the application of the process to the specific project under assessment.

To perform this work, the AsBo needs to perform sampling checks and in-depth vertical slice assessment³ of the evidence related to selected requirements (samples) for in-depth assessment.

The work to be performed by the AsBo is to:

- Give assurance that the requirements capture process for the essential requirement safety and safe integration between subsystems meets the requirements laid down in Annex I of the CSM RA;

³ Vertical slice assessment: thorough end-to-end review of the application of the requirement capture process for the selected samples. The purpose is to check a representative cross-sectional slice of the results from the actual implementation of the requirement capture process and to cover all the steps of the development process.

- Give assurance that the requirements capture process for essential requirements other than safety either meets the requirements in Annex I of CSM RA when the applicant or the entity managing the change decides to apply this methodology, or provides a similar level of assurance when another methodology is used;
- Give the assurance that requirements capture process is systematic and allows a proper identification and management of the requirements (implementation, verification and validation) throughout the entire development process;
- Form an expert judgement on the correct application of the requirements capture process for the concerned project and on the suitability of the results:
- Form an expert judgment on the suitability of the vehicle and/or vehicle type to meet the essential requirements (at least for safety and safe integration between subsystems), and
- Deliver an assessment report that contains the results of the independent assessment concerning the points mentioned above.

The outputs from NoBo(s) and DeBo(s), in particular the reports accompanying the certificates, contain the evidence that is necessary to prove that the requirements coming from the TSIs and the applicable national rules have been properly managed.

While the legal texts do not contain the obligation to provide the reports issued by NoBo and/or DeBo (and the related evidence) to the AsBo for requirements capture, the AsBo could need them for performing the necessary sampling. The applicant or the entity managing the change should agree with the AsBo whether to provide the complete evidence produced by NoBo and/or DeBo to the AsBo or to provide only the necessary elements upon request of the AsBo.

Some TSIs and/or national rules require the application of the risk assessment process of CSM RA for certain defined parameters (e.g., 4.2.4.2.2 of LOC&PAS TSI). The final responsibility of the conformity assessment of the relevant TSIs and/ or national rules lies with the NoBo(s) and/ or DeBo(s). The assessment report issued by the AsBo, where the TSIs and/or the national rules require the application of the risk assessment process of CSM RA for certain aspects, should be treated by the NoBo(s) and/or DeBo(s) as any other evidence provided by the applicant or the entity managing the change in the framework of the EC verification procedure for other requirements (e.g., a test report where testing is required by TSIs and/or national rules).

- › The **authorising entity** shall assess the requirements capture process and/or the evidence related to requirements capture in the framework of issuing vehicle and/or vehicle type authorisations
- › Last but not least, the **NSAs for the area of use** shall assess the evidence of the process for requirements capture related to the applicable national rules in the framework of the issuing of a vehicle and/or vehicle type authorisation when the Agency is the authorising entity.

3.3.1.6. Cases of authorisation for which is it necessary to perform a requirements capture

The supporting evidence for requirements capture needs be included in the file accompanying the application for authorisation cases:

- › First authorisation pursuant to Article 14(1)(a) of Regulation (EU) 2018/545;
- › Extension of the area of use pursuant to Article 14(1)(c) of Regulation (EU) 2018/545;
- › New authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, and
- › Combined application cases pursuant to Article 14(3) of Regulation (EU) 2018/545:
 - new authorisation and authorisation for an extended area of use, or
 - first authorisation and conformity to type.

The requirements capture process covers all the relevant requirements for the vehicle and/ or the vehicle type concerned. In case of a first authorisation, the whole vehicle type and/ or vehicle should be covered by the requirements capture process. In case of a new authorisation, the requirements capture process should cover the changed parts and the interfaces between the changed and the unchanged parts. Finally, for an

extension of the area of use, the requirements capture process should cover the aspects related to national rules applicable for the extended area of use that do not require a change of the vehicle and/or vehicle type (such a change should be covered by a new authorisation in the original area of use).

For the authorisation cases listed below, there is a need to submit an application for authorisation, but it is not necessary to perform a requirements capture process nor to include any evidence in the file accompanying the application for authorisation:

- › Renewed vehicle type authorisation pursuant to Article 14(1)(b) of Regulation (EU) 2018/545, or
- › Authorisation for placing on the market in conformity to an already authorised vehicle type pursuant to Article 14(1)(e) of Regulation (EU) 2018/545

On the other hand, Article 15 of Regulation (EU) 2018/545 outlines scenarios where changes to an already authorised vehicle and/or vehicle type do not require a new authorisation pursuant to Article 21(12) of Directive (EU) 2016/797 and Article 14(1)(d) of Regulation (EU) 2018/545:

- › 15(1)(a): a change occurs that does not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems. In this case there is no need for verification by a conformity assessment body, and the initial EC DoVs for the subsystems and the vehicle type authorisation remains valid and unchanged.
- › 15(1)(b): a change occurs that introduces a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules, but which do not have any impact on the basic design characteristics of the vehicle type and does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.
- › 15(1)(c): a change occurs in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.

Even for these scenarios, applicants and/or entities managing changes still need to go through a requirements capture process to ensure that the applicable requirements are managed in a systematic and structured way and that the decision on whether Article 21(12) of Directive (EU) 2016/797 is triggered or not is justified. The evidence of the requirements capture process need to be produced and retained by the entity managing the change.

In other words, a requirements capture and management process must be performed for all vehicle projects, regardless of the categorisation of the change, whether an authorisation is necessary or not, or whether a change is considered significant or not following the application of CSM RA.

3.3.1.7. Mandatory use of the risk assessment process set out in Annex I of CSM RA for the requirements capture process

Article 13 of Regulation (EU) 2018/545 requires that, for the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of CSM RA is used to identify and implement safety requirements and ensure safe integration of a vehicle's subsystems. This always requires an independent assessment by an AsBo, regardless of whether the change is considered significant or not, or whether the change triggers a new authorisation of the modified vehicle and/or vehicle type or not (i.e., the categorisation of the change pursuant to Article 15(1) of Regulation (EU) 2018/545), in order to ensure that the risk management process:

- › is compliant with the risk management process in Annex I of the CSM RA Regulation;
- › allows the systematic identification of all safety risks and associated safety requirements, and
- › covers the implementation, verification, and validation of the safety requirements.

For the independent assessment of the requirements capture process for essential requirements other than safety and safe integration between subsystems, when the methodology applied does not follow the process described in Annex I of the CSM RA, the applicant or the entity managing the change is allowed not to involve

an AsBo and use other independent assessment instead (see section 3.3.1.9). It should be noted that even in such case, an AsBo can perform the independent assessment too.

When a change to an existing vehicle and/or vehicle type does not have any potential impact in safety and/or safe integration between subsystems (e.g., can be classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545), and this can be demonstrated without the need to perform a risk assessment, it is not mandatory that the requirements capture process for essential requirements other than safety follows the process of Annex I of CSM RA. This means that the involvement of an AsBo for the independent assessment of such requirements capture process would not be mandatory.

3.3.1.8. Significant changes according to Regulation (EU) 402/2013 and requirements capture

For the capture of requirements related to safety and safe integration between subsystems, the risk management process described in Annex I of CSM RA shall be used, regardless of whether the change is considered significant or not, or whether there is a need for a new authorisation or not. This also requires an independent assessment by an AsBo, regardless of whether the change is considered significant or not.

In addition, in the case of a change to an existing vehicle and/ or vehicle type, the CSM RA shall be applied. If the change is considered significant, the risk management process of CSM RA shall be applied, an AsBo shall independently assess the risk management process and shall issue a safety assessment report pursuant to Article 15 of the CSM RA.

The independent assessment for both aspects can be performed by the same AsBo, although the legal framework does not oblige to have the same company playing the role of AsBo for both topics. However, contracting the same AsBo may bring synergies between the independent assessment of the risk management process as defined in the CSM RA and the assessment of the requirements capture process for the essential requirement safety and the safe integration between subsystems prescribed in Article 13 of Regulation (EU) 2018/545 (see section 3.11.1.14). This may be a straightforward addition to an AsBo's role in particular if the CSM RA process is also used for requirements capture of all essential requirements, with the necessary adaptations.

3.3.1.9. Requirements capture of essential requirements other than safety

A systematic and system engineering-based approach is needed to address all vehicle requirements, not just the safety requirements. An applicant or an entity managing the change has two options to address requirements capture and management for the essential requirements other than safety:

- › Follow the fundamental elements of the risk management process in the CSM RA for all requirements, **with some adaptations** that are necessary, as risk assessment and evaluation is not directly applicable to requirements other than safety requirements (e.g., using a hazard record is not suitable for essential requirements other than safety).

This includes the independent assessment of the requirements capture, that can be carried out by an AsBo (this may be a straightforward addition to the AsBo's scope of assessment for essential requirement safety), but also by an independent assessor other than an AsBo.

If an AsBo has not been appointed for the independent assessment of the requirements capture, the applicant will need to submit the evidence related to the requirements capture to the authorising entity as part of the authorisation process. The authorising entity will assess the evidence as part of the authorisation process to verify that a requirements capture process has been undertaken, and that it systematically identified and managed all requirements throughout the entire development process, including verification and validation.

- › Use another, equivalent, process, which fits in the development practices of the applicant or of the entity managing the change. It is important that the methodology used provides the same level of assurance as the CSM RA. The independent assessor, if any, could be an AsBo.

Please note that when the methodology does not include an independent assessment, the demonstration that it provides the same level of assurance will be difficult (see section 3.11.2.1).

When considering whether another methodology provides the same level of assurance, an applicant or an entity managing the change should take into account whether the process implemented incorporates the key elements of a requirements capture process in EN 50126-1 standard and CSM RA.

- System Definition - The system and/or change being implemented needs to be defined in the context of the railway network and its area of use. This aspect is of paramount importance for the next steps of the process.
- Specification of Requirements - All requirements to address the essential requirements need to be captured in requirements specifications and, as appropriate, fed into design specifications.
- Implementation of Requirements - Requirements need to be implemented, and design traceability, from the requirements through design specifications and into verification and testing needs to be performed.
- Demonstration of Compliance - All requirements need to be validated and evidence needs to be gathered to demonstrate that requirements are met.

If a novel or poorly defined process is adopted, then there is a strong risk that those principal characteristics required of requirements capture and management will not be met, and the process of assessment by an AsBo or the authorising entity will take significantly longer. Examples of development methods that could be considered an appropriate basis for a requirements capture process would be those that are compliant with the systems engineering method defined in EN 50126-1. The more standardized is the process (closer to the principles of Annex I of CSM RA, e.g., EN 50126-1), the fewer issues will be raised by the AsBo and/or authorising entity during the assessment of the evidence of the requirements capture process.

The Figure 5 provides a schematic view of the relationships between CSM RA and EN 50126-1 life cycle in terms of main steps of the requirements capture process related to the essential requirement safety and the safe integration between subsystems.

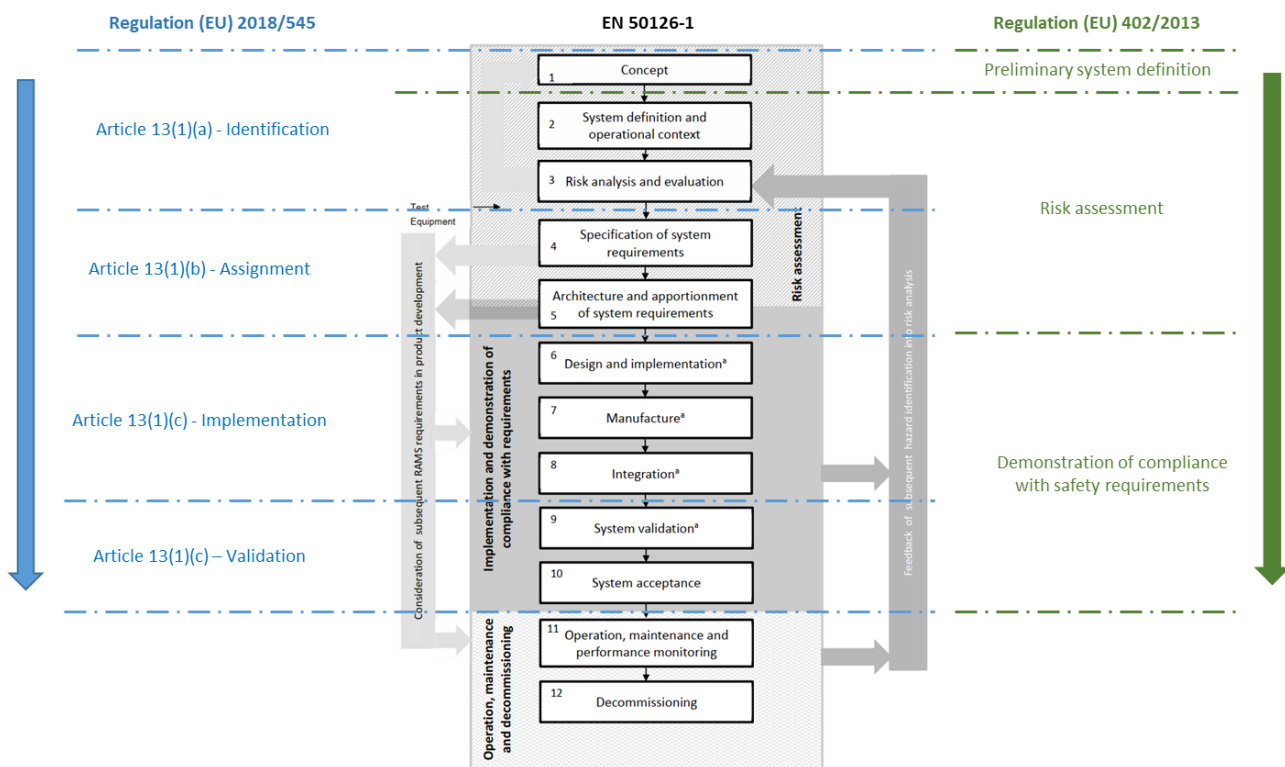


Figure 5: requirements capture in Regulation (EU) 2018/545 vs CSM RA process and system life cycle in EN 50126-1

The Figure 6 provides a graphical description of how the system life cycle in EN 50126-1 fits with the risk management process in Annex I of CSM RA. The fundamental elements of a requirements capture process are addressed by the main boxes (implementation of requirements and demonstration of compliance are covered by a single box), with the numbers in the individual boxes providing an indication of where these processes align with the phases of the EN50126-1 system life cycle.

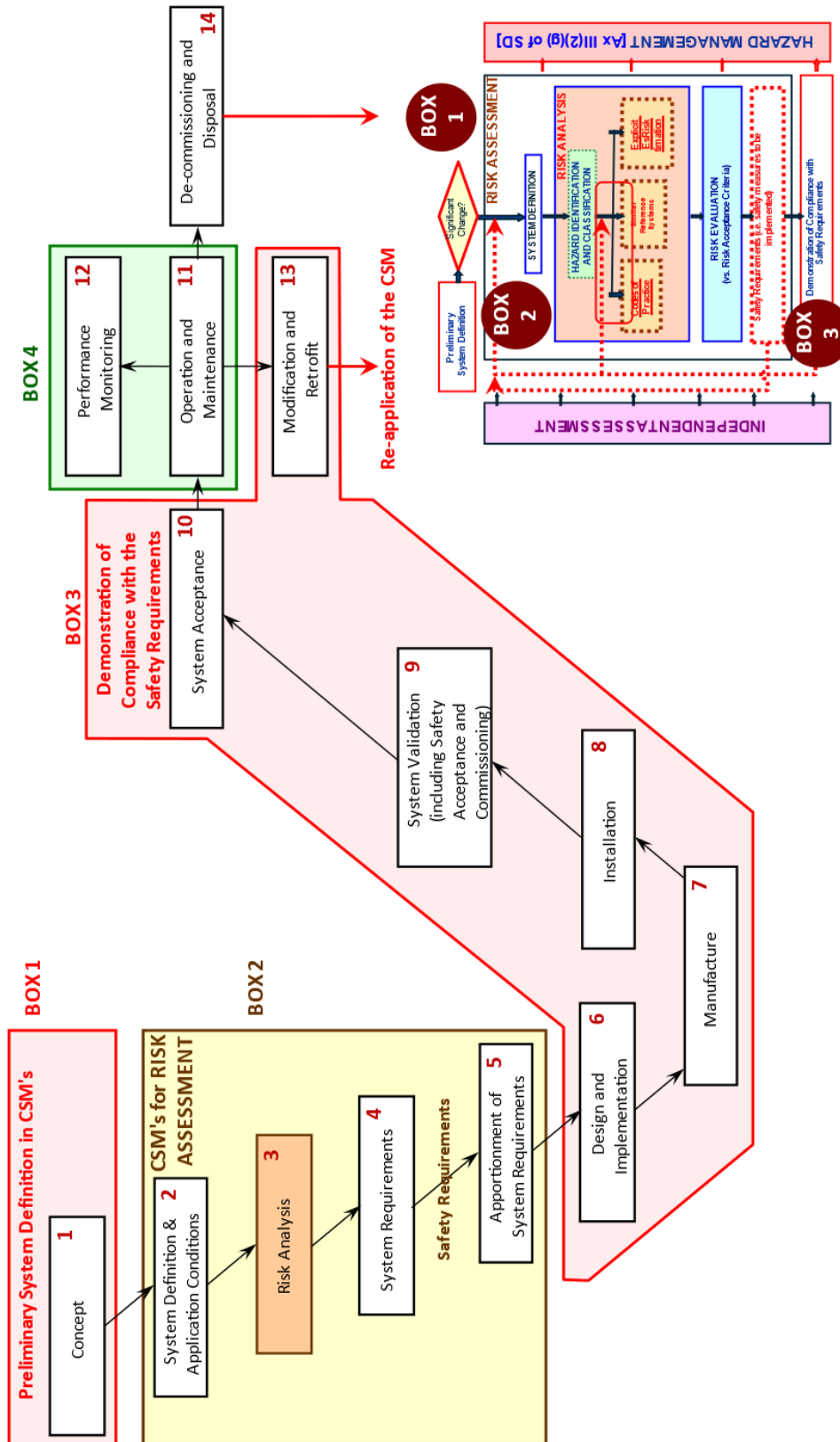


Figure 6: A requirements capture process based on the CSM RA process

The applicant or the entity managing the change has to document and produce evidence for the whole requirements capture process. There is no obligation to use a specific tool or approach to produce the evidence of the application of the requirements capture process, as long as the applicant or the entity managing the change demonstrates that all the aspects above have been followed.

The CSM RA specifies a hazard record as the central document to manage safety requirements. It shall be “created or updated by the proposer during design and implementation”. The hazard record acts as a safety requirements management document and is used to show the status of the safety requirements and provide traceability into the design and implementation of those safety requirements. A similar mechanism (in terms of a tool that allows the proper management of the requirements) is required for the requirements capture process of essential requirements other than safety.

Although the literal reading of Regulation (EU) 2018/545 would suggest the use of a Hazard Log/Record for registering all requirements, i.e., not only the safety related information, in practice this is not mandatory. Regulation (EU) 2018/545 allows to use any other means or tools (e.g., a centralised repository tool) which enable the applicant or the entity managing the change to demonstrate a systematic recording and management of the non-safety requirements.

Usually for that purpose, the manufacturers largely use specific IT tools, or in-house data bases, registers, check lists, and tools for systematically tracing down, and managing the implementation of, the requirements identified/captured at the start of the project till the associated validation tests are done to demonstrate the actual and correct implementation of every requirement. This logic and systematic management of all essential requirements is equivalent to the concept of a Hazard Log/Record, which ensures that no requirement is forgotten (see example of requirements matrix on section 3.11.4).

3.3.1.10. AsBo competences for assessing the requirements capture process

Annex II of the CSM RA requires the AsBo to fulfil the following requirements:

- › all requirements of the ISO/IEC 17020:2012 standard; those are general criteria and requirements concerning the AsBo "independence, competence, integrity and impartiality";
- › specific criteria and requirements needed for carrying out the independent assessments requested in Article 6 of the CSM RA

AsBos are accredited or recognised, pursuant to Article 7 of CSM RA, which means that the criteria in Annex II of the CSM RA are met, for one, several or all areas of competence related to the different subsystems (structural and functional) that compose the EU railway system:

- › Infrastructure
- › Energy
- › Control-command and signalling
- › Rolling stock
- › Traffic operation and management
- › Maintenance
- › System safe integration
- › Other

Additionally, point 3 in Annex II of the CSM RA requires that the AsBo shall be accredited or recognised for wider or transversal competencies, such as the competence needed to assess the overall consistency of the risk management and the safe integration of the system under assessment, which includes the ability of the AsBo to check the following:

- › the organisation or arrangements put in place by the proposer to ensure a coordinated approach;
- › the methodology for the evaluation of methods and resources deployed by various stakeholders, and
- › the technical aspects necessary for assessing the system as a whole.

To fulfil the requirements of the CSM RA, an AsBo should be accredited or recognised for “at least one technical area of competence in point 2 in Annex II and the competence in point 3 in Annex II for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole”.

It is important to know that the CSM RA does not give details for the competence requirements defined in its Annex II, which are broad requirements. For example, it does not specify the specific engineering disciplines, such as embedded real-time systems, telecommunications, hardware, software, human factor, etc. necessary for every structural sub-system. This makes it difficult to ascertain whether an AsBo has sufficient competence, experience, and knowledge to fulfil its roles and responsibilities. For those reasons, further details about the requirements for the technical knowledge and competence of the AsBos can be found in the Recommendation for Use (RFU) number 3, developed by the Agency and the AsBo Cooperation group. This RFU is publicly available at the website of the Agency:

https://www.era.europa.eu/domains/common-safety-methods/risk-evaluation-assessment-csm_en

The abovementioned RFU number 3 defines explicitly the competence requirements necessary for an AsBo to be allowed to independently assess the requirement capture process covering a whole vehicle (and the safe integration between subsystems).

For the purposes of the independent assessment of the requirements capture process of a vehicle and/or vehicle type, the AsBo should include in the scope of its accreditation or recognition all the subsystems that compose the vehicle. In case of new authorisation case (changes to an existing vehicle and/or vehicle type), where only one of the subsystems is impacted, only the competences for the subsystems impacted by the change are considered necessary, although the independent assessment shall also cover the safe integration between mobile subsystems. Needless to say, for vehicles that are only composed of the rolling stock subsystem (e.g., wagons), the AsBo performing the independent assessment of the requirements capture process only needs the competence related to rolling stock in the scope of its accreditation / recognition.

However, due to the systemic nature (process oriented, sample checks and in-depth vertical slice assessments) of the independent assessment to be performed concerning the requirements capture process, an accredited or recognised AsBo whose competences cover at least the rolling stock subsystem is capable of assessing the requirements capture process for the whole vehicle. An AsBo is not obliged to have internally, within its organisation or entity, all the technical competences necessary for carrying out the independent assessment. Pursuant to the conditions in clauses 6.1 and 6.3 of ISO/IEC 17020:2012, the AsBo can either hire-in external experts, or subcontract parts of the assessment.

In this case, the AsBo does not have the competence which is subcontracted in the scope of its accreditation or recognition the full scope of the subcontracted parts. Therefore, the AsBo has to ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in the ISO/IEC 17020:2012 or in other relevant conformity assessment standards. In any case, the AsBo remains responsible for the whole independent assessment, including the subcontracted part. When the subcontracted part is an entire structural subsystem (e.g., control-command and signalling) fully covered by a TSI, the AsBo should mutually recognise the assessments performed by another AsBo, accredited, or recognised for at least the subcontracted scope.

Clauses 6.1 and 6.3 of ISO/IEC 17020:2012 standard are further discussed in the Recommendation for Use (RFU) number 8, which is under development by the Agency and the AsBo Cooperation group. The RFU will be publicly available at the website of the Agency.

The information concerning the areas covered by the accreditation or recognition of the AsBo recorded in ERADIS (https://eradis.era.europa.eu/safety_docs/assessments/bodies/default.aspx, section 5 “Classification”) should be up to date and consistent with the evidence of the accreditation or recognition

issued by the competent body, to avoid unnecessary delays during the authorisation process. This aspect is assessed by the authorising entity in the framework of an application for authorisation.

3.3.1.11. In-house AsBos for the assessment of the requirements capture process

The CSM RA allows the use of all three types (A, B and C) of inspection bodies as defined in section § 4.1.6 and Annex A of the ISO/IEC 17020:2012 standard. In all cases, the AsBo must be accredited or recognised, pursuant to Article 7 of CSM RA, which provides assurance about their competence, independence, and impartiality.

“In-house” AsBos of both types B and C, according to points A.2 and A.3 of ISO/IEC 17020:2012 standard, are allowed to perform the assessment of the requirements capture process. It is worth underlining that type B AsBos can only provide services to the organisation of which they form part. Type C AsBos can also provide services to other parties.

The CSM RA does not forbid that the same company plays several roles (e.g., NoBo, DeBo and/or AsBo), as long as it fulfils the necessary requirements and is properly accredited or recognised with respect to the relevant requirements for each of those roles. Following the CSM RA definition, an AsBo is a competent external or internal (“in-house”) individual, organisation or entity which is at least independent from the “design, risk assessment, risk management, manufacture, supply, installation, operation/use, servicing and maintenance” of the vehicle and/or vehicle type under assessment.

Hence, one of the key requirements that an AsBo needs to fulfil for being accredited or recognised is independence and impartiality. This means that AsBos should have in place the necessary measures and barriers to ensure independency from other companies, or parts of the company to which it belongs (for types B and C AsBos).

3.3.1.12. Relationship between entities performing an independent safety assessment (CENELEC standards) and AsBos

The European railway legislation does not define any role for the CENELEC independent safety assessor (ISA). Furthermore, the section 4.2.1.1 of the CCS TSI makes compulsory the independent safety assessment by an AsBo. Hence, this independent assessment cannot be performed by a CENELEC ISA. In addition to that, section 4.2.1.1 the CCS TSI states explicitly that “[...] *the application of the specifications as referred to in Appendix A, Table A 3 [...]*” (i.e. of the CENELEC 5012x series standards) “[...] *is an appropriate means to fully comply to the risk management process [...]*” of the CSM RA for “[...] *interoperability constituents and subsystems [...]*”, provided the independent assessments are carried out by an AsBo accredited or recognised for the CCS scope instead of a CENELEC ISA.

The methodologies described in CSM RA and the CEN/CENELEC standards (EN 50126/50128/50129) are not contradicting each other and should not be considered as two separate and consecutive tools. On the contrary, it is reasonable to use them in an integrated and complementary way.

However, the AsBo and the CENELEC independent safety assessor (ISA) are not equivalent, although their roles and working methods have many similarities.

Furthermore, the scope of work of the AsBo is broader than the CENELEC ISA. The CENELEC 50128 and 50129 standards request an ISA only for signalling systems. The CSM RA makes compulsory the appointment of the AsBo for the independent safety assessment of all significant changes, regardless of whether they relate to control-command and signalling subsystem, rolling stock subsystem, infrastructure subsystem etc. Article 13 of Regulation (EU) 2018/545 also requires the appointment of an AsBo for the independent assessment of the requirements capture process related to the essential requirement safety and the safe integration between subsystems.

Consequently, when the EU legislation requires the appointment of an AsBo to a project, and when contractually, or through a notified national rule, the use of CENELEC 50126, 50128 and 50129 standards (with an independent safety assessor) is also required, the applicant or the entity managing the change is required to appoint an AsBo which:

- › is accredited or recognised according to the CSM RA, and
- › also fulfils the competence requirements of a CENELEC ISA.

In that case, the independent safety assessment carried out by such an AsBo shall include also all necessary independent safety assessment activities that should be fulfilled by the CENELEC ISA.

In case an applicant or an entity managing the change would appoint an ISA, whereas that shall not be possible for a scope of work already covered by EU legislation, it is important to keep in mind that an AsBo is not obliged to mutually recognise the work and the report of a CENELEC ISA. Pursuant to clause 6.3 of the ISO/IEC 17020:2012 standard, the AsBo is:

- › responsible for verifying itself that the ISA has the right level of competence and independence, and that the ISA uses working methods similar to the ones in CSM RA, or
- › allowed to perform additional checks or assessments, if deemed necessary.

3.3.1.13. Performing the requirements capture process for platforms of vehicles

The process(es) in place for capturing and managing the requirements should be applied to all projects to be developed by an applicant or entity managing the change, in order to ensure a systematic and structured management of the requirements. The requirements capture process shall apply to vehicle platforms (a platform in this context should be understood as a shared set of common design, engineering, and production efforts, as well as major components, over a number of outwardly distinct types/variants/versions) or vehicle families and may have particularities aiming at simplifying or improving the way in which requirements are managed for projects that belong to the same vehicle platform or vehicle family.

However, and due to the fact that according to Article 13(1) of Regulation (EU) 2018/545 the requirements capture covers the implementation, verification, and validation as well, and production of the necessary documentary evidence, it is necessary to consider not only the general aspects of the process applied for a vehicle platform, but also the application of the process to the specific project under assessment. Consequently, the evidence of the application of the requirements capture process to a specific project shall also reflect the implementation, verification, and validation for that specific project.

The AsBo responsible for the independent assessment of the requirements capture for the essential requirements safety and for the safe integration of the subsystems shall also assess the assignment, implementation, verification, and validation steps. The independent assessment may require sample checks and in-depth vertical slice assessments to be carried out by the AsBo in order to build its expert judgement on whether the process is robust enough, has been thoroughly and consistently applied and its application leads to satisfactory results in terms of management of the (safety) requirements.

That being said, it is possible to make a distinction between:

- › a generic platform for which the requirements capture process was formally applied and documented by the applicant or the entity managing the change, and independently assessed by an AsBo, and
- › a specific application of the requirements capture process (already assessed for a generic platform) to specific vehicles and/or vehicle types belonging to the platform.

The requirements capture process of the generic platform do not need to be reassessed for every specific vehicle type, vehicle type variant and/or vehicle type version belonging to the platform or vehicle family. The AsBo performing the independent assessment of the specific application should mutually recognise the work performed by the AsBo for the generic platform, and the independent assessment should be limited to the application of the requirements capture process to the specific project (vehicle type/variant/version) under consideration and to the applicability and validity of the independent assessment of the generic platform. This approach is commonly known in the industry under the terminology “1 + Δ” (“1 + Delta”), where “Δ” represents the gap/difference between the generic platform and the specific application.

In order to do so, the AsBo independently assessing the specific application shall have access to the outcomes of the independent assessment of the generic platform if this was done by another AsBo.

The independent assessment of the generic platform should remain valid unless there are changes in the main elements of the requirements capture process, such as the:

- › Applicability of the process for the generic platform to the specific project under consideration (vehicle type/variant/version);
- › Applicable legal framework;
- › Requirements capture process (identification, assignment, implementation, and validation);
- › Organisational changes (e.g., design and/or manufacturing locations, subcontracting of engineering activities, etc.);
- › Suppliers;
- › Tools supporting the process, and/or
- › Roles and responsibilities of the actors involved in the process.

The entity managing the change should inform the AsBo that performed the independent assessment of the generic platform in case of modification of the requirements capture process. The AsBo will decide if there is a need to perform a new independent assessment and to produce the necessary evidence (new or amended assessment report) or not.

3.3.1.14. Grouping of 15(1)(b) changes in one independent assessment

Requirements capture must be carried out even if there is no need to apply for an authorisation following a change to an already authorised vehicle or vehicle type. In other words, a requirements capture and management process must be performed for all vehicle projects, regardless of whether an authorisation is necessary or not, or whether a change is considered significant or not following the application of CSM RA.

If during the process of categorisation of the change pursuant to Article 15(1) of Regulation (EU) 2018/545 there has been considerations around safety (e.g., to decide whether there is a potential impact on safety triggering Article 21(12)(b) of Directive (EU) 2016/797 or not), the requirements capture process for the essential requirement safety (and the safe integration between subsystems) shall be independently assessed by an AsBo, pursuant to Article 13 of Regulation (EU) 2018/545 (risk assessment process in Annex I of CSM RA applies).

Please note that for other essential requirements, the entity managing the change can decide whether to apply the methodology in Annex I of CSM RA or use another methodology that provides the same level of assurance.

When, with the support of the requirements capture process, a change is classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545, there is no need for the entity managing the change to submit an application for authorisation through the OSS. Still, the entity managing the change shall:

- › Undertake a requirements capture process;
- › Produce the concerned documentation, and
- › Keep the documentation related to requirements capture at the disposal of the authorities.

Further details can be found in section 3.3.3.2.2.

In such cases, when there are safety considerations being made and as a result, the independent assessment by an AsBo is required, the entity managing the change, under its sole responsibility, can decide to cover the aspects related to the independent assessment of the requirements capture process for a number of individual 15(1)(b) changes implemented over time within one single independent assessment by an AsBo.

Grouping the independent assessment of the requirements capture process for a number of 15(1)(b) changes should be limited to:

- › Changes related to the same vehicle and/or vehicle type (including its variants and versions), and
- › Changes not considered significant according to CSM RA.

The time elapsed between the implementation of the first change and the issuing of the (safety) assessment report for a batch of successive changes (i.e., a group changes) falling under Article 15(1)(b) of Regulation (EU) 2018/545 should be agreed with the concerned AsBo, although it is recommended that the timeframe for grouping changes remains below 4 months⁴ and in any case does not go beyond 12 months.

Concerning the independent assessment of the requirements capture process for a batch of different 15(1)(b) changes implemented over time, the entity managing the change can proceed in a step wise approach, provided that:

- › There is a well-established baseline (starting point), be it:
 - the last vehicle type authorisation pursuant to Regulation (EU) 2018/545, thus supported by a requirements capture process and the relevant independent assessment by an AsBo, or
 - the latest modification of the vehicle and/or vehicle type implementing a batch of Article 15(1)(b) changes, where the requirements capture process was independently assessed by an AsBo who has produced the relevant independent assessment report.
- › The requirements capture process describes in an explicit way:
 - the modular approach for grouping in a single independent assessment by an AsBo a number of 15(1)(b) changes implemented over time, and
 - the conditions under which this can be done (aspect normally covered by the change management process of the applicant or of the entity managing the change).
- › The entity managing the changes:
 - Documents the application of the requirements capture process to every change, and
 - Keeps a register of all successive 15(1)(b) changes that will form the batch of changes

When the conditions above are met, the entity managing the change, rather than appointing AsBo for the independent assessment of the requirements capture process related to each and every specific 15(1)(b) change at the moment they are implemented, can instead appoint an AsBo for “one” independent assessment covering all changes in the batch. In that case:

- › the AsBo does not need to assess again the content of the previous baseline;
- › the AsBo should mutually recognise the results of the independent assessment of the previous baseline; as far as this is possible, and in order to limit the independent assessment workload, the entity managing the change can appoint for the independent assessment of a batch of changes the same AsBo that assessed the previous baseline.
- › The independent assessment by the AsBo shall be limited to:
 - the application of the requirements capture process to all the changes grouped in a batch;
 - the safe integration of those changes with the previous baseline, and
 - the verification of the applicability and validity of the independent assessment of the previous baseline.

3.3.1.15. Requirements capture and independent assessment by an AsBo for the installation on an on-board CCS system in an existing vehicle

The requirements capture process covers all the relevant requirements for a vehicle and/ or a vehicle type. In case of a first authorisation, the whole vehicle type and/ or vehicle should be covered by the requirements capture process. In case of a new authorisation as a consequence of a change, the requirements capture process should cover the changed parts, but also the interfaces between the changed and the unchanged parts.

⁴ Proposed 4 months timeframe by analogy to the timeframe set-up in Article 16(4) of Regulation (EU) 2018/545 for authorising entities to issue a reasoned decision concerning notifications of changes to vehicles: entities managing the changes can implement 15(1)(b) changes after submitting the notification, the modified vehicles can restart operation immediately after, without waiting for the reasoned decision.

According to Articles 39(4) and 40(3) of Regulation (EU) 2018/545, the checks to be performed by the Authorising Entity and the NSAs for the area of use concerning the evidence for requirements capture in case of a new authorisation should cover the parts that are changed but also the impact of such changes in the unchanged parts.

The Article 13(2) of Regulation (EU) 2018/545 clarifies that the requirements capture process shall cover the technical compatibility and the safe integration of the subsystems within the vehicle.

In most cases, the retrofitting a vehicle with on-board CCS requires also to perform changes in the rolling stock subsystem (e.g., driver's desk, DMI, brake system, train interface unit, etc.). In addition, the requirements capture process should cover both mobile subsystems, rolling stock and on-board control-command and signalling, even if the rolling stock subsystem is not changed because safety integration needs to be ensured. As a consequence, the independent assessments to be performed concerning the requirements capture process should cover both subsystems as well, and because essential requirement safety and safe integration between subsystems are at stake, an AsBo should be involved.

It should be noted that the CCS TSI requires that an AsBo independently assesses the correct application of the risk management process set out in Annex I of CSM RA, as well as the appropriateness of the results from this application to the CCS mobile subsystem. This is additional to the requirements capture process related to the essential requirement safety and the safe integration between subsystems, although there are clear synergies and overlaps between the two independent assessments.

However, the independent assessment for both aspects can be performed by the same AsBo. The legal framework does not oblige to have the same company playing the role of AsBo for both topics. However, contracting the same AsBo may bring synergies between the independent assessment of the risk management process as defined in the CSM RA for the requirements capture process for the essential requirement safety and the safe integration between subsystems prescribed in the Regulation (EU) 2018/545 and for the safety specific aspect of the CCS subsystem according to §3.2.1 of CCS TSI.

When there are different AsBos involved, the AsBo for the requirements capture is still the sole responsible for this assessment, although it shall mutually recognise the work performed by the AsBo mandated by the CCS TSI (for the same scope of work).

3.3.1.16. Requirements capture and independent assessment by an AsBo in case of installation of new cab radio on an existing vehicle

The installation of a cab radio in an existing vehicle may have safety impacts in the rolling stock subsystem (e.g., installation of antennas, redesign of the driver's desk, interfaces with the ETCS on-board in case of EDOR, etc.). As a consequence, the requirements capture needs to cover the safe integration between both subsystems, and the requirements capture process performed by the applicant (concerning essential requirement safety and safe integration between subsystems) needs to be independently assessed by an AsBo.

3.3.2. Article 14: Identification of the relevant authorisation

1. The applicant shall identify and choose the relevant authorisation from the following cases:
 - (a) first authorisation: the vehicle type authorisation and/or the vehicle authorisation for placing on the market issued by the authorising entity for a new vehicle type, including its variants and/or versions if any, and, where applicable, the first vehicle of a type, pursuant to Article 21(1) of Directive (EU) 2016/797;
 - (b) renewed vehicle type authorisation: the renewal of a vehicle type authorisation pursuant to Article 24(3) of Directive (EU) 2016/797 which does not require a change in design of the vehicle type;
 - (c) extended area of use: the vehicle type authorisation and/or the vehicle authorisation for placing on the market issued by the relevant authorising entity for an already authorised

vehicle type and/or vehicle in order to extend the area of use without a change of the design, pursuant to in Article 21(13) of Directive (EU) 2016/797;

(d) new authorisation: the vehicle type authorisation and/or vehicle authorisation for placing on the market issued by the authorising entity after a change of an already authorised vehicle and/or vehicle type, pursuant to Articles 21(12) or 24(3) of Directive (EU) 2016/797;

(e) authorisation in conformity to type: the vehicle authorisation for placing on the market for a vehicle or a series of vehicles that conform to an already authorised and valid vehicle type on the basis of a declaration of conformity to that type, pursuant to Article 25(1) of Directive (EU) 2016/797. Where applicable, there shall be a clear identification of the vehicle type version and/or the vehicle type variant to which the vehicle or series of vehicles is conform.

2. In cases of vehicle type authorisations pursuant to cases (c) and (d), the applicant, if he is the holder of the existing vehicle type authorisation, shall decide whether the authorisation will result in the creation of:

(a) a new vehicle type; or

(b) a new vehicle type variant within the existing type on which it is based.

If the applicant is not the holder of the existing type the authorisation shall result in the creation of a new type in accordance with Article 15(4).

3. An applicant may combine:

(a) a request for new authorisation with a request for an authorisation for an extended area of use; or

(b) a request for a first authorisation with a request for authorisation in conformity to type.

The timeframes set out in Article 34(1) and (2) shall apply to the combined application. Where appropriate, it may result in the issuing of several authorisation decisions by the authorising entity.

For description of the process, see the flowchart for Substage 1.1 in section 4.

The first step is for the applicant, based on the description of the project, to identify and take a decision concerning the authorisation case that is applicable. The applicant is responsible for the decision concerning the authorisation case that is applicable to the project. When there is a change in the applicable requirements of the relevant Union law and/ or any relevant national rule, the holder of the vehicle type authorisation, through the configuration management of the vehicle type, should verify if:

- › The vehicle type authorisation remains valid (i.e., if it is still possible to place on the market more vehicles conforming to the authorised vehicle type) e.g., when the transitional provisions of the Union law so allow; or
- › There is a need to request a renewed vehicle type authorisation, or a new authorisation, and whether this should result in the authorisation of new vehicle type or vehicle type variant / version.

Vehicles already authorised for placing on the market should normally remain authorised even if the vehicle type authorisation has been rendered invalid by a change in the rules. However, in exceptional cases also the vehicles already authorised for placing on the market may be affected by a change in the rules (Article 4(3)(h) of Directive (EU) 2016/797).

If new versions/ variants are introduced for an authorised vehicle type then those vehicles already authorised for placing on the market should remain authorised without prejudice to the provisions in Article 4(3)(h) of Directive (EU) 2016/797. New vehicles can be built and authorised in conformity to type to all vehicle type variants and vehicle type versions that are still valid (taking into account any changes to the rules), as long as the EC certificates remain valid.

Pre-engagement (Article 22 – Article 24 of Regulation (EU) 2018/545) will mitigate the risk of making the wrong choices; consequently, the right choice is confirmed in the pre-engagement baseline, if any. Nevertheless, the applicant can decide to change the authorisation case before the issuing of the opinion that establishes the pre-engagement baseline, if any.

Further details on the content of the file accompanying the application for authorisation depending on the applicable authorisation case can be found in section 3.11.1.

3.3.2.1. First authorisation case – 14(1)(a)

A first authorisation (for a new design) can be issued for a vehicle type, including its variants and/ or versions, if any, and/ or a vehicle. When a first authorisation is issued for a vehicle then the vehicle type should be authorised at the same time. In this case it is clear that the vehicle is in conformity with the vehicle type so no declaration of conformity to type is required for that vehicle. All other vehicles of that vehicle type will be authorised according to case (e): authorisation in conformity to type.

Pursuant to Article 14(3)(b) of Regulation (EU) 2018/545, it is also possible to combine in the same application through the OSS a first authorisation (with or without a vehicle) and an authorisation in conformity to type for a series of identical vehicles.

3.3.2.2. Renewed vehicle type authorisation case – 14(1)(b)

The renewed vehicle type authorisation is used where it is necessary to apply a change that has been made to a TSI or national rule to a vehicle type, so that future vehicles conforming to the vehicle type conform to the changed rule. The changed rule itself will determine whether the vehicle type authorisation needs to be renewed.

The renewed vehicle type authorisation is limited to the case where, after assessment against the changed rule(s), it is proven that the vehicle type conforms without any change to the vehicle type, i.e., the basic design characteristics and/or the basic parameters..

When there is a change in the vehicle type, this no longer falls under renewed vehicle type authorisation case, and it should be considered as a change to an already authorised vehicle type, see section 3.3.3.

A vehicle type authorisation remains valid for an indefinite period, only requiring a renewal if a change to the rules specifies that the existing vehicle type authorisations become invalid in respect of a specific parameter. In this case, the renewal of vehicle type authorisation only requires verification of the changed parameters for which the new rule renders the existing vehicle type invalid.

In other words, each of a vehicle type's parameters (its basic design characteristics) retains "grandfather's rights" indefinitely until a new/ updated rule explicitly states that a new requirement for a parameter applies to an existing vehicle type that will need to be rechecked to achieve a renewed vehicle type authorisation.

3.3.2.3. Extended area of use case – 14(1)(c)

For an authorisation extending the area of use of a vehicle type **without changes to the vehicle type** (necessary condition to apply this authorisation case), the existing vehicle type authorisation remains valid. This applies irrespective of which legal framework the vehicle type authorisation was issued for, except for the case when the vehicle type authorisation has been suspended or revoked.

On the basis that the vehicle type meets the essential requirements in the original area of use, the authorising entity (with input from the concerned NSAs for the area of use) should grant an extension of area of use based on that the applicant provides evidence that the technical compatibility between the vehicle and the network that forms the new part of the area of use has been checked; such check should be performed on the basis of the applicable TSIs and notified national rules.

Checks already carried out at the first authorisation should not be repeated.

When there is a need to perform **changes classified pursuant to Article 15(1)(b) or (c)** of Regulation (EU) 2018/545 (such changes do not require a new authorisation unless the entity managing the change is not the holder of the vehicle type authorisation) **in combination with an extension of the area of use**, the holder of the vehicle type authorisation should first process the 15(1)(b) or (c) changes as required (configuration

management of the vehicle type, e.g. update the EC type examination certificates and EC DoVs, update ERATV, request the publication of a version in ERATV for a 15(1)(c) change, etc.). Then it can apply for an extension of the area of use. The NSAs of the original area of use do not need to be involved in the application for the extension of the area of use.

If the starting point is a version created following a 15(1)(c) change, it is possible to perform an extension of the area of use starting from that version. However, the result of the extension shall be a new type (it cannot be a version), pursuant to Article 14(2) of Regulation (EU) 2018/545.

In addition, when the vehicle is not fully compliant with the LOC&PAS TSI or WAG TSI in force, has been authorised under Directive 2008/57/EC or is in operation before 19 July 2010, the provisions of section 7.1.4 of LOC&PAS TSI (see section 3.2.6 of the guideline for the application of the LOC&PAS TSI) or 7.2.2.4 of WAG TSI apply (see section 3.6 of the guideline for the application of the WAG TSI) .

The rules laid down in section 7.4.2.3, 7.4.3 and 7.4.4 of CCS TSI also apply for the extension of the area of use, regardless of the regime under which the previous authorisation took place and the date of authorisation (or entry into operation); this requires in some cases the installation of ETCS and/or GSM-R. When this happens, and the exceptions provided by the CCS TSI for not installing ETCS and/or GSM-R do not apply, there is a change in the vehicle and/or vehicle type, hence the applicant interested in extending the area of use may:

- › apply for a combined new authorisation in the original area of use following the installation of ETCS and/or GSM-R and an extension to the new area of use, pursuant to Article 14(3)(a) of Regulation (EU) 2018/545, see sections 3.3.2.3.3 and 3.3.2.5, or
- › request a non-application of the CCS TSI pursuant to Article 7 of Directive (EU) 2016/797 in order not to install ETCS and/or GSM-R and apply for an extension to the new area of use.

Where the already authorised vehicles and/or vehicle type benefited from non-application of TSIs or part of them, the applicant shall seek derogation(s) in the MSs of the new area of use in accordance with Article 7 of Directive (EU) 2016/797. For cases where there may be a derogation already granted (e.g., the case in section 3.3.2.3.1), the applicant should verify whether the scope of the granted non-application covers the vehicles whose area of use will be enlarged or not. If they are not covered, the applicant shall also request a non-application of the TSIs in the MSs of the extended area of use.

The holder of the vehicle type authorisation can either add a new vehicle type version to the existing vehicle type or decide to create a new vehicle type. This is an administrative decision of the holder of the vehicle type authorisation.

3.3.2.3.1. Extension of the area of use where there is a valid vehicle type covering the extended area of use

When there is a valid vehicle type authorisation covering the whole area of use, and neither the particular rules in the TSIs are applicable or require changes the vehicle and/or vehicle type nor the National Implementation plans impose additional constraints, e.g.

- › Planned migration of a network(s) where the existing vehicles are already operating (or part of a network) to Baseline 3, where existing vehicles with Baseline 2 could not be operated anymore
- › Existing vehicles operate using a class B system in a network equipped with both trackside ETCS and class B systems, but class B system will be decommissioned hence no more vehicles equipped only with on-board class B system can be operated there

the company interested in extending the area of use can apply for an authorisation in conformity to the relevant type/version for the existing vehicles, pursuant to Article 14(1)(e) of Regulation (EU) 2018/545, provided that the EC type examination certificates remain valid.

3.3.2.3.2. *Extension of the area of use where identical vehicles are already authorised and in operation in the extended area of use*

The company interested in extending the area of use for cases where there are identical vehicles already authorised in the extended area of use, without a valid vehicle type authorisation covering the whole area of use, should apply for an authorisation for an extension of the area of use pursuant to Article 14(1)(c) of Regulation (EU) 2018/545:

› Rolling Stock Subsystem:

The fact that there are identical vehicles authorised in the extended area of use can be used for the demonstration of compliance with the particular rules for the extension of the area of use laid down in the TSIs (see section 3.3.2.3):

- Proof compliance with alternative specifications deemed to have equivalent effect to the relevant requirements set out in the TSI and/or
- Gather evidence that the requirements for technical compatibility with the network of the extended area of use are equivalent to the requirements for technical compatibility with the network for which the rolling stock is already authorised or in operation

For such demonstration, the applicant should apply the risk management process set out in Annex I of Regulation (EU) No 402/2013 that allows use of a code of practice and/or similar reference system(s).

Indeed, the TSI require that the equivalent effect of alternative specifications to the requirements of the TSI and the equivalence of requirements for technical compatibility with the network shall **be justified and documented** by the applicant. The justification must be assessed and confirmed by an AsBo.

The applicant shall also take into consideration the impact of the modifications in the vehicles that remain authorised only in the original area of use (if any) since the moment the authorisation was granted in the extended area of use. It shall also consider the modifications brought to vehicle authorised in both areas of use since they were authorised. This with the objective of ensuring that the reference vehicles (vehicles authorised in both the original and the new area of use) are identical to the vehicles seeking authorisation in the new area of use. Such demonstration shall be assessed by an AsBo.

› CCS Subsystem:

The normal procedure for the extension of the area of use is to be applied. The compliance with requirements defined in clause 7.4.2.3 of CCS TSI shall be evaluated according to the TSI requirements and the specifications in Annex A of the TSI; it is not possible to use alternative specification or equivalence of the requirements for technical compatibility for ETCS or GSM-R.

This also includes the potential obligation to install ETCS and/or GSM-R, in which case there is a need to apply for a new authorisation (case (d)) combined with an extension of area of use (case (c)), pursuant to Article 14(3)(a) of Regulation (EU) 2018/545 (see section 3.3.2.3.3).

Once a new vehicle type or version of the vehicle type (depending on whether the applicant is the holder of the vehicle type authorisation or not) is authorised, other existing vehicles concerned can be authorised by means of the authorisation case described in Article 14(1)(e) of Regulation (EU) 2018/545 (authorisation for placing on the market of a vehicle in conformity to an authorised type, see section 3.3.2.6).

The possibility to authorise vehicles in conformity to the new vehicle type or version is limited to existing vehicles (already authorised or in operation before 19 July 2010 in the original area of use). Newly built vehicles shall comply with the latest TSIs in force (including transitional provisions) or benefit from a non-application of the concerned TSIs.

In all cases, the vehicles seeking an extension of the area of use shall:

- › remain authorised or in operation in the original area of use;
- › have a valid registration in the National Vehicle Register or in the European Vehicle Register, and
- › have been maintained in a safe state of running, in accordance with Regulation (EU) 2019/779, where applicable; this aspect should be managed by the concerned RU(s) under the provisions of their SMS.

3.3.2.3.3. *Change in the area of use that requires modifications in the vehicle and/or vehicle type*

When an entity managing the change wishes to change (rather than extend) the area of use of an already authorised vehicle, performing some changes in order to make the vehicle compatible with the new area of use, and the modified vehicle will not remain authorised in the original area of use, it should not be considered as an extension of the area of use.

The extension of the area of use pursuant to article 14(1)(c) of Regulation (EU) 2018/545 and to article 21(13) of Directive (EU) 2016/797 refers to extending the area of use of a vehicle that is already authorised. This is not the case in the described scenario: the modified vehicles are not authorised in the original area of use, and in some cases, they cannot actually be authorised in original area of use, as after the changes necessary to make them compatible with the networks in the new area of use they are no longer technically compatible with the networks of the original area of use.

The authorisation case should be a new authorisation following article 14(1)(d) of Regulation (E) 2018/545, although some of the concepts of the extension of the area of use pursuant to article 14(1)(c) of the Regulation are applicable as well:

- › the technical compatibility with the network in new area of use needs to be assessed (as it would be the case of an extension of the area of use), and
- › there is no need to apply for a new authorisation in the original area of use (in case this would be technically possible) because the modified vehicles will not be operated there anymore.

If the area of use of the modified vehicle and/or vehicle type will be limited to 1 MS, the applicant can choose which entity can be the authorising entity: the Agency or the NSA. If the new area of use covers more than 1 MS, then the applicant should apply to the Agency for a new authorisation pursuant to article 14(1)(d) of Regulation (E) 2018/545 with an area of use covering such MSs.

There is no need to request a new authorisation in the original area of use because the changes are only necessary for the new area of use; the vehicles that were already authorised in the original area of use will not be changed and remain in conformity with the authorised vehicle type covering the original area of use.

The new type or variant of a vehicle type that will be authorised as a result of the new authorisation cannot be used to extend the area of use back to the original one.

The assessments to be performed should be limited to:

- › the requirements applicable to the changed parts (and the interfaces with the modified parts);
- › For rolling stock - locomotives and passenger coaches: the requirements defined in sections 7.1.4(1), (2), (3), (4) and (6) of LOC&PAS TSI;
- › For rolling stock - freight wagons: the requirements defined in sections 7.2.2.4(1), (2),(3),(4) and (6) of WAG TSI, and
- › For the control-command and signalling subsystem: the requirements defined in sections 7.4.2.3, 7.4.3 and 7.4.4 of CCS TSI.

3.3.2.4. New authorisation case – 14(1)(d)

A new authorisation is required in the following cases:

- › Changes to an already authorised vehicle type and/ or vehicle that meet the criteria set up in Article 21(12) of Directive (EU) 2016/797.
- › A new vehicle type is created based on an already authorised vehicle type, pursuant to Article 15(4) of Regulation (EU) 2018/545.

Decision criteria if a new authorisation is required according to the criteria of Article 21(12) of Directive (EU) 2016/797:

- a) *“Changes are made to the values of the parameters referred to in point (b) of paragraph 10 which are outside the range of acceptable parameters as defined in the TSIs”*

A new authorisation is required if the values for the basic design characteristics are out of the range specified in the TSIs, see section 3.2.2.2

- b) *“The overall safety level of the vehicle concerned may be adversely affected by the works envisaged”*

The actors should ensure that “railway safety is generally maintained and, where reasonably practicable, continuously improved” therefore, a change should not be contemplated if it **will** adversely affect the overall level of safety of the vehicle concerned.

It can thus be inferred that this clause relates to the **potential** to adversely affect the overall level of safety of the vehicle concerned, and not to whether the change in its real implementation will actually have a negative impact on safety or not.

An entity managing a change, when deciding if Article 21(12)(b) is triggered or not, should not take into consideration the activities undertaken to ensure that safety will not be adversely impacted (calculation notes, simulations, tests, involvement of conformity assessment bodies etc.). Considering such activities would mean that the decision is taken after the change is implemented, verified and validated (an “ex-post” evaluation). However, such activities always take place regardless of the authorisation case, yet there is a need for an authorising entity to issue an authorisation. The Article 21(12)(b) concerns the potential of a change to impact safety adversely before its implementation, verification and validation (“ex-ante” evaluation), and the associated need for an authorising entity to deliver an authorisation when the potential exists. The Article 21(12)(b) does not relate to whether a change actually impacts or not safety in the end, because the level of safety shall be maintained and improved where possible, which means that a change that decreases the level of safety shall not be implemented.

To evaluate whether the overall level of safety of the vehicle concerned may be affected, the entity managing the change should use its requirements capture process for the essential requirement safety and compare the risk assessment before and after the implementation of the change (considering all the activities that are required for the implementation of the change, not only the final solution). When there are no new safety requirements and the (new) risk assessment:

- › Does not contain new hazards/risks;
- › Does not require changes in the existing control or mitigation measures;
- › Does not require new control or mitigation measures for the existing hazards/risks, and
- › The risk acceptance category for each risk remains unchanged

it could be considered that Article 21(12)(b) is not triggered. This assessment should be independently assessed by an AsBo in the framework of the requirements capture process related to essential requirement safety. When it is clear that the change does not have the potential to impact safety without the need to perform any risk assessment, the independent assessment by an AsBo would not be needed.

When there is no existing risk assessment (e.g., vehicles placed on the market under Directive 2008/57/EC or before), the entity managing the change should:

- › Perform the risk assessment of the situation before the change under consideration (limited to the changed parts and the interfaces with the unchanged parts);
- › Perform the risk assessment of the changed vehicle (also limited to the changes and the operations needed to implement the change)
- › Analyse the differences between both risk assessments (for the impacted parts) as mentioned above, concerning new hazards/risks, mitigation measures, etc.

It should be noted that if a change does not affect basic design characteristics, and therefore does not require authorisation on the grounds of rules compliance pursuant to Article 21(12)(a) and/ or (c) of Directive (EU) 2016/797, it may still have the potential to adversely affect the overall level of safety of the vehicle concerned and therefore trigger a new authorisation.

c) *“it is required by the relevant TSIs.”*

See article 4(3)(h) of Directive (EU) 2016/797.

The holder of the vehicle type authorisation can either add a new vehicle type variant to the existing vehicle type or decide to create a new vehicle type. This is an administrative decision of the holder of the vehicle type authorisation. The scope of the assessment is limited to the changes and the interfaces with the unchanged parts, regardless of the choice of the holder.

When the starting point for the new authorisation is a variant of an existing vehicle type, this authorisation case can still be used, but the result of the authorisation process will be a new type (it is not possible to add a new variant to an existing variant of a vehicle type).

From the point of view of the evaluation of Article 21(12) of Directive (EU) 2016/797 and the requirements capture process, all changes implemented in the vehicle and/or vehicle type since the last time it was authorised should be considered. In other words, the starting point for the evaluation of the criteria in Article 21(12) and the applicable requirements is the last authorisation and not the status of the vehicle type and/or vehicle just before the implementation of the last change. It is not mandatory that such (past) changes comply with the rules in force at the moment the application for authorisation is submitted; they should comply with the applicable rules at the moment they were implemented. In any case, all changes performed should be documented and traced to the applicable requirements, and the related evidence should be part of the file accompanying the application.

3.3.2.5. Extended area of use requiring changes to the vehicle and/or vehicle type – 14(3)(a)

When a vehicle and/or vehicle type needs changes to enable it to be authorised and operate over an extended area of use in another MS(s) then the holder of the vehicle type authorisation will need to apply for both a new authorisation (case (d)) and an extension of area of use (case (c)), pursuant to Article 14(3)(a) of Regulation (EU) 2018/545. For this case, the Agency should be the authorising entity. Only the elements of the vehicle and/or vehicle type that are changed, their interfaces with the unmodified parts, the compatibility with the networks to which the area of use is to be extended and the requirements when particular rules for the extension of the area of use apply (see section 3.3.2.3) should be checked.

The application for the combined new and extended area of use authorisations could be sent at the same time but the authorising entity should take care of the correct sequence for issuing the authorisations. The extension of an area of use can only be performed for a vehicle and/ or vehicle type that is already authorised.

When issuing the vehicle type authorisation for the combined case, the OSS will generate two EINs: one of them will correspond to the new authorisation following the changes to the vehicle and/or vehicle type, and another one to the extension of the area of use of the newly authorised vehicle type/or variant mentioned above. Both EINs can be referred to in a single authorisation document (the two legal acts are included in a single document); it's also possible to issue two independent authorisation documents, each with its own EIN.

3.3.2.6. Authorisation in conformity to type case – 14(1)(e)

The authorising entities issue the authorisation in conformity to type for a vehicle or a series of vehicles on the basis of a declaration of conformity to vehicle type (based on the relevant modules e.g., SD, SH1) submitted by the applicant.

An authorisation in conformity to type can only be issued as long as the vehicle type authorisation and the EC certificates for subsystems and ICs (including QMS approval) were valid when the application is submitted or when the concerned IC was placed on the market (see section 3.11.2.2). If a change in the rules renders a vehicle type authorisation invalid, then the vehicle type will need a renewed authorisation before further vehicles can be authorised in conformity to type.

The declaration of conformity to vehicle type can only be issued by the applicant after the production of the vehicle or series of vehicles (if the applicant decides to include several vehicles in a single application for authorisation) conforming to the vehicle type. Due to this, it is not possible to apply for an authorisation in conformity to type in advance of a planned production of a vehicle or a series of vehicles, because the declaration of conformity to the vehicle type is part of the file accompanying the application for authorisation. In other words, the vehicles should exist and should have undergone all the applicable conformity assessments (e.g., serial testing).

An applicant for an authorisation in conformity to type should verify whether:

- › There are provisions in TSIs and national rules that may render the vehicle type invalid or impose limitations on the placing on the market of vehicles which do not comply with the latest requirements, and
- › There is enough information (drawings, technical specifications, etc.) related to the design and manufacturing process to sign the declaration of conformity to an already authorised type.

3.3.2.6.1. *Vehicles from heterogeneous origin modified to conform to a single vehicle type*

Vehicles from a heterogeneous origin (e.g., vehicles originally identical that then evolved differently over time, vehicles with some similarities but with relevant differences, etc.) that are changed to conform to a single vehicle type may require different modifications to arrive to the final status. Even if the scope of the changes is the same for all concerned vehicles (e.g., the parts that will be modified are identical in all of them), the modified vehicles may not conform to the same vehicle, because there may be other relevant differences. In such cases, there should be a reference vehicle type for each group of (homogeneous) vehicles. The entity managing the change can then submit an application for authorisation for placing on the market independently for each (homogeneous) group of modified vehicles.

When the modification process includes restoring the vehicles to a status in which they would be homogenous (i.e., setting up a common starting point), such modifications should be:

- › Part of the design process;
- › Subject to surveillance of the QMS by the NoBo, and
- › Covered by the related vehicle type authorisation.

When the different starting points (and subsequent operations to arrive to the target status) are already taken into account in the design, the production, the NoBo surveillance and the vehicle type authorisation, the modified vehicles will be homogeneous and conform to the same vehicle type.

3.3.2.6.2. *Applications in conformity to type where the applicant is not the vehicle type holder*

Intellectual property rights are not linked with the practical arrangements for vehicle authorisation, this is a commercial/contractual issue. The Directive (EU) 2016/797 and the Regulation (EU) 2018/545 do not prohibit that an entity other than the holder of the vehicle type authorisation builds new vehicles conforming to a type that they don't hold and/or submits an application for authorisation in conformity to such type as long as they have the necessary:

- › knowledge and information to build the vehicles and issue the declaration of conformity to type, and
- › documentation to submit an application for authorisation respecting the requirements of Annex I of Regulation (EU) 2018/545 (i.e., EC certificates of verification, including QMS approval, covering the relevant manufacturing sites), see section 3.11.1.

The content of the file accompanying the application for authorisation is the same irrespective of whether the applicant is the holder of the vehicle type authorisation or not. It is the sole responsibility of the applicant to secure that it has enough information and knowledge to ensure that the vehicles in the scope of the application are conforming to the authorised vehicle type; the authorising entity should not assess this aspect.

The applicant for authorisation in conformity to type does not become the holder of the vehicle type authorisation.

3.3.2.6.3. *Subsequent authorisation in conformity to type*

When assessing an application for authorisation for placing on the market in conformity to an authorised vehicle type, the authorising entity has the choice to indicate in the OSS webform if it is the case of a subsequent application or not.

A subsequent application means that this authorisation follows a previous (first) application for authorisation in conformity to type for which the authorising entity has already issued the corresponding vehicle authorisation.

In such case, most of the subsequent application and the file accompanying the application is identical to the (first) application one already assessed positively. Usually, the differences relate only to the identification of the vehicles seeking authorisation and to the EC declaration of conformity; there can be more differences for cases where there was a need to update the EC certificates due to 15(1)(b) changes or there are different provides for ICs.

This would allow authorising entities to process the application in a more efficient way (e.g., it's mostly a comparison exercise against the preceding application, if documents are still valid and consistent with the information in ERATV and ERADIS). The OSS will produce different (simplified) webforms for subsequent applications in conformity to type.

The following conditions to consider a conformity to type application as subsequent are recommended:

- › The applicant, the contact person of the applicant identified in the OSS and the reference type should be the same as in the related first conformity to type application;
- › When the time elapsed since the first conformity to type application and/or the previous subsequent conformity to type application is more than 12 months, an application in conformity to type should be treated always as a first conformity to type;
- › After a number of subsequent applications in conformity to type have been processed (i.e., 10), the next conformity to type application should be considered a first conformity to type application.

The decision of an authorising entity to classify an application in conformity to type as subsequent is taken considering the conditions above but also the experience from previous applications for the same vehicle type and/or applicant.

3.3.3. Article 15: Changes to an already authorised vehicle type

1. Any changes to an authorised vehicle type shall be analysed and categorised as only one of the following changes and shall be subject to an authorisation as provided below:
 - (a) a change that does not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems. In this case there is no need for verification by a conformity assessment body, and the initial EC declarations of verification for the subsystems and the vehicle type authorisation remain valid and unchanged;
 - (b) a change that introduces a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules but which do not have any impact on the basic design characteristics of the vehicle type and do not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797;
 - (c) a change in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797;
 - (d) a change that requires a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.
2. When a change falls under point (b) or (c) of paragraph 1, the technical files accompanying the EC declarations for verification for the subsystems shall be updated and the holder of the vehicle type authorisation shall keep available the relevant information upon request of the authorising entity and/or the NSAs for the area of use.
3. When a change falls under point (c) of paragraph 1 the holder of the vehicle type authorisation shall create a new vehicle type version or a new version of a vehicle type variant and provide the relevant information to the authorising entity. The authorising entity shall register in ERATV the new version of the vehicle type or the new version of the vehicle type variant in accordance with Article 50.
4. If the entity managing the change is not the holder of the vehicle type authorisation and the changes made to the existing vehicle type are categorised as (b), (c) or (d) of paragraph 1, the following shall apply:
 - (a) a new vehicle type shall be created;
 - (b) the entity managing the change shall become the applicant; and
 - (c) the application for authorisation of the new vehicle type may be based on the existing vehicle type and the applicant may choose the authorisation case specified in Article 14(1)(d).

3.3.3.1. Responsibility for managing changes to an authorised vehicle type

Changes to an authorised vehicle type should be covered by the configuration management of the vehicle type. The configuration management of an authorised vehicle type is the responsibility of the holder of the vehicle type authorisation. The categorisation of the change is the responsibility of the entity managing the change (which can be the holder of the vehicle type authorisation or not).

When the entity managing the change decides that the change does not trigger the criteria in Article 21(12) of Directive (EU) 2016/797 and does not introduce a deviation in the technical file(s) accompanying the EC DoV(s), it only takes responsibility for the management of the change.

When the entity managing the change:

- › Decides that the criteria are triggered and a new authorisation is required;
- › Identifies that there is an impact on the technical file(s) accompanying the EC DoV(s), and/ or
- › Is not the holder of the vehicle type authorisation;

it should establish the EC DoV(s) for the affected mobile subsystem(s) (including non-modified parts) and submit an application for vehicle type authorisation and/ or vehicle authorisation for placing on the market.

It should be noted that pursuant to Article 15(5) and Annex IV 2.3.3 of Directive (EU) 2016/797, Decision 2010/713/EU (e.g., module SB point 8) and Article 6 of Regulation (EU) 2019/250, the applicant for placing on the market a (modified) mobile subsystem is responsible for:

- › Appointing a NoBo and/or a DeBo for performing the EC verification procedure of the modified parts and the interfaces with the unmodified parts, if the modification affects the conformity with the applicable TSIs and/or national rules (if this happens, a new EC certificate is needed);
The responsibility of defining the scope of the certification lies with the applicant. It is not in the scope of a NoBo/DeBo to request evidence from the applicant to ensure the completeness and adequacy of the contracted certification.
- › Informing the NoBo and/or the DeBo that performed the original EC verification if the changes impact the conformity assessments already performed, and
- › Deciding if a new EC DoV for the modified subsystem is necessary.

The applicant for placing on the market a (modified) mobile subsystem shall also analyse if there are other applicable laws or requirements that are impacted by the change and require further assessments to be performed (see sections 3.3.1.3 and 3.3.1.4). Similarly, the applicant for authorisation, in the framework of the requirements capture process, shall also ensure that there are no other requirements (e.g., EU law) applicable to the vehicle and/or vehicle type that needs to be taken into account.

3.3.3.2. The categories of changes to an authorised vehicle type

In the framework of the Regulation (EU) 2018/545, the concerned authorising entity should not assess the decision taken by the entity managing the change regarding the classification of the change nor agree/disagree with it. The responsibility of the classification of the change in one of the categories described in article 15(1) of the Regulation lies with the entity managing the change. The exception to this rule is the assessment of notifications of changes pursuant to Article 16(4) of Regulation (EU) 2018/545, where the concerned authorising entity needs to evaluate the correct categorisation of the change, see section 3.3.4.1. This is further described in the flowchart for Substage 1.1, section 4.

A modification in the documentation that was part of the file accompanying an application for a vehicle type authorisation that is not related to a modification in the technical characteristics of the vehicle type should not be considered a change to the vehicle type in the framework of Article 15(1) of Regulation (EU) 2018/545.

The technical file accompanying the EC DoV is constituted by the documents (drawings, diagrams, descriptions, calculations, functional specifications, technical specifications, test reports, simulation reports etc.) that allowed the conformity assessment bodies to evaluate conformity with the mandatory rules (TSIs and national rules) and the applicants to establish conformity with the applicable EU law. Changes in such documents introduce differences in the technical file as compared to the one that forms the basis for the issued vehicle type authorisation. Such differences do not constitute “deviations” in the sense of Article 15(1) of Regulation (EU) 2018/545 when they are of editorial nature and relate to correction of errors in the documents (e.g., correction of typographic errors or other spelling mistakes, update of incorrect references to other documents, wording improvements etc.). Any other modification of the documents that constitute the file accompanying the EC DoVs should be considered as a deviation.

When in order to establish if basic design characteristics are impacted below the thresholds specified in the TSIs there is a need for a reference value, i.e., the value for the concerned parameter before the change, but there is no vehicle type authorisation nor an EC DoV and accompanying technical file (including an assessment by a NoBo), it should be assumed that the changes are beyond the thresholds hence a new authorisation pursuant to Article 21(12)(a) would be required.

3.3.3.2.1. *Changes that do not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems – 15(1)(a)*

This category of change has no impact on the verifications performed and consequently on the vehicle and/or vehicle type or the documentation that forms the basis for the issued vehicle type authorisation (namely the file accompanying the application for authorisation, which includes the technical files accompanying the EC DoV(s) for the subsystem(s)), therefore it does not have to be included in the configuration management of the vehicle type. However, the change is part of the maintenance of the vehicle(s) and needs to be covered by the configuration management of the vehicle(s).

Changes to vehicles authorised under previous regimes and not subject to an EC verification procedure, hence not covered by an EC DoV, can still be classified pursuant to Article 15(1)(a) or Regulation (EU) 2018/545, despite the fact that in this case there will be no accompanying technical files, if there is no need to perform new verifications by a conformity assessment body.

3.3.3.2.2. *Changes that introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems but do not impact basic design characteristics nor require a new authorisation – 15(1)(b)*

For changes classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545, when the entity managing the change is the holder of the vehicle type authorisation, there is neither a need to apply for a new authorisation nor to request the creation of a version in ERATV. This because the design (basic design characteristics) is still considered to be conforming to the already authorised type, despite the changes brought by the holder.

However, there is an impact on the documentation that forms the basis for the issued vehicle type authorisation, the technical file accompanying the EC DoV(s) for the mobile subsystem(s), therefore it is to be covered by the configuration management of the vehicle type. The holder of the vehicle type authorisation shall perform its legal duties: ensuring that the authorised vehicle type keeps meeting the essential requirement during its lifespan, that the documentation related to the type and the associated data is always up to date. These obligations also include inter-alia:

- › Document the change, the assessments performed and the rationale behind the decision for categorising the change (i.e., requirements capture and application of CSM RA);
- › Provide the documentation related to the change to the authorising entity upon request;
- › Inform the NoBo(s) that issued previous certificate(s)

This category of change may impact the conformity of the subsystems with the mandatory rules or the validity of certificates of conformity. In such case, the conformity assessment bodies shall perform the necessary verifications and issue the relevant certificates; the corresponding ERATV entries shall be updated, see section 3.8.4.1.3.

The applicant for placing on the market of the mobile subsystems can decide whether there is a need or not for a new EC DoV for the mobile subsystem(s) following a 15(1)(b) change. The NoBo that issued the type or design examination certificate is responsible to decide if the previously issued certificate remains valid after the 15(1)(b) change. That being said, if the references of the certificate(s) and/or the technical file accompanying the EC DoV(s) are modified, it is expected that the EC declaration are updated as well, as they normally contain the references to the certificate(s) and to the accompanying technical file(s).

Please note that the LOC&PAS and WAG TSI establish thresholds for certain basic design characteristics below which the change, despite impacting a basic design characteristic, can still be classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545, e.g.:

- › Increase in minimum horizontal curve radius > 5 m: 15(1)(c) change
- › Change in braking performance above +/- 10%: 15(1)(c) change

- › Increase in minimum horizontal curve radius < 5 m: 15(1)(b) change
- › Change in braking performance within +/- 10%: 15(1)(b) change

1. TSI clause	2. Related basic design characteristic(s)	3. Changes impacting the basic design characteristic and not classified as 21(12)(a) of Directive (EU) 2016/797	4. Changes impacting the basic design characteristic and classified as 21(12)(a) of Directive (EU) 2016/797
4.2.3.6. Minimum curve radius	Minimum horizontal curve radius capability	Increase of minimum horizontal curve radius of more than 5 m	N/A
4.2.4.5.5 Braking performance – Parking brake	Maximum gradient on which the unit is kept immobilized by the parking brake alone (if the vehicle is fitted with it)	Change of declared maximum gradient of more than ± 10 %	N/A

Figure 7: LOC&PAS TSI table 17a examples of changes in BDCs to be classified as 15(1)(b)

Changes to vehicles authorised under previous regimes and not subject to an EC verification procedure, hence not covered by an EC DoV, can still be classified pursuant to Article 15(1)(b) or Regulation (EU) 2018/545 if there is a need for conformity assessment bodies to perform verifications (which would impact the technical file accompanying the EC DoV if there would be any) but basic design characteristics are not impacted.

3.3.3.2.3. A change in the basic design characteristics of the vehicle type that does not require a new authorisation – 15(1)(c)

This category of change has an impact on the basic design characteristics and it has an impact on the documentation that forms the basis for the issued vehicle type authorisation. The changes to the vehicle and/or vehicle type do not trigger the criteria set out in Article 21(12) of Directive (EU) 2016/797 for when a new authorisation is required. It is to be covered by the configuration management of the vehicle type. A new version of the vehicle type or a new version of a variant of the vehicle type should be created, see section 3.8.4.1.1.

3.3.3.2.4. A change of the vehicle type that requires a new – 15(1)(d)

The changes trigger the criteria set out in Article 21(12) of Directive (EU) 2016/797 for when a new authorisation is required, see section 3.3.2.4. It is to be covered by the configuration management of the vehicle type.

This is also applicable for vehicles authorised before the implementation of Directive (EU) 2016/797, see recital (16) of Regulation (EU) 2018/545.

3.3.3.3. Changes managed by an entity which is not the holder of the vehicle type authorisation

Should an entity which is not the holder of the existing vehicle type authorisation wish to make a change to the vehicle type and/ or to the documentation that forms the basis for an issued vehicle type authorisation (change category (b), (c), (d) or change (extend) the area of use) it can:

- › Ask the existing holder of the vehicle type authorisation to manage the change for them in which case the existing holder of the vehicle type authorisation remains the holder of the vehicle type authorisation; or
- › Manage the change itself. In this case, the entity requests the authorisation of a new vehicle type and becomes the applicant. This entity becomes holder of the vehicle type authorisation for the new vehicle type and takes the responsibility for the configuration management of the new vehicle type as a whole.

This means that for:

- › Further changes to the newly authorised vehicle type are out of the scope of Article 15(4) of Regulation (EU) 2018/545, because the entity managing such changes will also be the holder of the vehicle type authorisation, and
- › The holder of the newly authorised vehicle type can also apply for authorisation for placing on the market of vehicles in conformity to the new type, pursuant to Article 14(1)(e) of Regulation (EU) 2018/545, both for changes to existing vehicles (to render them conform with the new type) and for newly manufactured vehicles.

The entity managing the change will need to ensure that:

- › The vehicle type authorisation for the vehicle type it wishes to base its new authorisation on is still valid for the intended scope of the new authorisation, and
- › It has sufficient information (documentation) concerning the vehicle type to make the change in order for the new vehicle type to fulfil the requirements and for the configuration management of the new vehicle type (see section 3.3.2.6.2).

Another entity can make changes to the vehicle type on behalf of the holder of the vehicle type authorisation as long as the necessary contractual arrangements are put in place, but the holder of the vehicle type authorisation will be the applicant for authorisation of the new vehicle type or new variant of a vehicle type. In such case, the role of holder of the new vehicle type authorisation will remain allocated to the entity that holds the existing vehicle type authorisation.

Table 4 : Summary of categories of changes to vehicle types and authorisation cases

Change	Entity managing the change	
	Holder of the vehicle type authorisation	Not holder of the vehicle type authorisation
Category 15(1)(a)	No change to vehicle type. No authorisation.	
Category 15(1)(b)	No change to vehicle type. No authorisation. Technical files accompanying the EC declarations for verification of the subsystems and ERATV entry should be updated. Information should be made available to authorising entity and/or NSAs for the area of use upon request	Entity managing change becomes the applicant. Apply for first authorisation or a new authorisation of a vehicle type (new type).
Category 15(1)(c)	Request creation of a new version of vehicle type or a new version of a vehicle type variant. Provide relevant information to the authorising entity. The authorising entity registers the new version of the vehicle type or vehicle type variant in ERATV	Entity managing change becomes the applicant. Apply for first authorisation or a new authorisation of a vehicle type (new type).
Category 15(1)(d)	Apply for new authorisation. (May choose first authorisation)	Entity managing change becomes the applicant. Apply for first authorisation or a new authorisation of a vehicle type (new type).

3.3.3.4. Possibilities to create variants and versions from a vehicle or vehicle type

As already explained in sections 3.2.2.13, 3.2.2.14 and 3.2.2.16, the possibilities to create variants or versions are limited due to the definitions of variant, version, authorisations cases new authorisation and authorisation case extension of the area of use, together with the provisions in Article 14(2) and 15(4) of the Regulation (EU) 2018/545 making a difference depending on whether the entity managing the change or the applicant are the holder of the existing vehicle type authorisation or not.

The following schematic, which complements table 5 in section 3.3.3.3, summarizes the different possibilities for creating variants and versions, considering also whether the entity managing the change is the holder of the vehicle type authorisation or not.

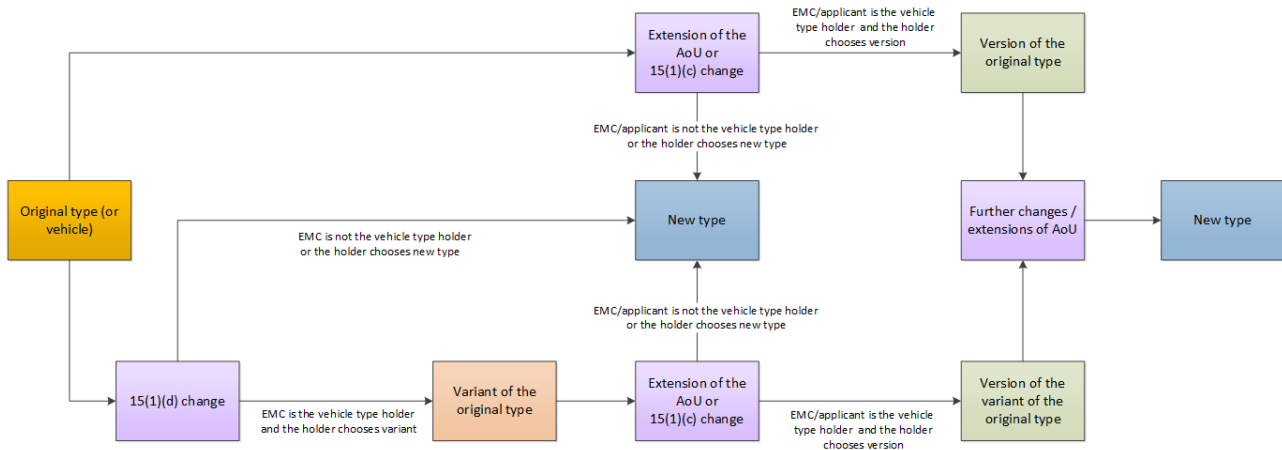


Figure 8: Possibilities for creating variants and versions

3.3.4. Article 16: Changes to an already authorised vehicle

1. Changes to an already authorised vehicle which are linked to substitution in the framework of maintenance and limited to replacement of components by other components fulfilling identical functions and performances in the framework of preventive or corrective maintenance of the vehicle do not require an authorisation for placing on the market.
2. Any other changes to a vehicle shall be analysed and categorised in accordance with Article 15(1).
3. The entity managing the change shall request a new authorisation for placing on the market in accordance with Article 14(1)(d) when a change falls under Article 15(1)(d).
4. If the entity managing changes categorised in accordance with Article 15(1)(b) and (c) to an already authorised vehicle is not the vehicle type authorisation holder it shall:
 - (a) assess the deviations from the technical files accompanying the EC declarations for verification for the subsystems;
 - (b) establish that none of the criteria set out in Article 21(12) of Directive (EU) 2016/797 are met;
 - (c) update the technical files accompanying the EC declarations for verification for the subsystems;
 - (d) notify the changes to the authorising entity.

This may apply to a vehicle or a number of identical vehicles.

The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information.
5. Every change to a vehicle shall be subject to configuration management under the responsibility of the keeper or of the entity entrusted by it.

3.3.4.1. Notification of changes to vehicle(s) according to Article 16(4) of Regulation (EU) 2018/545

Article 16(4) of Regulation (EU) 2018/545 applies to entities managing changes that are not holders of the concerned vehicle type authorisation. This can occur either when there is no vehicle type authorisation (e.g., vehicle authorised before Directive 2008/57/EC) or when the entity managing the change is a different organisation than the holder of the vehicle type authorisation. When the entity managing the change is the holder of the vehicle type authorisation, Article 16(4) cannot be applied.

For cases where the entity managing the change is not the holder of the vehicle type authorisation, it shall make a choice between:

- › Applying for a new authorisation, pursuant to Article 15(4). The entity managing the change will become the holder of the new type that will be authorised. The new type can be used for the subsequent authorisation of vehicles in conformity to that type
- › Submitting a notification pursuant to Article 16(4), which can cover a number of identical vehicles. In this case, the entity managing the changes does not become the holder of any type (as there is no new type to be authorised). For subsequent (identical) vehicles, the entity managing the change can submit new notifications.

The legal framework does not impose any limit on the number of vehicles to be covered by a notification, nor on the number of notifications that can be submitted (e.g., to cover the whole fleet of identical vehicles).

In case of changes classified pursuant to Article 15(1)(c) or Regulation (EU) 2018/545, when the entity managing the change is not the holder of the vehicle type authorisation, it is not possible to request the creation of a version in ERATV pursuant to Article 15(3). The entity managing the change shall make the choice between a new authorisation or a notification, as described above.

The notifications of changes to vehicles pursuant to Article 16(4) of Regulation (EU) 2018/545 should be sent by the entity managing the change to the authorising entity that would be concerned if an application for authorisation would be required. In the case where the notification is to be addressed to the Agency acting as authorising entity, the process for submitting a notification is described on the website of the Agency:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=948

In the case where the notification is to be addressed to the concerned NSA acting as authorising entity the entity managing the change should contact the concerned NSA to establish where to send the notification.

Where the Agency as authorising entity has received the notification, the authorising entity may need to consult with the concerned NSAs for the area of use in those cases where it is necessary to check the parameters according to national rules. The concerned NSAs for the area of use should provide to the authorising entity the results of their assessment for the following aspects:

- › The applicable national rules are properly identified in the form for submission of the notification;
- › The national rules applied for the conformity assessment of the changes are the ones in force at the time of submission of the notification;
- › The applicable national rules do not require a new authorisation for the changes in consideration, and
- › National rules are properly considered in the requirements capture process for the essential requirement safety and the safe integration between subsystems

The concerned NSAs for the area of use should respond to the request without undue delay and at least within 1 month of the request.

The entity managing the change can implement the change subject to notification and the modified vehicles can be used immediately after, there is no need to wait for a reasoned decision from the concerned authorising entity. However, if the result of the assessment of the authorising entity is that the categorisation performed by the entity managing the change is wrong, and that the change triggers article 21(12) of Directive (EU) 2016/797 and requires a new authorisation, the entity managing the change shall submit an application for authorisation through the OSS, without prejudice of Article 26 of Directive (EU) 2016/797 and Article 53 of Regulation (EU) 2018/545 (the authorisation of the already modified vehicles may be suspended, depending on the particularities of the changes and the corrective measures proposed by the RU).

It should be noted that when the entity managing the change makes a change to a vehicle categorised in accordance with Article 15(1)(c) and based on the definition of vehicle type in Article 2(26) of Directive (EU) 2016/797, the vehicle will no longer belong to and be in conformity with the authorised vehicle type.

3.3.4.2. Bringing a vehicle in conformity to another vehicle type version (created following a 15(1)(c) change)

Considering that changes that are classified pursuant to Article 15(1)(c) of Regulation (EU) 2018/545 do not trigger the need for a new authorisation but the need to publish a version in ERATV (pursuant to Article 15(3) of Regulation (EU) 2018/545), the existing vehicles conforming to the parent type that are modified to be conform to a version of a type do not require a new authorisation for placing on the market in conformity to the version. The keeper shall update the registration in NVR/ECVVR/EVR in order to make reference to the newly created version (rather than to the parent type).

However, vehicles that are newly built in conformity to a version of vehicle type/variant version need to receive an authorisation for placing on the market, pursuant to Article 14(1)(e) of Regulation (EU) 2018/545.

3.3.4.3. Bringing a vehicle in conformity to another vehicle type

Considering that changes to an authorised vehicle that are classified pursuant to Article 15(1)(d) of Regulation (EU) 2018/545 trigger the need for a new authorisation, moving vehicles between different vehicle types (i.e. performing the necessary changes in vehicles to make them conform to another type) and/or variants of different types where the target type/variant is not yet authorised cannot be managed by means of the authorisation case referred to in Article 14(1)(e) of the Regulation (EU) 2018/545. The new vehicle type/variant shall be authorised first.

Changes made to vehicles in order to bring them in conformity to an already authorised variant (or new type deriving from the existing one) of the vehicle type they were previously conforming with will require the issuing of a new declaration of conformity to the vehicle type variant and an application for authorisation for placing on the market in conformity to type/variant pursuant to Article 14(1)(e) of Regulation (EU) 2018/545.

3.3.4.4. Changes to vehicles categorised pursuant to Article 15(1)(b) of Regulation (EU) 2018/545 when the entity managing the change is also the holder of the vehicle type authorisation

When an entity managing a change who is also the holder of the vehicle type authorisation categorises a change according to Article 15(1)(b) of Regulation (EU) 2018/545, there is no need to involve the authorising entity nor to update the vehicle register (NVR/ECVVR/EVR). The change can be implemented without further actions. The keeper remains responsible for ensuring the configuration management of the vehicles though.

3.3.4.5. Changes linked to the substitution in the framework of maintenance

The Article 16(1) of the Regulation (EU) 2018/545 covers changes in vehicles (not vehicle types) related to maintenance, i.e., replacing broken, malfunctioning or worn out components. Where the replacement is 100% identical to the substituted one, such change does not require an authorisation nor any other update in technical files or ERATV. However, in some cases, it is not possible to find 100% identical spare parts in the market (e.g., due to obsolescence, bankruptcy of the manufacturer etc.), and there is a need to use other components with identical functions and performances, although not identical.

In this framework, "identical functions and performances" should be understood as follows: the new component does not have new functionalities itself or add new functionalities to the system into which it is integrated, does not trigger a change in performance (be it an increase or a decrease) nor impacts adversely safety (the level of safety is at least kept, without new hazards/risks). It's meant to be a one to one replacement (same input, same output, same working principles), linked to maintenance (preventive or corrective), and following a "plug & play" approach: remove the old component, install the new one, no other modification or adaptation is needed. The operations to fit the new component shall be identical to those that would be needed to replace it by another 100% identical components. In other words, it's the substitution of an element by an identical one, which may be slightly different due to evolution over time, obsolescence, change of provider etc.) but still equivalent.

The management of changes to vehicles falls into the responsibility of the keeper of the vehicles, and is subject to supervision by NSAs (i.e., if a wrong allocation of a change to category 16(1) of Regulation (EU) 2018/545 is detected, responsibility falls into the keeper and the NSA could trigger the necessary actions pursuant to Article 26 of Directive (EU) 2016/797, including suspension and revocation of the authorisation).

3.3.5. Article 17: Identification of the rules including non-application of TSIs

1. Based on the choice of the authorisation case in accordance with Article 14 and the requirements capture set out in Article 13 the applicant shall identify all applicable rules, in particular the TSIs and national rules.

The applicant shall also consult and take into account the list of TSI deficiencies that is published on the Agency website.

In that case, the applicant shall identify the acceptable means of compliance issued by the Agency that is to be used in conjunction with the TSIs for the vehicle type authorisation and/or vehicle authorisation for the placing on the market process when establishing compliance with the TSIs.

2. The applicant shall identify any case which requires the non-application of TSIs and submit its application to the concerned Member States in accordance with the provisions of Article 7 of Directive (EU) 2016/797. When non-application of TSIs concerns vehicles with an area of use covering more than one Member State, the authorising entity and the concerned NSAs for the area of use of the vehicle have to coordinate with the applicant on the alternative measures to take in order to promote the final interoperability of the project.
3. When a new version of a TSI provides for transitional measures, the applicant may already select requirements from this new version of that TSI during the transitional period, if this new version explicitly allows it.
4. Where, pursuant to paragraph 3, requirements from a newer version of a TSI are selected the following shall apply:
 - (a) the applicant may select the requirements to be applied from different versions of a TSI and shall:
 - i. justify and document the consistency between the sets of requirements selected from different versions of a TSI to be applied;
 - ii. specify the partial selection of requirements from different versions of a TSI in the application for authorisation as required by Annex I;
 - iii. where there is a pre-engagement baseline and where relevant, the applicant shall request to the authorising entity an amendment or update of that pre-engagement baseline for the concerned TSI in accordance with the provisions in Article 24(4).
 - (b) the authorising entity when assessing the application shall check the completeness of the TSI requirements proposed by the applicant;
 - (c) the applicant shall not be required to submit a request for non-application of the TSI pursuant to Article 7 of Directive (EU) 2016/797 for those requirements.
5. Where this is provided for by the Member State legislation, the applicant may select requirements from different national rules in the same way as laid down in paragraph 3 for TSIs.
6. The applicant and the notified body or bodies may use the acceptable means of compliance referred to in Article 6(3) of Directive (EU) 2016/797 in the context of an EC verification of conformity, pending the adoption of the concerned TSIs.
7. The applicant and the designated body or bodies may use the acceptable national means of compliance referred to in Article 13(2) of Directive (EU) 2016/797 in the context of demonstrating compliance with national rules.

The applicant is responsible for identifying and ensuring that all applicable requirements are met. This does not prevent the applicant from seeking support, advice or consultancy services from third parties.

3.3.5.1. Identification of the applicable rules

The applicable rules are those in force when the applicant submits its request (the application) through the OSS, pursuant to Article 4(2) of Directive (EU) 2016/797. The TSIs contains specific provisions that allow, under certain circumstances, to apply previous versions of the TSIs; further guidance can be found in section 3 of the guidelines for the application of the LOC&PAS and WAG TSIs.

For the categorisation of changes pursuant to Article 15(1) of Regulation (EU) 2018/545 in vehicles authorised before 2008/57/EC or placed in service before 19 July 2010 (i.e., non-TSI compliant vehicles), the rules to consider are the ones in force when the entity managing the changes performs the analysis. This also includes the evaluation of the effect of the changes in the unchanged parts.

To take into account that vehicle authorisation projects often have a long duration from the identification of the applicable rules to the submitting the request through the OSS, the rules (TSIs and national rules) should have transition arrangements specified. There is also a possibility for non-application of TSIs according to Article 7 of Directive (EU) 2016/797, see section 3.3.5.4. The case that would be likely to be applicable in between the design phase and the application for authorisation would be Article 7(1)(a) (“...which is at an advanced stage of development or which is subject to a contract in the course of performance on the date of application of the TSI(s) concerned”).

The Reference Document Database (RDD) is nowadays the tool to publish and classify national rules related to vehicle authorisation:

<http://rdd.era.europa.eu/rdd/>

The status of the process of cleaning-up the national rules that are applicable in addition to the TSIs is summarized in the landing page of RDD.

3.3.5.2. Applicability of section 7.1.4 of LOC&PAS TSI to special vehicles such as On Track Machines (OTMs)

Further clarifications can be found in the guide for the application of the LOC&PAS TSI, that is available on the website of the Agency.

3.3.5.3. TSI deficiencies

See sections 2.3 and 2.5 of the guide for the application of the TSIs, available in the website of the Agency (https://www.era.europa.eu/domains/technical-specifications-interoperability_en).

3.3.5.4. Non-application of TSIs

See section 2.4 of the guide for the application of the TSIs, available in the website of the Agency (https://www.era.europa.eu/domains/technical-specifications-interoperability_en).

Where according to Article 7 of Directive (EU) 2016/797 the MS(s) have allowed the applicant not to apply one or more TSIs or parts of them this should only be applicable for a particular project covering a specific series of vehicles and in a defined area of use.

It follows therefore that the vehicle type authorisation will be valid only for the series of vehicles where the MS(s) have allowed the applicant not to apply one or more TSIs or parts of them and in the conditions specified by the non-application requested. If a manufacturer wants to get a new or later series of vehicles of this type authorised, they will need to get a new set of non-application allowances to support a new vehicle type and vehicle authorisation for placing on the market for a vehicle or a series of vehicles authorised in conformity to type.

3.3.5.5. TSIs and National rules

See section 2.7.1 of the guide for the application of the TSIs, available in the website of the Agency (https://www.era.europa.eu/domains/technical-specifications-interoperability_en).

3.3.5.6. Partial selection of requirements from a newer version of a TSI as compared to the TSI applied for the assessment

Further guidance can be found in the guidelines for the application of the TSIs.

3.3.5.7. Acceptable means of compliance

Further guidance can be found in the guidelines for the application of the TSIs.

3.3.5.8. Innovative solutions

Further guidance can be found in the guidelines for the application of the TSIs.

3.3.5.9. Acceptable national means of compliance

See section 2.7.1 of the guide for the application of the TSIs, available in the website of the Agency (https://www.era.europa.eu/domains/technical-specifications-interoperability_en).

3.3.6. Article 18: Identification and definition of the necessary measures to use the vehicle for tests on the network

The applicant shall identify and define, on the basis of national rules for testing, the necessary measures to use the vehicle for tests on the network.

In respect of tests on the network, parameter 1.4 “National requirement for testing” of the above decision includes national rules (where they exist) for tests on the network. The national rules recorded against this parameter provide information on what has to be done/ delivered by an applicant to use a vehicle for tests on the network of a MS.

3.3.7. Article 19: Temporary authorisation to use the vehicle for tests on the network

1. Temporary authorisation to use the vehicle for tests on the network may only be issued by the NSA when it is required and specified in the national legal framework of the Member State.
2. NSAs assessing applications for temporary authorisation to use the vehicle for tests on the network shall do so in accordance with the relevant national legal framework.

When it is necessary to issue a temporary authorisation to use the vehicle for tests on the network the responsibility belongs only to the concerned NSA for the area of use. As specified in Article 21(3) and 21(5) of Directive (EU) 2016/797 the right to request the applicant to conduct tests on the network belongs only to the authorising entity and/ or the concerned NSAs for the area of use. The IM should not request that the applicant should conduct tests on the network and should not impose any technical requirements on the design of a vehicle (see section 3.2.6 for responsibilities of the IM).

Tests on the network are often needed in order to provide evidence of conformity as part of the EC verification of subsystems. They therefore have to take place before the vehicle type is authorised and/ or the vehicle is authorised for placing on the market and before the full suite of evidence of compliance with relevant requirements has been compiled. Currently, depending on the concerned MS and its legal framework, the assurance that the risks of operating the vehicle are being managed can be achieved in different ways, as described in the following sections.

3.3.7.1. Temporary authorisation to use the vehicle for tests on the network

When a MS legal framework specifies that a temporary authorisation is required in order to use the vehicle for tests on the network, it should specify the:

- › Process to be followed;
- › Documentation required, including the format in which it is to be provided;

- › Decision criteria to be applied for issuing a temporary authorisation to use the vehicle for tests on the network; and
- › Timeframes to be respected by the concerned NSA for the assessment.

The timeframe for an NSA to issue a temporary authorisation to perform tests on the network is not defined in the Directive (EU) 2016/797 nor in the Regulation (EU) 2018/545. Once the decision has been made, the RU and IM will require time to put in place the necessary arrangements for the tests on the network. The applicant should take into account the time needed for these processes when planning the timing for its application for temporary authorisation to use the vehicle for tests on the network and carrying out the tests on the network.

The temporary authorisation to use the vehicle for tests on the network is issued for the purposes of testing only: it does not permit a vehicle to be brought into use for the carriage of passengers, freight or for any other purpose for which it is intended to be placed on the market.

It is recommended that the applicant, the concerned RU, the concerned NSA and the IM work together to agree an overall strategy for the temporary authorisation to use the vehicle for tests on the network, so that time scales are not extended by the need to submit a series of applications to cover each stage of the testing separately. Instead, a single application defining the testing milestones with pass/ fail criteria for each can form the basis for a single temporary authorisation to use the vehicle for tests on the network and permit the IM to put the arrangements in place for the full schedule of tests on the network.

3.3.7.2. Application of the railway undertaking's safety management system

Whether or not the national legal framework of a MS includes the legal requirement for a temporary authorisation to use the vehicle for tests on the network, the RU operating the vehicles for tests on the network should use its SMS to manage the risks through the operational planning, asset management and interface arrangements. In the case where the concerned NSA has granted a temporary authorisation to use the vehicle for tests on the network it is not necessary for the RU to duplicate the evaluation of the elements that form part of the national legal framework for the temporary authorisation to use the vehicle for tests on the network.

For the purposes of using vehicles for testing on a network for the area of use, the SMS of the RU should include general arrangements for using vehicles for tests on the network. These will require the preparation of more specific processes and procedures within a test plan which will cover the actual tests on the network to be conducted. If there is no requirement for a temporary authorisation to use the vehicle for tests on the network, then it would be expected that the RU's processes and procedures include the items that would otherwise be specified for a temporary authorisation to use the vehicle for tests on the network (see section 3.3.7.1 above). They will in all cases have to apply the CSM RA to evaluate the impact of using the vehicle for tests on the network and whether they constitute a significant change that requires the application of the risk management process of the CSM RA (below).

Any residual operational risks arising from the using the vehicle for tests on the network should be managed through the SMS, for example:

- › Interfaces with the IM;
- › The selection of the driver/ driver manager controlling the train movements during the tests on the network;
- › The role of other persons permitted to be on board the train;
- › The arrangements to start and finish the tests on the network including how the vehicle will travel between its stabling location and the test site; and
- › Emergency arrangements including the steps to be taken if any agreed safety parameters are exceeded.

The SMS will include the processes to be followed to ensure that all parties who can be affected by the tests on the network have been consulted and that the agreed arrangements have been effectively communicated.

3.3.7.3. Assessment of the risks

The use of a vehicle for tests on the network means that there are aspects of the vehicle that are not fully known, such as the performance of the braking system or the effectiveness of communication between on-board and ground-based systems: this is why the tests on the network are required. The safety management process, which includes risk assessments, provides a structured way of identifying the means to control the risks that would normally be managed through the application of rules, and so may form part of the concerned NSA's process for issuing a temporary authorisation to use the vehicle for tests on the network. Similarly, it may be part of the RU's and IM's arrangements for managing safety where no process for issuing a temporary authorisation to use the vehicle for tests on the network exists.

The applicant and the RU will have to cooperate to ensure that the evaluation of the risks takes into account the engineering elements of the vehicle and the operational aspects of using the vehicle for tests on the network.

The process of requirements capture and identification of rules that takes place at an early stage of the project will provide a basis for the hazard identification. The hazards that are not yet controlled through compliance with rules may be managed through a combination of risk acceptance principles.

The assessment of risks should take into account whether updates should take place as the tests on the network proceeds. Whether conducted as a single or multiple stage process, an on-going review of the validity of the inputs to the risk assessment forms a part of the arrangements for the management of safety. In the case of tests on the network, the results obtained will indicate whether the conclusions of the risk assessment can continue to be used or if a new assessment is required: for example, geographical variations in the effectiveness of communications systems may indicate that more detailed tests on the network are required, with the potential need to review the risk assessment to support this.

3.3.7.4. The infrastructure manager's arrangements for the tests on the network

In order to request track access to use a vehicle for tests on the network the applicant should consult the national rules referred to under parameter 1.4 of Decision 2015/2299/EU. These rules address the national procedural requirements for tests on the network (see section 3.3.7), and should describe the:

- › Timeframe for access to the infrastructure; and
- › The required information that the applicant should provide to the IM.

The IM should evaluate the nature of the tests to be performed on the network and the conditions required in order to identify and provide, within 3 months of the request:

- › Operational conditions to be applied to the vehicle during the tests on the network such as avoiding operation with the traction system in degraded mode (i.e., a reduced number of converters in service on the test train);
- › Any necessary measures to be taken in relation to the infrastructure to ensure safe and reliable operation during the tests on the network (e.g., not causing disruption to traffic); and
- › Any necessary measures in the infrastructure installations during the tests on the network (e.g., higher than usual voltage in the catenary).

The IM should provide information on the infrastructure to the applicants and the RUs in a non-discriminatory way. This is achieved through recording the relevant information in RINF, the IM's Network Statement, and through the provision of any other relevant information.

If it is needed, the concerned NSAs for the area of use should apply any appropriate measures to ensure that the IM(s) allows the necessary tests on the network to take place within the timescales specified above.

The allocation of train paths is a separate process dealt with by the RU and the IM and it is not covered by the practical arrangements for vehicle authorisation.

3.3.8. Article 20: Identification of the intended conditions for use of the vehicle and other restrictions

The applicant shall identify the intended conditions for use of the vehicle and other restrictions linked to the vehicle type.

Conditions for use of the vehicle and other restrictions are part of the technical characteristics of the vehicle and/or vehicle type and form the boundaries for how the vehicle is intended to be used. The CfUs:

- › Are basic design characteristics, pursuant to Article 48(c)(iii) of Regulation (EU) 2018/545 (see section 3.8.2);
- › Should be formulated in technical terms, not by geographical area (e.g., the line between A and B).
- › Are covered by Decision 2011/665/EU on ERATV by means of:
 - Coded conditions for use and other restrictions (parameter 3.1.2.3), and
 - Non-coded restrictions for use and other restrictions (parameter 3.1.2.4)
- › Might require negotiation and agreement between the applicant, RU, keeper and/or IM, in particular in the case of exported constraints to operation and/or maintenance of the vehicle;
- › Should be considered by the user of the vehicle under its SMS;

There are three broad stages to the identification of CfUs:

- › **Design stage:** during the first stage of the vehicle authorisation process (stage 1: preparation of the application, see section 3.3), the applicant should identify the intended CfUs (such as gauge, maximum speed, speed limits arising from the isolation of parts of the braking system, temperature range etc.) that are applicable, taking into account the technical characteristics of the vehicle and/or vehicle type and its intended operation conditions.
- › **Conformity assessment:** it may be necessary to add further CfUs as a result of the conformity assessment (stage 3: conformity assessment, see section 3.5) in order to comply with the relevant requirements (e.g., limitation in the maximum operating speed in degraded operating conditions such as the unavailability of some brake modules or a limitation in the number of allowed configurations of pantographs, etc.). These CfUs are to be defined by the applicant, in agreement with the concerned assessment bodies. See section 3.5.3 for further information of mitigation of non-conformities with TSIs by means of CfU.

There may be some CfU arising from equipment failure, such as a reduction in speed when the air suspension is deflated, that may be identified as part of the conformity assessment against the harmonised standards that are applicable. It is not intended that the effect of every potential component failure is incorporated into the CfUs. Nonetheless the assessment of these scenarios forms a part of the design process.

Some of the CfUs will be derived from the requirements capture as well as the risk assessment process, in particular, the use of the risk assessment process specified in the Annex I of CSM RA for the safety related requirements (essential requirement safety within the subsystems and safe integration of subsystems).

Where the CfUs are safety related, they should be cross-checked by the concerned AsBo, in order to ensure that they are consistent with the risk assessment process performed by the applicant and do not introduce additional safety risks; role is to check that the risk assessment process set out in Annex I of CSM RA has been applied when required. It is not the role of the AsBo to check whether the CfUs that the applicant has included in the application for vehicle authorisation:

- May hinder the operation of the vehicle from a commercial point of view or not (e.g., reduction in the maximum operating speed, low mileage between maintenance operations, etc.); or
- To perform the technical evaluation of possible CfUs which are necessary to remedy non-conformities with TSIs and/or national rules.

NoBos and/ or DeBos, each for the parts they are responsible for, should also cross-check the CfUs, in order to confirm that they are consistent with the assessments performed (including CfU for ICs and how they are transferred to CfU for subsystems, where relevant). The applicant will then compile the file accompanying the application for authorisation and submit the application for authorisation through the OSS (stage 4: submitting the application, see section 3.6). All the CfU identified until this stage should be specified in the application for authorisation.

CfU should be focused on important aspects that shall be respected in order to ensure that the essential requirements are met (including technical compatibility with the network) and that the subsystems are technically compatible with each other and safely integrated into a vehicle, e.g., operational constraints (speed limitations in degraded modes, pantograph configurations allowed etc.). The applicant should not consider as CfU aspects that do not impose any condition for the operation of the vehicle, or any other restriction, and are rather:

- Observations, remarks or statements from conformity assessment bodies (NoBos, DeBos and/or AsBos) or other parties;
- References to documents (e.g., driver or operation manual, maintenance plan, risk assessment, list of constraints exported to operation, maintenance and/or infrastructure, etc.);
- Duplication of values for technical parameters,
- Etc.

The applicant is responsible for ensuring that the constraints that are exported to other actors and/or activities (e.g., maintenance, operation, etc.) are properly considered in the relevant documents (e.g., maintenance plan, drivers manual, etc.). It should be noted that such exported constraints are not always CfU, from the point of view that they do not impose a condition for the use of the vehicle. Each exported constraint needs to be analysed by the applicant to decide whether they should be considered a CfU in the sense of Article 20 of the Regulation (EU) 2018/545 or not.

The applicant for authorisation shall also ensure that the EC certificates of verification, the EC DoVs, and the application file are consistent. If there is a need to update the certificates or the declarations to align them with the CfU that the applicant wants to propose, it shall liaise with the conformity assessment bodies and/or with the applicants for placing on the market of the mobile subsystems / manufacturers.

Please note that CfU for the vehicle and/or vehicle type are to be indicated in:

- OSS application form (vehicle and/or vehicle type level), and
- When the Agency is the authorising entity, see section 3.11.1.2 (template to be filled-in)

CfUs for mobile subsystems are to be described in the EC DoV (which will rely upon the conditions and limits for use in the EC certificates of verification), either directly in the declarations or in a separate document when they are long and/or complex. In such case, the document shall be referenced and attached to the declaration and shall be considered as a part of the declaration.

- › **Authorisation process:** the authorising entity and/ or the NSAs for the area of use can specify further CfUs as a result of their assessment of the application and the file accompanying the application (stage 5: processing the application, section 3.7, and stage 6: final documentation and authorisation, section 3.8.2).

The authorising entity and/ or the concerned NSAs for the area of use should not check if the CfU (including exported constraints) proposed by the applicant are reasonable from a commercial point of view (e.g., risk not meeting the contractual obligations of the manufacturer with the RU by imposing CfU that may render the operation of the vehicle difficult) nor to check if the exported constraints have been accepted by the concerned actor. The scope of the assessment should be limited to the consistency, completeness, and relevance (including the cross-check by the concerned assessment bodies) of the set of CfU proposed by the applicant.

The authorising entity and the concerned NSAs for the area of use can also remove some of the CfUs proposed by the applicant, if the proposal of the applicant does not actually impose any condition for use of the vehicle or any other restriction.

The issued vehicle type authorisation and/ or vehicle authorisation for placing on the market (stage 6: final documentation and authorisation, see section 3.8.2) should reflect all the CfU identified.

The applicant has the possibility to appeal in a case of disagreement with CfU imposed by the authorising entity, see section 3.8.5.

In case of a new authorisation and/or an extension of the area of use, the applicant should include in the application form the CfU from the previous authorisation that are still applicable, despite not being in the scope of the assessments to be performed by the authorising entity (inherited CfU), see also section 3.8.2.3. The CfU in the application for authorisation should be coherent with the CfU mentioned in the EC DoVs, although they don't need to be identical, i.e., not all CfU mentioned in an EC DoV are relevant for the vehicle (some CfU are relevant for the integration between mobile subsystems only).

3.3.9. Article 21: Identification of the conformity assessments

The applicant shall identify the necessary conformity assessments pursuant to the provisions of Annex IV of Directive (EU) 2016/797.

3.3.9.1. Authorisation of pre-defined formations

Chapter 2.2.1 of LOC&PAS TSI defines:

- › **Unit:** generic term used to name the rolling stock; a "unit" can be composed of several "**vehicles**".
- › **Train:** operational formation consisting of one or more units
- › **Fixed formation:** train formation that can only be reconfigured within a workshop environment

Fixed formations should normally be authorised as a whole, because this units are not designed to be dismantled and reassembled out of a workshop, as there is a need for specific tools and equipment, software, know-how, etc. This because there are physical connections which are not plug and play, software that depends on the number and type of vehicles (e.g., traction, train protection system, train control and monitoring system, doors), etc.

Furthermore, individual vehicles cannot operate on their own, and require of other vehicles to meet the essential requirements.

- › **Predefined formation:** train formation of several units coupled together, which is defined at design stage and can be reconfigured during operation.

If an applicant requests an authorisation of a predefined formation, the Authorising Entity will deliver one single type authorisation, describing the possibilities for reconfiguration during operation; the composition cannot be changed to another configuration not included in the authorisation (e.g., with more coaches, or a different locomotive type).

- › **Multiple operation:** operational formation consisting of more than one unit (e.g., trainsets designed so that several of them can be coupled and operated as a single train, from 1 driver's cab, locomotives designed in a way that several of them can be incorporated into a train and controlled from one driver's cab).
- › **General operation:** a unit is designed for general operation when the unit is intended to be coupled with other unit(s) in a train formation which is not defined at design stage

If an applicant request for the authorisation of coaches for general operation, the train composition is out of the scope of the authorisation process and shall be managed by the RU under the scope of its SMS. The Authorising Entity can deliver the authorisation of the coaches, with the relevant conditions and restrictions of use regarding the coupling with other coaches/vehicles (if any).

It is possible to authorise vehicles of a pre-defined formation or a fixed formation individually, as if they were intended for general operation, with a number of CfU linked to the integration at train level (and many other aspects that could not be checked on isolation, because they are requirements at train level).

However, the authorisation may not cover certain aspects that can only be assessed at train composition level. Some characteristics or some assessments of a unit intended to be used in general operation, will require defined limits regarding the train formations, as specified in chapters 4.2 and 6.2.7 of the LOC&PAS TSI.

Predefined formations can be considered midway between fixed formation and units for general operation, from the point of view that they can be reconfigured out of a workshop (no need for specific tools, procedures etc.), but still, there are some constraints to take into account, due to the design of the different vehicles.

For authorisation purposes, both approaches are acceptable: defining a number of pre-defined configurations to be authorised, or authorising the individual vehicles with a series of restrictions and CfU that would allow the RU to configure units within the envelope of the authorisation of each vehicle (provided that the conformity assessments also cover certain aspects that can only be evaluated at train composition level).

The authorisation of individual vehicles with CfU covering all the operational envelope of a pre-defined formation provides the highest level of flexibility to the RU for re-configuring the vehicles without any intervention of authorising entities or registration entities. On the other hand, defining the relevant CfU and other restrictions to be taken into account when re-configuring the vehicles is more complex; determining the worst-case scenarios for the conformity assessment in order to cover all operational configurations at train composition level is also more complex.

Please note that when a unit intended for use in fixed or predefined formation is assessed, the formations for which such assessment is valid shall be defined by the applicant, covered by the assessments to be performed by the conformity assessment bodies, and described in the EC certificate of verification using one of the following characteristics (pursuant to §4.1.2 of LOC&PAS TSI):

- › Trainset in fixed formation and, when required, predefined formation(s) of several trainsets of the type under assessment for multiple operation;
- › Single vehicle or fixed rakes of vehicles intended for predefined formation(s), or
- › Single vehicle or fixed rakes of vehicles intended for general operation and when required, predefined formation(s) of several vehicles (locomotives) of the type under assessment for multiple operation.

The LOC&PAS TSI contains specific requirements for:

- › Units intended to be used in general operation (§6.2.7), see also section 2.7.5 guide for the application of the TSIs
- › Units to be used in predefined formation(s) (§6.2.8)
- › Units to be included in an existing fixed formation (§6.2.9)
- › Passenger coaches not limited to a particular are of use to be used in predefined formations (§7.1.1.5.1), see also section 3.2.3.1 of the guide for the application of the TSIs
- › Passenger coaches not limited to a particular are of use to be used in general operation (7.1.1.5.2), see also section 3.2.3.2 of the guide for the application of the TSIs

The guide for the application of the TSIs is available in the website of the Agency (https://www.era.europa.eu/domains/technical-specifications-interoperability_en).

Concerning the registration of authorised vehicles in ECVVR/EVR:

- › Vehicles of a fixed formation can still be registered in ECVVR/EVR individually, despite having 1 authorisation covering the fixed formation.

As explained in the application guide for ECVVR, a “trainset” (fixed or pre-defined formation) can be registered with 1 EVN for the whole train, or with 1 EVN per vehicle, even if there are no individual authorisations per vehicle.

The choice is left for each Registering Entity, with the advice to do it always in the same way once the decision is taken by a given Registration Entity (have a consistent approach for all registrations).

- › If an EVN is assigned to the whole train, and a vehicle is substituted by another (identical) one, with its own identification, there is a need to update the concerned ECVVR/EVR entry to include the identification of the substitute vehicle; a new EVN for the whole train may be required. There is the possibility to indicate in the ECVVR/EVR the manufacturer’s serial number (or equivalent) to identify the vehicles.
- › When a change in a vehicle impacts the technical characteristics that contribute to define the EVN, a new EVN is required.
- › If EVNs are assigned per vehicle, at the level of ECVVR/EVR, there is no identification of the fixed or predefined formation to which they belong. The re-configuration formations does not impact the vehicle register.

3.4. Chapter 3 - Stage 2: Pre-engagement

3.4.1. Article 22: Pre-engagement

1. Upon the applicant’s request, the authorising entity and the concerned NSAs for the area of use shall handle pre-engagement applications to set the pre-engagement baseline before an application for a vehicle type authorisation and/or vehicle authorisation for placing on the market is submitted. The pre-engagement application shall be formally submitted by the applicant through the one-stop shop and be accompanied by a file containing at least the required information specified in Article 23.
2. The timeframe from the issuing of the opinion referred to in Article 24(2) to the applicant’s submission of the application for vehicle type authorisation and/or vehicle authorisation for placing on the market shall not exceed 84 months.
3. The selection of authorising entity made by the applicant for the pre-engagement shall be binding until, either:
 - (a) the concerned application for vehicle type authorisation and/or vehicle authorisation for placing in the market has been submitted by the applicant;
 - (b) the timeframe from the issuing of the opinion referred to in Article 24(2) to the applicant’s submission of the application for vehicle type authorisation and/or vehicle authorisation for placing on the market as specified in paragraph 2 has expired; or
 - (c) the applicant has requested to end the pre-engagement.
4. When during the pre-engagement, the applicant wishes to change the authorising entity it shall request the termination of the existing pre-engagement. The applicant may then send a new pre-engagement application to a new authorising entity.
5. The applicant may introduce an application for authorisation through the one-stop-shop at any time during the pre-engagement process. In this case, the pre-engagement phase is terminated.
6. In case of pre-engagement, the points set out in Article 41 related to the identification and the categorisation of issues shall be used, in view of tracking issues raised with the applicant by the authorising entity and, when applicable, the concerned NSAs for the area of use.

For description of the process, see the flowchart for Stage 2 in section 4.

The pre-engagement phase is not mandatory for the applicant (they can request the authorising entity to take part in the pre-engagement or they can directly submit the application and the file accompanying the application). If the applicant chooses not to submit an application for pre-engagement the steps described in

sections 3.4.1 - 3.4.3 will not be performed and the applicant will not have the benefits of pre-engagement described below. However, if the applicant requests to have a pre-engagement, it is mandatory for the authorising entity and the concerned NSAs for area of use to provide this service to the applicant, subject to fees and charges.

The pre-engagement covers prior formal exchanges of information between the applicant, the authorising entity and the concerned NSAs for the area of use.

The pre-engagement activities should support the setting up of the pre-engagement baseline for the vehicle type authorisation and/ or vehicle authorisation for placing on the market process and foster the exchange of information on the applicable requirements and on the content and maturity level of the file accompanying the application. The authorising entity and the concerned NSAs for the area of use should agree on the pre-engagement baseline

Pre-engagement is beneficial for:

- › Facilitating early contact between the parties;
- › Developing the relationship between the authorising entity, the concerned NSAs for the area of use and the applicant;
- › Verifying that the applicant has been provided with sufficient information so that it knows what is expected from it, including establishing the scope of the application;
- › Reaching a common understanding for the interpretation of the applicable rules (in particular transition clauses) to establish the baseline for the applicable rules, and
- › Clarifying how the vehicle authorisation process will be conducted and how decisions will be made.

In addition to the mandatory elements of pre-engagement required to be included in the file accompanying the pre-engagement application, the process also offers the potential to have an early involvement of the parties that have a formal role in the authorisation process, such as NoBos (for the identification/confirmation of applicable TSIs), DeBos (for the identification/confirmation of the applicable national rules) and/or AsBos (for the aspects related to requirements capture), but also engage with others parties which do not have a formal role in the authorisation process such as the IM or RUs potentially affected by the introduction of the new vehicles, in respect of other aspects that may need to be considered after an authorisation has been issued such as route compatibility assessment.

Pre-engagement should not be used to perform preliminary assessments of the application by the authorising entity/ the concerned NSAs for the area of use. The assessment of the application by the authorising entity/ the concerned NSAs for the area of use should start when the applicant has sent a complete application through the OSS as described in section 3.7.3.

The pre-engagement stage is considered to be the right time for the concerned NSAs for the area of use to prepare the arrangements referred to in Article 37(1) of Regulation (EU) 2018/545 concerning the classification of national rules and cross-acceptance, see section 3.7.6.

The pre-engagement stage it's also a good opportunity to discuss already known non-conformities. It is important for a smooth development of the authorisation process to give visibility on the issues and to start the relevant discussions on how to deal with them.

For the sake of transparency and clarity of exchanges between the Agency as authorising entity, the concerned NSAs for the area of use and the applicant, the approach to follow in any instance of non-compliance identified at the pre-engagement stage should be recorded and tracked following the same principles used for the authorisation itself (issues log). If this approach is used it will facilitate the transfer of knowledge in case the members of the assessment team change i.e., between pre-engagement and the submission of the application for authorisation. The issues from pre-engagement will not be automatically transferred to the application for authorisation but the assessment team can access the issues recorded for the pre-engagement stage through the OSS using the reference to the pre-engagement baseline provided by the applicant in its application.

3.4.2. Article 23: Pre-engagement file

The pre-engagement file accompanying the pre-engagement application shall contain the following:

- (a) a description of the vehicle type and/or vehicle to be authorised, including where applicable the intended variants and/or versions, and a description of the tasks and activities to develop it;
- (b) the applicant's choice of the authorising entity and of the authorisation case or cases pursuant to Article 14;
- (c) a specification of the intended area of use;
- (d) a specification of the anticipated conditions for use of the vehicle and other restrictions identified pursuant to Article 20;
- (e) the applicant's planning for its part of the vehicle authorisation process, including the planning that covers tests on the network, when applicable;
- (f) an identification of the methodology for the process for the requirements capture in accordance with Article 13;
- (g) the list of the rules and requirements identified by the applicant as those that are to be applied in accordance with Article 17 to Article 18;
- (h) a list of the identified conformity assessments pursuant to Article 21, including the modules to be applied and the use of Intermediate Statements of Verification ('ISV'), where applicable;
- (i) a description of the practical arrangements to use the vehicle for tests on the network, where applicable;
- (j) a list of the content of the documentation that the applicant anticipates to submit to the authorising entity and the concerned NSAs for the area of use for the vehicle type authorisation and/or vehicle authorisation for placing on the market;
- (k) a proposal concerning the language to be used for the vehicle authorisation process pursuant to Article 10;
- (l) a description of the applicant's organisation for its part of the vehicle authorisation process including but not limited to the applicant's contact information, contact persons information, requests for setting up coordination and meetings with the authorising entity and the concerned NSAs for the area of use.

3.4.2.1. Incomplete pre-engagement file

The mandatory content of the file accompanying the pre-engagement application is defined in Article 23 of the Regulation (EU) 2018/545. It is possible however to deliver a pre-engagement baseline when some of the mandatory aspects are either missing from the file or there is not enough information to arrive to an opinion on the approach proposed by the applicant. Those aspects will then not be covered by the pre-engagement baseline.

When the applicant submits a pre-engagement file which is essentially incomplete (e.g., from all the aspects referred to in Article 23, only some of them are addressed in the file), the concerned authorising entity may reject the pre-engagement application. In any case, the baseline issued should only address the aspects for which the applicant has provided enough information to arrive to an opinion on the approach chosen by the applicant.

For cases when an applicant is interested in some of the aspects covered in Article 23, the applicant should consult with the concerned authorising entity whether submitting an incomplete pre-engagement application is the preferred way or there are other options allowed. When the Agency is the authorising entity, the potential applicants seeking some advice concerning specific aspects of their projects have the possibility to request a **chargeable service**, as described in the Agency website:

https://www.era.europa.eu/agency-you/procurement/chargeable-services_en

Please note that a chargeable service is not a consultancy service to

- › help applicants to build an application file for a specific application;
- › pre-assess certain evidence of the application file ahead of the submission of the application;
- › assess the categorisation of a change, or
- › provide binding interpretation of the EU legal framework (which is the sole competence of the Court of Justice of the European Union).

It should be considered instead as a way to provide applicants further guidance and support in understanding the requirements for building and submitting the application (the process).

3.4.2.2. *Applicant's planning*

In recording the applicant's planning for its part of the vehicle authorisation process (point (e)) the applicant should provide, at an early stage, a breakdown of the activities proposed to support the application for authorisation, in particular the elements that will form a part of the application. This is anticipated to include a first project plan to identify the expected dates for each stage. The applicant may need to update and amend this first project plan at later stages.

The file accompanying the pre-engagement application, with regards to the applicant's planning, should cover aspects such as:

- › Communication arrangements and meetings, if any, with the authorising entity and the concerned NSAs for the area of use;
- › When applicable, the request(s) for non-application of TSIs;
- › Performing conformity assessments and establishing evidence, including a description of the methods of working with the conformity assessment bodies. The identified conformity assessments are to be detailed in list of the identified conformity assessments as specified in point (h);
- › Conducting tests on the network, where relevant, with application(s) for temporary authorisation and the practical arrangements specified in point (i); and
- › Submitting the formal application.

For some items of the pre-engagement file a list is required, whereas for others a description will suffice. For example, a description of planning for using a vehicle for tests on the network will usually include details of location, IM, test train operator, matters for which tests on the network are proposed, the vehicles to be used, a reference to the management procedures and confirmation of the extent to which arrangements are in place at the time of preparing the pre-engagement file. It is unlikely that it would be necessary to list the individual tests on the network, the specific dates or the staff members involved.

3.4.3. Article 24: Pre-engagement baseline

1. Within one month from the date of receipt of the pre-engagement application the authorising entity and the concerned NSAs for the area of use shall inform the applicant that the pre-engagement file is complete or ask for the relevant supplementary information, setting a reasonable deadline for the provision thereof.
2. Where the applicant is informed that their file is complete, the authorising entity and the concerned NSAs for the area of use shall issue through the one-stop shop an opinion on the approach proposed by the applicant in the pre-engagement application no later than two months after the acknowledgement that the file is complete. That issued opinion establishes the pre-engagement baseline, including a determination of the version of the TSIs and national rules that are to be applied for the subsequent application for authorisation without prejudice to paragraph 4.

3. The pre-engagement baseline shall specify which language shall be used pursuant to Article 10.
4. In case of changes affecting the pre-engagement file which are relevant for the pre-engagement baseline, the applicant shall send an amended and updated pre-engagement application only considering the changes and the interfaces with the unchanged parts. This may occur in the following situations:
 - (a) changes to the design or to the assessment methodology resulting from major safety issues;
 - (b) changes in legal requirements invalidating the pre-engagement baseline; or
 - (c) any changes voluntarily introduced by the applicant.
5. The authorising entity and where applicable the concerned NSAs for the area of use shall within 1 month review and issue an opinion on the amended and updated pre-engagement application and record that opinion in an amended and updated pre-engagement baseline.

3.4.3.1. Pre-engagement baseline – legal status

The pre-engagement baseline is established based on an opinion issued by the authorising entity and the concerned NSAs for the area of use concerning the approach proposed by the applicant in the pre-engagement application.

Legislation takes precedence over the pre-engagement baseline, pursuant to article 4(2) of Directive 2016/797. This means that any changes to legislation will take precedence over the pre-engagement baseline. New/ changed TSIs, national rules and other regulations to be considered should specify their scope and transitional arrangements.

The pre-engagement baseline is a legal obligation for the authorising entity and the concerned NSAs for the area of use and if there are errors in the established pre-engagement baseline, they can be held liable in the event of negative consequences caused by the error affecting the applicant negatively.

3.4.3.2. Change of authorising entity during or after the pre-engagement stage

If the applicant wishes to change the authorising entity during or after the pre-engagement stage and wants to have a pre-engagement baseline issued by the new authorising entity, it will result in the pre-engagement process restarting from the beginning with a new application for pre-engagement.

The rationale for requiring a new application for pre-engagement is that the applicant will have to develop new relationships with the parties involved and agree a new pre-engagement baseline. However, the applicant can reuse the applicable parts of its initial application for pre-engagement.

3.4.3.3. Timescales for pre-engagement

In order to ensure that pre-engagement does not become an open-ended commitment on the part of the parties involved there is a legally permitted maximum period of pre-engagement of 84 months (this is in order to ensure consistency with transitional periods defined in TSIs and national rules, validity of EC certificates, arrangements with the IM, planning, etc.). The 84 months time frame will allow the pre-engagement baselines to be automatically set to “expired” in the OSS and archived. The aim with the time frame is to avoid having inactive and/ or obsolete pre-engagement baselines in the OSS. If the time frame for the pre-engagement baseline expires the applicant can send a new pre-engagement application or can choose to not continue the pre-engagement. This is the choice of the applicant.

3.4.3.4. Validity of the pre-engagement baseline

In the case of changes pursuant to Article 24(4) of Regulation (EU) 2018/545 (where the pre-engagement baseline is impacted and it's therefore not anymore valid for certain aspects), the applicant can decide to send an amended and updated pre-engagement application in order for the pre-engagement baseline to be amended, updated and to keep its validity. The amended and updated pre-engagement application only has to consider the changes and the interfaces with the unchanged parts.

Any changes to the pre-engagement file that do not affect the pre-engagement baseline should be communicated by the applicant to the authorising entity and the concerned NSAs for the area of use but do not require an amended and updated pre-engagement application.

3.4.3.5. *Amendment of a pre-engagement baseline*

When the applicant wishes to amend and update an already issued pre-engagement baseline, it shall submit an application through the OSS, identifying the baseline to be updated and amended in the relevant field. The file accompanying the pre-engagement application shall be limited to the elements of the baseline that needs to be changed.

The outcome will be an amended and updated pre-engagement baseline that will keep the unchanged elements of the original baseline and include an opinion on the changed (or new) elements of Article 23 of the Regulation (EU) 2018/545.

3.5. Chapter 4 - Stage 3: Conformity assessment

For description of the process, see the flowchart for Stage 3 in section 4.

All the necessary conformity assessments for vehicle type authorisation and/ or vehicle authorisation for placing on the market are covered by this stage. However, the detailed conformity assessments (subsystems, parts of subsystems, stages of the verifications, ICs) are not developed here. Conformity assessments for subsystems are the responsibility of the applicant for the purpose of Article 15 of Directive (EU) 2016/797. See section 3.3.3 for guidance on identification of rules and acceptable means of compliance.

3.5.1. Article 25: Conformity assessment

Each conformity assessment body shall be responsible for compiling the documents and producing all necessary reports related to its conformity assessments performed pursuant to Article 26.

3.5.1.1. Conformity assessment bodies (CABs)

“Conformity assessment body”⁽⁵⁾ is generic terminology defined in the ISO/ IEC 17000 standard. Very frequently, the acronym CAB is used. The term is also defined in Article 2(42) of Directive (EU) 2016/797. Article 2(41) of Directive (EU) 2016/797 also defines the term “conformity assessment”.

The Directive (EU) 2016/797 sets out different “conformity assessment bodies”. The role of each of these bodies is to assess the conformity of a product, process, system, etc. against a given set of requirements and/ or legislation. In the context of vehicle type authorisation and/ or vehicle authorisation for placing on the market, the following conformity assessment bodies can be involved:

- › Notified body (NoBo) notified by a MS for the assessment of conformity of a structural sub-system against the relevant Union law (TSIs). The NoBo provides thus an independent assessment of the technical compliance with the relevant Union law (TSIs).
- › Designated body (DeBo) designated by a MS pursuant to Article 15(8) of Directive (EU) 2016/797 for the assessment of conformity against national rules. The DeBo thus provides an independent assessment of compliance against the applicable national rules.

The requirements and responsibilities of NoBos and DeBos are addressed in Chapter VI of Directive (EU) 2016/797.

The notifying authorities are responsible for the assessment, notification and monitoring of conformity assessment bodies, pursuant to article 27 of Directive 2016/797. In the event of a lack of continued fulfilment of the requirements and responsibilities of a NoBo, the notifying entity can restrict, suspend or withdraw the notification of the concerned NoBo, following the provisions of Article 39 of Directive (EU) 2016/797.

⁵ “Conformity assessment body” is defined in section § 2.5. of the ISO/IEC 17000 standard as a “body that performs conformity assessment services”.

3.5.1.2. Perform conformity assessment

In addition to TSIs and national rules, other applicable legislation of the Union (Directives, Regulations etc.), see section 3.3.1.4, may also require that certain conformity assessments are carried out. The applicant is responsible for performing the necessary conformity assessments in accordance with the provisions of the relevant Union law (including transposition to national legal frameworks in case of Directives) and providing the relevant final evidence of compliance required by each law in the file accompanying the application.

When the relevant TSIs and/ or the national rules require the use of CSM RA, they also specify the detailed assessment methodology (if needed, i.e., how to apply the Regulation) and the assessment criteria. In this case, the role of the NoBo and/ or the DeBo is to check whether this was applied, i.e., whether an AsBo confirmed the correct application of CSM RA as required by the relevant TSI or national rule. A NoBo or DeBo may not have the competency to carry out assessments described in the relevant TSI or national rule and/ or in CSM RA itself, but the same company may be accredited for more than one role and could therefore also execute more than one assessment role.

In any case, the final responsibility of the conformity assessment of the relevant TSIs and/ or national rules lies with the NoBo(s) and/ or DeBo(s). The assessment report issued by the AsBo, where the TSIs and/or the national rules requires the application of CSM RA, should be treated by the NoBo(s) and/or DeBo(s) as any other evidence provided by the applicant in the framework of the EC verification procedure for other requirements (e.g., a test report where testing is required by TSIs and/or national rules).

Further information can be found in the clarification note ERA1209/186 on the acceptance by a NoBo of the results of an independent assessment carried out by an AsBo, available at the website of the Agency:

https://www.era.europa.eu/domains/applicants/applications-vehicle-type-authorisations_en

3.5.2. Article 26: Perform verifications and establish evidence

1. The applicant shall, as applicable per authorisation case, perform the necessary checks in order to establish the evidence referred to in Annex I.
2. The authorising entity and the concerned NSAs for the area of use shall not prescribe the requirements for the evidence to be included in the technical files accompanying the EC declarations of verification of the subsystems, but where there is a justified doubt, they may request the applicant to carry out additional verifications.

The applicant, for the purpose of Article 15 of Directive (EU) 2016/797 shall:

- › Choose the EC verification modules from Decision 2010/713/EU to be used, amongst those allowed by the relevant TSIs (see section 4.2 of the guidelines for the application of the TSIs);
- › Identify the evidence to be delivered to demonstrate the compliance of the subsystem with the requirements;
- › Establish the technical documentation to be used to assess the conformity of the subsystem with the requirements of the relevant rules (TSIs, national rules, other Union law);
- › Appoint the relevant conformity assessment bodies (NoBos, DeBos, AsBos);
- › Check if the results of the conformity assessment and the evidence provided by the conformity assessment bodies is enough for demonstrating that the subsystems and the vehicle (type) meet the applicable requirements (in particular, the essential requirements of Directive (EU) 2016/797);
- › Establish the relevant EC declarations for the subsystem, following Annex II or III of Regulation (EU) 2019/250 (Annex V of Directive 2008/57/EC describes the content of the EC DoV for subsystems authorised before the relevant date), and
- › Compile the technical files accompanying the EC DoVs.

The manufacturer of ICs should:

- › Choose the EC verification modules from Decision 2010/713/EU to be used, amongst those allowed by the relevant TSIs;
- › Identify the evidence to be delivered to demonstrate the compliance of the IC with the requirements;
- › Establish the technical documentation to be used to assess the conformity of the IC with the requirements of the relevant rules (TSIs, national rules, other Union law);
- › Appoint the relevant conformity assessment body (NoBos), and
- › Establish the relevant EC declarations of conformity/suitability for use, following Annex I of Regulation (EU) 2019/250, and
- › Compile the file accompanying the EC declarations of conformity/suitability for use.

The NoBo(s) should :

- › Carry out the EC verification procedure;
- › Issue the EC certificates of conformity/suitability for use for ICs, following Annex V of Regulation (EU) 2019/250
- › Issue the EC certificates of verification for the mobile subsystems in accordance with Annex V of Regulation (EU) 2019/250; and
- › Compile the file with the documents that shall accompany the EC certificates.

The EC verification procedure described in Article 15 of Directive (EU) 2016/797 requires that the subsystem is to meet the requirements of the Union Law and any relevant national rules. Therefore, the conformity check should be performed against these requirements, NoBo for TSIs and DeBo for national rules. As a consequence, the responsibilities of the DeBo(s) should be the same as for the NoBo(s), mutatis mutandis.

In the case of changes to an already authorised vehicle type the applicant should inform the conformity assessment body(ies) that holds the technical documentation related to the EC type examination of all the modifications that may affect the conformity of the subsystem with the requirements of the relevant TSIs or the validity of the certificates, as described in Decision 2010/713/EU. However, the applicant can choose a different conformity assessment body to perform the verifications related to the changed vehicle type.

Requirements for evidence to be produced should be covered by the TSIs and national rules. They should provide sufficient information on the assessment phases for each requirement (e.g., see chapter 6 and appendix H, table H.1 of LOC&PAS TSI, and section 4.3 of the guidelines for the application of the TSIs), hence determining the type of documentation needed (e.g., drawings, calculations, simulations, test specification, test report etc.):

- › TSIs and national rules define for each requirement the mandatory demonstration (design review, type test etc.) to be carried out by the applicant.
- › Other means may define documents/ information that are non-mandatory and give a presumption of conformity such as:
 - Guidelines (for TSIs and national rules)
 - Recommendation for use (RFU) issued by NB-Rail, which can be found in their website:
<https://www.nb-rail.eu/official-documents>
 - Acceptable means of compliance.

The requirements capture process and the related evidence are the responsibility of the applicant for authorisation and/or the entity managing the change. NoBo(s) and DeBo(s) do not have a formal role in this process, although the companies playing those roles may provide input to the applicant.

3.5.2.1. Validity of EC certificates

The objective of the “EC” verification procedure is to demonstrate that the applicable requirements for a subsystem have been fulfilled. It is mostly based on the certificates of verification issued by the conformity assessment bodies. While a type examination certificate of verification for a subsystem is valid, it can be used by applicants as one of the elements that are necessary to establish the EC DoV for the subsystem.

A vehicle type authorisation is mostly based on the type examination certificates for the subsystems that compose the vehicle. However, the validity of the vehicle type authorisation is independent of the validity of the certificates. The circumstances under which a vehicle type authorisation may no longer be valid are described in sections 3.3.2.2 and 3.9. In particular, TSIs may contain transitional provisions that affect the validity of a vehicle type authorisation irrespective of the validity of the related EC certificates.

The validity/ expiry date (if any) of the certificates issued by NoBos is defined by the provisions in the applicable TSIs and in the Decision 2010/713/EU. It should be noted that with the latest amendments brought to the LOC&PAS and WAG TSIs, specific provisions are defined regarding validity of type certificates and the standard duration of 7 / 10 years for validity of EC certificates of verification (concept of phase B) may no longer apply. The EC certificates issued against the amended TSIs will not have a defined validity. See also :

- › Sections 3.1.2 and 3.2.5 of the guide for the application of the LOC&PAS TSI
- › Sections 3.1.2 and 3.5 of the guide for the application of the WAG TSI

Provisions related to certificates issued by NoBos should apply mutatis mutandis to certificates issued by DeBos.

3.5.2.2. Use of ISVs

See section 4.2.1 of the guide for the application of the TSIs, available in the website of the Agency (https://www.era.europa.eu/domains/technical-specifications-interoperability_en).

3.5.2.3. Maintenance documentation

The processes of vehicle type authorisation and authorisation for placing on the market of vehicles and the subsequent use (including operation and maintenance) of vehicles are two separate processes with different provisions. However, some maintenance documents (e.g., maintenance plan, maintenance instructions) are part of the description of the vehicle type and are needed to keep vehicles of the type in their design operating state whilst in use. The technical file accompanying the EC DoV should include the information needed to maintain the integrity of the design operating state of the vehicle throughout its lifecycle.

Requirements on the maintenance documentation are described in the TSIs (e.g., chapter 4.2.12.3 of LOC&PAS TSI).

3.5.3. Article 27: Correction of non-conformities

1. The correction of non-conformities with TSIs and/or national rules requirements shall be carried out by the applicant, unless a non-application of TSI in accordance with Article 7 of Directive (EU) 2016/797 has been granted. That may apply mutatis mutandis for national rules when allowed by the Member State’s national legal framework.
2. In order to mitigate a situation of non-conformity the applicant may, alternatively, do one or more of the following:
 - (a) change the design; in which case the process shall begin anew from the requirements capture set out in Article 13, for the modified elements only and those elements affected by the change;
 - (b) establish conditions for use of the vehicle and other restrictions in accordance with Article 20; in which case the conditions for use of the vehicle and other restrictions shall be defined by the applicant and checked by the relevant conformity assessment body.

3. The applicant's proposal for conditions for use of the vehicle and other restrictions as pursuant to Article 20 to correct a non-conformity shall be based on the necessary conformity assessments pursuant to Article 25.

The Regulation (EU) 2018/545 foresees the possibility to mitigate non-conformities with TSIs and national rules by means of establishing CfU. However, this option should only be used for certain cases.

The TSIs, the national rules and other EU legislation are mandatory rules, and subsystems and vehicles should comply with the technical requirements laid down in the mandatory rules. The legal framework foresees the following possibilities to deviate from a requirement established in a mandatory rule:

- a) When the project benefits from a granted non-application request of the concerned requirement(s) of the TSI(s), pursuant to Article 7 of Directive (EU) 2016/797;
- b) In case of deficiencies in the applicable TSIs, pursuant to Article 6 of the Directive (EU) 2016/797; pending the amendment of the TSI, a Technical Opinion issued by the Agency, at the request of the Commission, shall constitute acceptable means of compliance and may therefore be used for the assessment of projects, pending the adoption of a revised TSI;
- c) In case of innovative solutions, pursuant to Article 10 of Regulation (EU) 2014/1302 and Article 10a of Regulation (EU) 2013/321: the positive opinion issued by the European Commission constitutes acceptable means of compliance;
- d) When it is possible to mitigate the non-conformity (e.g., bringing the vehicle in conformity to the TSIs and/or national rules) by applying some CfUs, pursuant to Article 27(2)(b) of Regulation (EU) 2018/545;
- e) When the authorisation decision contains time limited CfUs, as an exceptional temporary measure, where the conformity to the TSIs and/or national rules could not be completely proven before the issuing of the authorisation and/or national rules require that the applicant produces a plausible estimate of compliance, pursuant to Article 46(6) of Regulation (EU) 2018/545, or
- f) The TSIs may allow deviations from certain technical requirements if certain conditions are met:
 - For rolling stock subsystem : for the upgrade/renewal of existing vehicles not covered by an EC DoV placed in service before 1 January 2015, where the basic parameter is improved in the direction of the TSI defined performance and the entity managing the change demonstrates that the corresponding essential requirements are met and the safety level is maintained and, where reasonably practicable, improved (section 7.1.2.2a of Annex I of Regulations (EU) 2014/1302 and section 7.2.2.3 of Annex I of Regulation (EU) 2013/321);
 - ICs not covered by an EC declaration of conformity or suitability for use, as described in Articles 8, 8a, 8b and 8c of Regulation (EU) 2013/321, and/or
 - ICs and subsystems not implementing all functions, performance, and interfaces (partial fulfillment of CCS TSI requirements), as described in section 6.1.1.2 of the CCS TSI.

The paragraphs below do not apply for this particular case, because the procedure to follow is already described in the TSIs.

Where a non-conformity is known by the manufacturer/applicant since the early stages of a project (e.g., derives from a contractual arrangement with its customer, or was identified in the design stage) and it is not covered by the cases described in paragraphs a, b or c above, the use of CfU as a mitigation measure should not be accepted. The applicant should use any other of the possibilities provided by the legal framework, in particular the one envisaged in Article 27(2)(a) of Regulation (EU) 2018/545 (change the vehicle type) or request a non-application of the concerned requirements of the TSIs pursuant to Article 7 of Directive (EU) 2016/797, where allowed.

When non-conformities are identified during the conformity assessment procedure, the applicant should, as a general rule, correct them and bring back the subsystem in conformity with the TSIs, pursuant to Articles 27(1) and 27(2)(a) of the Regulation (EU) 2018/545, or request a non-application of the concerned requirements of the TSIs. When it is not possible to:

- › correct the identified non-conformities;
- › request a non-application of the concerned requirements of the TSIs, or
- › follow the procedure for deficiencies or innovative solutions because of the impact in the project (need to redesign the vehicle and/or vehicle type, delays and costs associated with the redesign and assessment of the new design, time for approval of a request for non-application of a TSI, etc.),

then Article 27(2)(b) of Regulation (EU) 2018/545 allows to apply CfU to mitigate the non-conformity, where this is feasible (some non-conformities cannot be mitigated in this way) and duly justified.

This should be limited to cases where the non-conformity was not known and could not have been reasonably anticipated, and it's only discovered in the latest stages of the EC verification procedure and/or authorisation process. This is typically the case of non-conformities found during the on-track testing campaign, obliging to adopt some measures impacting the operational envelope of the vehicle (e.g., limitation in speed, limitation in cant deficiency, limitation in the configuration for operation in multiple unit etc.).

When CfU are used to mitigate a non-conformity with the TSIs and/or national rules, the applicant should provide in the file accompanying the application through the OSS a description of the requirements not complied with and/or the requirements whose compliance could not be completely proven, and the CfU identified as mitigating measures, including the relationships between them. In case of time limited CfU, the applicant should also provide the planning for providing the missing evidence.

The conformity assessment bodies shall assess the proposed CfU and confirm that the non-conformity and any associated risk are mitigated, which means that:

- › The vehicle fulfils the requirements of the TSIs and/or national rules when the CfU are applied, and
- › The CfU do not negatively impact the essential requirements.

The outcomes of their assessments shall be clearly included in the assessment reports, in particular, in the assessment report covering the process

for requirements capture.

In case of time limited CfU, it is the responsibility of the applicant to provide the necessary evidence before the time limit in the vehicle type authorisation. The vehicle type authorisation issued will no longer be valid after its expiry date. Similarly, the authorisations for placing on the market of the vehicles issued in conformity to the vehicle type that had a time limit will also have the same time limit and will no longer be valid after the expiry date of the vehicle type authorisation.

3.6. Chapter 5 - Stage 4: Submitting the application

For description of the process, see the flowchart for Stage 4 in section 4.

3.6.1. Article 28: Establishment of evidence for the application

The applicant for a vehicle type authorisation and/or a vehicle authorisation for placing on the market shall establish the evidence for the application by:

- (a) putting together the EC declarations of verification for the subsystems composing the vehicle and providing the evidence, in the technical file accompanying the EC declarations, of the conclusions of the conformity assessments done following the identification carried out pursuant to Article 21;
- (b) ensuring that interfaces between subsystems that are not defined in TSIs and/or national rules, are covered by the requirements capture referred to in Article 13 and meet the essential requirements set out in Article 3.1 of Directive (EU) 2016/797.

The applicant that establishes the EC Declaration for Verification for subsystem(s) as specified in Article 15 of Directive (EU) 2016/797 (the applicant for placing on the market of a mobile subsystem) should:

- › Establish the EC DoV for subsystem(s), including conditions for the interfaces with other subsystems; and
- › Take the full responsibility for the subsystem.

The EC DoV is established at the level of the subsystem; therefore, it is an intermediate document in the process leading to the vehicle type authorisation and/ or vehicle authorisation for placing on the market.

This approach will allow the mobile subsystem to be placed on the market without the need for any authorisation.

However, a mobile subsystem cannot be used until it is part of a vehicle/ vehicle type that is authorised. The subsystem verification of interfaces with other subsystems required under Article 15(3) of Directive (EU) 2016/797 requires a check only of items specified in the TSI. It follows that until the TSIs fully specify the interface on-board control-command and signalling - rolling stock it is not an exhaustive check of technical compatibility and safe integration between the subsystems but simply a check of what is required by the TSIs (if anything).

A full check of technical compatibility and safe integration of the two sub-systems follows later when the subsystems are together and integrated to form a vehicle.

Although vehicle type authorisation and/ or vehicle authorisation for placing on the market is a stage that follows the EC DoV for the mobile subsystem(s) the documentation for authorisation is mostly to be found in the technical files accompanying each EC DoV.

The “Blue Guide⁽⁶⁾” (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC>) identifies, in its section 4.1.1, how a manufacturer may demonstrate conformity with the essential requirements, which by analogy applies to subsystems and vehicles. It complements the list of contents to be covered by the “technical file accompanying the EC DoV for a sub-system” to be found in Article 15(4) of Directive (EU) 2016/797 and point 2.4 of Annex IV of Directive (EU) 2016/797 (see section 3.11.1.6 of this document).

3.6.2. Article 29: The compilation of the file accompanying the application

1. The applicant shall prepare and compile in a structured way the content that is required for the file accompanying the application in accordance with Annex I.
2. For the authorisation referred to in Article 14(1)(b), (c), (d), and (e), the applicant shall check the validity of the existing vehicle type authorisation.
3. The applicant shall, for the authorisation referred to in Article 14(1)(c) and (d), submit the documentation necessary for the authorising entity to issue its decision, including where available any documentation accompanying the file for the previous authorisation.

3.6.2.1. New authorisation or extension of area of use

In cases of new authorisation or extension of the area of use, the applicant should provide additional relevant documentation to the existing full accompanying file (e.g. documentation for a new authorisation shall cover the parts of the vehicle that are changed and their impacts on the unchanged parts of the vehicle; documentation for an extension of the area of use shall cover, for the extended area of use, the applicable requirements – TSIs and national rules – and the technical compatibility between the vehicle and the network). This should be seen as complementary documentation to the existing file and not that the applicant should provide all the documentation used for the previous authorisation process.

The scope of the assessments to be performed shall be limited to the aspects (e.g., TSIs, national rules, etc.) impacted by the change and/or applicable in the extended area of use. However, if the authorising entity finds out or is informed by a NSA for the area of use involved in the new authorisation/extension of the area

⁶ Commission Notice 2022/c 247/01 *The ‘Blue Guide’ on the implementation of EU products rules 2022*

of use of a potential non-compliance with the mandatory rules (i.e. TSIs, national rules, other EU law) inherited from the previous authorisation, the issue will be further investigated and the necessary measures will be taken on a case by case basis (e.g. discuss with the authorising entity that issued the previous authorisation, amendment or update of the issued vehicle type authorisation, or suspension/revocation pursuant to Article 26 of Directive (EU) 2016/797).

3.6.3. Article 30: Application content and completeness

1. For the application to be considered complete by the authorising entity and when relevant by the concerned NSAs for the area of use it shall contain the information set out in Annex I.
2. For the authorisation extended area of use referred to in Article 14(1)(c), the following points shall apply:
 - (a) the documentation to be added to the original full accompanying file for the decision issued in accordance with Article 46 by the applicant shall be limited to aspects concerning the relevant national rules and the technical compatibility between the vehicle and the network for the extended area of use;
 - (b) when the original vehicle type authorisation included non-applications of TSIs, the applicant shall add the relevant decisions for non-application of TSIs in accordance with Article 7 of Directive (EU) 2016/797 covering the extended area of use to the original full accompanying file for the decision issued in accordance with Article 46;
 - (c) in case of vehicles and/or vehicle types authorised under Directive 2008/57/EC or before, the information to be added by the applicant to the original file for the aspects covered by point (a) shall also include the applicable national rules.

The application form should contain documentary evidence covering at least the items specified in Annex I of Regulation (EU) 2018/545, see also section 3.11.1, and in particular 3.11.1.6.

In the case of vehicle types authorised under Directive 2008/57/EC or before (no extension of the scope of the TSIs), the information to add to the original file should also include the applicable national rules for all parameters.

In addition, when the Agency is the authorising entity, applicants are kindly asked to fill-in an include in the file accompanying the application the following documents:

- › TEM_VEA_060 values for ERATV parameters: complementary information to the values for the ERATV parameters:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2676

Please note that in case of types/variants following a new authorisation and types/versions following an extension of the area of use, only the information related to ERATV parameters impacted should be filled in.

While the use of this template by applicants is not mandatory, filling-in this template is considered as a mean to fulfil the legal obligation for applicants to provide the information required in point 18.13 of Annex I of Regulation (EU) 2018/545.

The information in the form should be revised by the concerned NoBos for the assessment of the compliance of the mobile subsystems with the requirements of the TSIs. This verification by the NoBos is not compulsory. Nevertheless, being NoBos in charge of the preparation of the files accompanying the type examination certificate(s), they are in the best position (most efficient in terms of time/cost) to double check that the information provided by the applicant is consistent with the file that they have prepared, the assessments they have performed and the documents used for the assessment.

The revision by the NoBo(s) / DeBo(s) should be focused on checking that the values declared by the applicant, and the references to the documents where the values can be found, are consistent with the results of the conformity assessment of the requirements in the TSI(s) performed during the EC verification procedure, including the documents used for the assessment.

The outcomes of the verification by the NoBos can take any other form (e.g., a dedicated section in the file accompanying the EC certificates of verification).

- › TEM_VEA_061 links to ERADIS for EC certificates and EC declarations: complementary information to the EC certificates of verification, EC certificates of conformity, EC DoVs and EC declarations of conformity uploaded to the OSS library:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2673

- › TEM_VEA_062 conditions for use of the vehicle and other restrictions: complementary information to the CfU described in the application form in the OSS (in terms of coded and non-coded restrictions):

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2674

The use of these templates by applicants is not mandatory.

3.6.4. Article 31: The submission of the application for authorisation through the one-stop shop

1. The application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market shall be formally submitted by the applicant through the single entry point of the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 and shall contain the information set out in Annex I.
2. When submitting its application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market the applicant shall select the authorising entity in accordance with Article 21(5) and 21(8) of Directive (EU) 2016/797.
3. The selection of authorising entity made by the applicant shall be binding until the decision on the issuing of the vehicle type authorisation and/or the vehicle authorisation for placing on the market or the refusal of the application has been taken by the authorising entity or the application has been terminated by the applicant.
4. The applicant's file shall be referred through the one-stop shop to the concerned NSAs for the area of use.

All applications for vehicle authorisation should be submitted through the single entry point of the OSS referred to in Regulation (EU) 2016/796 regardless of who will be the authorising entity. This also includes vehicles that are in the scope of Directive (EU) 2016/797 but that are not (and not intended to be) covered by TSIs (e.g., tram-trains, metric track gauges) with the exception only for those tram-trains for which Directive (EU) 2016/797 allows MSs to define a specific procedure.

The applicant should submit its application for a vehicle type authorisation/ vehicle authorisation for placing on the market through the single entry point of the OSS, using the electronic application form and select the authorising entity when the area of use is limited to one MS.

If a MS has adopted national rules requiring a specific authorisation procedure to be followed for authorisation of tram-trains (where Directive (EU) 2016/797 allows for this), the Agency should not be involved in the authorisation process.

When the area of use is for more than one MS, the OSS will select the Agency as authorising entity by default (see section 3.2.2.1). When the area of use is limited to one MS, the applicant can choose the authorising entity. In this latter case, only the Agency and the concerned NSA for the area of use will be proposed by the OSS for selection by the applicant.

From the moment this selection is made and the application is submitted, the applicant will not be able to change its choice of authorising entity, unless the applicant terminates its initial application and triggers a new application to the other authorising entity. In such a case, the applicant should restart the whole authorisation process from the beginning.

It is only the applicant that can terminate an application. The authorising entity has to take a decision (either positive or negative) when an application has been submitted through the OSS.

If the MS has not excluded from the scope of the Directive (EU) 2016/797 and thus has not adopted any particular national authorisation procedure for tram-trains, Article 21 of Directive (EU) 2016/797 should apply. The applicant can therefore choose either the Agency or the NSA in the case of authorisation for an area of use limited to one MS. However, in this case the TSIs do not apply, only national rules are applicable, so the part of the assessment by the authorising entity covering rules will be covered by the assessment by the concerned NSAs for the area of use.

In the case of an authorisation in conformity to type, it is beneficial if the authorising entity is the same entity that issued the vehicle type authorisation, as it may be in a better position to perform some of the checks described in Annex II of Regulation (EU) 2018/545 (e.g., non-application of TSIs linked to the type, validity of the existing type authorisation etc.).

The application should be made sufficiently in advance of when the applicant requires the vehicle type authorisation and/ or vehicle authorisation for placing on the market. The applicant should take into account that the maximum time frames specified in Article 34 of Regulation (EU) 2018/545 may be extended if it is found during the check of completeness of the application that there is missing information or if a justified doubt is raised (and it is in duly recorded agreement with the applicant to extend the timeframe).

In its planning for its project the applicant for a vehicle type authorisation and/ or vehicle authorisation for placing on the market needs to take into account that the issued authorisation is only a milestone and that there are additional aspects that need to be considered before a vehicle can be used as intended. Factors to be considered by the applicant in its planning for when the application needs to be submitted should include:

- › The extent of pre-engagement, if any, that has been performed;
- › The timescale for submitting the application and the subsequent assessment by the authorising entity;
- › The complexity of and/ or uncertainties concerning the application; and
- › Any additional time required for the checks before the use of authorised vehicles (checks of authorisation, registration, route compatibility and integration into the composition of the train where it is intended to operate, see Article 23 of Directive (EU) 2016/797).

The OSS will assign a unique identification number (V-YYYYMMDD-XYZ for applications for vehicle and/or vehicle type authorisation, P-YYYYMMDD-XYZ for pre-engagement applications).

3.7. Chapter 6 - Stage 5: Processing the application

For description of the process, see the flowchart for Stage 5 in section 4.

3.7.1. Article 32: Application completeness check

1. The authorising entity shall check the completeness of the information and documentation provided by the applicant in the application in accordance with Article 30.
2. The concerned NSAs for the area of use shall :
 - (a) check that the area of use is correctly specified for its part;
 - (b) raise any issues concerning the completeness of the information and documentation provided for the assessment of the applicable national rules as specified in Annex III.

3. The completeness check referred to in paragraph 1 and 2 shall constitute a verification by the authorising entity, and the concerned NSAs for the area of use that:
 - (a) all the required information and documents referred to in Article 30 have been provided by the applicant in the application for vehicle type authorisation and/or vehicle authorisation for placing on the market;
 - (b) the provided information and documentation provided is considered relevant to allow the authorising entity and the concerned NSAs for the area of use to perform their assessments in accordance with Article 38 to Article 40.

The Regulation (EU) 2018/545 provides for a clear separation between completeness check and assessment. It is not possible to start the assessment if the application is not declared complete before, i.e., the minimum content in Annex I of the Regulation (see section 3.11.1) can be found in the library of the OSS.

In case of missing documents, documents not relevant or with wrong content (e.g., there is an EC certificate but does not correspond to the vehicle type under assessment), expired certificates etc., an application cannot be declared complete and assessment phase should not start.

The completeness check includes the verification that the necessary documents are available in the file accompanying the application in the OSS and that the documents do not miss any essential content, i.e., contain what they are supposed to contain and with the necessary level of detail.

The detailed assessment of the content of the documents is to be performed during the assessment stage. When the assessors raise issues related to the (detailed) content of documents during the completeness check, it is still possible to declare the application complete, and leave those issues open for the assessment stage.

3.7.2. Article 33: Acknowledgement of application

1. The one-stop shop shall generate an automatic acknowledgment of the receipt of the application to the applicant.
2. The assessment of the application shall start on the date of receipt of the application.

The automatic acknowledgement of receipt of the application will state that the date of receipt of the application is the first working day common to all concerned authorities. The OSS will calculate the date based on the available information on public holidays, as introduced in the system by the Agency and the NSAs for the area of use.

The automatic acknowledgement of the receipt of the application will be sent by the OSS to the applicant, the authorising entity and the concerned NSAs for the area of use.

3.7.3. Article 34: Timeframe for the assessment of the application

1. The authorising entity and the concerned NSAs for the area of use shall evaluate, each for their own part, the completeness of the application as specified in Article 32 within one month following the date of receipt of the application. The authorising entity shall inform the applicant accordingly.
2. Where the applicant is informed that their file is complete, the final decision over the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be taken no later than four months after the acknowledgement that the file is complete.
3. The decision of the authorising entity shall be issued within one month following the date of receipt of the application in case of authorisation in conformity to type in accordance with Article 14(1)(e).
4. If the applicant is informed that its file is not complete, the final decision over the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be taken no later than

four months following the submission of the missing information by the applicant, unless the application is fundamentally deficient, in which case it shall be rejected.

5. In the course of the assessment, even if the application is complete as referred to in paragraph 2, the authorising entity or the concerned NSAs for the area of use may, at any time, request supplementary information, setting a reasonable deadline for the provision thereof, without suspending the assessment unless the provisions of paragraph 6 apply.
6. When a justified doubt has been raised by the authorising entity or the concerned NSAs for the area of use and the applicant is required to provide supplementary information, the authorising entity may suspend the assessment and in duly recorded agreement with the applicant extend the timeframe beyond what is set out in Article 21(4) of Directive (EU) 2016/797. The timeframe for providing the supplementary information shall be proportionate to the difficulty for the applicant to provide the information requested. The assessment and the timeframe shall resume after the applicant provides the requested information. In the absence of agreement with the applicant, the authorising entity or the concerned NSAs for the area of use shall take its decision based on the available information.

The OSS calculates the deadline based on the established first working day common to the Agency and to the concerned NSAs for the area of use and the legal timeframes. If the deadline falls into a non-working day (e.g., weekend), it shall be considered as moved to the next available working day. Please note that this action is not performed by the OSS automatically, a manual intervention from the authorising entity is needed (manual update of the OSS dashboard for the concerned application).

The timeframes specified in Article 34 of Regulation (EU) 2018/545 should be recognised as the maximum time frames for the tasks and not target times. The involved parties should strive to complete their tasks without unnecessary delay.

The authorising entity, in conjunction with the concerned NSAs for the area of use, can suspend the application if the information supplied is incomplete pursuant to Article 34(4) of Regulation (EU) 2018/545. The assessment of the application (and the 4 month timeframe for the assessment) will start when the applicant has submitted all the missing information.

The authorising entity and the concerned NSAs for the area of use may ask, each for their respective part in the course of the assessment, for additional information and clarifications, also including any instances of non-compliance. Such requests should:

- › Always specify a timeframe for the response (appropriate to the complexity of the topic); and
- › Not suspend the timeframe for the assessment unless justified doubts are identified that prevent the assessment, or parts of it to continue.

This is a mechanism that allows the applicant to provide additional evidence (to resolve issues identified during the assessment) without any suspension of the timeframe of the assessment. This is different from justified doubts where the timeframe for the assessment can be extended by the authorising entity if there is a duly recorded agreement with the applicant (see section 3.7.11).

The authorising entity and the concerned NSAs for the area of use should be as specific as possible, to assist the applicant in understanding the level of detail expected in the response, without imposing the action(s) to resolve it.

To be satisfactory, the applicant's written response should be sufficient to allay the concerns expressed and to show that its proposed arrangements will meet the requirements. It should include new text and/ or rephrasing to replace what was unsatisfactory in the application, with an explanation of how this deals with the identified deficiencies. The applicant may, in addition, supply relevant supporting information as well as amend/ add relevant text to the text contained in the application. If the authorising entity and/ or the concerned NSAs for the area of use does (do) not agree with the proposed measures and/ or timescales, it (they) should promptly contact the applicant to resolve the issue.

3.7.4. Article 35: Communication during the assessment of the application

1. The authorising entity, the concerned NSAs for the area of use and the applicant shall communicate through the one-stop shop as regards any issue referred to in Article 41.
2. The status of all stages of the vehicle authorisation process, the decision on the application and the documented reasons for that decision shall be communicated to the applicant through the one-stop shop.
3. The guidelines of the Agency and of the NSAs shall indicate arrangements for communicating between themselves and with the applicant.

3.7.5. Article 36: Information management concerning the assessment of the application

1. The authorising entity and the concerned NSAs for the area of use shall register in the one-stop shop the outcomes of the stages of the vehicle authorisation process in which they are involved, each for their respective part of the assessment as applicable, including all the documents relating to the application concerning the following:
 - (a) receipt;
 - (b) handling;
 - (c) assessment;
 - (d) conclusions of the assessment of the application as specified in Article 45;
 - (e) final decision to issue or not the vehicle type authorisation or the vehicle authorisation for placing on the market;
 - (f) final documentation for the vehicle type authorisation and/or the vehicle authorisation for placing on the market in accordance to Article 47.
2. The final decision to issue or not the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be communicated to the applicant through the one-stop shop.
3. For the documents listed in paragraph 1, the authorising entity and the concerned NSAs for area of use shall use the document control process provided by the one-stop shop.
4. Where the NSAs use an information management system for processing the applications addressed to them, they shall transfer all relevant information to the one-stop shop.

In addition to the documents that shall be mandatorily stored in the OSS, any intermediate working documents, including informal correspondence with the applicant, can be archived in the OSS.

3.7.6. Article 37: Coordination between the authorising entity and the concerned NSAs for the area of use for the assessment of the application

1. For the purpose of the assessment of the application, the concerned NSAs for the area of use shall plan, organise and agree on the necessary arrangements in order to take into account the classification of national rules and cross-acceptance referred to in Article 14(10) of Directive (EU) 2016/797. The agreed arrangements for the assessment of the application shall be communicated to the authorising entity and the applicant.
2. The authorising entity and the concerned NSAs for the area of use shall coordinate with each other in order to address any issues including any instances that may require an amendment of the application and/or request for supplementary information, where providing supplementary information has an impact on the timeframe of the assessment or has the potential to have an impact on their work, and agree on the way forward.

3. When concluding the coordination activities referred to in paragraph 2, the authorising entity and the concerned NSAs for the area of use shall take each for their own part the decision to inform the applicant through the OSS of any instances that may require an amendment of the application and/or request for supplementary information.
4. Before the authorising entity takes its final decision and before the concerned NSAs for the area of use submit their assessment files, the authorising entity and relevant NSAs for the area of use shall:
 - (a) discuss the outcome of their respective assessment; and
 - (b) agree on conditions for use and other restrictions and/or exclusions of area of use to be included in the vehicle type authorisation and/or in the vehicle authorisation for placing on the market.
5. On the basis of outcome of the coordination activities referred to in paragraph 4 of this Article, the authorising entity shall provide to the applicant its documented reasons for the decision. In so doing it shall take into account the assessment files of the concerned NSAs for the area of use, referred to in Article 40(6), regarding the issuing or refusal of the vehicle type authorisation and/or vehicle authorisation for placing on the market, including any conditions for use of the vehicle and other restrictions and/or exclusions of area of use to be included in the vehicle type authorisation and/or vehicle authorisation for placing on the market.
6. Records of the coordination activities shall be taken by the authorising entity and maintained in the one-stop shop in accordance with Article 36.

3.7.6.1. Coordination between the authorising entity and the concerned NSAs for the area of use

The concerned NSAs for the area of use should take into account the classification of national rules and cross-acceptance referred to in Article 14(10) of Directive (EU) 2016/797 (and the Implementing Act referred to in that article) and put in place the necessary arrangements in accordance with Article 37(1) of Regulation (EU) 2018/545. This should be done with the aim of avoiding duplication of assessments for those national rules that are classified as equivalent for the concerned MSs and area of use.

For equivalent national rules the NSAs for the concerned area of use should apply the principle of mutual recognition for the following aspects for assessment listed in Annex III of Regulation (EU) 2018/545: point 5; point 6; point 7; point 9; point 10; point 12 and point 13.

The arrangements should take into account:

- › Logical grouping of aspects and national rules to be assessed i.e., it can be helpful to assess a particular subject theme;
- › Language of the documentation provided by the applicant in order to reduce the need for translation; and
- › Distribution of workload and other planning aspects.

The arrangements should at least describe:

- › In the case where the assessment of a parameter with equivalent national rules is shared by several NSAs for the area of use, which NSA for the area of use is responsible for the different aspects of the assessment ; and
- › The planning and coordination of the assessments.

The arrangements should be documented and agreed by the concerned NSAs for the area of use and then communicated to the applicant and the authorising entity through the OSS.

The Agency, in its role of authorising entity, may disagree with CfU proposed by the NSAs for the area of use, in particular when the proposed CfU are not linked to a CfU of the vehicle or any other type of restriction, and may decide to include them as remarks, observations etc. in the issued authorisation instead, or not to include them at all in the issued authorisation. In this case, the Agency will consult and coordinate with the concerned NSAs for the area of use before taking its final decision and before issuing the vehicle type authorisation. Further guidance on CfU can be found in section 3.3.8.

3.7.6.2. Exclusion of networks from the area of use

When the decision of the authorising entity results in the exclusion of networks from the area of use as compared to the application following a negative assessment by a NSA for the area of use, as referred to in Article 21(7) of Directive (EU) 2016/797, and the applicant can provide satisfactory evidence at a later stage (after the issuing of the authorisation), it can send a new application to the Agency requesting an extension of the area of use.

3.7.6.3. Recognition of authorisations issued by the Federal Office of Transport of Switzerland

The *Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road (LTA)*, as amended by Decision 1/2013 of the Community/Switzerland Inland Transport Committee (ITC), provides for mutual recognition of authorisations for placing in service of sub-systems and vehicles issued in accordance with Directive 2008/57/EC.

Issuing of authorisations pursuant to Directive 2008/57/EC remained valid until 16 June 2020 or 31st October 2020 in the relations between Switzerland and the EU MSs transposing Directive (EU) 2016/797, as amended by Directive (EU) 2020/700. Authorisations issued until such dates remain valid after, under the conditions subject to which they were issued.

Switzerland has started to apply substantive provisions of Directive (EU) 2016/797 since 1 December 2019 (under the Swiss Railways Ordinance). In addition, the LTA framework has been complemented by several decisions of the ITC (Decision No 2/2019, as amended by the Decisions No 1/2020, 2/2020, 2/2021 and 1/2022). These Decisions establish transitory measures which apply from 13 December 2019, and include Regulation (EU) 2018/545 in the Annex I of the LTA framework, together with the list of substantive provisions of Directive (EU) 2016/797 applicable in Switzerland.

Further details on the possibilities and conditions for the Agency to recognize authorisations issued by the Swiss National Safety Authority and to manage applications that include Switzerland in the area of use can be found in the document ERA1209/047, available at the website of the Agency:

https://www.era.europa.eu/domains/applicants/applications-vehicle-type-authorisations_en

3.7.7. Article 38: Assessment of the application

The assessment of the application shall be carried out by the authorising entity and the concerned NSAs for the area of use to establish a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities in the design, manufacture, verification and validation stages of the vehicle and/or vehicle type in order to ensure conformity with the essential requirements of the applicable legislation so that it may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions of use and other restrictions specified within the application.

3.7.7.1. Reasonable assurance

Reasonable assurance is a legal concept and mainly used within finance and auditing. It is relevant to use for vehicle authorisation as it is a more process oriented check rather than a detailed assessment. Although the authorising entity and the NSAs for the area of use should reach the confidence that the applicant and the actors supporting the applicant have fulfilled their responsibilities it is not necessary for them to establish with absolute certainty that this is the case. The level of engagement required by the authorising entity and the NSAs for the area of use to reach a reasonable assurance should be proportional and take account of the:

- › Complexity and risk associated with the vehicle/type being authorised (in respect to the technical characteristics or the changes to the technical characteristics that are being authorised);
- › Quality of the evidence and documentation supplied by the applicant;
- › Return of experience related to technical and operational matters in vehicles with similar technical characteristics and/ or similar components that may be relevant; and
- › Confidence gained in the applicant, based on experience from meetings etc.

The detailed assessments are performed by the conformity assessment bodies and therefore there is no need for the authorising entity and the NSAs for the area of use to duplicate those assessments. In the process of reaching reasonable assurance, the authorising entity and the NSAs for the area of use shall avoid duplication of works between the different assessors involved.

The actors supporting the applicant include any entity making a significant contribution to ensuring, assuring or verifying that the vehicle type or vehicle being authorised meets the essential requirements. They include but are not limited to the applicant(s) that have performed the placing on the market of the subsystem(s) of which the vehicle and/ or vehicle type is composed, NoBos, DeBos, AsBos, contractors and sub-contractors.

3.7.7.2. Scope of the assessment

To have reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities, the authorising entity and the concerned NSAs for the area of use should satisfy themselves of the:

- › Efficacy of the process followed by the applicant and the supporting actors; and
- › Consistency, completeness and relevance of the documentation provided by the applicant.

The requirements for the assessment of the application to be carried out by the authorising entity and the concerned NSAs for the area of use are specified in Annexes II and III of the Regulation (EU) 2018/545 (in accordance with Articles 39 and 40 of the Regulation). Distinct parts of the application require different approaches to checking, which can include:

- › Is the submission complete? Has the applicant included everything it has said it is including?
- › Have defined requirements been explicitly complied with? This includes requirements for signatories, and document structures in accordance with Union legal requirements, for items such as EC DoVs.
- › Are application elements within their period of validity? Many aspects of the application have limited periods of validity, such as the accreditation of conformity assessment bodies, the validity of EC certificates etc.
- › Is cross-referencing consistent? Applications are complex documents, and it is not unusual for items such as certificates to be updated in one part of the application but not another. If a pre-engagement baseline exists, is the application consistent with it?
- › Are selected rules and the choice of the case of authorisation valid? Consider whether the scope of the rule is compatible with the way it is being used in the application. Has it been superseded? Are non-conformities with the applicable mandatory rules dealt with in an appropriate way and are alternative solutions capable of comprehensively controlling any associated risks?

Note that in case of a non-conformity with a rule, it is the responsibility of the authorising entity/ the concerned NSAs for the area of use to evaluate the alternative solutions (if any); the outcomes from an AsBo should be taken into account, but the AsBo cannot decide on the alternative solutions to be applied. See also section 3.5.7 of this guideline, related to Article 27 “Correction of non-conformities” of the Regulation (EU) 2018/545.

- › Is an existing vehicle type, where used, still relevant and does it have a valid vehicle type authorisation? This can be affected by changes to the rules and standards applicable to the existing vehicle type, and by differences in the characteristics of the vehicle type for which an application is being made as compared to the vehicle type being used as a basis.
- › Have processes been correctly applied? This requires consideration of the defined elements of the processes and the participation of the correct actors. The assessor should acknowledge that the application of, for example, a risk assessment process can result in a range of reasonable outcomes and that the submission should not be rejected provided the proposed conclusions are justifiably in that range.

- › Is there evidence to support assertions? For example, where compliance with a rule/ standard has been declared the assessor may choose to review the completeness of the supporting evidence concerning the assessment methodology required by the rule as an indicator of whether the assessment processes have been correctly applied (e.g., if a type test is required, there should be a supporting type test report, see section 4.3 of the guidelines for the application of the TSIs).

The authorising entity and the concerned NSAs for the area of use should not:

- › Repeat or duplicate systematically work carried out by other bodies (e.g., NoBo, DeBo, AsBo); and
- › Use the authorisation process to check or evaluate the competence of conformity assessment bodies.

If a concerned NSA for the area of use or the authorising entity becomes aware of what it considers sub-standard work by conformity assessment bodies it could apply a higher level of scrutiny to parts of the verification and assessment process carried out by that conformity assessment body.

3.7.8. Article 39: The assessment of the application by the authorising entity

1. The authorising entity shall assess the aspects specified in Annex II.
2. Where a vehicle type authorisation and/or vehicle authorisation for placing on the market is to be issued for an area of use that is limited to the networks within one Member State and where the applicant has requested for the NSA to be the authorising entity in accordance with Article 21(8) of Directive (EU) 2016/797, the authorising entity shall, in addition to the assessments specified in paragraph 1, assess the aspects referred to in Annex III. In that case the authorising entity shall, in addition to those aspects listed in Annex III, also check whether there is any relevant information recorded pursuant to Article 8(2) and shall take it into account for the assessment of the application. Any issues raised shall be recorded in the issues log as specified in Article 41.
3. When a non-standardised methodology for the requirements capture has been used by the applicant, the authorising entity shall assess the methodology applying the criteria laid down in Annex II.
4. The authorising entity shall check the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture irrespective of the method used. For a new authorisation as specified in Article 14(1)(d) the assessment performed by the authorising entity shall be limited to the parts of the vehicle that are changed and their impacts on the unchanged parts of the vehicle. The checks to be performed by the authorising entity for an “extended area of use” authorisation as specified in Article 14(1)(c) shall be limited to the applicable national rules and to the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out at the previous authorisation shall not be repeated by the authorising entity.
5. An assessment report shall be issued by the authorising entity and shall contain the following:
 - (a) clear statement on whether the result of the assessment is negative or positive as per the applicant’s request for the concerned area of use and, where appropriate, conditions for use or restrictions;
 - (b) summary of the assessments performed;
 - (c) report from the issues log for the concerned area of use;
 - (d) filled-in checklist giving evidence that all aspects specified in Annex II, and when applicable Annex III, have been assessed.

3.7.8.1. Check of the applied methodology for requirements capture (only applicable in case it is not a standardised methodology)

With regards to the methodology for requirements capture, the authorising entity should assess the methodology for requirements capture used by the applicant in case it is not a standardised methodology. The check of the applied methodology for the requirements capture to be made by the authorising entity should follow the criteria laid down in Annex II of Regulation (EU) 2018/545. See section 3.11.2.1.

3.7.8.2. Check of the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture

The authorising entity and the concerned NSAs for the area of use should perform a high-level check⁷ (meaning a completeness, relevance and consistency verification) of the evidence from the methodology used for the requirements capture.

It is not envisaged that the authorising entity and the concerned NSAs for the area of use performs an exhaustive check of all the evidence supporting the requirements capture/ risk assessment performed by the applicant for non-safety related aspects, for which there is no independent assessment performed by an AsBo.

Its role should be more systemic, focused on the process followed by the applicant to capture and fulfil the requirements; in order to do so, the authorising entity may need to check in detail some supporting evidence. The depth and extent of the checks are described in Annex II and Annex III of Regulation (EU) 2018/545. Further details can be found in sections 3.3.1.9, 3.11.1.4 and 3.11.2.1.

3.7.8.3. Return of experience

The authorising entity shall check if there is any relevant information pursuant to Article 8(2) of Regulation (EU) 2018/545, see section 3.2.8.1, and take it into account in their assessments, in addition to the aspects specified in Annex II of the Regulation. When there are issues raised concerning the return of experience, they should be recorded in the issues log, see section 3.7.10. This will ensure that the other members of the assessment team also have access to the information.

3.7.8.4. Frequently raised issues in applications for authorisation in conformity to an authorised type

The Agency, when acting as authorising entity, often finds the following **issues in applications for authorisation in conformity to an authorised type**:

- › Wrong identification of the reference type (ERATV type ID): a proper identification of the reference type is a key element for this authorisation case; in addition, there is a need to ensure consistency between the identification of the reference type in the declaration of conformity to the type and in the application form;
- › Wrong identification of the vehicles in the scope of the application (EVNs): the different digits in the EVN do not correspond to the technical characteristics of the vehicles seeking authorisation;
- › Inconsistency between the identification of the vehicles (EVNs) in the application form and in the declaration of conformity to type: the EVNs are different / do not match;
- › Inconsistency between the information in ERATV for the concerned reference type and the documentation provided in the file accompanying the application through the OSS, e.g.
 - The references to the EC type examination certificates in ERATV do not match the references of the EC type examination certificates provided in the application (typical case of some changes that are classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545, see section 3.8.4.1.3), and/or
 - The CfU in the application form are different from the ones in the concerned ERATV entry (coded and non-coded restrictions).

A typical occurrence of this issue is when the list of CfU exceeds the maximum length allowed by the OSS, but the applicant does not realise when filling-in the form. In such cases and when the applicant becomes aware of it, it should agree with the concerned Authorising Entity the way forward (e.g., include all CfU in a document to be made available in the file accompanying

⁷ High-level and low-level are typically terms used to classify, describe and point to specific goals of a systematic operation. High-level checks refer to assessments that are more abstract in nature and related to overall goals and systemic features. Low-level checks involve more specific individual evaluations, focusing on the details.

the application for authorisation and make reference to the document in the fields for coded and non-coded restrictions in the OSS application from);

- › Expired EC certificates (in the file accompanying the application and/or in ERADIS): while in some cases, the EC certificates of conformity and/or suitability for use (ICs) can be expired at the time of submission of the application, they shall be valid when the ICs were placed on the market (see section 3.11.2.2); however, in many cases there is no evidence of the date of placing on the market in the file accompanying the application;
- › Inconsistency between the EC certificates and EC declarations provided in the file accompanying the application through the OSS and the documentation published in ERADIS:
 - Different document references and/or document versions;
 - Same document references and versions but different content;
 - Missing documents;
 - Expired EC certificates in ERADIS while the document provided in the application is still valid (and the other way around);
- › When there is a need to update part of the documentation in the file accompanying the application (e.g., EC certificates of verification), the impact of this update in other documents within the accompanying file (e.g., EC DoVs) is not taken into account by the applicant, leading to inconsistencies within the file;
- › The application covers vehicles that, at the moment of submission are not yet manufacturer/retrofitted and/or subject to all the necessary conformity assessments (e.g., routine testing not yet finished);
- › The application includes documentation related to ICs that were not assessed during the issuing of the concerned vehicle type authorisation (e.g., new providers for ICs);
- › The application includes ICs from manufacturers covered by the vehicle type authorisation but with new manufacturing facilities not covered by the NoBo QMS approval;
- › The application does not identify, from the different providers for ICs covered by the vehicle type authorisation, which are the ones actually used in the vehicle(s) seeking authorisation;

Errors in the file accompanying the application, or in the application form itself, originate delays in the processing and issuing of the vehicle authorisations for placing on the market. For a swift and prompt delivery of authorisations in such cases, applicants should produce good quality files, with the necessary content (see section 3.11.1), and in particular, paying enough attention to avoid the mistakes mentioned above.

3.7.9. Article 40: The assessment of the application by the concerned NSAs for the area of use

1. The concerned NSAs for the area of use shall assess the aspects listed in Annex III. The assessments to be performed by the NSAs for the area of use shall only concern the relevant national rules for the area of use taking into account the agreed arrangements referred to in Article 37(1).
2. In the assessment of the requirements capture, the NSAs for the area of use shall check the completeness, relevance and consistency of the evidence produced by the applicant from the applied methodology for requirements capture.
3. For a new authorisation referred to in Article 14(1)(d), the assessment performed by the NSAs for the area of use shall be limited to the parts of the vehicle that are changed and their impacts on the unchanged parts of the vehicle.
4. The checks to be performed by the NSAs for the area of use for an extended area of use authorisation referred to in Article 14(1)(c) shall be limited to the applicable national rules and to the technical

compatibility between the vehicle and the network for the extended area of use. Checks already carried out during the previous authorisation shall not be repeated by the NSAs for the area of use.

5. In accordance with Articles 6 and 14 of Directive (EU) 2016/797, the NSAs for the area of use shall, in addition to those aspects specified in Annex III, check if there is any relevant information recorded pursuant to Article 8(2) and shall take it into account for the assessment of the application. Any issues raised shall be recorded in the issues log as specified in Article 41.
6. An assessment files shall be issued by the NSAs for the area of use and shall contain the following:
 - (a) a clear statement on whether the result of the assessment is negative or positive as per the applicant's request for the concerned area of use and where appropriate conditions of use and restrictions;
 - (b) a summary of the assessments performed;
 - (c) a report based on the issues log for the concerned area of use;
 - (d) a filled-in checklist giving evidence that all aspects listed in Annex III have been assessed.

3.7.9.1. The role of the NSAs for the area of use in the assessment of an application

The NSAs for the area of use should verify the completeness, relevance and consistency of the application, according to Annex III of the Regulation (EU) 2018/545 (see section 3.11.3) in respect of the relevant national rules applicable in the area of use specified by the applicant (see section 3.3.5.1). The evaluation of the technical compatibility with the networks beyond the requirements of the mandatory rules, in particular when this is based on consultation with the IMs and/or specific statements or declarations from the IMs, is out of the scope of the assessments to be performed by the NSAs for the area of use.

The NSAs for the area of use should also coordinate with NSAs of the neighbouring Mss in respect of vehicles travelling to stations close to the border (consultation and/or agreements referred to in Article 21(8) of Directive (EU) 2016/797 and Article 12 of Regulation (EU) 2018/545).

3.7.9.2. Check of the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture

Further guidance can be found in section 3.11.2.1.

3.7.9.3. Return of experience

The concerned NSAs for the area of use in their assessment should in addition to those aspects specified in Annex III of Regulation (EU) 2018/545, check if there is any relevant information pursuant to Article 8(2) of the Regulation and to take it into account in their assessments, see section 3.2.8.1. When there are issues raised concerning the return of experience, they should be recorded in the issues log, see section 3.7.10. This will ensure that the other members of the assessment team also have access to the information.

3.7.10. Article 41: Categorisation of issues

1. The authorising entity and, when applicable the concerned NSAs for the area of use, shall record issues identified during the course of their assessment of the application file in an issues log and categorise them as follows:
 - (a) 'type 1': issue that requires a response from the applicant for the understanding of the application file;
 - (b) 'type 2': issue that may lead to an amendment of the application file or minor action from the applicant; the action to be taken shall be left to the judgement of the applicant and shall not prevent the issuing of the vehicle type authorisation and/or the vehicle authorisation for placing on the market;

- (c) 'type 3': issue that requires an amendment to the application file by the applicant but does not prevent the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market with additional and/or more restrictive conditions for use of the vehicle and other restrictions as compared to those specified by the applicant in its application, but the issue must be addressed in order to issue the vehicle type authorisation and/or vehicle authorisation for placing on the market; any action to be performed by the applicant to resolve the issue shall be proposed by the applicant and shall be agreed with the party that identified the issue;
 - (d) 'type 4': issue that requires an amendment of the application file by the applicant; the vehicle type authorisation and/or vehicle authorisation for placing on the market shall not be delivered unless the issue is resolved; any action to be performed by the applicant to resolve the issue shall be proposed by the applicant and shall be agreed with the party that identified the issue. Type 4 issue shall include in particular non-compliance pursuant to Article 26(2) of Directive 2016/797.
2. Following the response or the action taken by applicant according to the issue, the authorising entity or the concerned NSAs for the area of use shall re-evaluate the issues it identified, re-classify where relevant and assign one of the following status for each of the issues identified:
- (a) 'issue pending' when the evidence provided by the applicant is not satisfactory and additional information is still required;
 - (b) 'issue closed out' when a suitable response has been provided by the applicant and no residual matter of concern remains.

3.7.10.1. Recording issues in the issues log

During the assessment of the application the authorising entity and the concerned NSAs for the area of use are likely to identify issues where the content of the application is unclear, there are questions arising from relevant information pursuant to Article 8(2) of Regulation (EU) 2018/545 or it is lacking in evidence. These issues will require a response from the applicant.

All the aspects resulting from the assessment that are appropriate to take into account for the decision should be recorded in the issues log, not only those aspects that would prevent the authorising entity from taking the decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market.

Editorial or presentational concerns, or typographical errors, should not be taken as grounds for asserting that the applicant has not demonstrated compliance unless they affect the clarity of the evidence provided by the applicant.

The applicant can respond to an issue through the OSS by, for example, uploading a document, providing additional information, etc.

It is likely, when the assessment team consists of several assessors, that the applicant would receive the same or similar requests concerning issues identified by the different assessors. The issues log in the OSS can help to prevent that the same issue is raised several times by different assessors. Before raising an issue, the assessor should consult the issues log and see if the issue already is recorded by another assessor.

The issues should be recorded in the issues log in the OSS as soon as they are identified, to allow the applicant to answer them quickly and prevent that other assessors raises the same issues in another entry. Similarly, the grouping of several issues in a single entry in the issues log should be avoided, especially if they are of heterogeneous nature; this practice would make the follow-up and closure of the entry in the OSS grouping all issues more difficult.

3.7.10.2. Categorisation of issues

The issues will vary in significance, and categorisation is a useful tool to assist in resolving them appropriately. Each category of issue will require a different approach.

3.7.10.2.1. 'type 1' issue

A 'type 1' issue relates to additional explanations to be provided by the applicant concerning:

- › understanding how the file accompanying the application is structured in the OSS library;
- › where to find certain evidence or documents in the OSS library;
- › unclear statements or conclusions in the documentation;
- › potential contradictions between documents,
- › etc.

Issues categorised as 'type 1' do not require modifications in the file accompanying the application. A failure to close out a 'type 1' issue does not constitute grounds for rejecting an application. If the issue is not satisfactorily closed out the authorising entity will use its judgement to proceed with the assessment using the available information.

Concerning issues categorised as 'type 1', the life cycle of the issue could be summarized in the following main steps:

- › An aspect of the application is not clear. The applicant is invited to clarify it.
- › The applicant provides a response.
- › If the response successfully resolves the uncertainty the issue is 'closed out'.
- › If the response does not resolve the situation, or there is no response, the issue is classified as 'issue pending'. The applicant may be asked to clarify further.

3.7.10.2.2. 'type 2' issue

A 'type 2' issue relates to minor amendments to be performed by the applicant on the file accompanying the application, such as;

- › fixing incorrect references to or between documents (including dates of issuing and/or versions);
- › improving wording in unclear statements or conclusions in the documentation (e.g., results of the independent assessment of the requirements capture process in the AsBo assessment report);

A failure to close out a 'type 2' issue does not constitute grounds for rejecting an application. If the issue is not satisfactorily closed out the authorising entity will use its judgement to proceed with the assessment using the available information.

With regards to issues categorised as 'type 2', the life cycle of the issue could be summarized in the following main steps:

- › An amendment of the application file or a minor action by the applicant is required. The applicant is advised of this.
- › The action is left to the applicant.
- › The applicant provides a response containing the amendment of the file or the result of the action taken by the applicant.
- › If the response contains a satisfactory resolution to the issue it is 'closed out'.
- › If the response does not resolve the issue, or there is no response, the issue is classified as 'issue pending'.

3.7.10.2.3. 'type 3' issue

A 'type 3' issue relates to major amendments to be performed by the applicant on the file accompanying the application. More restrictive or additional CfU are required for taking the decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market.

'type 3' issues may result in an authorisation with conditions and restrictions of use at the end of the assessment time if the relevant information is provided by the applicant; it can be possible that the additional information provided by the applicant closes the issue without any additional CfU.

Examples of 'type 3' issues are:

- › Non-conformity with the requirement of a TSI at the design speed of the vehicle (e.g., running dynamics at 200 km/h). However, at a lower speed (e.g., 160 km/h), the results of the conformity assessment show compliance with the TSI requirements and would allow the issuing of the authorisation with a reduced maximum allowed speed.
- › Non-conformity with the requirement of a TSI under certain operating conditions (e.g., pantograph-catenary interaction parameters in double composition when the active pantographs are the ones located at both ends of the composition are exceeded). A CfU that forbids such configuration in operation, while all other possible configurations fulfil the requirements, would allow the issuing of the authorisation.

When a 'type 3' issue is raised to the applicant:

- › The applicant is invited to propose the actions to be taken (more restrictive CfU).
- › The entity that raised the issue, either the authorising entity or the NSA for the area of use, assesses the proposal.
- › If satisfactory, the proposal for more restrictive conditions or restrictions forms part of the application. The issue is 'closed out'; the assessment proceeds and the issue no longer prevents taking the decision to issue of the vehicle type authorisation and/ or vehicle authorisation for placing on the market.
- › If unsatisfactory, the proposal is rejected. The issue remains as 'issue pending' and the applicant is invited to make further proposals.
- › If no satisfactory proposal for more restrictive CfU can be found, authorising entity will take a negative decision and will reject the application.

3.7.10.2.4. 'type 4' issue

'type 4' issues requires an amendment to the application file by the applicant is required (non-conformity). The issue has to be resolved before the decision to issue of the vehicle type authorisation and/ or vehicle authorisation for placing on the market can be taken. It can form the basis for a justified doubt, as specified in Article 42 of Regulation (EU) 2018/545.

If 'type 4' issues cannot be closed out before the end of the defined timeframe for the assessment – or the extended timeframe when a justified doubt has been raised and in duly recorded agreement with the applicant the timeframe has been extended – the application will be refused. For this category of issues, in principle it is not possible to define additional CfU that allow the issuing of the authorisation (otherwise, it would have been initially categorised as a 'type 3' issue). But after further analysis of the issue and discussion with the applicant, a 'type 4' issue maybe closed out with the application of CfU.

Examples of 'type 4' issues are:

- › The EC certificates and EC declarations do not correspond with the references provided in ERATV (EC type or design examination certificates) and/or the information available in ERADIS

- › The evidence referred to in the AsBo report for requirements capture that was used as a basis for the independent assessment do not include a hazard log, risk assessment, description of the process followed by the applicant, etc.
- › The EC verification procedure does not consider the rules for the extension of the area of use for existing non-TSI compliant vehicles authorised under Directive 2008/57/EC or in operation before 19 July 2010
- › Missing translations for the evidence related to the national rules, to be assessed by the NSAs for the area of use following the language policy described in their guidelines
- › The CfU in the application form in the OSS are not consistent with the documentation in the file accompanying the application in the OSS (EC certificates and declarations and accompanying files, NoBo report, AsBo report for requirements capture, etc.) nor with the coded and non-coded restrictions in ERATV

For those cases where a ‘type 4’ issue is raised:

- › The applicant is invited to propose actions to be taken to resolve the issue. The applicant submits a written proposal for the actions to be taken to resolve the issue and the timeframe needed to provide the amendment for the application file; the proposed timeframe cannot go beyond the legal timeframe for the authorising entity to issue the authorisation (4 months since the application is acknowledged as complete), unless a justified doubt is raised (see section 3.7.11).
- › The entity that raised the issue, either the authorising entity or the NSA for the area of use, assesses the proposal.
- › If satisfactory, the entity that raised the issue informs the applicant.
- › If unsatisfactory, the entity that raised the issue informs the applicant of the reasons why the proposal is unsatisfactory and the issue is classified as ‘issue pending’. The applicant should provide an amended proposal taking into account the reasons given.
- › The applicant provides the amendment to the application file according to the accepted proposal before the end of the timeframe for assessment.
- › If satisfactory, the amendment is included in the application file. The issue is ‘closed out’; the assessment proceeds and the issue no longer prevents from taking the decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market.
- › If unsatisfactory, the amendment is not included in the application file. The issue remains as ‘issue pending’ and the applicant should make further amendments to the application file.
- › If the applicant has not provided an amendment within the legal timeframe for the assessment of the application, the authorising entity will take its decision based on the available information, which for a type 4 issues means that the application will be refused.

Authorising entities and NSAs for the area of use should monitor timeframes established for type 4 issues continuously. If the end of the agreed timeframe and/or the legal timeframe for assessment is approaching, and the applicant has not provided an amendment to the application file allowing to close the type 4 issue, authorising entities and/or NSAs for the area of use are encouraged to contact the applicant and request confirmation of whether it would be able to respect the agreed timeframe or not and agree a new timeframe where this is feasible.

When the legal timeframe for assessment approaches and the applicant confirms that it will not be able to provide the missing evidence on time, the authorising entity can either take the decision based on the available information (rejection of the application) or in duly justified cases it may propose to extend the timeframe by means of a justified doubt, see section 3.7.11. This shall not be used as a method to extend the timeframe for assessment indefinitely, but as an exceptional measure to be used in justified cases where the applicant needs more time than planned to amend the application file.

3.7.11. Article 42: Justified doubt

1. Where there is a justified doubt, the authorising entity and/or the concerned NSAs for the area of use may, alternatively, do one or more of the following:
 - (a) perform a more thorough and detailed check of the information provided in the application;
 - (b) request supplementary information from the applicant;
 - (c) request that the applicant conducts tests on the network.
2. The request from the authorising entity and/or the concerned NSAs for the area of use shall specify the matter that requires action from the applicant but shall not specify the nature or content of the corrective actions to be performed by the applicant. The applicant shall decide on what is the most suitable way for it to answer to the request from the authorising entity and/or the concerned NSAs for the area of use in.
3. The authorising entity shall coordinate with the concerned NSAs for the area of use regarding the actions proposed by the applicant.
4. The authorising entity and the concerned NSAs for the area of use shall, without prejudice to the provisions of Article 35, use the issues log referred to in Article 41 to manage any justified doubts. A justified doubt shall always:
 - (a) be classified as a type 4 issue pursuant to Article 41 (1)(d);
 - (b) be accompanied by a justification; and
 - (c) include a clear description of the matter that needs to be answered by the applicant.
5. Where the applicant agrees to provide supplementary information, pursuant to points (b) and (c) of paragraph 1 at the request of the authorising entity and/or the concerned NSAs for the area of use, the timeframe to provide that supplementary information shall be established in accordance with Article 34(5) and Article 34(6).
6. Where it is possible to remove a justified doubt by introducing additional and/or more restrictive conditions for use of the vehicle and other restrictions as compared to those specified by the applicant in its application and the applicant so agrees, a vehicle type authorisation and/or vehicle authorisation for placing on the market may be issued under such conditions for use of the vehicle and other restrictions.
7. Where the applicant does not agree to provide further information to remove the justified doubt raised by the authorising entity and/or the concerned NSAs for the area of use, the authorising entity shall take a decision on the basis of the available information.

The management of a justified doubt should be carried out through the issues log referred to in Article 41 of Regulation (EU) 2018/545.

The authorising entity and/or the concerned NSAs for the area of use raising a justified doubt should clearly mention that it is a justified doubt when identifying such a 'type 4' issue so that the applicant is made aware.

Because it is not possible to predict when a justified doubt could be raised or the time needed to process a justified doubt, there are no timeframes specified in the legal texts for authorising entities and NSAs for the area of use to raise a justified doubt. However, if the authorising entity and/or the concerned NSAs for the area of use have a justified doubt they should without delay raise and process the justified doubt.

A justified doubt may be identified during the assessments performed by the authorising entity/ concerned NSA for the area of use and it can concern inter-alia the following aspects:

- › Fulfilment of the essential requirements during the different stages of the process (design, manufacturing, verification and validation) by the applicant and by the supporting actors, in order to ensure conformity with all the relevant legislation;

- › Aspects of the vehicle type that could prevent the safe use in the area of use when used with the defined and intended CfU;
- › The process followed by the applicant and the supporting actors. For supporting actors this in particular refers to issues concerning the competencies of and the work performed by NoBo, DeBo and/ or AsBo and that can be grounds for restriction, suspension or withdrawal of their notification as specified in Article 39(1) of Directive (EU) 2016/797 or which justify measures according to Article 11(2) of Regulation 402/2013/EU;
- › Consistency and relevance of the documentation provided (including missing translations pursuant to Article 10 of the Regulation (EU) 2018/545, see section 3.2.10);
- › Non-compliance pursuant to Article 26(2) of Directive 2016/797; and/ or
- › Relevant information recorded pursuant to Article 8(2) of Regulation (EU) 2018/545.

The raised justified doubt should be duly substantiated with details of the matters that, in the view of the authorising entity/ concerned NSA for the area of use, have not been carefully considered in the application. These details should be specific and clearly identify the parts of the application file that are inadequate.

The means used for addressing the justified doubt are the responsibility of the applicant. The authorising entity/ concerned NSA for the area of use are required to describe the basis for the justified doubt so that it is clear to the applicant what is needed to remove the doubt, but not to impose a solution.

In the event that a justified doubt is raised by the authorising entity/ concerned NSAs for the area of use and where the applicant, in duly recorded agreement with the authorising entity, agrees that there is a need to provide further information, the applicant should propose the corrective actions and the timeframe (including an extension of the timeframe for the assessment, if needed, see section 3.7.3). The authorising entity and the concerned NSA for the area of use will review the proposal and inform the applicant about the results of their assessment.

Depending on the nature of the justified doubt, the applicant may need additional time to provide the supplementary information (in particular, if tests on the network are necessary). In such a case, the authorising entity can, with the duly recorded agreement of the applicant, and in coordination with NSAs for the area of use which are concerned by the justified doubt (if any), agree an extension of the timeframe for the assessment beyond the 4 months foreseen in Article 21(4) of Directive (EU) 2016/797; NSAs for the area of use are not allowed to extend the timeframe for the assessment on their own initiative. Further details can be found in section 3.7.3).

In the case of a disagreement with any decision of the authorising entity/ concerned NSA for the area of use (on the justified doubt itself, on the timeframe and/ or on the corrective actions) that results in a refusal of the authorisation request, the applicant can start the review and appeal procedure.

The authorising entity should not issue a vehicle type authorisation and/ or vehicle authorisation for placing on the market if the raised justified doubt(s) has not been resolved and the application and the file accompanying the application has not been amended accordingly by the applicant.

A 'type 4' issue, as specified in Article 41(1)(d) of Regulation (EU) 2018/545, will not always be a justified doubt. If it is clear, (i.e., there is no doubt that evidence provided does not allow the issuing of the authorisation) that the issue will lead to the direct rejection of the application, then a 'type 4' issue, not being considered as a justified doubt, should be raised. In such a case there will be normally no extension of the timeframe for assessment.

When the applicant has not provided an amendment within the extended timeframe following a justified doubt, the authorising entity should take its decision based on the available information, which for a type 4 issue means that the application will be rejected, and no authorisation will be delivered.

3.7.12. Article 43: The checks to be performed by the authorising entity concerning the assessments performed by the concerned NSAs for the area of use

1. The authorising entity shall check whether the assessments from the NSAs for the area of use are consistent with each other as regards the results of the assessments referred to in Article 40(6)(a).
2. Where the result from the check referred to in paragraph 1 demonstrates that the assessments of the NSAs for the area of use are consistent, the authorising entity shall verify that:
 - (a) the checklists referred to in Article 40(6)(d) have been filled-in completely;
 - (b) all relevant issues have been closed.
3. Where the result from the check in paragraph 1 demonstrates that the assessments are not consistent, the authorising entity shall request the concerned NSAs for the area of use to further investigate the reasons. As a result of this investigation, alternatively, one or both of the following shall apply:
 - (a) the authorising entity may review its assessment as referred to in Article 39;
 - (b) the concerned NSAs for the area of use may review its assessment.
4. The outcomes of investigations of the NSAs for the area of use referred to in paragraph 3 shall be shared with all the NSAs for the area of use involved in the application for the vehicle type authorisation and/or the vehicle authorisation.
5. Where a checklist referred to in paragraph 2(a) is incomplete or where there are issues that have not been closed pursuant to paragraph 2(b), the authorising entity shall request the concerned NSAs for the area of use to further investigate the reasons.
6. The NSAs for the area of use shall provide replies to requests from the authorising entity with regard to inconsistencies in the assessments referred to in paragraph 3, incompleteness in the checklists referred to in paragraph 2(a) and/or issues that are not closed in accordance with paragraph 2(b). The authorising entity shall take full account of the assessments performed by the NSAs for the area of use concerning the applicable national rules. The extent of checks performed by the authorising entity shall be limited to the consistency of the assessments and the completeness of the assessments referred to in paragraphs 1 and 2.
7. In case of disagreement between the authorising entity and the concerned NSAs for the area of use, the arbitration procedure referred to in Article 21(7) of Directive (EU) 2016/797 shall be applied.

The checks to be performed by the authorising entity concerning the assessments performed by the concerned NSAs for the area of use should only be a check of the completeness of the assessments performed (checklists complete and all issues closed) and the consistency between the assessments of the application performed by the NSAs for the area of use. It should not be a check of the detailed assessments performed by the NSAs for the area of use.

3.7.13. Article 44: Arbitration under Article 21(7) of Directive (EU) 2016/797 and Article 12(4)(b) of Regulation (EU) 2016/796

Where the Agency acts as the authorising entity, it may suspend the authorisation process, in consultation with the concerned NSAs for the area of use, during the cooperation needed to reach a mutually acceptable assessment and where applicable, until the Board of Appeal takes a decision, within the timeframes set out in Article 21(7) of Directive (EU) 2016/797. The Agency shall give the applicant reasons for the suspension.

For description of the process of arbitration, review and appeal, see the flowchart for Stage 5, including the flowcharts for Substage 5.1 and 5.2, in section 4.

3.7.13.1. Arbitration under Article 21(7) of Directive (EU) 2016/797

The disagreement of the Agency with an assessment of one or more NSAs for area of use should be notified to the concerned NSAs for the area of use, through the OSS, together with the reasons for that disagreement.

In the case where the authorising entity disagrees with the recommendation of an NSA for the area of use or identifies any issue during its assurance process, it should review them together with the concerned NSAs for the area of use. Any such review should involve the applicant where necessary, to agree on a mutually acceptable assessment and if agreement cannot be achieved, the authorising entity should take appropriate actions.

The area of use should be identified in the application form by the applicant. However, in the case of arbitration between the Agency and the concerned NSAs for the area of use, there could be additional exclusions of part(s) of the network(s) concerned by the intended area of use, in accordance with Article 21(7) of Directive (EU) 2016/797.

Where no mutually acceptable agreement between the authorising entity and the concerned NSAs for the area of use can be reached, and the decision by the authorising entity includes networks of the area of use for which the concerned NSAs for the area of use have issued a negative assessment, the concerned NSAs for the area of use can refer the matter for arbitration to the Board of Appeal in accordance to the rules of procedure for the Board of Appeal.

The vehicle type authorisation and/ or vehicle authorisation for placing on the market process can be suspended during the duration of the arbitration, including the coordination to reach mutually acceptable assessment. The Agency should give the applicant reasons for the suspension.

3.7.13.2. Arbitration under Article 12(4)(b) of Regulation (EU) 2016/796 (Board of Appeal)

In cases where no consistency of the decisions can be ensured within one month of the beginning of the coordination process between the Agency and the concerned NSA(s), the matter should be referred by the concerned NSA(s) for arbitration to the Board of Appeal in accordance with the rules and procedures for the Board of Appeal. The arbitration procedure only applies when the Agency is the authorising entity.

As specified in Article 21(7) of Directive (EU) 2016/797 the arbitration procedure needs to be resolved within 1 month. During the time the arbitration procedure is applied the authorisation process can be suspended and the time frame referred to in section 3.7.3 is then also suspended. The Agency should give the applicant reasons for the suspension.

The decision of the Board of Appeal taken within the arbitration process should be notified to the Agency and the concerned NSA(s) in accordance with the rules and procedures for the Board of Appeal.

The Agency and the concerned NSA(s) should take their final decisions in compliance with the findings of the Board of Appeal, acting within the framework of their internal procedures and should provide a statement of reasons for that decision.

3.7.14. Article 45: Conclusion of the assessment of the application

1. The authorising entity shall ensure that the process for the assessment of the application has been carried out correctly by checking in an independent manner that:
 - (a) the different stages of the process for the assessment of the application have been correctly applied;
 - (b) there is sufficient evidence to show that all relevant aspects of the application have been assessed;
 - (c) written responses to type 3 and 4 issues and requests for supplementary information have been received from the applicant;

- (d) type 3 and 4 issues were all resolved or where not resolved, together with clearly documented reasons;
 - (e) the assessments and decisions taken are documented, fair and consistent;
 - (f) the conclusions reached are based on the assessment files and reflect the assessment as a whole.
2. Where it is concluded that the process for the assessment of the application has been correctly applied, a confirmation of the correct application of paragraph 1, accompanied by any comments, shall suffice.
 3. Where it is concluded that the process for the assessment of the application has not been correctly applied, then reasons for reaching that conclusion shall be clear and specific.
 4. In conclusion of the assessment activities, the authorising entity shall complete an assessment file covering paragraphs 2 or 3 on the basis of the assessment files issued in accordance with Article 39(5) and Article 40(6).
 5. The authorising entity shall provide documented reasons for its conclusion in the assessment file referred to in paragraph 4.

In the context of the conclusion of the assessment activities to “check in an independent manner” means that a person within the organisation of the authorising entity that has not been directly involved in the assessment of the application performs the checks. It could be another assessor that has not been involved in the assessment that is to be checked.

3.7.15. Article 46: Decision for the authorisation or the refusal of the application

1. The authorising entity shall take a decision to issue the vehicle type authorisation and/or vehicle authorisation for placing on the market or to refuse the application within one week following the completion of the assessment without prejudice to the provisions of Article 34. That decision shall be taken on the grounds of the documented reasons referred to in Article 45(5).
2. The vehicle type authorisation and/or vehicle authorisation for placing on the market shall be issued by the authorising entity where the assessment of the aspects listed in Annex II and where applicable Annex III support a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their responsibilities to the extent required, in accordance with Article 38.
3. Where, following the assessment of the aspects listed in Annex II and where applicable Annex III do not support a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities to the extent required, in accordance with Article 38, the authorising entity shall refuse the application.
4. The authorising entity shall state the following in its decision:
 - (a) any conditions for use of the vehicle and other restrictions;
 - (b) the reasons for the decision;
 - (c) the possibility and means of appealing the decision and the relevant time limits.
5. The conditions for use of the vehicle and other restrictions shall be defined according to the basic design characteristics of the vehicle type.
6. The authorisation decision shall not contain any time limited conditions for use of the vehicle and other restrictions, unless the following conditions are fulfilled:
 - (a) it is required because the conformity to the TSIs and/or national rules cannot be completely proven before the issuing of the authorisation; and/or

- (b) the TSIs and/or national rules require that the applicant produces a plausible estimate of compliance.

The authorisation may then include a condition that real use demonstrates performance in line with the estimate within a specified period of time.

7. The final decision to issue the vehicle type authorisation and/or vehicle authorisation for placing on the market or to refuse the application shall be recorded in the one-stop shop and communicated together with the assessment files through the one-stop shop to the applicant and the concerned NSAs for the area of use.
8. Where the decision either refuses the application or issues the vehicle type authorisation and/or vehicle authorisation for placing on the market subject to different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application, the applicant may request that the authorising entity reviews its decision in accordance with Article 51 of this Regulation. Where the applicant is not satisfied with the reply of the authorising entity, it may bring an appeal before the competent authority in accordance with Article 21(11) of Directive (EU) 2016/797.

3.8. Chapter 7 – Stage 6 Final documentation and authorisation

For description of the process, see the flowchart for Stage 6 in section 4.

3.8.1. Article 47: Final documentation for the vehicle type authorisation and/or vehicle authorisation for placing on the market

1. A vehicle type authorisation and/or vehicle authorisation for placing on the market shall take the form of a document containing the information referred to in Article 48 and/or Article 49.
2. The issued vehicle type authorisation and/or vehicle authorisation for placing on the market shall be assigned a unique European identification number ('EIN') of which the structure and content are defined and administrated by the Agency.
3. Different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application may be included in the vehicle type authorisation and/or vehicle authorisation for placing on the market.
4. The authorising entity shall date and duly sign the vehicle type authorisation and/or vehicle authorisation for placing on the market.
5. The authorising entity shall ensure that the decision issued in accordance with Article 46 and the full accompanying file for that decision are archived pursuant to Article 52.

The full accompanying file for the decision issued in accordance with Article 46 of Regulation (EU) 2018/545 is composed of the application and the file accompanying the application submitted by the applicant and all the documents used by the authorising entity to arrive at its decision, including the authorising entities decision.

The decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market should be based on the information provided for in the application and in the (final) assessment file.

The authorising entity should complete the administrative closure by ensuring that all documentation and records are reviewed, organised and archived.

The authorising entity should co-ordinate with the concerned NSAs for the area of use to identify lessons learned to be used for future assessments. This can include information on issues and risks as well as practices that worked well that can be applied to future assessments and possibly shared with (or even learned from) other bodies for continual improvement.

3.8.2. Article 48: The information in the issued vehicle type authorisation

The vehicle type authorisation issued by the authorising entity shall contain the following information:

- (a) the legal basis empowering the authorising entity to issue the vehicle type authorisation;
- (b) identification of:
 - (i) the authorising entity;
 - (ii) the application;
 - (iii) authorisation case as specified in Article 14;
 - (iv) the applicant for the vehicle type authorisation;
 - (v) the EIN associated to the vehicle type authorisation.
- (c) an identification of the basic design characteristics of the vehicle type:
 - (i) stated in the type and/or design examination certificates;
 - (ii) the area of use of the vehicle;
 - (iii) the conditions for use of the vehicle and other restrictions;
 - (iv) the reference, pursuant to the provisions of Article 16 of Regulation (EU) 402/2013, including the document identification and the version, to the written declaration by the proposer referred to in Article 3(11) of Regulation (EU) 402/2013, covering the vehicle type.
- (d) An identification of:
 - (i) the vehicle type ID, in accordance with Annex II to Commission Decision 2011/665/EU¹ ;
 - (ii) the vehicle type variants, where applicable;
 - (iii) the vehicle type versions, where applicable;
 - (iv) values of the parameters set out in the TSIs and, where applicable, in the national rules, for checking the technical compatibility between the vehicle and the area of use;
 - (v) the vehicle type's compliance with the relevant TSIs and sets of national rules, relating to the parameters referred to in paragraph 1(d)(iv).
- (e) reference to the EC declarations of verification for the subsystems;
- (f) reference to other Union or national law with which the vehicle type is compliant;
- (g) reference to the documented reasons for the decision referred to in Article 45(5);
- (h) date and place of the decision to issue the vehicle type authorisation;
- (i) signatory of the decision to issue the vehicle type authorisation; and
- (j) the possibility and means of appealing the decision and the relevant time limits including information about the national appeal process.

¹Commission Implementing Decision 2011/665/EU of 4 October 2011 on the European register of authorised types of railway vehicles (OJ L 264, 8.10.2011, p. 32)

3.8.2.1. Withdrawal of time limitations in an issued authorisation caused by an administrative issue

It is not unusual to find temporary restrictions or time limitations in the validity of issued authorisations. When there is a need to withdraw a temporary limitation in an authorisation that was introduced due to an open issue, and closing-out the issue will not require further changes in the vehicle and/or vehicle type (technical characteristics are not impacted), the applicant shall submit to the authorising entity or to the national safety authority (NSA) the evidence required to solve the problem by any agreed means.

Examples of such issues are:

- › Missing evidence (e.g., final versions of the test reports), when the applicant and the conformity assessment bodies can produce enough evidence to demonstrate that the vehicle type meets the essential requirements, allowing that the authorising entity reaches enough level of assurance to issue a time limited authorisation;
- › Pending updated versions of documents (e.g., some updates are needed in the documents already included in the file accompanying the application to better clarify certain aspects, to solve inconsistencies, to provide additional information, etc.);
- › Need to update ERADIS with the latest versions of EC certificates and/or declarations, where the previous versions are already uploaded to ERADIS and minor issues need to be corrected;
- › Etc.

The authorising entity or the NSA that issued the authorisation should withdraw the temporary limitation without the need to issue a new authorisation, and update ERATV accordingly.

For the cases where an NSA issued the authorisation:

- › The NSA should withdraw the limitation, irrespectively of the legal regime in which the authorisation was issued and the current legal regime in the concerned Member State (e.g., authorisation issued under Directive 2008/57/EC, to be modified by an NSA of a MS having already transposed the Directive (EU) 2016/797).
- › It may be an update of the existing authorisation, a letter overriding the limitation etc., depending on the possibilities allowed by the applicable national legal framework in each MS. The applicant can send the missing documentation to the concerned NSA by any agreed means.
- › The Agency will not play any role, irrespectively of the area of use of the authorised vehicle type.

It should be noticed that time limits are only allowed in certain cases, pursuant to article 46(6) of Regulation (EU) 2018/545 and should be avoided as far as possible.

3.8.2.2. Modification of the CfU in an issued vehicle type authorisation

The vehicle type authorisation and the vehicle authorisation for placing on the market shall specify the CfU, according to article 21(10)(d) of the Directive and articles 48 and 49 of Regulation (EU) 2018/545. Authorisation for placing in service under on Directive 2008/57/EC may also contain conditions and other restrictions, pursuant to article 21(6) of the Directive.

CfU are basic design characteristics, pursuant to articles 46(5) and 48(c)(iii) of the Regulation (EU) 2018/545. Therefore, changes in the CfU that are stated in the issued authorisation should be dealt with by the application of article 15 of Regulation (EU) 2018/545.

3.8.2.2.1. *The modification of the CfU requires changes in the vehicle and/or vehicle type*

Depending on the categorisation of the change (which should take into account the impact in the CfU) according to article 15(1) of the Regulation and depending on whether the entity managing the change is also the holder of the vehicle type authorisation, there are several possibilities.

Where the entity managing the change is the holder of the vehicle type authorisation:

- › If the change is categorized as 15(1)(b), the concerned authorising entity or NSA can modify the CfU without the need to issue a new authorisation through the OSS. It may be an update of the existing authorisation, a letter overriding the limitation etc.
- › If the change is categorized as 15(1)(c), in addition to the modification of the CfU, there is a need to create a version of the vehicle type in ERATV, pursuant to article 15(3) of the Regulation. The entity that would be the authorising entity in case such change would require a new authorisation should take the responsibility of creating the version, based on the

information provided by the entity managing the change and on the data available in ERATV for the vehicle type.

In order to move existing vehicles from the parent type/variant to the versions as a result of a 15(1)(c) change, there is no need to submit an application for authorisation for placing on the market in conformity to the newly created version. The keeper shall update its records (configuration management of the vehicles) and request an update of the NVR/ECVVR/EVR.

- › If the change is categorized as 15(1)(d), there shall be an application for a new authorization through the OSS. The entity managing the change can choose the authorising entity (Agency or concerned NSA) if the area of use covers one MS; if the area of use covers more than one MS, the Agency shall be the authorising entity.

If the entity managing the change is not the holder of the vehicle authorisation or there is no vehicle type authorisation and therefore there is no holder of the vehicle type authorisation, all changes categorized as 15(1)(b), (c) or (d) of Regulation (EU) 2018/545 trigger a new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545.

When a change is classified as 15(1)(b) or (c), and it only impacts vehicle(s), the entity managing the change that is not the holder of the vehicle type authorisation can submit a notification pursuant to Article 16(4) of Regulation (EU) 2018/545.

3.8.2.2.2. The modification of the CfU does not require further changes in the vehicle and/or vehicle type

When the modification of the CfU do not require any further changes to the vehicle and/or vehicle type nor impacts the values for technical parameters, and the concerned CfU:

- › Were not recorded in the concerned ERATV entry (coded and non-coded restrictions) but were properly included in the issued vehicle type authorisation;
- › Don't have any impact in the operational envelope of the vehicle type (e.g., speed, load, cant deficiency, number of units coupled, etc.);
- › Are not related to parameters linked to technical compatibility with the network (e.g., load, gauge, active pantograph layout, etc.);
- › Duplicate values of technical parameters (e.g., basic parameter 4.2.1 Reference profile vs coded restriction 3.1.2.3 – 2.1, basic parameter 4.1.3 wheelset gauge vs coded restriction 3.1.2.3 – 2.2 wheelset gauge, etc.);
- › Impose an obligation to the applicant to provide additional evidence or documentation, specify the criteria that the additional evidence or documentation shall fulfil in order to be considered acceptable and do not entail any change in the operational envelope or in the area of use, and/or
- › Do not impose any particular CfU of the vehicle or restriction (e.g., observations, remarks or statements from the conformity assessment bodies and/or authorising entities, references to the drivers manual, reference to the maintenance plan, reference to the risk assessment, etc.)

this can be considered as a change that does not actually impact the basic design characteristic “Conditions for use of the vehicle and other restrictions” and can then be classified pursuant to Article **15(1)(a)** of Regulation (EU) 2018/545, when there is no impact in the files accompanying the EC DoVs, or **15(1)(b)** when there is a need to update the accompanying technical files (which will normally be the case).

The authorising entity or the NSA that issued the authorisation should withdraw the concerned CfU and issue a new revision of the issued authorisation without the need for the applicant to apply for a new authorisation pursuant to Article 14(1)(d) of the Regulation (EU) 2018/545, and update ERATV accordingly.

For other cases, the entity managing the change shall analyze the effect of modifying the CfU (i.e., the change) and decide whether this can be allocated to article 15(1)(c) or 15(1)(d) of the Regulation. In the case where the entity managing the change is the holder of the vehicle type authorisation:

- › If the change is categorized as 15(1)(c): the concerned authorising entity or NSA can modify the CfU without the need to issue a new authorisation, and a version of the vehicle type in ERATV needs to be created.
- › The keeper shall update its records (configuration management of the vehicles) and request an update of the NVR/ECVVR/EVR. There is no need to apply for an authorisation for placing on the market in conformity to the new version. If the change is categorized as If 15(1)(d): there shall be an application for a new authorization through the OSS.

If the entity managing the modification of the CfU is not the holder of the vehicle authorisation, and the modification is categorized as 15(1)(c) or (d) of Regulation (EU) 2018/545, a new authorisation pursuant to Article 14(1)(d) of the Regulation is required.

When the modification in the CfU is classified as 15(1)(b) or (c), and it only impacts vehicle(s), the entity managing such modification can submit a notification pursuant to Article 16(4) of Regulation (EU) 2018/545.

3.8.2.3. CfU inherited from the existing authorisation

In case of a new authorisation and/or an extension of the area of use, the vehicle type authorisation to be issued shall contain all CfU that are relevant for the use of the vehicles after the change and/or extension of the area of use, including CfU from the parent type/variant or vehicle that are inherited and should be preserved (they are basic design characteristics from a previous authorisation process). The authorising entity should only modify such CfU in case of conflict with the new CfU (e.g., a CfU applicable before the change is not anymore applicable, or a CfU in the original area of use is not valid for the extended area of use) , following consultation with the concerned NSA.

The issued vehicle type authorisation should differentiate between the CfU that are inherited, the inherited CfU that are impacted by the changes and/or the extension of the area of use (if any) and the new CfU arising from the new authorisation process.

3.8.3. Article 49: The information in the issued vehicle authorisation for placing on the market

The vehicle authorisation for placing on the market issued by the authorising entity shall contain the following information:

- (a) the legal basis empowering the authorising entity to issue the vehicle authorisation for placing on the market;
- (b) identification of the:
 - (i) authorising entity;
 - (ii) application;
 - (iii) authorisation case as specified in Article 14;
 - (iv) applicant for the vehicle authorisation for placing on the market;
 - (v) EIN associated to the vehicle authorisation for placing on the market.
- (c) the reference to the vehicle type registration in ERATV, including the information on the vehicle type variant and/or vehicle type version, when applicable;
- (d) identification of the:
 - (i) vehicles;
 - (ii) areas of use;

(iii) conditions for use of the vehicle and other restrictions.

- (e) reference to the EC declarations of verification for the subsystems;
- (f) reference to other Union or national law with which the vehicle is compliant;
- (g) reference to the documented reasons for the decision referred to in Article 45(5);
- (h) in case of an authorisation in conformity to type pursuant to Article 14(1)(e), the reference to the declaration of conformity with an authorised vehicle type, including information on the vehicle type version and/or vehicle type variant when applicable;
- (i) the date and place of the decision to issue the vehicle authorisation for placing on the market;
- (j) the signatory of the decision to issue the vehicle authorisation for placing on the market; and
- (k) the possibility and means of appealing the decision and the relevant time limits, including information on the national appeal process.

3.8.3.1. Identification of the vehicles

A vehicle that has been registered is identified by its European Vehicle Number (EVN), a numeric identification code as defined in Appendix 6 of Decision 2007/756/EC.

After a vehicle authorisation for placing on the market has been issued for a vehicle, the vehicle should be registered in the NVR. The registering entity, based on the request for registration of the keeper, should assign an EVN to the vehicle. The issuing of the vehicle authorisation for placing on the market and the registration of the vehicle may be combined, take place in parallel or be done in sequence (vehicle authorisation for placing on the market issued before registration), depending on the internal procedures of the registering entity and the authorising entity. A common practice for the registration entity is to pre-reserve for the keeper a number that will become the EVN when the vehicle is registered.

Nevertheless, before the vehicle authorisation for placing on the market is issued the vehicle needs to be identified. When there is no EVN reserved when the application for vehicle authorisation for placing on the market is submitted by the applicant, the identification of the vehicle can be done by using the manufacturer's own system for identification of the vehicle or by identification of the product serial number.

3.8.4. Article 50: Registration in ERATV and ERADIS

1. The ERATV shall be completed by the authorising entity using the information provided by the applicant as part of the vehicle type authorisation application. The applicant shall be responsible for the integrity of the data provided to the authorising entity. The authorising entity shall be responsible for checking the consistency of the data provided by the applicant and making the ERATV entry available to the public.
2. The authorising entity shall ensure that the European Railway Agency Database of Interoperability and Safety ('ERADIS') has been updated as appropriate before delivering a vehicle type authorisation and/or vehicle authorisation for placing on the market.
3. For modifications pursuant to Article 15(1)(c) and 15(3), the authorising entity shall register in ERATV the new version of a vehicle type or the new version of a vehicle type variant, using the information provided by the holder of the vehicle type authorisation. The holder of the vehicle type authorisation is responsible for the integrity of the data provided to the authorising entity. The authorising entity shall be responsible for checking the consistency of the data provided by the holder of the vehicle type authorisation and making the ERATV entry available to the public.

Pending the registration of the new version of a vehicle type or the new version of a vehicle type variant, the vehicles modified to be conforming to the new version may already be operated without delay.

3.8.4.1. ERATV

The vehicle type authorisations issued shall be recorded in ERATV by the concerned authorising entity. The applicant, if the authorising entity so requests, can fill-in certain parts of the draft ERATV entry, on behalf of the authorising entity (auxiliary user).

Further information on ERATV (in particular, the application guide) can be found here:

https://www.era.europa.eu/domains/registers/eratv_en

3.8.4.1.1. Requesting the creation of a draft ERATV entry

When the Agency is the authorising entity, the process for requesting the creation of a draft type prior to the submission of an application through the OSS is described here:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2676

This process shall also be applied for requesting the creation of a version in ERATV following a change classified pursuant to Article 15(1)(c) of Regulation (EU) 2018/545.

The creation of a draft ERATV entry can be requested long before the submission of the concerned application for vehicle type authorisation. Similarly, when the authorising entity gives ERATV “auxiliary users” permission to fill-in certain parts of a draft ERATV entry (i.e., sections 3 conformity with TSIs and 4 technical parameters), this activity can also be performed ahead of the submission of the application for authorisation.

3.8.4.1.2. Changes and/or extension of the area of use of vehicles without a type authorisation / ERATV entry

In case of vehicles without a matching vehicle type authorisation or when such type authorisation is not registered in ERATV (e.g., vehicles authorised before Directive 2008/57/EC), it is still possible to use the authorisations cases described in Articles 15(1)(c) – extension of the area of use – and/or 15(1)(d) – new authorisation – of Regulation (EU) 2018/545, provided that there is evidence that the vehicles are actually authorised and in operation.

In the majority of the cases for vehicles authorised before Directive 2008/57/EC, no EC verification procedure was performed, no NoBo was appointed for the certification of compliance with the requirements of the TS, there was no issued vehicle type authorisation and as a result there is no ERATV entry. This means that there is no reliable data (i.e., checked by a NoBo and by an authorising entity before publication in ERATV) from the existing authorisation.

For this reason, ERATV entries following new authorisations and/or extensions of the area of use should only contain the values for the parameters impacted by the changes and/or the extended area of use (which are in the scope of the EC verification procedure and of the vehicle type authorisation); the values for all other parameters should be left empty (using the “Exceptional mode” of ERATV).

If the values for all parameters would be filled-in in ERATV, the authorising entity for the new authorisation and/or the extension of the area of use, which shall ensure the consistency and coherency of the data to be included in ERATV, does not have the possibility to fulfil its legal duty, as there is no assurance of the accuracy or consistency of the data provided by the applicant.

See also section 3.8.4.1.4.

3.8.4.1.3. Update of EC type or design examination certificates following 15(1)(b) changes

In case of changes classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545, when there is an impact on the EC type or design examination certificates following new verifications by the conformity assessment bodies, the corresponding ERATV entry shall be updated. If not, it will not be possible to deliver authorisations for placing on the market in conformity to the concerned type for newly built vehicles if the EC type or design examination certificates in the file accompanying the application do not match the ones referenced in ERATV.

Because the EC type examination certificates refer to subsystems as a whole, there shall be only 1 EC type examination certificate per subsystem listed in a given ERATV entry. In some specific circumstances (e.g., new EC certificate only covering the changes and not making use of the previous EC certificate, therefore not covering the whole subsystem) there may be a need for referring more than 1 EC type examination certificate for a subsystem.

The responsibility of requesting an update of the concerned ERATV entry and of the accuracy and integrity of the related data lies with the holder of the vehicle type authorisation (configuration management of the vehicle type). The update of an ERATV entry does not constitute an acceptance by the concerned authorising entity of the categorisation of the change performed by the entity managing the change.

When the Agency was the authorising entity that issued the type authorisation, the process for requesting such update is described here:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2675

3.8.4.1.4. ERATV entries following a new authorisation and/or an extension of the area of use

The values for the ERATV parameters shall derive from an issued vehicle type authorisation, which shall rely on the EC verification procedure (i.e., assessment of the requirements of the TSIs by a Notified Body).

In case of a new authorisation and/or an extension of the area of use, the authorising entity shall follow a "delta" approach: the vehicle type authorisation issued following the changes and/or the extension of the area of use only covers the changes (and the impact in the unchanged parts) and the extended area of use. As a result, the ERATV entry, which is a digitalisation of the issued vehicle type authorisation, shall cover only the "delta" and contain only the values for the parameters impacted by the changes and/or the extended area of use, no matter if most of the parameters in section 4 have no value; there are no limits concerning how many values can be left empty.

Because the ERATV entry shall include the type ID of the type/variant from which the new type/variant/version derives, where values for the parameters that are not impacted can be found.

Such types can be used by applicants for submitting applications for authorisation for placing on the market using the authorisation case described in Article 14(1)(e) of Regulation (EU) 2018/545, conformity to type. The changes to be performed in the vehicles shall match the changes assessed in the framework of the concerned vehicle type authorisation; this authorisation case cannot be used to apply a change to vehicles that differ from the vehicle and/or type used as a starting point for the new authorisation (see section 3.3.2.6).

3.8.4.2. Compilation of entries in ERATV

The Directive (EU) 2016/797 includes the concepts of vehicle type and authorisation of a vehicle type, which were already present in Directive 2008/57/EC. The Regulation (EU) 2018/545 further defined and specified this concept by identifying two categories: variant of a vehicle type, and version of a vehicle type or of a variant of a vehicle type.

Due to the definitions of variant and version in the Regulation:

- › Versions of versions are not allowed;
- › Versions can be created both from a type or from a variant of a type, and
- › An extension of the area of use should result in the creation of either a new type or a new version.

This has an impact for the holders of vehicle type authorisations, as it does not allow to further evolve a version and obliges always to create new types. The holder of a vehicle type authorisation can always decide to apply for a new type even in case of extension of the area of use, restarting anew the counter for possible subsequent configurations (variants and versions).

However, this will result in different types and/or versions depending on the area of use for authorisation and the sequence of authorisations over time followed by the holder of the vehicle type authorisation, while the technical characteristics of all types/versions would be identical.

When applying for the authorisation for placing on the market of vehicles in conformity to an already authorised type, the applicant needs to identify the type/version that the vehicle conforms with. This choice also defines the area of use of such vehicle (that of the reference type/version). Due to the fact that it is not possible to choose several type/versions for a given vehicle when applying for an authorisation in conformity to an already authorised type, this prevents the authorisation in certain combinations of MSs in the area of use, although the vehicle would be de facto authorised in all the concerned MSs.

A similar situation occurs for versions created after the addition of an ETCS system compatibility (ESC)/ Radio system compatibility (RSC) to an existing vehicle type or variant of a vehicle type, pursuant to section 7.2.1a.1 of CCS TSI, and for versions as a result of a change classified pursuant to Article 15(1)(c) or Regulation (EU) 2018/545, because the subsequent evolutions (namely, adding more ESCs/RSCs or performing subsequent 15(1)(c) changes) of the newly created version would not be allowed.

The following section provides the conditions under which it may be possible to compile existing ERATV entries (normally, versions) into a new one, allowing for a clear ERATV entry to be used when submitting applications for authorisation for placing on the market in conformity to type.

3.8.4.2.1. Compilation of entries created in ERATV following an extension of the area of use to another EU MS

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, an authorising entity may decide to create in ERATV a new version compiling types or versions of a vehicle type, already registered in ERATV following an authorisation for an extension of the area of use. Each of the existing entries that will be compiled remain valid and may be used by applicants to apply for authorisations for placing on the market in conformity to type.

The compilation of types⁸ and/or versions is not an authorisation, but a service output that compiles existing entries in ERATV, created following an extension of the area of use of a given type or variant.

While there is no limit in the number of compilations allowed, the requestor should explain the reasons for a particular compilation (e.g., contract signed to provide vehicles with an intended area of use not covered by any other version, while the same vehicle type is de facto authorised in all MSs of the area of use), without the need to provide the supporting documentation.

The result of the compilation will be a new ERATV entry. The type ID will be assigned as if it was a new version of the parent type or variant. This new version will compile the values for the different parameters (including coded and non-coded restrictions) TV corresponding to the ERATV entries that will be compiled. In the comments section, it will describe both the parent type or parent variant and the different ERATV entries compiled (including their type IDs).

The conditions that shall be met for compiling already authorised types⁸ and/or versions are:

- › The requestor shall be the holder of the vehicle type authorisation for the parent type or variant and for all the ERATV entries that will be compiled;
- › All ERATV entries shall derive from the same type or from the same variant, it's not possible to compile versions from a type with versions from a variant of such type;
- › All the ERATV entries that will be compiled should have been authorised by the concerned authorising entity following the procedure laid down in Regulation (EU) 2018/545 and should be registered in ERATV under Directive (EU) 2016/797;

⁸ Type authorised following an extension of the area of use when the holder of the vehicle type authorisation decides that a new type is to be created, pursuant to Article 14(2) of Regulation (EU) 2016/545

- › The different ERATV entries to be compiled should refer to the same TSIs, including non-applications granted, alternative specifications, selection of requirements from newer versions (cherry picking) and other sections not complied with);
- › There shall be no changes in the technical characteristics between the different ERATV entries to be compiled; in other words, the ERATV entries to be compiled shall correspond to the same design;
- › The differences allowed between the ERATV entries to be compiled are those related to the:
 - Values for the ERATV parameters that can be different due to the fact that each type⁹ and/or version is authorised in a different area of use, such as:
 - area of use;
 - CfU when they are related to national rules or other local particularities of the concerned area of use;
 - reference to the written declaration covering the requirements capture for the essential requirement safety and safe integration between subsystems;
 - Additional, or different technical characteristics due to the different combinations of track gauge, electrification system and CCS class-B system, and/or
 - ESCs / RSCs.
 - National rules for specific cases, open points and aspects not covered by TSIs in case of versions following extension of the area of use;
 - References to the type or design examination certificates;
 - Dates of original authorisation;
 - Dates of creation of the records in ERATV, and/or
 - Authorisation document references.
- › There shall be no contradictions or inconsistencies between the different basic design characteristics of the different ERATV entries to be compiled, in particular coded and non-coded restrictions.
- › All the transitions between MSs in the area of use of the ERATV entries to be compiled (cross-border operation) shall be covered by the existing authorisations, meaning that the possibilities for cross-border operation between MSs of the area of use of the compiled version shall remain unchanged as compared to the existing individual types⁹ and/or versions, and no additional transitions can be included as a result of the compilation.

3.8.4.2.2. *Compilation of versions created following the addition of an ETCS system compatibility (ESC) type /Radio system compatibility (RSC) type*

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, an authorising entity may decide to create a new version compiling existing ERATV versions of a vehicle type or of a variant of a vehicle type, when these versions were the result of adding one or more ESCs/RSCs to an authorised vehicle type or variant of a vehicle type. The existing versions will remain valid. The new ERATV entry will have a type ID corresponding to a new version of the parent type or variant.

In the comments section, the new entry will describe both the parent type or variant and the different existing versions from which the ESCs/RSCs are taken (including their type IDs).

The conditions that shall be met for combining already published versions are:

⁹ Type authorised following an extension of the area of use when the holder of the vehicle type authorisation decides that a new type is to be created, pursuant to Article 14(2) of Regulation (EU) 2016/545

- › The requestor shall be the holder of the vehicle type authorisation for all the versions from which the ESCs/RSCs will be taken;
- › All versions shall derive from the same type or from the same variant, it's not possible to compile versions from a type with versions from a variant of such type;
- › All the versions that will be compiled should have been submitted for publication in ERATV by the concerned authorising entity;
- › There shall be no changes in the technical characteristics between the different versions to be compiled; in other words, the versions to be compiled shall have the same design;
- › The differences allowed between the ERATV entries related to the versions to be compiled are:
 - ESCs/RSCs;
 - References to the type or design examination certificates for the control, command and signalling subsystem;
 - Reference to the written declaration covering the requirements capture for the essential requirement safety and safe integration between subsystems, and/or
 - Dates of creation of the records in ERATV.

3.8.4.2.3. Compilation of versions created following 15(1)(c) changes

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, an authorising entity may decide to create a new version compiling existing ERATV versions of a vehicle type or of a variant of a vehicle type, when these versions were the result of a change classified pursuant to Article 15(1)(c) of Regulation (EU) 2018/545. The existing versions will remain valid.

The new ERATV entry will have a type ID corresponding to a new version of the parent type or variant.

In the comments section, the new entry will describe both the parent type or variant and the different existing versions from which the different 15(1)(c) changes come from (including their type IDs).

The conditions that shall be met for combining already published versions are:

- › The requestor shall be the holder of the vehicle type authorisation for all the versions from which the 15(1)(c) changes come from;
- › All versions shall derive from the same type or from the same variant, it's not possible to compile versions from a type with versions from a variant of such type;
- › All the versions that will be compiled should have been submitted for publication in ERATV by the concerned authorising entity;
- › The 15(1)(c) versions to be compiled shall have the same design and therefore the same values for the technical characteristics in ERATV for parameters not impacted by the changes;
- › The differences allowed between the ERATV entries related to the versions to be compiled are:
 - Values for the ERATV parameters related to basic design characteristics impacted by the 15(1)(c) changes. The cumulative effect of the different 15(1)(c) changes for the same ERATV parameter as compared to the type or variant from which all versions derive should be considered when analysing the thresholds allowed in the applicable TSIs;
 - References to the type or design examination certificates;
 - Reference to the written declaration covering the requirements capture for the essential requirement safety and safe integration between subsystems, and/or
 - Dates of creation of the records in ERATV.

3.8.4.2.4. *Compilation of entries in ERATV from different origins*

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, an authorising entity may decide to create new versions compiling existing types¹⁰ *and/or* versions even if the reasons for the creation of such versions are different, e.g.

- › Performing a 15(1)(c) change to a type¹⁰ and/or version authorised as a result of an extension of the area of use;
- › Adding an ESC type to a type¹⁰ and/or version authorised as a result of an extension of the area of use;
- › Performing a 15(1)(c) change to a version created as a result of adding an ESC type;
- › Adding an ESC type to a version created as a result of a 15(1)(c) change,
- › Etc.

The new ERATV entry will have a type ID corresponding to a new version of the common parent type or the common parent variant.

In the comments section, the new entry will describe both the parent type/variant and the different existing ERATV entries that are compiled (including their type IDs).

The conditions that shall be met for combining already published versions are:

- › The requestor shall be the holder of the vehicle type authorisation for the parent type or variant and for all the ERATV entries that will be compiled;
- › All the ERATV entries shall derive from the same type or from the same variant, it's not possible to compile versions from a type with versions from a variant of such type;
- › All the ERATV entries that will be compiled should have been submitted for publication in ERATV by the concerned authorising entity;
- › The ERATV entries to be compiled shall have the same technical characteristics (i.e., same design);
- › The differences allowed between the ERATV entries to be compiled are:
 - Values for the ERATV parameters that can be different related to the fact that types¹⁰ and/or versions following extension of the area of use are authorised in different MSs (area of use, CfU, etc.);
 - Values for the ERATV parameters related to basic design characteristics impacted by the 15(1)(c) changes. The cumulative effect of the different 15(1)(c) changes for the same ERATV parameter as compared to the type or variant from which all versions derive should be considered when analysing the thresholds allowed in the applicable TSIs;
 - ESCs/RSCs;
 - National rules for specific cases, open points and aspects not covered by TSIs in case of versions following extension of the area of use;
 - References to the type or design examination certificates;
 - Dates of original authorisation;
 - Reference to the written declaration covering the requirements capture for the essential requirement safety and safe integration between subsystems;
 - Dates of creation of the records in ERATV, and/or
 - Authorisation document references.

¹⁰ Type authorised following an extension of the area of use when the holder of the vehicle type authorisation decides that a new type is to be created, pursuant to Article 14(2) of Regulation (EU) 2016/545

3.8.4.2.5. Adding a version to an already published version

When there is a need to add a new version (not yet published in ERATV) to an already published version, this can be done in two different ways:

- › Request the publication of the new version from the parent type, and then request the compilation of the two versions; this will result in 2 new versions created in ERATV, or
- › Request the publication of a new version from the (common) parent type, including all the information for both the existing version and for the new one to be “added” in a single request; this will result in a new version that will contain all the elements.

Below there is an example of the two options mentioned above:

- › Version following a 15(1)(c) change #1 to parent type: version 1 published in ERATV
- › Version following a 15(1)(c) change #2 to be added to version 1:
 - Option 1:
 - New version 2 considering 15(1)(c) change #2 to parent type to be published in ERATV following a request with the details to change #2 only, and
 - New version 3 to be published in ERATV compiling version 1 and version 2, hence incorporating 15(1)(c) changes #1 and #2 to the parent type
 - Option 2:
 - New version 2 from parent type to be published in ERATV considering both changes #1 and #2 in one single request, completely independent of version 1

3.8.4.2.6. Process to request to the Agency a compiled of version

The process to request the creation of a new compiled version, when the Agency is the concerned authorising entity, is described in the following FAQ:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2672

There are some parameters in ERATV that are designed to have a single value (e.g., date of original authorisation). For such cases, the requestor should compile the different values in the template [TEM_VEA_092](#). The Agency will introduce the relevant information in the comments section of the ERATV when it's not possible to include it in the concerned field in ERATV.

Similarly, some other parameters in ERATV are not accessible for auxiliary users (e.g., coded and non-coded restrictions). The requestor should provide the compiled information by means of the template [TEM_VEA_092](#). The Agency will introduce the relevant information in ERATV.

3.8.4.3. ERADIS

Under the 4th Railway Package, EC declarations (verification, conformity and/or suitability for use) and EC certificates (verification, conformity and/or suitability for use) use shall be uploaded to ERADIS by the concerned actors:

- › Applicants for placing on the market of mobile subsystems: EC DoVs
- › Manufacturers of ICs: EC declarations of conformity/suitability for use
- › NoBos: EC certificates (verification, conformity and/or suitability for use)

These obligations are independent from any authorisation process or any submission through the OSS. The NoBos shall populate ERADIS when the certificates are issued, and applicants/manufacturers shall populate ERADIS when the products (be it subsystems or ICs) are placed on the market. Furthermore, the vehicle authorisation for placing on the market and/or the vehicle type authorisation cannot be delivered, pursuant to article 50(2) of Regulation (EU) 2018/545).

In case of new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, the certificates and declarations related to the ICs to be uploaded in ERADIS are only those impacted by the change.

When the Agency is the authorising entity, the applicant is kindly requested to provide additional information related to EC declarations and certificates uploaded to ERADIS, with the objective of facilitating the assessment of the consistency of the documents in the file accompanying the application with ERADIS. Further information can be found here:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2673

3.8.4.4. Vehicle registration in NVR/ECVVR/EVR

Each vehicle should be registered in the concerned vehicle register (NVR/ECVVR/EVR), specifying the vehicle type/variant/version it conforms with. Vehicle registration is done upon the keepers request and is not part of the vehicle authorisation process.

Further information about ECVVR and EVR (including application guides) can be found here:

https://www.era.europa.eu/domains/registers/ecvvr_en
https://www.era.europa.eu/domains/registers/evr_en

3.8.4.5. Responsibility of the integrity of the data to be included in the registers

The entity keeping the register (i.e., the registering entity for the vehicle register, the Agency for ERATV and ERADIS) should perform the basic check against the specifications (e.g., format of data, mandatory/ optional fields, etc.) and/ or the reference data.

The applicant is responsible for providing technical data for ERATV and for the integrity (i.e., accuracy and correctness) of the data they provide. The authorising entity is responsible to validate and check the consistency of the data (namely, to verify that the data introduced by the applicant is consistent with the technical documentation of the vehicle as available in the OSS).

Regarding NVR/ECVVR/EVR, the keeper provides the data and it is responsible for the integrity of the data. The registering entity checks the global consistency and updates NVR/ECVVR/EVR.

3.8.4.6. The planned International Registry of Mobile Assets – Railway equipment

The Luxembourg Protocol to the Cape Town Convention on International Interests in Mobile Equipment on Matters specific to Rail Rolling Stock (the Rail Protocol) is a global treaty that focuses on facilitating financing of railway vehicles by providing an international recognition and registration of financial security interests of such assets. There is already a similar regime in place for aircraft (www.internationalregistry.aero/ir-web/).

The Rail Protocol was adopted in 2007. It needs 4 ratifications and a certificate of readiness from OTIF, as secretary to the Supervisory authority to enter into force. The status (27th June 2017) was that there were 3 ratifications (European Union, Gabon and Luxembourg), 7 signatures (France, Germany, Italy, Mozambique, Sweden, Switzerland and United Kingdom) and ongoing discussions with 19 Governments.

The Rail Protocol will provide a system for rights of creditors whose interests will be registered, and searchable at an international registry to be based in Luxembourg and operated by Regulis SA (same as for the International Registry of Mobile Assets – Aircraft). It applies to financing of railway vehicles operated domestically as well as internationally and it will also introduce a new global unique and permanent numbering system for railway vehicles (URVIS).

The identification number (URVIS) will be:

- › Affixed to the vehicle;
- › Associated in the International Registry with the manufacturer's name and the manufacturer's identification number for the vehicle; or
- › Associated in the International Registry with a national or regional identification.

The vehicle can be registered in the international registry and the vehicle assigned with the URVIS number before, during or after the vehicle authorisation for placing on the market has been issued. Also, existing vehicles authorised under another regime can be registered.

The applicant will be able to use the URVIS number to identify the vehicle in its application for vehicle authorisation for placing on the market.

For more information on the Rail Protocol and the associated International Registry:

www.unidroit.org
www.railworkinggroup.org

3.8.5. Article 51: Review under Article 21(11) of Directive (EU) 2016/797

1. Where the decision of the authorising entity contains a refusal or different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application, the applicant may request the review of the decision within one month from the date of its receipt. That request shall be submitted by the applicant through the one-stop shop.
2. The request for review shall include a list of issues that, in the view of the applicant, have not been properly taken into consideration during the vehicle authorisation process.
3. Any supplementary information which has been developed and filed through the one-stop shop after the date of issuing of the authorisation decision shall not be admissible as evidence.
4. The authorising entity, where applicable in coordination with relevant NSAs for the area of use, shall ensure impartiality of the review process.
5. The review process shall address the issues justifying the negative decision of the authorising entity in accordance with the applicant's request.
6. Where the Agency acts as the authorising entity, a decision to reverse or not its decision shall be subject to review in coordination with the relevant NSAs for the area of use, where applicable.
7. The authorising entity shall confirm or reverse its first decision within two months from the date of receipt of the request for review. That decision shall be communicated to the relevant parties through the one-stop shop.

For description of the process see the flowchart for Substage 5.2 in section 4.

3.8.5.1. Review

The applicant can, within 1 month from the receipt of the decision, request a review under Article 21(11) of Directive (EU) 2016/797 when the decision:

- › Refuses the issuing of an authorisation, or
- › Contains different CfU as compared to those specified by the applicant in its application.

In both cases, the decision is considered to be negative. To request the review of the decision, the applicant shall use the relevant option in the actions button of the OSS, explaining in detail which are the aspects that have not been properly considered by the authorising entity by means of a document uploaded to the OSS in the relevant section of the library. Please note that no new evidence can be accepted at this stage; the review request shall be based on the evidence already provided in the file accompanying the application.

Where the negative decision is reversed within the review process, the authorising entity should issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market without delay.

3.8.5.2. Appeal

If a negative decision of the authorising entity is confirmed following a review request, the applicant may bring an appeal before the Board of Appeal within 2 months from the receipt of the decision following the review request (for applications for which the Agency has been selected as an authorising entity) or before the national appeal body (for applications for which the relevant NSA has been selected as the authorising entity), in accordance with the national procedure.

Any appeal against a decision of the Agency should be brought before the Board of Appeal in accordance with the rules of procedure for the Board of Appeal.

Where the Board of Appeal finds that the grounds for appeal are founded, the Agency in coordination with the concerned NSAs for the area of use should take its final decision in compliance with the findings of the Board of Appeal without delay and in any case, not later than one month following the notification of findings by the Board of Appeal.

The decision of the Board to refuse the appeal should be recorded in the OSS and reflected in the file accompanying the application. After the completion of the appeal process, the final decision of the authorising entity, including the findings notified by the Board of Appeal, should be notified to the applicant and the concerned NSAs for the area of use, through the OSS.

Decisions taken on the basis of the findings of the Board of Appeal can be appealed before the General Court of the European Union.

To file an appeal to the Board of Appeal, it shall follow the rules of procedure of the Board of Appeal. The process is described in the following section of website of the Agency:

https://www.era.europa.eu/agency-you/board-appeal_en

3.8.6. Article 52: Archiving of a decision and the full accompanying file for the decision issued in accordance with Article 46

1. The decision and the full accompanying file for the decision issued in accordance with Article 46 shall be retained in the one stop shop for at least 15 years.
2. The full accompanying file for the decision of the authorisation entity issued in accordance with Article 46 shall include all documents used by the authorising entity and the assessment files of the concerned NSAs for the area of use.
3. After the expiry of the retention time set out in paragraph 1, the decision given in accordance with Article 46 for the issue of a vehicle type authorisation and/or a vehicle authorisation for placing on the market, and its full accompanying file shall be moved to a historical archive and kept for a period of five years after the termination of the service life of the vehicle, as recorded in the register referred to in Article 47 of Directive (EU) 2016/797.

3.8.6.1. The end of the service life of a vehicle

When the end of the service life of a vehicle arrives, the concerned vehicle register (NVR/ECVVR/EVR) needs to be updated accordingly. The Decision (EU) 2018/1614, repealing Decision 2007/756/EC, contains the:

- › Provisions for withdrawal of registration; and
- › Codes for “withdrawal” of an authorisation (registration status). This contains, for example, the date of official scrapping and/ or other disposal arrangement and the code of withdrawal mode.

3.9. Chapter 8 - Suspension or revocation or amendment of an issued authorisation

3.9.1. Article 53: Suspension, revocation or amendment of an issued authorisation

1. Temporary safety measures in the form of suspension of a vehicle type authorisation may be applied by the authorising entity in accordance with Article 26(3) of Directive (EU) 2016/797.
2. In the cases referred to in Article 26(3) of Directive (EU) 2016/797 and following a review of the measures taken to address the serious safety risk, the authorising entity that issued the authorisation may decide to revoke or amend the authorisation in accordance with Article 26(4) of Directive (EU) 2016/797.
3. The applicant may launch an appeal against the decision to revoke or amend an authorisation in accordance with Article 26(5) of Directive (EU) 2016/797.

4. The authorising entity shall inform the Agency where there is a decision to revoke or amend an authorisation and give the reasons for its decision. The Agency shall inform all NSAs of the decision to revoke or amend an authorisation and the reasons for the decision.

The conditions for when a vehicle type authorisation and/ or vehicle authorisation for placing on the market can be suspended, revoked or amended are defined in Article 26 of Directive (EU) 2016/797.

The criteria for revocation is that the vehicle type is proven not to have met the essential requirements at authorisation. Revocation is therefore an action to be taken to deal with defective design or manufacture of a vehicle type or vehicles of a vehicle type. It is not to be used in the case of failure to meet the essential requirements due to actions or inactions of the SMS of the RU or entity in charge of maintenance (ECM) (e.g., a SMS that does not properly control maintenance leading to vehicles no longer meeting the essential requirements).

In the case of a revocation of a vehicle type authorisation there is no automatic revocation of the vehicle authorisation for placing on the market for vehicles conforming to that type; this is a case by case decision to be taken following an analysis on whether the vehicles have the same issue or not. If the problem exists as well for the vehicles, the concerned vehicles should be withdrawn, meaning that they can no longer be used, pursuant to article 26(8) of Directive (EU) 2016/797.

3.9.2. Article 54: The effect of suspension or revocation or amendment of an issued authorisation on the registration in ERATV, ERADIS and Vehicle registers

1. When the authorising entity takes a decision to revoke, suspend or amend a vehicle type authorisation it shall update the ERATV accordingly, subject to the provisions of Article 26(4) of Directive (EU) 2016/797, and ensure that ERADIS is updated accordingly.
2. The Member State where the vehicle is registered shall ensure that any decision to revoke or amend a vehicle type authorisation and/or a vehicle authorisation for placing on the market is reflected in the register referred to in Article 47 of Directive (EU) 2016/797.

3.10. Chapter 9 - Final provisions

3.10.1. Article 55: Transitional provisions

1. Where a NSA recognises that it will not be able to issue a vehicle authorisation in accordance with Directive 2008/57/EC before the relevant date in the Member State concerned, it shall inform the applicant and the Agency immediately.
2. In the case referred to in Article 21(8) of Directive (EU) 2016/797, the applicant shall decide whether to continue to be assessed by the NSA or to submit an application to the Agency. The applicant shall inform both of them and the following shall apply:
 - (a) in cases where the applicant has decided to submit an application to the Agency, the NSA shall transfer the application file and the results of its assessment to the Agency. The Agency shall accept the assessment carried out by the NSA;
 - (b) in cases where the applicant has decided to continue with the NSA, the NSA shall finalise the assessment of the application and decide on the issue of the vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with Article 21 of Directive (EU) 2016/797 and this Regulation.
3. Where the area of use is not limited to one Member State, the authorising entity shall be the Agency and the procedure set out in point (a) of paragraph 2 applies.
4. In cases referred to in paragraphs 2 and 3, the applicant shall submit a revised application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market by means of the one-stop

shop, in accordance with this Regulation. The applicant may request assistance for supplementing the file from the authorising entities involved.

- 4a. Notwithstanding paragraphs 1 to 4, in those Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and where Directive (EU) 2016/797 shall apply from 16 June 2020, the NSA shall, at the request of the applicant, continue to carry out the assessment of the applications for a vehicle type authorisation and/or a vehicle authorisation for placing on the market in accordance with Directive 2008/57/EC, beyond 16 June 2020, provided that it shall issue the vehicle type authorisation and/or vehicle authorisation before 30 October 2020.

Where a NSA recognises that it will not be able to issue a vehicle type authorisation and/or vehicle authorisation before 30 October 2020, it shall inform the applicant and the Agency immediately and paragraphs 2 to 4 shall apply.

5. A vehicle authorisation and/or vehicle type authorisation issued by the Agency between 16 June 2019 and 16 June 2020 shall exclude the network or networks in any of the Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and that have not yet transposed that Directive and not brought into force its national transposition measures. The NSAs of the Member States that have made such a notification shall:

- (a) treat a vehicle type authorisation issued by the Agency as equivalent to the authorisation for types of vehicles issued in accordance with Article 26 of Directive 2008/57/EC and apply paragraph 3 of Article 26 of Directive 2008/57/EC as regards this vehicle type;
- (b) accept a vehicle authorisation issued by the Agency as equivalent to the first authorisation issued in accordance with Article 22 or 24 of Directive 2008/57/EC and issue an additional authorisation in accordance with article 23 or 25 of Directive 2008/57/EC.

- 5a. A vehicle authorisation and/or vehicle type authorisation issued by the Agency between 16 June 2020 and 30 October 2020 shall exclude the network or networks in any of the Member States that have notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797. The NSAs of the Member States that have made such a notification shall:

- (a) treat a vehicle type authorisation issued by the Agency as equivalent to the authorisation for types of vehicles issued in accordance with Article 26 of Directive 2008/57/EC and apply paragraph 3 of Article 26 of Directive 2008/57/EC as regards that vehicle type;
- (b) accept a vehicle authorisation issued by the Agency as equivalent to the first authorisation issued in accordance with Article 22 or 24 of Directive 2008/57/EC and issue an additional authorisation in accordance with Article 23 or 25 of Directive 2008/57/EC.

6. In cases referred to in point (a) of paragraph 2 and in paragraphs 5 and 5a, the NSA shall cooperate and coordinate with the Agency to undertake the assessment of the elements set out in point (a) of Article 21(5) of Directive (EU) 2016/797.

7. Freight wagons compliant with paragraph 7.1.2. of the Annex of WAG TSI Regulation (EU) 321/2013 and with a vehicle authorisation for placing on the market shall be treated between 16 June 2019 and 16 June 2020 as vehicle with an authorisation for placing into service for the purpose of Directive 2008/57/EC by Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and that have not yet transposed that Directive and not brought into force its national transposition measures.

- 7a. Freight wagons compliant with paragraph 7.1.2 of the Annex of WAG TSI Regulation (EU) No 321/2013 and with a vehicle authorisation for placing on the market shall be treated between 16 June 2020 and 30 October 2020 as vehicles with an authorisation for placing into service for the purpose of Directive 2008/57/EC by Member States that have notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797.

8. Between 16 June 2020 and 30 October 2020, in Member States that have notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797, applicants for an authorisation for placing in service of a vehicle or a type authorisation for the purposes of Directive 2008/57/EC may submit to the national safety authority a file concerning the vehicle or vehicle type compiled in accordance with Articles 29(1) and 30(1) and complying with Annex I.

Applications for an authorisation for placing in service of a vehicle or a type authorisation in accordance with this Regulation shall be accepted by the NSA for the purposes of Directive 2008/57/EC.

3.10.2. Article 56: Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency or the Commission in accordance with Article 57(2) of Directive (EU) 2016/797.

It shall apply from 16 June 2020 in the Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and have not notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797.

Articles 55(5a) and 55(7a) shall apply from 16 June 2020 in all Member States.

Article 55(8) shall apply from 16 June 2020 in Member States that have notified the Agency and the Commission in accordance with Article 57(2a) of Directive (EU) 2016/797.

This Regulation shall apply in all the Member States from 31 October 2020.

However, Article 55(1) shall apply from 16 February 2019 in all Member States. The facilitation measures provided in Article 55(2), (3), (4) and (6) shall be made available from 16 February 2019. Article 55(5) of this Regulation shall apply from 16 June 2019 in all Member States.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

3.11. Annexes

Annex I of Regulation (EU) 2018/545 describes the information that should be included in the application and the file accompanying the application for authorisation. It does not relate to specific documents or evidence. The applicant can decide how to structure the file accompanying the application for authorisation as long as all the required information is included.

Annexes II and III describe the assessments to be performed by the authorising entity and the concerned NSAs for the area of use for the information in the application and the file accompanying the application for authorisation. When an NSA acts as an authorising entity, it should check the elements in both Annex II and Annex III. When the Agency acts as an authorising entity, it should assess the elements set out in Annex II, whereas the concerned NSAs for the area of use should assess the elements set out in Annex III for their respective part.

3.11.1. Annex I Content of the application

(M) means required information to be submitted by the applicant.

(O) means optional information that may still be submitted by the applicant.

1. Type of application (M):

- 1.1. Type authorisation
 - (a) Vehicle type variants (when applicable)
 - (b) Vehicle type versions (when applicable)
- 1.2. Authorisation for placing on the market
 - (a) Single vehicle; or
 - (b) Series of vehicles

2. Authorisation case (M):

- 2.1. First authorisation
- 2.2. New authorisation
- 2.3. Extended area of use
- 2.4. Renewed type authorisation
- 2.5. Authorisation in conformity to type

3. Area of use (M):

- 3.1. Member States
- 3.2. Networks (per Member State)
- 3.3. Stations with similar network characteristics in neighbouring Member States when those stations are close to the border as specified in Article 21.8 of Directive (EU) 2016/797 (when applicable)
- 3.4. Definition of the extended area of use (only applicable for the authorisation case "Extended area of use")
- 3.5. Whole EU network

4. Issuing authority (M):

- 4.1. The Agency; or
- 4.2. The national safety authority of the Member State (only applicable in case of an area of use limited to one Member State and requested by the applicant as specified in Article 21(8) of Directive (EU) 2016/797)

5. Applicant's information:

- 5.1. Legal denomination (M)
- 5.2. Applicant's name (M)
- 5.3. Acronym (O)
- 5.4. Complete postal address (M)
- 5.5. Phone (M)
- 5.6. Fax (O)
- 5.7. E-mail (M)
- 5.8. Website (O)
- 5.9. VAT number (O)
- 5.10. Other relevant information (O)

6. Contact person information:

- 6.1. First name (M)
- 6.2. Surname (M)
- 6.3. Title or function (M)
- 6.4. Complete postal address (M)
- 6.5. Phone (M)
- 6.6. Fax (O)
- 6.7. E-mail (M)
- 6.8. Languages spoken (M)

7. Current vehicle type authorisation holder (Not applicable in case of first authorisation) (M):

- 7.1. Legal denomination (M)
- 7.2. Type authorisation holder's name (M)
- 7.3. Acronym (O)
- 7.4. Complete postal address (M)
- 7.5. Phone (M)
- 7.6. Fax (O)
- 7.7. E-mail (M)
- 7.8. Website (O)
- 7.9. VAT number (M)
- 7.10. Other relevant information (O)

8. Conformity assessment bodies information (M):

- 8.1. Notified body(ies):
 - (a) Legal denomination (M)
 - (b) Notified body name (M)
 - (c) Notified body ID number (M)
 - (d) Acronym (O)
 - (e) Complete postal address (M)
 - (f) Phone (M)
 - (g) Fax (O)
 - (h) E-mail (M)
 - (i) Website (O)
 - (j) VAT number (M)
 - (k) Other relevant information (O)
- 8.2. Designated body(ies):

- (a) Legal denomination (M)
- (b) Designated body name (M)
- (c) Acronym (O)
- (d) Complete postal address (M)
- (e) Phone (M)
- (f) Fax (O)
- (g) E-mail (M)
- (h) Website (O)
- (i) VAT number (M)
- (j) Other relevant information (O)

8.3. Assessment body (CSM RA), not applicable for authorisation in conformity to type:

- (a) Legal denomination (M)
- (b) Assessment body (CSM RA) name (M)
- (c) Acronym (O)
- (d) Complete postal address (M)
- (e) Phone (M)
- (f) Fax (O)
- (g) E-mail (M)
- (h) Website (O)
- (i) VAT number (M)
- (j) Other relevant information (O)

9. Pre-engagement:

- 9.1. Reference to pre-engagement baseline (O)
- 9.2. Other relevant project information (O)

10. Description of the vehicle type (*to be specified according to decision 2011/665/EU Annex II) (M):

- 10.1. Type ID*:
- 10.2. Vehicle type versions (when applicable)
- 10.3. Vehicle type variants (when applicable):
- 10.4. Date of record in ERATV* (not applicable for first authorisation)
- 10.5. Type name*
- 10.6. Alternative type name* (when applicable)
- 10.7. Category*
- 10.8. Subcategory*

11. Information on the vehicles (to be specified according to decision 2007/756/EU ¹ when available) (M)

- 11.1. EVN numbers or pre-reserved vehicle numbers
- 11.2. Other specification of the vehicles when EVN numbers or pre-reserved vehicle numbers are not available

12. Reference to existing vehicle type authorisation (not applicable in case of first authorisation) (M)

13. Description of the changes as compared to the authorised vehicle type (only applicable in case of a new authorisation) (M)

14. Conditions for use of the vehicle and other restrictions (to be specified according to decision 2011/665/EU Annex II) (M):

- 14.1. Coded restrictions
- 14.2. Non-coded restrictions

15. CCS additional functions (M)

16. Applicable rules (M):

- 16.1. TSIs, including the legal reference in the Official Journal of the European Union
- 16.2. Specific TSIs clauses for an area of use covering the whole EU network (when applicable)
- 16.3. Specification of the selection of requirements from a newer version of a TSI as compared to the TSI applicable for the assessment (including withdrawn requirements) (when applicable)
- 16.4. National rules (when applicable)
- 16.5. Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797 (when applicable)
- 16.6. Applicable rules for the extended area of use.
- 16.7. Updated TSIs and/or national rules (only applicable for renewed type authorisation)

17. Applicant's confirmation and signature (M)

18. Annexes (M):

The information that shall be included in the application is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that the information is mandatory (M) for this authorisation case.

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
18.1	<p>The supporting evidence for the requirements capture in accordance with Article 13(1).</p> <p>If the applicant uses the methodology set out in Annex I of Regulation (EU) 402/2013, the supporting evidence consists of the declaration by the proposer referred to in Article 16 of Regulation (EU) 402/2013 and the safety assessment report referred to in Article 15 of Regulation (EU) 402/2013.</p> <p>If another methodology is used, the evidence required is that necessary to demonstrate that it provides the same level of assurance as the methodology set out in Annex I of Regulation (EU) 402/2013.</p>	X		X	X	
18.2	Mapping table indicating where the information needed for the aspects to be assessed according to Annex II and III can be found	X	X	X	X	
18.3	The relevant decisions for non-application of TSIs according to Article 7 of Directive (EU) 2016/797 (when applicable)	X	X	X	X	X
18.4	Declaration of conformity to the type and associated documentation (Article 24 Directive (EU) 2016/797)					X
18.5	EC Declarations of Verification for the mobile subsystems, including accompanying technical files (Article 15 Directive (EU) 2016/797).	X	X	X	X	
18.6	The file accompanying the application and the decision from the previous authorisation or when applicable the reference to the decision issued according to Article 46 and to the full accompanying file for the decision archived in the one-stop shop.		X	X	X	
18.7	<p>Specification of and where applicable⁸ a description of the methodology used for the requirements capture for the:</p> <p>a) essential requirements for subsystems as specified in Article 3 and Annex III of Directive (EU) 2016/797;</p> <p>b) technical compatibility of the subsystems within the vehicle;</p> <p>c) safe integration of the subsystems within the vehicle; and</p> <p>d) technical compatibility of the vehicle with the network in the area of use.</p>	X		X	X	

18.8	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems.	X		X	X	
18.9	When not fully covered by TSIs and/or national rules, the documentary evidence of the technical compatibility of the vehicle with the network in the area of use.	X		X	X	
18.10	Risk declaration (Article 16 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems for aspects not covered by the TSIs and the national rules.	X		X	X	
18.11	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle			X	X	
18.12	Risk declaration (Article 16 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle			X	X	
18.13	Information required for ERATV (according to Annex II of decision 2011/665/EU)	X		X	X	
18.14	Maintenance & operation documentation (including rescue), when not included in 18.4 and/or 18.5.	X		X	X	

¹ Commission Decision 2007/756/EC of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (notified under document number C(2007) 5357) (OJ L 305, 23.11.2007, p. 30)

⁸ Non standardised methodology

The file accompanying the application for authorisation of a vehicle and/or vehicle type is wider than the EC DoV(s) for the subsystem(s) that compose the vehicle and the file(s) accompanying the EC DoV(s). There are additional elements to be included that depend on the authorisation case, as described in the Annex I of the Regulation (EU) 2018/545 (e.g., evidence related to requirements capture, mapping tables, relevant decisions for non-application of TSIs, information required for ERATV, risk declaration by the proposer covering the requirements capture for the essential requirement "safety" and the safe integration between subsystems, etc.).

Some elements of the file accompanying the application for authorisation may be already present in a file accompanying the EC DoV for a subsystem; same applies for elements to be included in the file accompanying an EC certificate of verification (e.g., ISVs can be already included in the report issued by the notified body). In this case, it is not necessary to duplicate the elements but to provide the required traceability in the mapping tables. This in order to achieve a compromise between flexibility for applicants to build the file accompanying the application for authorisation, simplicity of the file accompanying the application for authorisation and easiness for authorising entities to find and assess the relevant information.

3.11.1.1. Point 10.1 – Type ID

When creating a draft entry, ERATV assigns a code (type ID) to the vehicle type/ vehicle type variant/ vehicle type version. The draft entry should be requested by the applicant before the submission of the application for authorisation through the OSS. The applicant can then include the type ID of the draft in the application for authorisation, together with other information required for ERATV (point 18.13). When the Agency is the authorising entity, the process to request the creation of a draft type in ERATV is described here:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2676

Please note that the type ID referred to in point 10.1 should relate to the vehicle type/vehicle type variant/vehicle type version seeking authorisation, and not to the type ID of an existing vehicle type upon which the application is based (e.g., a previous first authorisation followed by a new authorisation following a change to the already authorised vehicle type).

When an application contains several types, variants and/or versions, each one shall be identified by its own type ID.

3.11.1.2. Point 14 – Conditions for use of the vehicle and other restrictions (CfU)

CfU should be indicated in terms of coded and non-coded restrictions. Coded restrictions are described in the technical document can be found in the technical document “List of harmonised and national restriction codes” ERA/TD/2011-009/INT, available at the website of the Agency:

https://www.era.europa.eu/domains/registers/eratv_en

Some coded restrictions are also technical parameters, e.g.

- › 4.1.2.1 Maximum design speed - coded restriction 1.3 Speed restrictions
- › 4.1.5 Maximum number of trainsets or locomotives coupled together in multiple operation – coded restriction 1.4 Use in multiple operation (maximum number of trainsets authorised to be coupled together to operate as a single train)
- › 4.2.1 Reference profile – coded restriction 2.1 Kinematic gauge
- › 4.3.1 Temperature range – coded restriction 3.1 Climatic zone
- › 4.8.4 Minimum horizontal curve radius capability – coded restriction 1.1 Minimum curve radius
- › Etc.

When there are no differences between the technical parameter and the corresponding coded restriction (e.g., no actual limitation or constraint as compared to the nominal value), this should not be considered as a coded restriction and should not be indicated as such in the application form nor in the issue type authorisation / ERATV.

For the authorisation cases:

- › Extension of the area of use pursuant to Article 14(1)(c) of Regulation (EU) 2018/545;
- › New authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, or
- › Combined application case new authorisation and authorisation for an extended area of use pursuant to Article 14(3)(a) of Regulation (EU) 2018/545

the CfU of the vehicle and other restrictions to be identified in the application (that later on may be included in the issued authorisation and in the ERATV entry) are the ones related to the changes and/or the extension of the area of use. The CfU of the parent type/variant that are not impacted by the change/extension should not be included in the application for authorisation nor in the issued vehicle type authorisation / ERATV.

The CfU should reflect particularities that shall be taken into account to ensure that the vehicle type meets the essential requirements. Comments, remarks, observations, references to other documents (such as drivers manual, maintenance plan etc.) should not be recorded as non-coded restrictions, see section 3.3.8.

When the Agency is the authorising entity, the applicant is kindly requested to provide additional information related to the CfU, with the objective of facilitating the assessment of the consistency of the information in the application file. Further information can be found here:

https://www.era.europa.eu/can-we-help-you/faq/292_en?target_id=2674

3.11.1.3. Point 15 - CCS additional functions

CCS additional functions could be for instance: options according to the applicable specifications, national rules imposed by an NSA, Change Requests from other baselines or specific project requests:

- › Options allowed by the specifications (e.g., implementation of Euroloop, implementation of Cold Movement Detector on-board)
- › National rules (e.g., imposing the use of two radio communication capability for RBC handover to improve availability of the system, implementation of reporting for balises malfunction via text messages)
- › Change requests from other baselines (e.g., early implementation of any of the error corrections described in the technical opinions of the Agency)
- › Specific project requests (e.g., implementation of functions related to data recording other than the mandatory events in the specifications for the Juridical Recording Unit)

The applicant shall identify if they have implemented CCS additional functions in the ETCS on-board equipment or in the radio parts (EDOR or Cab radio). The NoBo should assess that these functionalities do not hinder interoperability. It is recommended (not mandatory) to use the template available in the CCS TSI application guide (Annex 9) to provide the list of additional functions.

3.11.1.4. Point 18.1 - The evidence for the requirements capture in accordance with Article 13(1).

Regulation (EU) 2018/545 requires applicants and entities managing changes to perform a requirements capture process. The evidence of requirements capture performed need to be part of the file accompanying the application for authorisation in the OSS, when an application is required.

In order for requirements capture to take place, there needs to be an appropriate traceability of all requirements that have been identified and captured, so that the identification, implementation, verification and validation, demonstration of implementation of the requirements is documented. The applicant or the entity managing the change has to document and produce evidence for the whole requirements capture process, covering all the steps of the EN 50126-1 V-Cycle. References to generic company standards which are applied for requirements capture and management are not considered sufficient evidence of requirements capture as they do not provide sufficient detail and evidence of the process that has been implemented and applied to a given project. However, the description can refer to or re-use, where needed, existing documents generated in the framework of other processes already established by the manufacturer/supplier that in the end compose the process for managing requirements (e.g., quality management, change management, requirement management processes, etc.).

General evidence of the identification of requirements and their validation will not be sufficient. The requirements capture process adopted must be seen to support the principles identified above down to the level of individual requirements, and the set of specified design and validation actions required to implement these requirements.

To achieve this objective, there should be an appropriate centralised tool (repository), which can be either a physical tool or an IT tool (table, spreadsheet, database, register, etc., see also section 3.3.1.9). There is no requirement to use any specific solution to document evidence of requirements capture as long as the applicant or the entity managing the change can show that the principles mentioned above are followed (see illustrative example of a requirements matrix in section 3.11.4). The amount of documentation and/or traceability needed depends on the complexity of the project (e.g., number and complexity of requirements for a new design of high speed train will be higher than for a wagon for or a small modification of an existing vehicle type).

The evidence should demonstrate that the requirements capture applied covers all the essential requirements, not only the essential requirement safety.

For the **essential requirement "safety" for the subsystems and for the safe integration between subsystems**, the supporting evidence for the requirements capture process includes:

- › Description of the methodology for requirements capture (point 18.7), confirming that the methodology follows Annex I of CSM RA;
- › Safety assessment report (Article 15 of CSM RA) issued by the AsBo (point 18.8); the section 4.2 of the clarification note ERA1209/146 (see section 3.3.1 of this document) contains a template for this report, and
- › Written declaration (Article 16 of CSM RA) by the applicant (point 18.10); the section 4.3 of the clarification note ERA1209/146 (see section 3.3.1 of this document) contains a template for this report.

For **essential requirements other than "safety"**, it is necessary to make a distinction concerning whether the principles of the methodology in Annex I of the CSM RA are used for all essential requirements or not:

- › If the principles of the methodology in Annex I of CSM RA are used for all essential requirements, the supporting evidence consists of the declaration(s) referred to in Article 16 of CSM RA (points 18.10 and 18.12 of Regulation (EU) 2018/545) and the assessment report referred to in Article 15 of CSM RA (points 18.8 and 18.11 of Regulation (EU) 2018/545).

As a rule, the evidence describing the details of the process and the evidence produced by the applicant or the entity managing the change as a result of the application of the requirements capture process (which should be the basis of the independent assessment performed by the AsBo) does not need to be included in the file accompanying the application for authorisation in this case. Should there be any justified doubt or need for further clarification, the necessary documentation can be provided by the applicant or the entity managing the change upon request of the authorising entity.

In any case, it is recommended that the applicant includes in the file accompanying the application for authorisation an extract, printout, export and/or detailed description or examples of the central repository tool used, so that the authorising entity has a better view on the methodology and workflow for managing hazards and requirements.

- › Applicants are allowed not to apply the methodology described in Annex I of CSM RA to essential requirements other than safety and safe integration. In such case, they are neither obliged to hire an AsBo to perform an independent assessment of the requirements capture process for essential requirements other than safety and safe integration, nor to have any type of independent assessment.

The evidence that needs to be submitted through the OSS should be enough to demonstrate that it provides the same level of assurance as the principles in the methodology of Annex I of CSM RA (see the criteria laid down in Annex II, point 7.2 Regulation (EU) 2018/545). When there is no independent assessment, it will be more difficult to demonstrate that the same level of assurance as compared to the methodology of Annex I of CSM RA is achieved, see section 3.3.1.9 and 3.11.2.1).

Please note that the declaration referred to in point 18.10 of Annex I of Regulation (EU) 2018/545 does not need to cover other essential requirements when the methodology does not follow the principles of Annex I of the CSM RA.

The required evidence can consist of a specific document describing the process in a detailed way, procedures, work instructions, templates, checklists, application guides, other documentation of processes already in place, an independent assessment report (where applicable), etc. In the end, everything that is needed to allow the authorising entity to assess whether the process respects the main principles of points 6 and 7 of Annex I of Regulation (EU) 2018/545 or not (see section 3.11.2.1) and therefore provides the same level of assurance.

In addition to this, it is necessary to include in the file accompanying application all the documentary evidence generated as a result of the application of the methodology (reports, logs, records, printouts of IT tools, lists, etc.). This is because when an unknown methodology is used, and in particular where no or poor independent assessment takes place, the authorising entity needs to do a similar work as the AsBo for the requirements capture of essential requirement safety, including checking that the process implemented provides the same level of assurance as the principles in the methodology of Annex I of CSM RA, performing spot-checks (sampling, vertical slice assessments, etc) to understand how requirements are managed from beginning to end.

3.11.1.5. Point 18.4 – Declaration of conformity to the type an associated documentation (Article 24 Directive (EU) 2016/797)

The mandatory content of the declaration of conformity to an authorised vehicle type is described in Annex VI of Regulation (EU) 2019/250.

The “associated documentation” referred to in point 18.4 of Annex I of Regulation (EU) 2018/545 should be understood as:

- › EC DoV(s) for the subsystem(s) (applicant);
- › Certificate(s) of verification for the subsystems (NoBo/DeBo);
- › EC declaration(s) of conformity and suitability for use of ICs (manufacturer or authorised representative);
- › Certificate(s) of conformity and suitability for use of ICs (NoBo);
- › ESC/RSC statements, when the vehicle and/or vehicle type is equipped with ETCS or GSM-R (not needed when the concerned ESC/RSC values in ERATV are ESC-EU-0 / RSC-EU-0 and/or ESC-NP-CCS7.4a / RSC-NP-CCS7.4a, or when the concerned ERATV entry does not contain any ESC/RSC type) and
- › Certificate(s)/declaration(s) issued in accordance with other legal acts of the Union.

The documents mentioned above shall be included in the accompanying the application; providing the references of the documents, or the references in ERADIS is not sufficient, as it does not provide a clear and stable view of the documents actually submitted and assessed.

It is not necessary to include the technical file(s) accompanying the EC declaration(s) nor the technical file(s) accompanying the certificate(s), neither for subsystems nor for ICs.

The applicant should include in the file accompanying the application for authorisation information about the ICs actually integrated into the vehicles seeking authorisation. In case of new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, this should cover only the ICs impacted by the change.

3.11.1.6. Point 18.5 – EC Declarations of Verification for the mobile subsystems, including accompanying technical files (Article 15 Directive (EU) 2016/797).

3.11.1.6.1. Content of the EC declarations of verification for the mobile subsystems

The Directive (EU) 2016/797, as amended by Directive (EU) 2020/700, imposes an obligation for applicants for the placing on the market of the subsystems to establish an EC DoV.

According to Regulation (EU) 2019/250, as amended by Regulation (EU) 2020/779, the EC declarations shall mention, inter alia:

- › All the applicable rules that the subsystem complies with (TSIs, national rules and other Union law). Where there are several amendments for a given rule, it should be made clear in the EC declaration the one that the subsystem complies with. The information concerning the transitional periods in the applicable TSIs that were applied should also be included in the EC declaration.

For the majority of the railway vehicle types there are other Directives that apply, see sections 3.3.1.4 and 3.11.2.3. Therefore, EC declarations not covering any Union law in the framework of an application for a first authorisation of a vehicle and/or vehicle type will normally be subject to issues through the OSS.

- › All certificates, reports or other outcomes required by the applicable rules at subsystem level (only when the applicable rules directly require some sort of certificate, report, statement, etc., issued by a conformity assessment body, inspection body, competent body etc.; when the outcomes relate to CE marking and/or self-declarations to be issued by the manufacturer, it is not necessary to mention them in the EC declaration).

It is not necessary to list the EC certificates and EC declarations related to ICs incorporated into the subsystem.

This includes the certificates issued by NoBos and DeBos, safety assessment reports issued by AsBos (when required by the rules, e.g., TSIs) etc.

Concerning TSIs, the Decision 2010/713/EC specifies for the different modules, which are the relevant certificates to be produced:

- Module SB: EC type examination certificate (§7 & §8.2)
- Module SD: EC certificate of verification (§8.1) and QMS approval certificate (§3.3 & §8.2)
- Module SF: EC certificate of verification (§4.5)
- Module SG: EC certificate of verification (§6.1)
- Module SH1: EC design examination certificate (§4.4), QMS approval certificate (§3.3 & §6.2) and EC certificate of verification (§6.1)

The Decision 2010/713/EC also requires that the audit reports for the QMS approval are referenced in the EC DoV (e.g., module SD §8.2).

- › All combination of modules allowed by the TSIs shall result in the issuing of an EC certificate of verification. In addition, Article 15 and §2.3 of Annex IV of Directive (EU) 2016/797 mention that the EC DoV can only be established on the grounds of an EC certificate of verification.
- › Conditions for use of the vehicle and other restrictions.
- › For the CCS subsystem, the ESC/RSC statements where applicable, see section 3.11.1.7.

The EC declaration(s) established after 31 October 2020 shall meet the requirements in Regulation (EU) 2019/250. In MSs that have not yet transposed the Directive (EU) 2016/797, Annexes IV and V of Directive 2008/57/EC may have been applicable until 31 October 2020 (depending on the transposition date in the concerned MS).

To determine which is the applicable legal text there are 2 cumulative criteria:

- › MS of establishment/seat of the applicant/manufacturer (declarant), and
- › The date of issuing of the declaration

As a result, an EC declaration shall:

- › be in conformity to Regulation (EU) 2019/250 in case the declaration is issued after 31 October 2020, no matter of the MS in which the issuer is established or has its seat;
- › be in conformity to Regulation (EU) 2019/250 in case the issuer of the declaration was established or had its seat in a MS which had transposed the Directive (EU) 2016/797 and the declaration was issued after the transposition date;

- › meet the requirements of Annexes IV or V of Directive 2008/57/EC in case the issuer of the declaration was established or had its seat in a MS which had not transposed the Directive (EU) 2016/797 and the declaration was issued before 30 October 2020;
- › meet the requirements of Annexes IV or V of Directive 2008/57/EC in case the declaration was established before 16 June 2019.

EC declaration(s) meeting the requirements of Regulation (EU) 2019/250 also meet the requirements of Annexes IV or V of Directive 2008/57/EC. The Agency, when acting as authorising entity, will accept EC declarations according to Regulation (EU) 2019/250 even if the legal text formally applicable in the concerned MS for the content of the declaration is the Directive 2008/57/EC.

In addition to the aspects above, for a **new authorisation** following upgrade/renewal of a subsystem (article 14(1)(d) of Regulation (EU) 2018/545) and/or **Extended area of use** (article 14(1)(c) of Regulation (EU) 2018/545), if the subsystem was placed on the market with an EC DoV, a reference to such EC declaration in the new EC declaration covering the modified subsystem is sufficient to cover the unmodified parts and/or the original area of use:

- › It is not necessary to transfer the applicable rules (in particular, national rules), the references to certificates/reports or the CfU from the previous EC DoV to the new one;
- › Only the rules, certificates, reports and/or CfU related to the modified parts (and the interfaces with the unchanged parts) and/or the extended area of use shall be listed in the new EC DoV.

If the subsystem was originally placed on the market without an EC DoV, or the vehicle was originally placed in service before Directive 2008/57/EC, only the rules, certificates, reports and/or CfU related to the modified parts and/or the extension of the area of use shall be listed in the new EC DoV.

3.11.1.6.2. Content of the EC declarations of conformity and/or suitability for use for interoperability constituents already placed on the market

The Regulation (EU) 2019/250 requires that the EC declarations of conformity and/or suitability for use for interoperability constituents, to be established by the manufacturer (or its authorised representative), describe the relevant Union law complied with, the references to the evidence required by the relevant Union law and the CfU.

However, EC declarations of conformity and/or suitability for use of ICs:

- › already placed on the market;
- › integrated in subsystems also placed on the market, and
- › being part of vehicle types and/or vehicles already authorised and in operation

do not always respect the concerned provisions of the Regulation (EU) 2019/250.

This is considered correct if the concerned EC declaration was following the requirements of the Annex IV of Directive 2008/57/EC when the IC was placed on the market and this was the applicable legal text in the MS where the manufacturer was established.

For other cases, if the applicant for vehicle authorisation can demonstrate and provide evidence that the concerned ICs, with the associated EC declarations of conformity and/or suitability for use not fulfilling the requirements of Regulation (EU) 2019/250, are already integrated into vehicle types and/or vehicles already authorised, the authorising entity should exceptionally accept such deviations.

When there is a need for a new or updated EC declaration of conformity and/or suitability for use (e.g. when the validity of an EC certificate of conformity and/or suitability for use expires), such EC declaration shall respect all the requirements of the legal texts regardless of the initial date of placing on the market of the IC, and assessing if the new or updated EC declaration of conformity and/or suitability for use fulfils the requirements of the Regulation (EU) 2019/250 should be in the scope of the checks to be performed by the authorising entity.

3.11.1.6.3. Content of the files accompanying the EC declarations of verification

The technical file accompanying an EC DoV, to be compiled by the applicant, comprises at least the following elements, pursuant to section 2.4 of Annex IV of Directive (EU) 2016/797:

1. **All necessary documents describing the characteristics of the subsystem.** This includes the elements necessary to describe the vehicle type and to document to a sufficient level of detail the verification of conformity carried-out by the conformity assessment bodies (e.g., NoBo and DeBo), such as:
 - 1.1. General description of the subsystem, its overall design and structure
 - 1.2. General and detailed drawings
 - 1.3. Electrical and hydraulic diagrams
 - 1.4. Control-circuit diagrams
 - 1.5. Description of data processing and automatic systems
 - 1.6. Results of design calculations made; examinations carried out
 - 1.7. Test program and reports
 - 1.8. Elements related to conditions and limits of use and instructions for servicing, monitoring, adjustment and maintenance
 - 1.9. Operation (including rescue)
 - 1.10. Etc.

Some (if not most) of these documents would be already including in the file accompanying the certificate(s) of verification. In such a case, it is not necessary to duplicate the documents, but to complement the missing parts (if any).

2. **List of ICs incorporated into the subsystem.**

3. **Verification of the conformity with TSIs.**

- 3.1. **EC certificate(s) of verification**, established by the notified body(ies)
- 3.2. **File accompanying the EC certificate(s) of verification**, compiled by the notified body(ies) in accordance with NB-Rail RFU-STR-011 and covering the scope of its activities.

This file should include calculation notes and records of the tests and examinations carried out by the notified body(ies), including inspection and audit reports, the results of the verification regarding the validity of ISVs and the documentation related to ICs.

Concerning ICs, in addition to the **EC certificates of conformity and/or suitability for use**, it should include **calculation notes, tests and examinations carried out, inspection and audit reports** (by analogy to the documentation accompanying declarations/certificates for the subsystems).

- 3.3. When the CCS subsystem is in the scope of the application for authorisation and the vehicle and/or vehicle type is equipped with ETCS or GSM-R, **ESC/RSC statements** (not needed when the concerned ESC/RSC values in ERATV are ESC-EU-0 / RSC-EU-0 and/or ESC-NP-CCS7.4a / RSC-NP-CCS7.4a, or when the concerned ERATV entry does not contain any ESC/RSC type).

4. Verification of the conformity with national rules

- 4.1. **Certificate(s) of verification**, established by the designated body(ies)
- 4.2. **File accompanying the certificate(s) of verification**, compiled by the designated body(ies) in accordance with NB-Rail RFU-STR-011, covering the scope of its activities. This file should include calculation notes and records of the texts and examinations carried out by the designated body(ies).

5. Evidence of the fulfilment of other legal acts of the Union (e.g., Certificate(s) of verification issued in accordance with other legal acts of the Union)

The documents mentioned above should be limited to the aspects impacted by the change in case of new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545.

The documents that form the file accompanying the application shall be included in the application; providing the references of the documents, or the references in ERADIS is not sufficient, as it does not provide a clear and stable view of the documents actually submitted and assessed.

Please note that the files accompanying the EC certificates of verification, to be compiled by the NoBos, already contain many of the necessary documents for the file accompanying the EC DoVs, to be compiled by the applicants for placing on the market of the mobile subsystems. It is not necessary to upload the documents twice to the OSS (one as part of the file accompanying the EC certificates of verification, and another one as part of the technical file accompanying the EC DoVs).

The technical file accompanying the EC DoVs should be limited to the minimum set of documents necessary for the conformity assessment bodies involved to arrive to their conclusion and for the applicant to establish the EC DoV; to avoid unnecessary burden, every other document not necessary for such purposes should not be part of the accompanying technical file.

3.11.1.7. Points 18.4 and 18.5 – ESC/RSC statements

The concept of ETCS system compatibility (ESC) and Radio System Compatibility (RSC) was introduced in the CCS TSI by Regulation (EU) 2019/776. There is a necessary transition period from the previous national rules defined in some MSs until the proper ESC/RSC values are defined by the IM and published in the Agency Technical Document.

For the case of adding or removing ESC/RSC statements as a new version of a vehicle type based on an already existing version of a vehicle type, please refer to section 3.8.4.2 (compilation of versions).

3.11.1.7.1. ESC/RSC statements to be included in the file accompanying the application

When a vehicle and/or vehicle type is equipped with ETCS (Level 1, 2 or 3) and/or GSM-R (voice and/or data):

- › **First authorisation** (article 14(1)(a) of Regulation (EU) 2018/545): at least one ESC/RSC statement shall be provided among the ESC/RSC types declared by each IM in the area of use selected by the applicant.

The available ESC/RSC types can be checked in the technical document TD/011REC1028 available at the website of the Agency:

<https://www.era.europa.eu/content/etcs-and-radio-system-compatibility-escrsc>

- › **Renewed vehicle type authorisation** (article 14(1)(b) of Regulation (EU) 2018/545): if the ETCS or the Radio part of the CCS subsystem is impacted, at least one ESC/RSC statement shall be provided among the ESC/RSC types declared by each IM in the Area of Use. A justification that the previous ESC/RSC statements are not impacted is also acceptable.
- › **Extended area of use** (article 14(1)(c) of Regulation (EU) 2018/545): at least one ESC/RSC statement shall be provided among the ESC/RSC types declared by each IM in the extended area of use.

- › **New authorisation** (article 14(1)(d) of Regulation (EU) 2018/545): if the ETCS or the Radio part of the CCS subsystem is impacted, at least one ESC/RSC statement shall be provided among the ESC/RSC types declared by each IM in the area of use. A justification that the previous ESC/RSC statements are not impacted is also acceptable.
- › **Authorisation in conformity to type** (article 14(1)(e) of Regulation (EU) 2018/545): the ESC/RSC statements registered in the vehicle type shall be provided. It is not needed to provide an ESC/RSC statement for the values ESC/RSC-EU-0 and/or ESC/RSC-NP-CCS7.4a.
- › **Combined new and extended area of use** (article 14(3)(a) of Regulation (EU) 2018/545): if the change is not related to ETCS/GSM-R, this is equivalent to the extended area of use case referred above. If the change is impacting ETCS or GSM-R, this is equivalent to new authorisation case above.
- › **Combined First and conformity to type:** (article 14(3)(b) of Regulation (EU) 2018/545) see first authorisation case above (first bullet point).

The operation in ETCS L0 or LNTC is not considered as an ETCS Class A operation, but a “Class B train protection legacy system” operation. For such cases, there concept of ESC/RSC does not apply. However, the transitions from/to Class B and ETCS should be covered in the relevant ESC types.

For a vehicles and/or vehicle types which are equipped with a certified ETCS on-board (level 1, 2 or 3) but are only authorised to operate under a Class B train protection system (e.g., there is a CfU not allowing the use of the ETCS), a new authorisation shall be requested to allow the vehicles to use the ETCS, and the relevant ESC Statement shall be provided as described above.

3.11.1.7.2. *Special values for the ESC/RSC parameters in ERATV*

In ERATV, all the ESC and RSC types for which the vehicle has demonstrated compatibility shall be registered in parameter 4.13.1.8 “ETCS System Compatibility”, in parameter 4.13.2.5 “Radio Voice System Compatibility” and in parameter 4.13.2.8 “Radio Data System compatibility”.

When filling-in a draft type in ERATV, only the ESC/RSC types with the status “valid”, as defined in the ESC/RSC technical document TD/011REC1028, are available for selection. In addition, it is possible to select 3 special values which do not correspond to ESC/RSC types:

- › **Not applicable** : to be used when the vehicle is not equipped with ETCS or GSM-R voice radio or GSM-R data radio. When this value is selected, it cannot be combined with any of the other ESC/RSC type identifiers.
- › **ESC-NP-CCS7.4a / RSC-NP-CCS74.a**: to be used when the checks were performed following (existing) national procedures, equivalent to the ones defined in ESC/RSC types. This may happen in different situations for example (not an exhaustive list):
 - The ESC/RSC type(s) do not have “valid” status in ESC/RSC technical document TD/011REC1028
 - The checks have been performed before the concerned ESC/RSC type(s) identifiers were changed to “valid” status

This special value can be combined with any other ESC/RSC type identifier, for a specific ESC/RSC ERATV parameter.

In any case, when the special value ESC-NP-CCS7.4a / RSC-NP-CCS74.a is selected, it is mandatory to indicate as a non-coded restriction the:

- Test specification(s) (either a proprietary document, or a specification defined in a national rule)
- Reference to the test report used to perform the check, and
- Lines or sections of the network for which the technical compatibility has been demonstrated.

Note: in RINF, special value ESC-NP-CCS7.4a / RSC-NP-CCS74.a are not available for selection. In the case of a section in RINF characterised by an ESC/RSC type value and a vehicle not having the corresponding ESC/RSC type value in ERATV but using the special value instead, the route compatibility is not automatically assumed; therefore, additional checks to verify the technical compatibility based on the document provided in the non-coded restriction mentioned about (test specification) may be necessary.

- › **ESC-EU-0 / RSC-EU-0:** in RINF, the meaning of this value corresponds to the case where IM has declared that no ESC/RSC are needed to demonstrate technical compatibility for any network/section of a network.

In ERATV this parameter can be selected for all CCS certified subsystems equipped with ETCS and/or GSM-R.

This special value can be combined with any other ESC/RSC type identifier, for a specific ESC/RSC ERATV parameter.

3.11.1.7.3. Inclusion of the ESC/RSC Statements into the EC declaration of verification of the subsystem

As indicated in the application guide of the CCS TSI, the references to the ESC/RSC statements should be included in the EC DoV for the subsystem, despite not being explicitly required by Regulation (EU) 2019/250.

The applicant should add the references to the ESC/RSC statements under the paragraph beginning with *“In accordance with the following certificate(s) and or report(s)”*. The applicant for placing on the market the subsystem establishing the EC DoV may also add an additional paragraph to include such references.

3.11.1.8. Point 18.6 - Evidence concerning previous authorisations

For vehicles and/ or vehicle types that have not received an authorisation pursuant to Directive (EU) 2016/797 the following documents are considered as equivalent:

- › When the vehicle/ vehicle type has received an authorisation pursuant to Directive 2008/57/EC:
 - The vehicle type authorisation decision issued pursuant to Article 26(1) or 26(2) of Directive 2008/57/EC and the decision(s) issued pursuant to Article 22 and 23 of Directive 2008/57/EC for a TSI conform vehicle, including the supporting files for the decisions.
 - The vehicle type authorisation decision issued pursuant to Article 26(1) or 26(2) of Directive 2008/57/EC and the decision(s) issued pursuant to Article 24 and 25 of Directive 2008/57/EC for a non-TSI conform vehicle, including the supporting files for the decisions.
 - The vehicle type authorisation issued pursuant to Article 26(1) or 26(2) of Directive 2008/57/EC and decision for the subsequent authorisation of vehicle(s) in conformity with the vehicle type pursuant to Article 26(3) of Directive 2008/57/EC.
- › When the vehicle/ vehicle type has received an authorisation before Directive 2008/57/EC was in force:
 - The decision(s) for the initial authorisation(s), including any supporting file(s). There should be a clear indication of the scope and the legal base for the decision; or
 - Where it is not possible to find documentary evidence of the issued authorisation and/ or the file accompanying the authorisation, the authorising entity should consider that the vehicle is authorised and has remained in service as long as it is still registered in NVR (registration not suspended / withdrawn, authorisation not expired or suspended).

3.11.1.9. Point 18.6 – Evidence concerning the area of use of vehicles used under RIC/RIV agreements following a change that requires a new authorisation

For vehicle authorisation purposes under Directive (EU) 2016/797 and Regulation (EU) 2018/545, the fact that a vehicle was once admitted by means of RIV/RIC agreements does not have any particular effect in addition to the grandfather rights provided by Article 54(2) of Directive (EU) 2016/797, section 7.1.4(7) of LOC&PAS TSI and section 7.2.2.4(7) of WAG TSI. The phasing out of the RIC/RIV agreements for vehicle authorisation purposes started with the Safety Directive 2004/49/EC (creation of the NSA role), Directive 2008/57/EC (NSAs as entities delivering authorisations of types and vehicles), and then Directive 2012/34/EU (separation of RUs, IMs and NSAs).

The technical heir of the RIV agreement is the WAG TSI, in particular section 7.1.2 laying down the conditions for having an area of use not limited to particular national networks. Similarly, the section 7.1.1.5 of LOC&PAS TSI describes the technical requirements for having authorisations of passenger coaches not limited to a particular area of use, which were part of the RIC agreement in the past.

In both cases, the requirements in the current TSIs are not equivalent to the requirements in the RIV/RIC agreements. A (past) RIV/RIC based admission is not equivalent to an authorisation not limited to any particular network ("Whole EU"), i.e., section 7.1.2 of WAG TSI or section 7.1.1.5 of LOC&PAS TSI.

The administrative heir of the RIV agreement is the General Contract for the Use of wagons (GCU), which is a multilateral contract based on the COTIF convention and specifies the mutual rights and obligations of wagon keepers and RUs with regard to the use of freight wagons in Europe and beyond. RIC agreement takes nowadays the form of a multilateral contract under the coordination of UIC. In both cases, the scope of the agreements is the exchange of (authorised) vehicles between RUs/keepers and does not relate to authorisation. Further information can be found in the following websites:

<https://gcubureau.org/>
<https://uic.org/special-groups/ric-a/>

The LOC&PAS and WAG TSIs specify that in case of changes to such vehicles, the area of use of the new authorisation will be limited to the actual area of operation before the implementation of the change, and not to the "historic" area of operation; the RIV/RIC marking should be removed from the vehicles and from ECVVR/EVR at that moment.

In particular, according to chapters 7.2.2.4 of WAG TSI and 7.1.4 of LOC&PAS TSI,

- › Vehicles used under RIV (Regolamento Internazionale Veicoli) or RIC (Regolamento Internazionale Carrozze) agreements shall be deemed authorised with the conditions under which they were used, including the area of use where they are operated, and
- › In case of a change requiring a new authorisation, the changed vehicles shall conserve the area of use in which they were operating without further checks on the unchanged parts.

In order to document the area of use in which the modified vehicles were operating, the following element(s) can be taken into consideration:

- › Data in the national vehicle registers (NVR) in accordance with Decision 2007/756/EC or in the European Centralised Virtual Vehicle Register (ECVVR) in accordance with Decision (EU) 2018/1614;
- › Maintenance records from Entities in Charge of Maintenance (ECMs) or contracts signed with ECMs for the provision of maintenance services, when the vehicles arrive to the workshops by their own means;
- › Evidence produced by the IMs regarding the allocation of capacity in the network;
- › Evidence produced by RUs regarding the incorporation of such vehicles into trains to cover services in certain networks/lines; the evidence related to the use of the vehicles in the framework of an exceptional transport is not considered suitable, because this type of operation is not representative of a normal commercial operation;

- › Contracts with leasing companies or RUs regarding the provision of traction services within certain networks/lines, and/or
- › Any other suitable evidence.

The markings in the vehicle and/or the information in the NVR/ECVVR/EVR regarding the area of use is not considered suitable evidence to demonstrate where the vehicles were being actually operated before the modification.

The applicant should provide the evidence of the area of operation in the file accompanying the application for authorisation. The fact that the vehicle to be modified was originally admitted by application of RIV/RIC agreements does not entail any other difference in the content of the file accompanying the application for authorisation nor in the assessments to be performed by the authorisation entity for a new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545. In particular:

- › The content of the file accompanying the application for authorisation is described in Annex I of Regulation (EU) 2018/545;
- › The rules to be applied (i.e., TSIs, national rules, other EU law) for the changed parts and the interfaces with the unchanged parts are those in force when the application is submitted, and
- › The assessments to be performed by the authorising entity and the NSAs for the area of use (following the documented area of operation mentioned above), are the same as any other vehicle and/or vehicle type that is modified and requires a new authorisation and summarized in Annex II of Regulation (EU) 2018/545.

In case of **interruption of operation** of the concerned vehicles (regardless of the duration), the entity managing the change should pay attention to the possible changes in the networks in which the vehicle was operating in the past that have occurred since the interruption and document the result of the research. Such changes may compromise the technical compatibility between the vehicles and the networks. The entity managing the change should also consider if, for similar vehicles, there have been changes done to maintain the technical compatibility between the vehicles and the networks which would be missing in the vehicles out of operation. This applies as well for out-of-service vehicles acquired for the purpose of being repaired/refurbished to return to service.

The conditions under which the vehicles have been operated, referred to in the LOC&PAS and WAG TSIs, remain valid for the unchanged parts. The scope of a new authorisation, and therefore the related CfU of the vehicle and other restrictions, are limited to the changed parts. However, the applicant should include as many evidence as possible with regards to the legacy CfU of the vehicle and other restrictions in the file accompanying the application through the OSS; otherwise there may be missing key elements in the authorisations for placing on the market following the modification, in particular where no evidence of the previous authorisation can be found (see sections 3.3.8 and 3.8.2.3).

The principles described above in this section should apply as well to notifications of changes to vehicles pursuant to Article 16(4) of Regulation (EU) 2018/545, because it cannot be assumed that a vehicle admitted under RIC/RIV agreements is equivalent to a vehicle with a “Whole EU” authorisation.

3.11.1.10. Point 18.7 - Specification of and where applicable ¹¹ a description of the methodology used for the requirements capture

The description of the methodology used for the requirements capture can refer to or re-use existing documents generated in the framework of other processes already established by the manufacturer/ supplier (namely quality management, change management or requirement management processes), see also section 3.11.1.4).

¹¹ Non standardised methodology

3.11.1.11. Point 18.8 – Content of the AsBo report covering the requirements capture process

The independent assessment report for the requirements capture process to be issued by the AsBo should contain:

- › a description of the AsBo's understanding of the scope of the project, and the scope of assessment that has been performed, including the life cycle phases that have been assessed;
- › the assessment activities that have been performed, in assessing requirements capture, including the samples or vertical slices taken, and choices made for spot checks of compliance evidence;
- › the other assessment reports and/or audit reports that have been mutually recognised or considered in the assessment of requirements capture; and
- › relevant detailed findings and a conclusion concerning the appropriateness of the requirements capture process to fulfil the provisions in Article 13 of regulation (EU) 2018/545 and the essential requirements specified in Annex III of Directive (EU) 2016/797 .

In the conclusions of its assessment of the requirements capture process, the AsBo needs to clearly state if:

- › the requirements capture process was systematic and has been applied to identify relevant sets of requirements (including EU legislation, standards and guidelines) that apply;
- › detailed requirements arising have been fed into the requirements specification, documentation specification and actions lists and that there is evidence to show that these requirements have been complied with and implemented; and
- › risks have been assessed following the process depicted in Annex I of the CSM RA.

The minimum content or the required structure for the assessment report to be issued by AsBos is not defined in the legal texts. In the clarification note ERA1209/146 (see section 3.3.1), a model template is proposed, summarising the main elements of the assessment report for the requirements capture process.

The proposed structure can be adapted to the AsBo documentation management system, provided that the template used by the AsBo contains all the necessary information and the document meets the usual requirements concerning quality and traceability (unique reference of the document, date of issuing, version/issue, history of changes etc.).

The AsBo which does not agree with some parts, is free to amend, or delete, them provided it reliably and unambiguously reports on how they actually performed the independent assessment, and what are all limits and conclusions of the independent assessment of the requirement capture.

In the template, guidance and/or explanatory text is identified in italics and grey colour. Standard texts which are proposed to be included (with the necessary adaptations) are regular font and black colour. The parts that need to be customized for the particularities of the project (e.g., applicant's name, name of the project) are identified in blue colour and between brackets.

The AsBo cooperation group is working on a Recommendation for Use further defining the structure and content of the assessment report to be issued by AsBo. Once this recommendation is issued, the clarification note ERA1209/146 will be adapted accordingly.

3.11.1.12. Point 18.9 - When not fully covered by TSIs and/ or national rules, the documentary evidence of the technical compatibility of the vehicle with the network in the area of use

When the technical compatibility with the network in the area of use is fully covered by TSIs and/or national rules (which is normally the case), there is no need to submit for this point the documents already submitted for point 18.5, which covers the results of the conformity assessment with regards to the TSIs and/or the national rules.

3.11.1.13. Point 18.10 – Content of the declaration by the applicant or the entity managing the change concerning the requirements capture process

An EC DoV (which is required to be made by applicants or entities managing the change for placing on the market the mobile subsystems in accordance with Directive (EU) 2016/797) must address all relevant European Union laws and national rules. Requirements capture and management requires a wider declaration of compliance, ensuring that a vehicle has satisfied all relevant requirements that are necessary to meet the essential requirements. This also incorporates all necessary harmonised standards, international standards, design codes and guidelines required.

From this point of view, the declaration to be established by the applicant for authorisation or by the entity managing the change concerning the requirements capture process can be considered as an equivalent declaration, although with a wider scope as compared the EC DoV(s): the vehicle as a whole, rather than covering only the individual mobile subsystems.

The minimum content or the required structure for the declaration to be issued by the applicant or by the entity managing the change pursuant to point 18.10 of Annex I of Regulation (EU) 2018/545 is not defined in the legal texts. In the clarification note ERA1209/146 (see section 3.3.1), a model template is proposed, summarising the main elements of the assessment report for the requirements capture process.

3.11.1.14. Points 18.8; 18.10; 18.11 and 18.12 – AsBo report and applicant’s declaration

Concerning the **requirements capture process** for the essential requirement “safety” within subsystems and safe integration between subsystems, the risk assessment process described in Annex I of CSM RA should be applied, which means that:

- › an AsBo shall perform an independent assessment and issue a (safety) assessment report, and
- › the applicant or the entity managing the change shall issue a (risk) declaration.

Both documents shall be included in the file accompanying the application for authorisation, according to points **18.8** and **18.10** of Annex I of Regulation (EU) 2018/545.

For cases where there is a need to obtain an authorisation pursuant to Article 21(12) of Directive (EU) 2016/797 (**new authorisation following a change** to an already authorised vehicle and/or vehicle type, pursuant to Article 14(1)(d) of Regulation (EU) 2018/545), the **application of CSM RA** is mandatory as well. If the change is considered **significant**, the safety assessment report to be issued by an AsBo referred to in Article 15 of CSM RA and the risk declaration to be established by the proposer (applicant/entity managing the change) according to Article 16 of the CSM RA should be included in the file accompanying the application for authorisation, as described in points **18.11** and **18.12** of Regulation (EU) 2018/545.

However, the (safety) assessment report covering the requirements capture should cover the aspects related to safety and safe integration between subsystems of the significant change too. Similarly, the (risk) declaration to be established by the applicant or by the entity managing the change for requirements capture process should cover safety and safe integration between subsystems too.

Due to this, and to avoid duplication of works and reduce the number of documents to be produced, the information referred to in points 18.8 and 18.11 (assessment report) on one hand, and 18.10 and 18.12 on the other (declaration) can be included in one single assessment report and one single declaration. But it is also possible that the information is covered by four independent documents (e.g., when the AsBo for the significant change in application of the CSM RA is different than the AsBo for the requirements capture process). The applicant or the entity managing the change, in agreement with the concerned AsBo(s), is free to decide which option is more suitable. This is summarized in Table 5.

In any case, the assessment to be performed by the AsBo for the requirements capture process shall cover the essential requirement safety and the safe integration between subsystems. The AsBo for the requirements capture remains the sole responsible for this assessment, although it shall mutually recognise the work performed by another AsBo in the framework of the significant change according to CSM RA (for the same scope of work).

Table 5 : Evidence related to AsBo assessment report and related declarations

Auth.case Scope	First, extension, renewed	New	
		Independent files	or Combined files
Requirements capture “safety”	AsBo report (18.8) Declaration (18.10)	AsBo report (18.8) Declaration (18.10)	AsBo report (18.8+18.11) Declaration (18.10+18.12)
CSM RA significant change	n.a.	AsBo report (18.11) Declaration (18.20)	

3.11.1.15. Point 18.14 Maintenance & operation documentation

The documentation related to maintenance should be included in the file accompanying the application for authorisation compiled by the applicant.

In the case of new authorisation and/ or authorisation for an extended area of use, it is not necessary to add the maintenance records (historical information related to the maintenance of the vehicles) to the application and the file accompanying the application. This aspect is to be managed by the RU under the provisions of its SMS.

3.11.2. Annex II Aspects for assessment by the authorising entity

The information that shall be assessed by the authorising entity is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that this aspect is mandatory to assess for this authorisation case.						
		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
1	Application consistent with the pre-engagement baseline (when applicable)	X	X	X	X	X
2	Authorisation case selected by the applicant is adequate	X	X	X	X	X
3	The TSIs and other applicable Union law identified by the applicant are correct	X	X	X	X	
4	Selected conformity assessment bodies (notified body(ies), assessment body (CSM RA)) have the proper accreditation or recognition as applicable	X	X	X	X	
5	Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797: 5.1 Validity (time and area of use); 5.2 Applicable to the project; and 5.3 Consistent with the identified and applied rules.	X	X	X	X	X
6	6.1 Is the applied methodology used for the requirements capture fit for purpose concerning the following aspects: (a) Has a standardised/accepted methodology been used?; and (b) Is the method intended for and suitable for the essential requirements it covers? 6.2 When the methodology applied is not standardised or covers other essential requirements than it is intended for, the following aspects shall be checked to evaluate if they are sufficiently considered and covered by the methodology:	X		X	X	

	<ul style="list-style-type: none"> (a) Degree of independent assessment applied (b) System definition (c) Hazard identification and classification (d) Risk acceptance principles (e) Risk evaluation (f) Requirements established (g) Demonstration of compliance with the requirements (h) Hazard management (log) 					
7	<p>Sufficient evidence from the methodology used for the requirements capture:</p> <p>7.1 When the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked:</p> <ul style="list-style-type: none"> (a) CSM on risk assessment, declaration by the proposer (Article 16 Regulation (EU) 402/2013) is signed by the proposer and supports that all identified hazards and associated risks are controlled to an acceptable level. (b) CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) supports the declaration by the proposer for the specified scope according to Article 13 and at least the essential requirement safety for subsystems and safe integration between subsystems within the vehicle. <p>7.2 When another methodology than the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked:</p> <ul style="list-style-type: none"> (a) System definition is complete and consistent with the design of the vehicle? (b) Hazard identification and classification is consistent and plausible? (c) All risks have been properly managed and mitigated? (d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement? (e) Structured and consistent management of the hazards throughout the process? (f) Is there a positive opinion from the independent assessment? 	X		X	X	
8	<p>EC Declarations of Verification and EC certificates (Article 15 Directive (EU) 2016/797), check:</p> <ul style="list-style-type: none"> 8.1 Signatures 8.2 Validity 8.3 Scope 8.4 Conditions for use of the vehicle and other restrictions, non-compliances 8.5 Non-application of TSIs (when applicable) 	X	X	X	X	

	<p>8.6 All applicable legislation is covered, including other non-railway related legislation</p> <p>8.7 Interoperability constituents (validity, scope, conditions for use of the vehicle and other restrictions):</p> <p>(a) EC certificates of conformity</p> <p>(b) EC certificates of suitability of use</p>					
9	<p>Reports from Conformity assessment bodies (Article 15 Directive (EU) 2016/797), check:</p> <p>9.1 Consistency with EC Declarations of Verification and EC certificates</p> <p>9.2 All applicable rules are covered</p> <p>9.3 Deviations & non-conformities (when applicable) are identified and match the non-application requests</p> <p>9.4 Combination of modules used is allowed</p> <p>9.5 Conditions for use of the vehicle and other restrictions are properly identified and are consistent with the conditions in the application for authorisation</p> <p>9.6 The supporting evidences used by the conformity assessment bodies are matching the applicable assessment phases described in TSIs (design review, type test, etc.).</p>	X	X	X	X	
10	Check of assessments from NSAs for the area of use, as specified in Article 43	X	X	X	X	
11	Validity of the original vehicle type authorisation		X	X	X	X
12	Original vehicle type authorisation is valid for the concerned area of use		X		X	X
13	Existing conditions for use of the vehicle and other restrictions		X	X	X	
14	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems positive opinion.	X		X	X	
15	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle (significant change) positive opinion			X	X	
16	Changes as compared to the authorised vehicle type are sufficiently described and match the CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013)				X	
17	EC Declarations of Verification and EC certificates are properly updated in relation to the changed and/or updated rules		X			
18	<p>Reports from conformity assessment bodies are properly updated in relation to the changed and/or updated rules:</p> <p>18.1 Changed and/or updated rules are covered</p>		X			

	18.2 There is evidence that the vehicle type still fulfils the requirements					
19	Evidence that the design of the vehicle type has not changed		X	X		
20	Identification of the vehicle or series of vehicles covered by the declaration of conformity to the vehicle type					X
21	Declaration of conformity to the type and supporting documents (Article 24 Directive (EU) 2016/797)					X

3.11.2.1. Points 6 and 7 - Assessment of the methodology for requirements capture and the related evidence

It is necessary to make a distinction concerning whether the key principles of the methodology in Annex I of the CSM RA are used for all essential requirements or not:

- › If the methodology in Annex I of CSM RA is used for all essential requirements, the supporting evidence consists of the declaration(s) referred to in Article 16 of CSM RA (point 18.10 of Regulation (EU) 2018/545) and the assessment report referred to in Article 15 of CSM RA (point 18.8 of Regulation (EU) 2018/545).

The assessment to be performed by the authorising entity and the NSAs for the area of use will be focused on the independent assessment report issued by the AsBo and on the declaration to be issued by the applicant.

Annex II of the Regulation (EU) 2018/545 summarizes the checks to be performed by the Authorising entity. With regards to the requirements capture process, the following aspects will be evaluated:

- General consistency and coherence of the information in the evidence provided
 - AsBo accreditation/recognition and classification in section 5 of ERADIS
 - Scope of the independent assessment (system under assessment, essential requirements covered), in particular how outcomes from other assessment bodies are considered
 - Clear statements concerning the results of the independent assessment concerning:
 - Compliance with the requirements of Annex I of CSM RA
 - For essential requirement safety and safe integration between subsystems, hazards and associated risks controlled to an acceptable level
 - Whole life cycle for requirements covered (from identification to validation)
 - All applicable requirements necessary to ensure that all the essential requirements are covered, and not only the mandatory rules (TSIs, national rules and other EU law).
 - Evidence used by the AsBo for the independent assessment
 - Scope of the declaration by the applicant and consistency with the independent assessment
 - Non-conformities raised by the AsBo (either closed or open, including history of the closed non-conformities)
- › If another methodology is used for essential requirements other than safety, the authorising entity will check that it provides the same level of assurance as the methodology of Annex I of CSM RA. The supporting evidence to perform the assessment will cover not only the independent assessment report (if any), but also the description of methodology, the description of the requirements capture process, the evidence of the application of the process etc. The following aspects will be evaluated:
 - General consistency and coherence of all the evidence provided
 - Degree of independent assessment and scope (complete V-Cycle)
 - Competences and independency of the independent assessor

- Assessment report from the independent assessor
- Aspects covered by the methodology:
 - System definition
 - Identification of requirements
 - Validation of requirements
 - Structured management of requirements in a centralised repository
 - Evidence to be produced
- Methodology for requirements capture (standardised / widely accepted, intended and suitable for the essential requirements covered)
- Implementation of the methodology in the requirements capture process

In the end, the authorising entity needs to do a similar work as the AsBo for the requirements capture of essential requirement safety, including checking that the process implemented provides the same level of assurance as the principles in the methodology of Annex I of CSM RA, performing spot-checks (sampling, vertical slice assessments, etc). to understand how requirements are managed from beginning to end. The more standardized is the process (closer to the key principles of Annex I of CSM RA, e.g., EN 50126-1), the fewer issues will be raised by the authorising entity during the assessment of the evidence of the requirements capture process.

When the methodology does not include an independent assessment, the demonstration that it provides the same level of assurance will face many challenges. Even if the authorising entity and the NSAs for the area of use will perform a detailed assessment of both the methodology and the results of its application (likewise an independent assessor), it cannot properly cover the whole life cycle of the vehicle and/or vehicle type (at this point, the vehicle and/or vehicle is already designed, manufactured and tested). In addition, solving eventual non-compliances found at this late stage of the process may be difficult, time consuming and in some cases not feasible without a significant delay in the authorisation process and/or additional costs.

The assessment to be performed by the NSAs for the area of use should be focused on the evidence of the application of the methodology concerning the requirements related to national rules, following the same principles described above (not an exhaustive check, but an assessment of the suitability of the process put in place by the applicant to manage the concerned requirements and risks); the assessment of the methodology is in the scope of the authorising entity. The assessments to be performed by the NSAs for the area of use are summarized in Annex III of the Regulation (EU) 2018/545.

It should be noted that the authorising entity and/ or the concerned NSAs for the area of use should not check if the CfU (including exported constraints) are reasonable from an economic point of view (e.g., risk not meeting the contractual obligations of the manufacturer with the RU by imposing CfU that may render the operation of the vehicle unfeasible), as long as they do not impact the fulfilment of the essential requirements (e.g., do not create a safety risk). The scope of the assessment should be limited to the consistency, completeness and relevance (including the cross-check by the concerned assessment bodies) of the set of CfU.

3.11.2.2. Point 8.2 – Validity of EC certificates for interoperability constituents

The EC certificates supporting the declarations of conformity and/or suitability for use of ICs can be expired at the moment the application for authorisation is submitted, as long as the concerned ICs were lawfully placed on the market or are covered by the exceptions provided by the TSIs to incorporate ICs with expired certificates (or with certificates issued against previous TSIs).

The applicant should provide adequate justification in the file accompanying the application for authorisation, such as invoices, purchase order, delivery receipt, acceptance evidence, registers from QMS etc.).

Please note that placing on the market means a “*First supply of a good for distribution, consumption or use on the market in the course of a commercial activity*”, where “*supply of a good for distribution*” means “*an existing and individually identifiable good, after the stage of manufacturing has taken place, is the subject matter of a written or verbal agreement between two or more legal or natural persons for the transfer of ownership*”. As a result, the concerned ICs should have been already manufactured and delivered.

3.11.2.3. Point 8.6 All applicable legislation is covered, including other non-railway related legislation

According to the Directive (EU) 2016/797, there is a clear obligation for the applicant to ensure that all relevant Union law is met. The requirements capture process is the right tool for the applicant to ensure that all risks are properly covered and traced to a relevant mitigation measure. These mitigation measures may well be the provisions of the applicable Union law (for some risks).

Annex II (and in particular, point 8.6) describes the aspects that are to be verified by the authorising entity in order to establish a “reasonable assurance” that the applicant has fulfilled its responsibilities. From this point of view, the authorising entity should check that the applicant has taken into account other EU legislation. It does not impose an obligation for the authorising entity to ensure or assess that the legislation is actually met. The check to be performed by the authorising entity is a consistency check between the outcomes of the requirements capture process and the EC DoV(s).

Under the "relevant Union law", there are some laws that are not applicable to railways. However, some other EU laws that are not railway specific or do not seem in principle applicable to railways must be respected in any case (e.g., REACH Regulation (EC) 1907/2006, Electromagnetic Compatibility Directive 2014/30/EU, Directive 2009/48/EC on the safety of toys when a train has a playground area for kids, etc.), see section 3.3.1.4.

3.11.2.4. Point 8.7 Interoperability constituents (validity, scope, conditions for use and other restrictions)

The NoBo(s) responsible for the conformity assessment of the mobile subsystem(s) have the duty to assess if the ICs to be integrated are compatible with the subsystem and meet the relevant TSI requirements. The checks to be performed by the authorising entity relate to the consistency between the certificates included in the file accompanying the application, the certificates in ERADIS and the certificates referred to in the file accompanying the certificates of verification issued by the subsystem NoBo.

3.11.2.5. Point 10 - Check of assessments from the concerned NSAs for the area of use, as specified in Article 43

The details of the checks to be performed by the authorising entity are specified in Article 43 of the Regulation (EU) 2018/545.

The task of the authorising entity is not to check, recheck or overcheck the assessment carried on by other parties involved in the authorisation process, but to check the consistency of this assessment.

3.11.2.6. Point 21 – Check of EC declarations of verification in authorisations in conformity to type

When assessing applications for vehicle authorisation for placing on the market in conformity to an authorised type, the content of the EC DoVs should not be systematically re-evaluated by the authorising entity, because this verification was already performed during the type authorisation process. The verifications should be limited to the traceability between the EC declaration(s), the EC certificate(s), the file accompanying the application, ERATV and ERADIS.

When there is a need for a new or updated EC DoV (e.g. in case of changes to the vehicle type that can be classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545), such EC declarations shall respect all the requirements of the legal texts, regardless of the initial date of placing on the market of the subsystem, and assessing if the new or updated EC DoV fulfils the requirements of the Regulation (EU) 2019/250 should be in the scope of the checks to be performed by the authorising entity when delivering an authorisation for placing on the market of vehicle(s) in conformity to an authorised type.

3.11.3. Annex III Aspects for assessment by the concerned NSAs for the area of use

This Annex is not applicable when the area of use covers the whole EU network and the TSIs contain specific conditions for this.

The information that shall be assessed by the concerned NSAs for the area of use in relation to the relevant national rules is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that this aspect is mandatory to assess for this authorisation case

		First authorisation	New authorisation	Extended area of use	Renewed type authorisation
1	Application consistent with the pre-engagement baseline (when applicable)	X	X	X	X
2	The area of use for the concerned Member State is correctly specified	X	X	X	X
3	The national rules and requirements for the concerned area of use identified by the applicant are correct.	X	X	X	
4	Selected conformity assessment bodies relevant for the concerned area of use (designated body(ies), assessment body (CSM RA)) have the proper accreditation or recognition as applicable.	X	X	X	X
5	Sufficient evidence from the methodology used for the requirements capture only for the national rules for the concerned area of use: 5.1 When another methodology than the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked: (a) System definition is complete and consistent with the design of the vehicle? (b) Hazard identification and classification is consistent and plausible? (c) All risks have been properly managed and mitigated? (d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement?	X	X	X	
6	EC Declarations of Verification and Certificates (national rules) (Article 15 Directive (EU) 2016/797), check: 6.1 Signatures 6.2 Validity 6.3 Scope 6.4 Conditions for use of the vehicle, other restrictions, non-compliances	X	X	X	X
7	Reports from conformity assessment bodies (Article 15 Directive (EU) 2016/797), check: 7.1 Consistency with EC Declarations of Verification and certificates. 7.2 Deviations & non-conformities (when applicable) are identified 7.3 Conditions for use and other restrictions are properly identified and are consistent with the conditions in the application for authorisation.	X	X	X	X

	7.4 The supporting evidences used by conformity assessment bodies are matching the applicable assessment phases described in national rules.				
8	Existing conditions for use of the vehicle and other restrictions		X	X	X
9	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems positive opinion.	X	X	X	
10	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle (significant change) positive opinion		X	X	
11	Changes as compared to the authorised vehicle type are sufficiently described and match the CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013)		X		
12	EC Declarations of Verification and EC certificates are properly updated in relation to the changed/updated national rules				X
13	Reports from conformity assessment bodies are properly updated in relation to the changed/updated rules: 13.1 Changed/updated national rules are covered 13.2 There are evidence that the vehicle type still fulfils the requirements				X

3.11.3.1. Point 5 - Sufficient evidence from the methodology used for the requirements capture only for the national rules for the concerned area of use

The NSAs for the area of use, in relation to national rules, will also have a role in checking the evidence of the application of a non-standard methodology for the requirements capture. The checks should be systemic, focused on the process and on the relevance of the national rules used as mitigation measures in the risk assessment process. In order to do so, the NSAs for the area of use may need to check in detail some supporting evidence.

3.11.4. Annex IV Requirements management matrix (illustrative example)

Below, an illustrative example of the main elements that the tool to manage the requirements should cover can be found. This does not mean that the table presented should be used as it is presented; its purpose is to **illustrate and give example of the granularity** that is considered necessary to provide proper evidence of the requirements capture process applied to the AsBo and to the authorising entity.

In terms of requirements capture, the requirements should be broken down to the smallest possible requirement from a given source that can be:

- › Identified;
- › Assigned;
- › Implemented, and
- › Validated.

From this point of view, one sole source (e.g., a TSI) can result in many detailed requirements. And then, such low-level requirements can result in many different requirements to be managed independently, either because there are different requirements or because they are to be assigned to different component/systems/functions or validated in a different way.

Managing all detailed (low level) requirements into a single “master list” of requirements is not necessary. E.g., source requirements can be broken down to single functions/elements/systems to which they need to be assigned. Then, for each function/element/system, the exercise should be repeated until the necessary level of granularity is achieved. However, it’s paramount that the traceability is kept in all steps, so that at any given moment it should be possible to trace back detailed requirements to the source requirements.

In the example presented in the tables, the Regulation (EU) 2014/1302 (TSI LOC&PAS) requires that vehicles are fitted with two white headlamps, in order to give visibility to the driver (in addition, the headlamps allow others to identify the train). From this particular clause of the TSI, two other requirements can be derived:

- › There shall be two lamps, and
- › The lamps shall be white.

The way to manage each of those requirements can be different, and impact different other elements of the vehicle:

- › The structure and outer shell of the car/locomotive should have space to accommodate the lights
- › The lamps themselves should be white

Of course, there are many other detailed requirements that the vehicle type shall fulfil:

- › The electrical system should provide electricity to the lights (normally through the auxiliary system, and/or the battery);
- › The train control system should be able to control the lights;
- › There should be an adequate way to turn on / off / dim the lights in the driver’s desk
- › The lights should have the right colorimetry and project a beam with the right direction, shape and intensity, etc.

However, these aspects are also covered by other TSI requirements as well and will be addressed by other requirements.

Sources of requirements

Requirement source	Essential requirement	Breakdown in requirements matrix needed?	Conformity assessment needed?
Reference for the sources of requirements, including reference document (with date and/or version). List all sources from which requirements necessary to meet essential requirements of Annex III of Directive (EU) 2016/797 derive (Directives, Decisions, Regulations, EN standards, UIC standards, other international standards, guidelines, customer specifications, in-house guidelines, in-house design codes etc.).	Describe the essential requirements of Annex III of Directive (EU) 2016/797 linked to the requirement: -Safety -Health -Reliability and availability -Environmental protection -Technical compatibility -Accessibility	Indicate whether there is a need to break down the detailed requirements within the source (typically, in case of complex sources containing many heterogeneous requirements).	Indicate whether the source of requirements envisages a conformity assessment (e.g., verification by a NoBo).
<i>Regulation (EU) 2014/1302, as amended by Regulations (EU) 2016/919, 2018/868, 2019/776 and 2020/387 (TSI LOC&PAS)</i>	<i>-Safety -Health -Reliability and availability -Environmental protection -Technical compatibility -Accessibility</i>	<i>Yes. Breakdown of requirements in the TSI necessary.</i>	<i>Yes. NoBo certificates and accompanying report.</i>
<i>Regulation no 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), with all amendments and corrigendum until 2021/01/25 (Regulation (EU) 2021/57)</i>	<i>-Environmental protection</i>	<i>No. List of materials installed in the vehicle compliant with REACH regulation is considered enough.</i>	<i>No.</i>

Requirements matrix

Article 13(1)(a) Identification					Article 13(1)(b) Assignment			Article 13(1)(c) implementation	
Unique ID	Requirement source	Requirement	Applicability	Applicability justification	Subsystem	Allocation	Responsible	Vehicle / subsystems specification(s)	
Unique identification of the requirement	Source of the requirement, including reference document (with date and/or version) and section within the document.	Description of the requirement. It doesn't have to be the text of the requirement in full, a meaningful summary is acceptable.	Indicate if the requirement is considered to be applicable or not to the project (Applicable/Not applicable)	Justification about why the requirements is considered to be not applicable.	Indicate to which subsystem the requirement applies: -Rolling stock (RS) -Control-command and signalling (CCS) -Vehicle (RS & CCS)	Indication to which functions/products the requirement is allocated to. The proposals in EN 15380 can be used; other project breakdown structure used by the applicant should be acceptable too.	Responsible person and/or team in charge of managing the requirement.	Reference to the vehicle specification(s), including date and/or version, and specific clauses where this requirement is assigned.	Short description of the document scope.
R00001	§4.2.7.1.1 of Regulation (EU) 2014/1302, as amended by Regulations (EU) 2016/919, 2018/868, 2019/776 and 2020/387	Two headlamps shall be provided at the front end of the train in order to give visibility for the train driver.	Applicable	Not applicable	RS	BE - Driver's cab metal paneling BE - Frame of driver's cab BE - Thermoplastic head	Structures - Mr John Doe	TD-1523 2022/01/12 §3.4.2	Technical specification of the vehicle.
R00002	§4.2.7.1.1 of Regulation (EU) 2014/1302, as amended by Regulations (EU) 2016/919, 2018/868, 2019/776 and 2020/387	The headlamps that shall be provided at the front end of the train shall be white.	Applicable	Not applicable	RS	KB - Train headlights	Systems engineering - Ms Jane Doe	PRC1234-1234 rev.2, §5.2.1.3	Purchase specification of the headlights.

Requirements matrix (cont.)

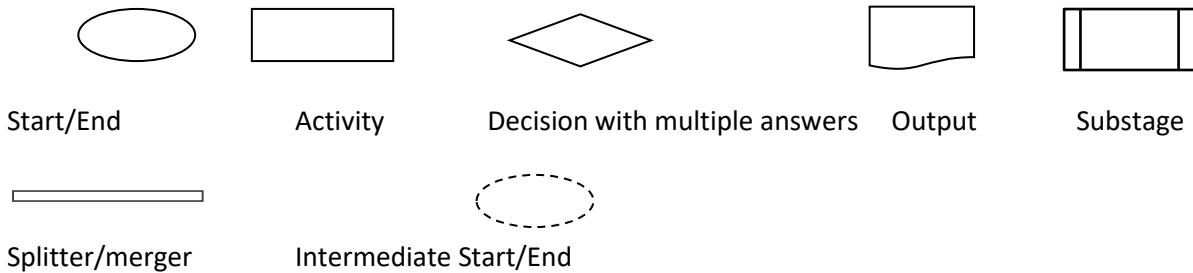
Article 13(1)(c) validation (design type)						Article 13(1)(b) conditions for use	Article 13(1) validation			
Design evidence		Type test evidence		Conformity assessment			Conditions for use and other restrictions	Status		
Reference to the evidence, including date and/or version), and specific clause(s) which demonstrates compliance with the requirement.	Brief description of the document scope. If not self-explanatory, please briefly describe how the evidence contributes to the demonstration of compliance.	Reference to type test evidence, including date and/or version), and specific clause(s) which demonstrates compliance with the requirement. If none, state 'Not Applicable'.	Brief description of the document scope. If not self-explanatory, please briefly describe how the evidence contributes to the demonstration of compliance.	Reference to validation evidence (including date and/or version) which demonstrates that the requirement has been met. State "Not applicable" if none.	Brief description of the document scope: -NoBo report -DeBo report -AsBo report -Inspection body report -Certificate -Self declaration -etc.	Clear status of the conclusion of the validation activities: -Compliant -Compliant with CfU and restrictions -Not compliant	Describe which are the CfU that arise from this particular requirement and/or as a result of the management of the requirement. A reference to another document is also allowed if there are many CfU (including date and/or version, and reference within the document). If none, state "Not applicable".	Describe the status of the requirement: -Open -Closed (transferred) -Closed (cancelled)	Brief description of the status of the requirement, in particular where it has been cancelled or transferred (exported). When transferred or exported, please describe the receiving party: -Operation -Maintenance -Infrastructure -etc. If none, state 'Not Applicable'.	Reference to the evidence of the transfer, including date and/or version, and specific clause(s). If none, state 'Not Applicable'. When the evidence of the transfer is already referenced in column S, state "See column S".
DRWABCDEF-1234 rev.2	End cars drawings.	Not applicable	Not applicable	256/1563-0000 rev.3, §5.4	NoBo report	Compliant	Not applicable	Closed	Not applicable	Not applicable
CCA4589340000 rev.0, §2.2.1	Technical specification of the headlight.	Not applicable	Not applicable	256/1563-0000 rev.3, §5.4	NoBo report	Compliant	Not applicable	Closed	Not applicable	Not applicable

4. Flowcharts

How to read the flowcharts

Symbols

Standard flowchart that describes the authorisation process, using 6 Unified Modelling Language symbols:

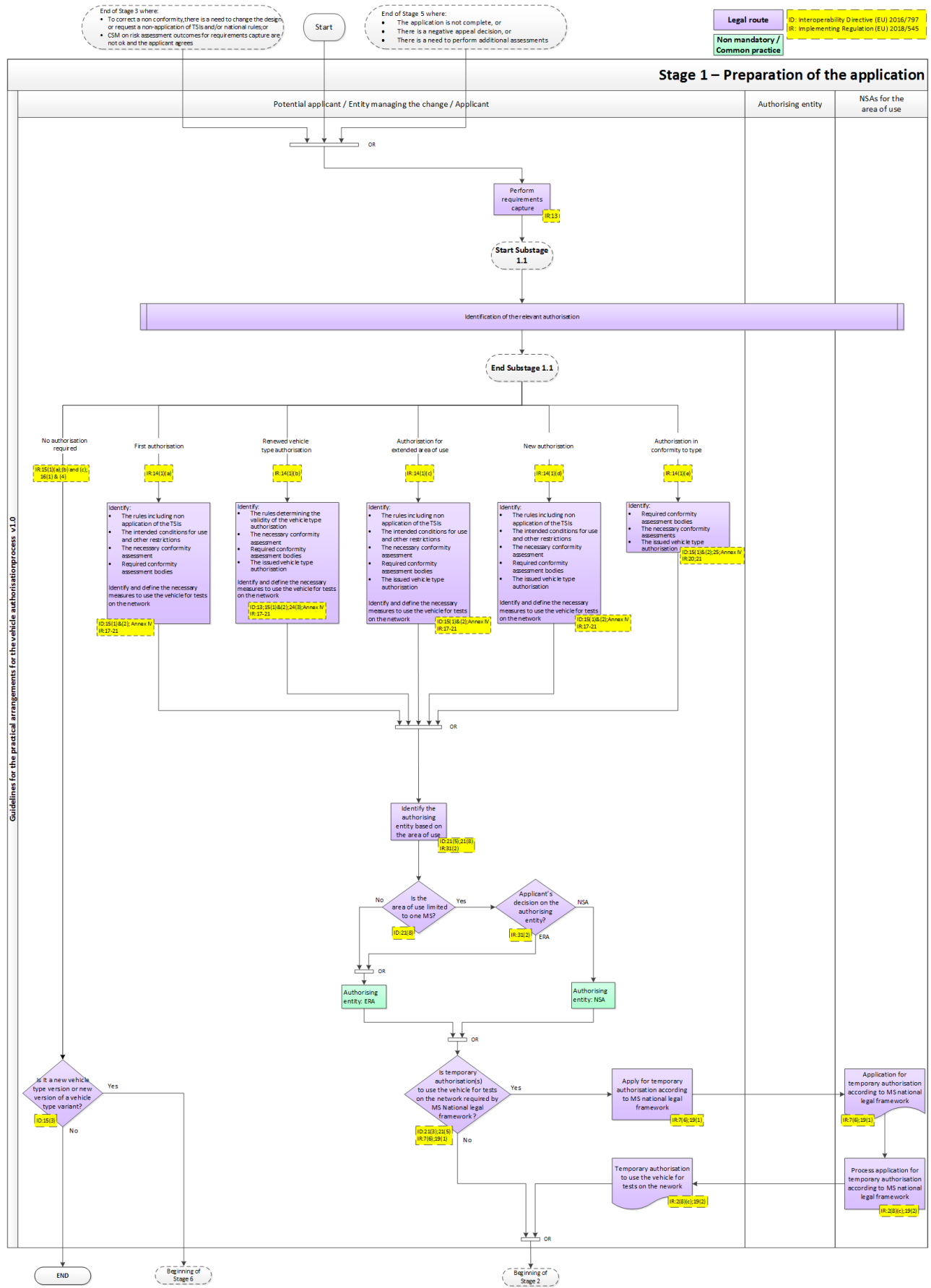


Principles

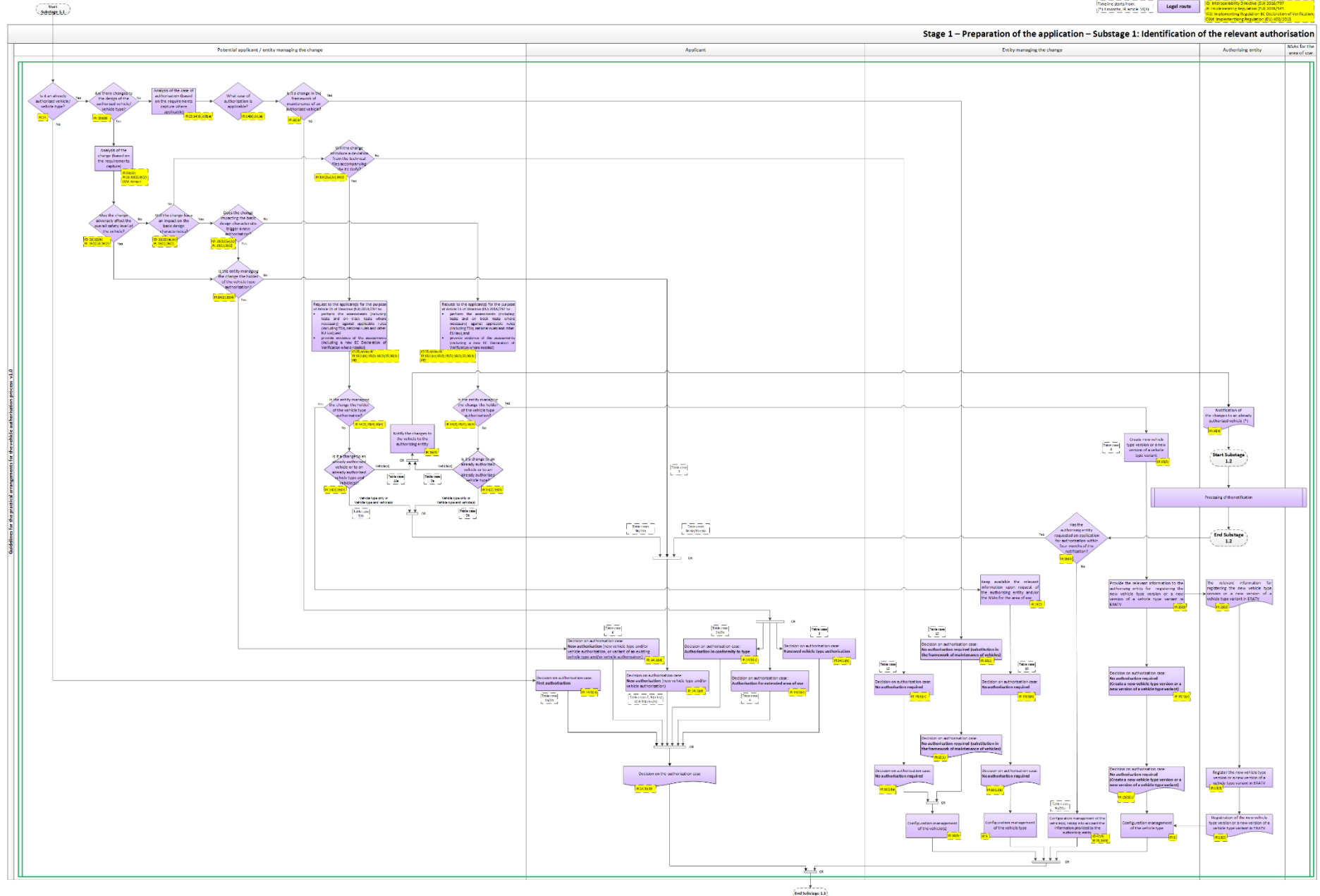
- › The symbols are linked with directed arrows.
- › It is indicated on the merger symbol if parallel arrows are considered as “And” or “Or”.
- › Splitter symbol is always considered as “And”.
- › The flowchart starts and ends with the same symbol.
- › An activity is an action that requires the use of a verb, e.g., Request, Provide, Modify.
- › A decision is often an answer to a question. The answer is often binary Yes/ No but may be also multiple alternatives.
- › An output is the result of an action and is often a document either paper based or electronic based.
- › Outputs are placed with the recipient.
- › The role indicated in the flowchart is to be understood as the role responsible for the activity. Other actors might be supporting but are not specified in the flowchart.
- › If there is a time frame defined in the legislation this is indicated where it starts in the activity/ decision/ output by a: (*).
- › The activities/ decisions/ outputs have been colour coded to indicate if it is:
 - Green = Recommended practice; and
 - Purple = Mandatory according to EU legislation.
- › References to legislation are placed next to the relevant activity/ decision/ output in a yellow box.
- › The following abbreviations are used for the legal references:
 - ID – Interoperability Directive (EU) 2016/797
 - IR – Regulation (EU) 2018/545
 - AIR – Regulation (EU) 2016/796
 - REG – Regulation (EU) 2019/250
 - CSM – Regulation (EU) 402/2013

List of flowcharts

- › Stage 1 – Preparation of the application
- › Stage 1 – Substage 1.1 – Identification of the relevant authorisation
- › Stage 1 – Substage 1.2 – Processing of the notification
- › Stage 2 – Pre-engagement
- › Stage 3 – Conformity assessment
- › Stage 4 – Submitting the application
- › Stage 5 – Processing the application
- › Stage 5 – Substage 5.1 – Arbitration
- › Stage 5 – Substage 5.2 – Review and appeal
- › Stage 6 - Final documentation

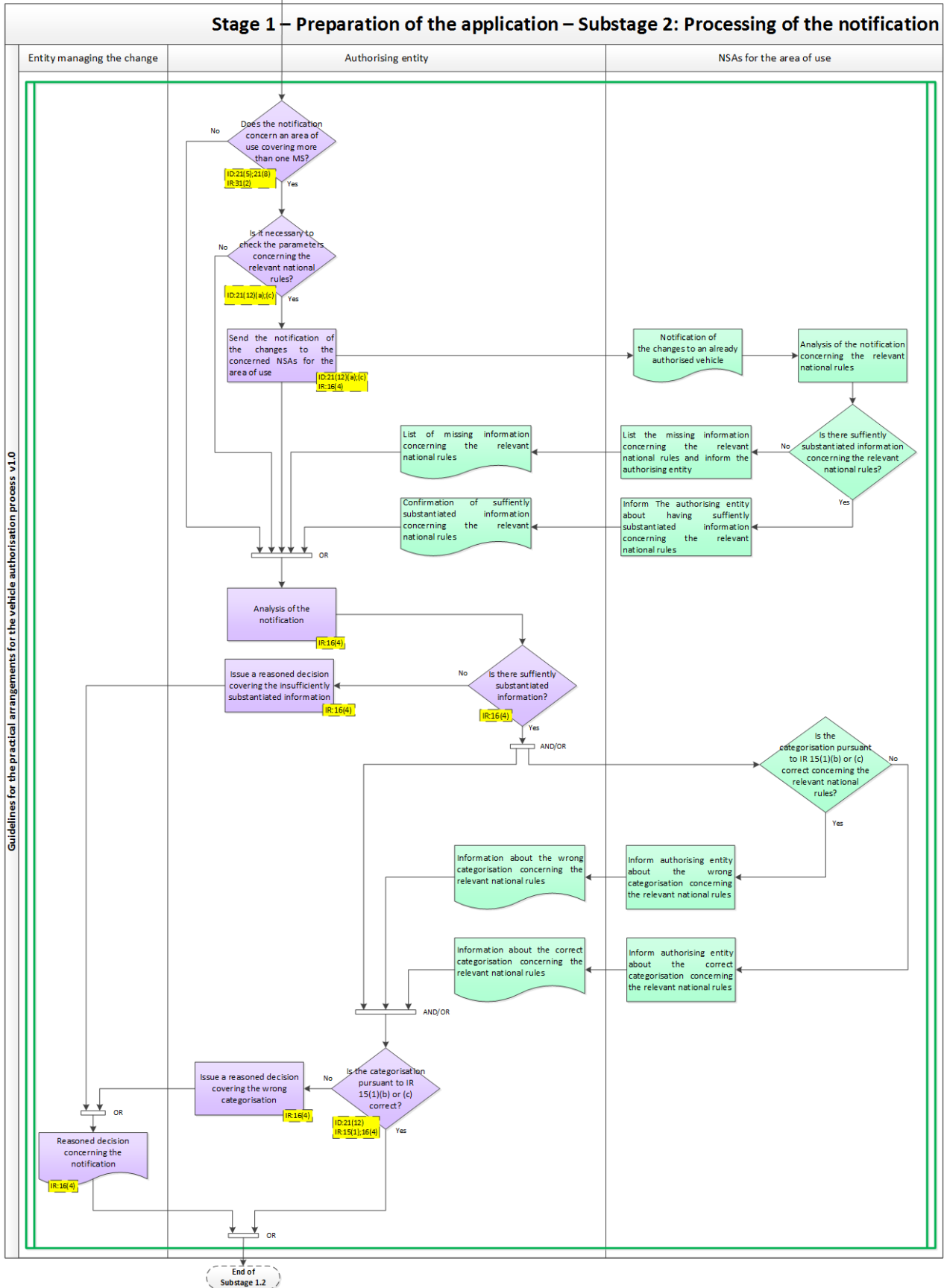


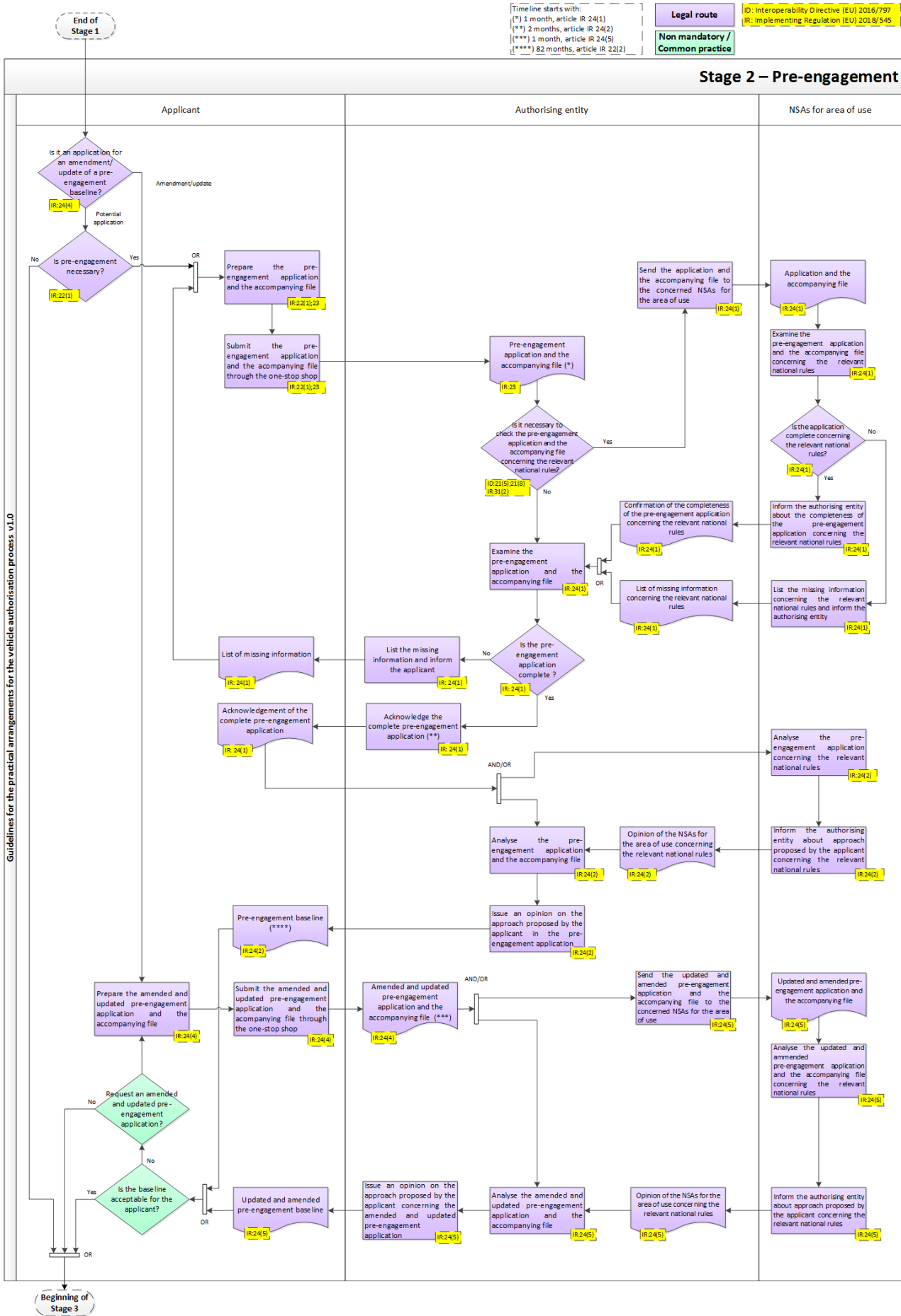
Legal route: [Interoperability Directive \(EU\) 2020/1091](#)
[on assessing the safety of the railway system](#)
[and on the technical specifications for interoperability](#)
[of the railway system](#)



Non mandatory/ Common practice ID: Interoperability Directive (EU) 2016/797
IR: Implementing Regulation (EU) 2018/545

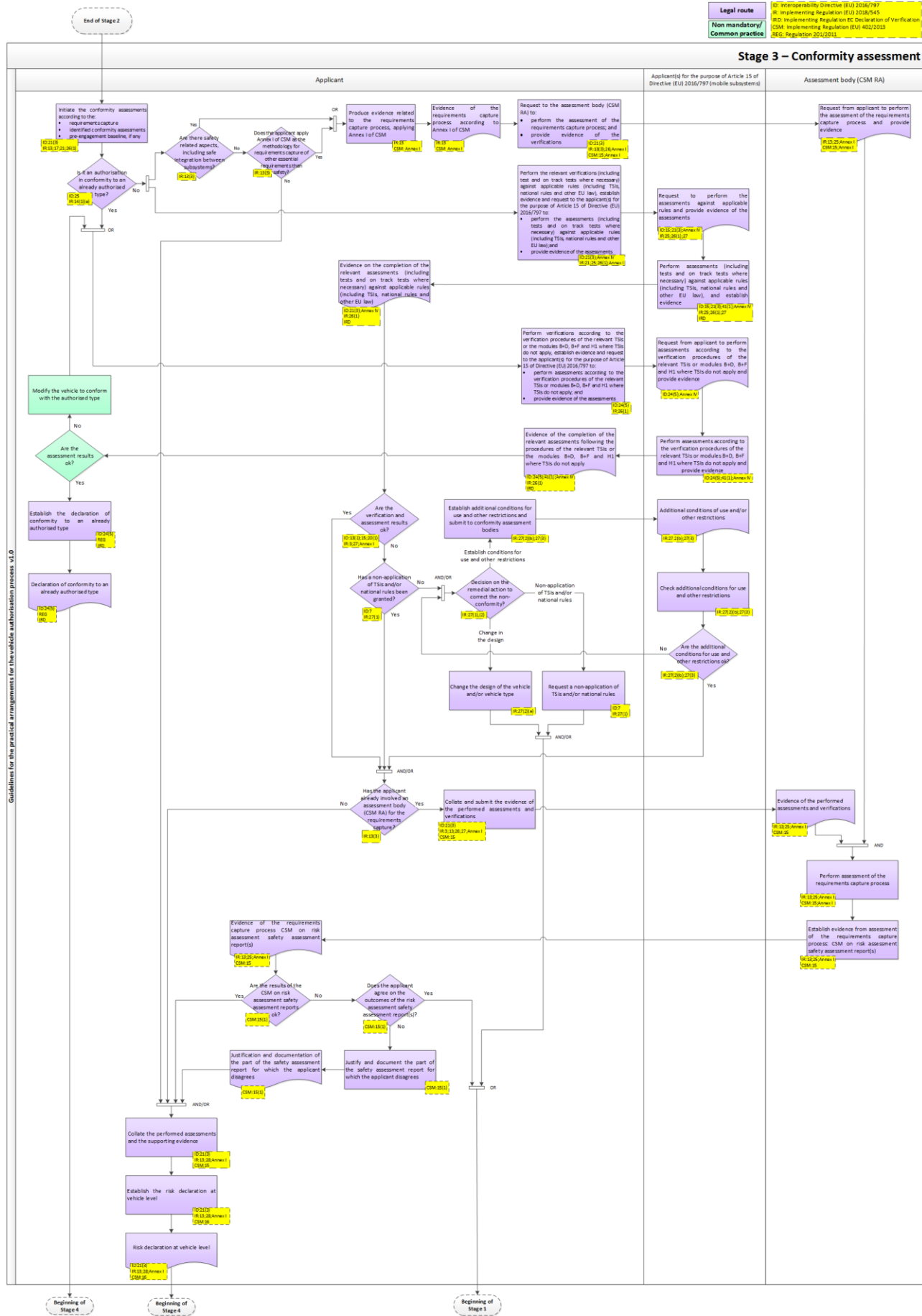
Legal route

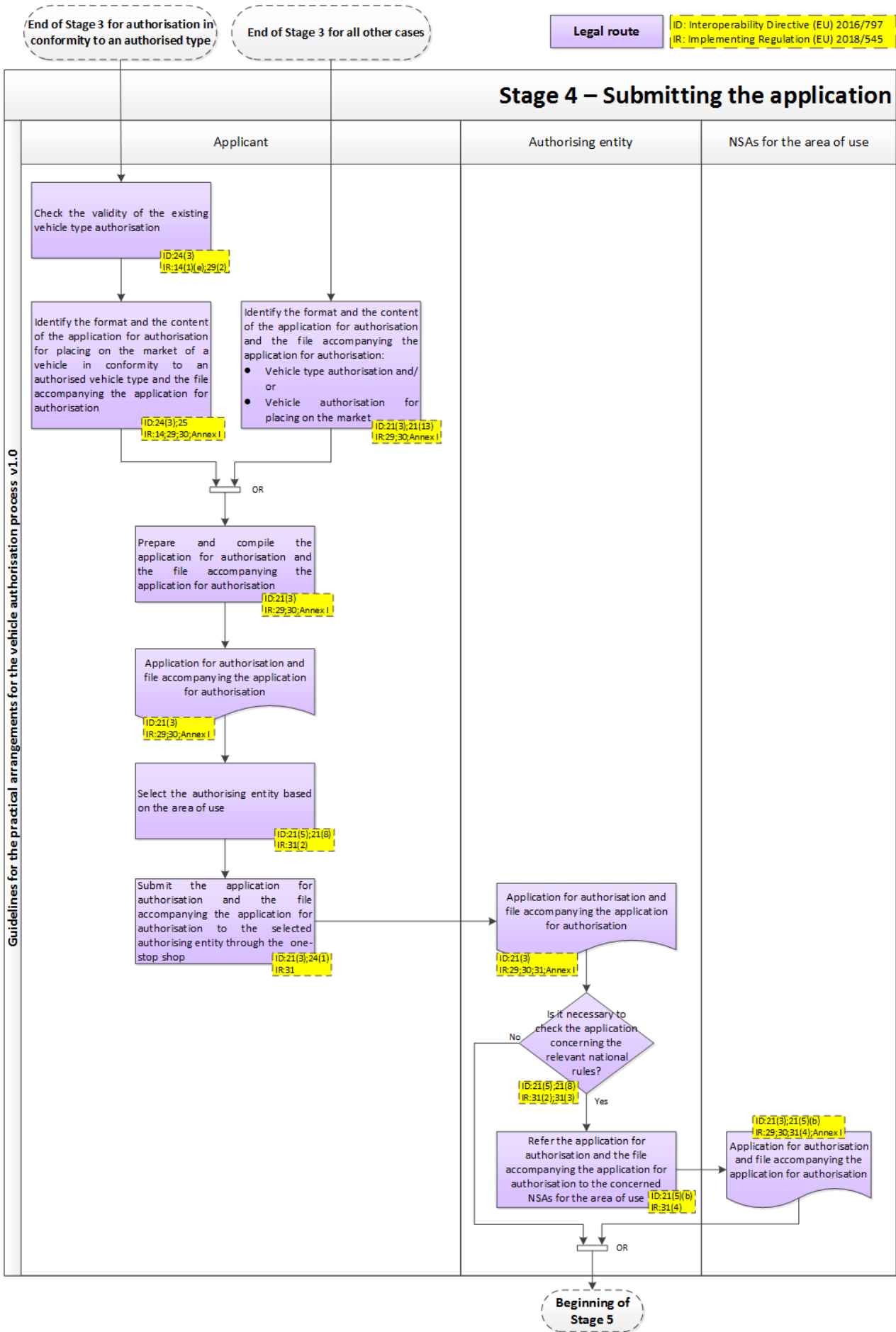




Legal route IR: Interoperability Directive (EU) 2016/797
IR: implementing Regulation (EU) 2018/545
IRD: Implementing Regulation EC Declaration of Verification
CSM: Implementing Regulation (EU) 402/2013
RSC: Regulation 2017/2011

Non mandatory/ Common practice

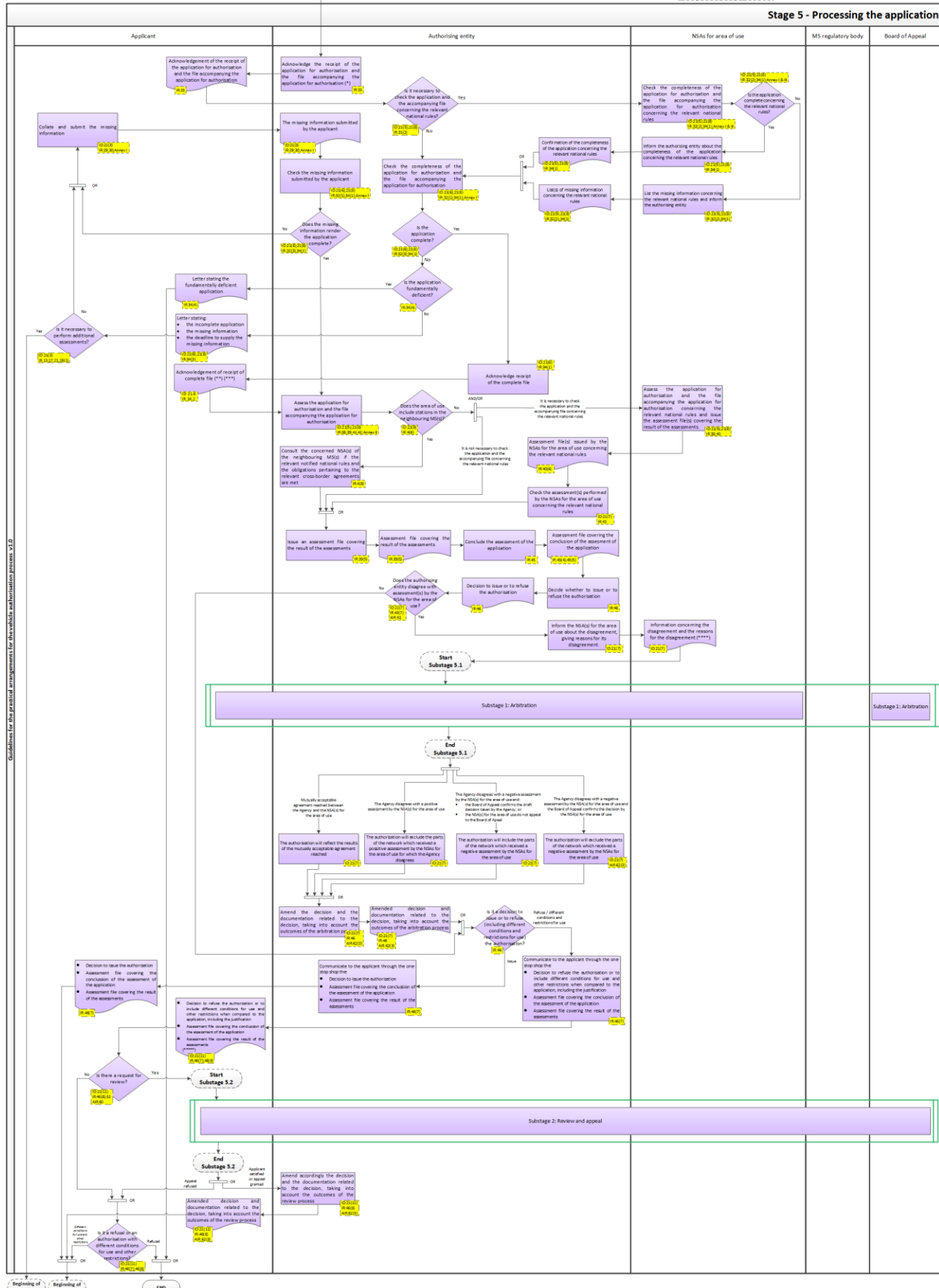


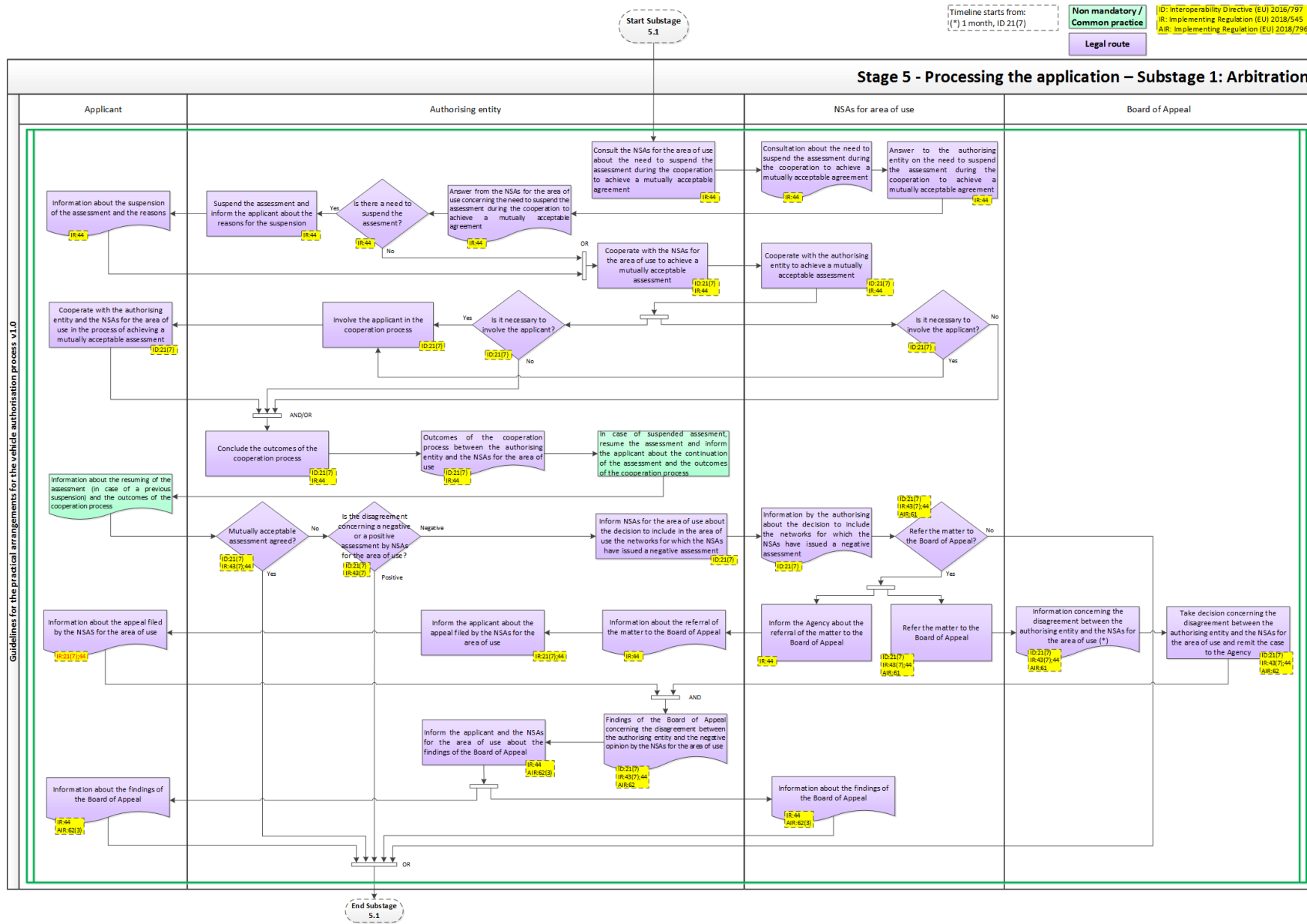


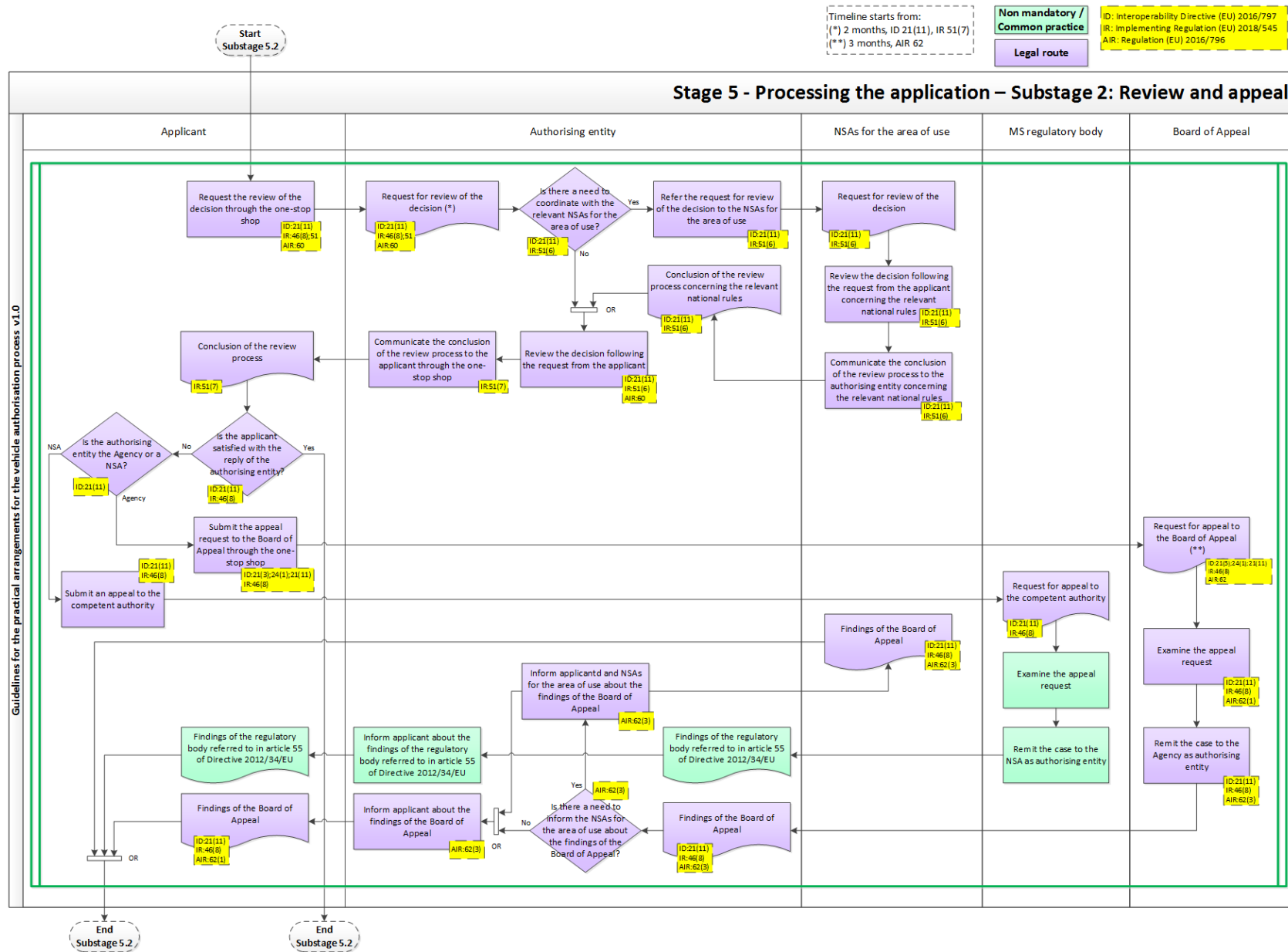
Timeline starts with:
 [] 1 month, ID 21(6) & 21(8)(a) 34(1)
 [] 1 month, ID 21(6) & 21(8)(a) 34(3)
 [] 1 month, ID 21(6)(a) 34(2)
 [] 1 month, ID 21(7)
 [] 1 month, ID 21(11)

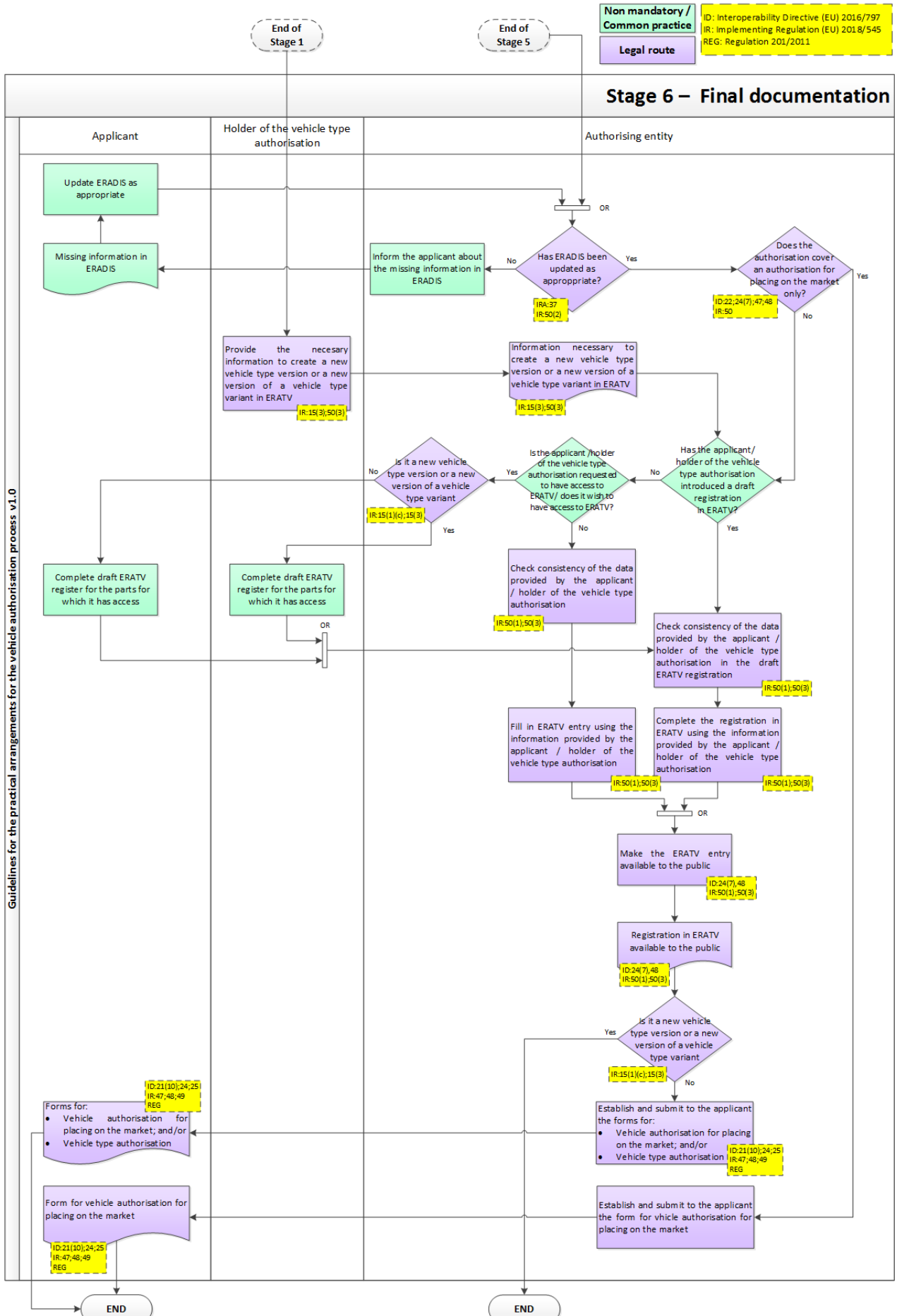
Non mandatory / Common practice
 [] Information received in ID 20(2)(7)
 [] All implementing measures in ID 20(2)(7)
 [] Implementing measures in ID 20(2)(7)

Legal route









5. Comment sheet**Document Review – Comment Sheet**

*Document commented: “Guidelines for the practical arrangements for the vehicle authorisation process”
v2.1 (ERA1209/222)*

<i>Requestor:</i>	The Agency
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	<i>Reviewer 1</i>	<i>Reviewer 2</i>	<i>Reviewer 3</i>	<i>Reviewer 4</i>	<i>Reviewer 5</i>
<i>Date:</i>					
<i>Name:</i>					
<i>Organisation:</i>					
<i>Email:</i>					

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0		

Conventions:

<i>Type of Comment</i>		<i>Reply by requestor</i>	
<i>G</i>	General	<i>R</i>	Rejected
<i>M</i>	Mistake	<i>A</i>	Accepted
<i>U</i>	Understanding	<i>D</i>	Discussion necessary
<i>P</i>	Proposal	<i>NWC</i>	Noted without need to change

Review Comments <if necessary add extra lines in the table>

<i>N°</i>	<i>Reference (e.g.Art, §)</i>	<i>Type</i>	<i>Reviewer</i>	<i>Reviewer's Comments, Questions, Proposals</i>	<i>Reply</i>	<i>Proposal for the correction or justification for the rejection</i>
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						