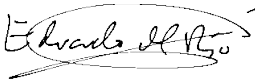




Moving Europe towards a sustainable and safe railway system without frontiers.

Clarification note

Compilation of versions

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Document History

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1.0	04/05/2022	Initial version

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regard to the specific topic referenced in the title. The clarifications contained in this document may be integrated in the next revision of the guidelines for the practical arrangements for the vehicle authorisation process, without prejudice of the formal process foreseen for updating the guideline.

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.

1. Description of the issue

The Directive (EU) 2016/797¹, as amended by Directive (EU) 2020/700², includes the concept of vehicle type and authorisation of a vehicle type, already present in Directive 2008/57/EC. Within the framework of this Directive, the Regulation (EU) 2018/545³, as amended by Regulation (EU) 2020/781⁴, 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 legal definitions of variant and version in the Regulation:

- › A variant of a vehicle type can only be the result of a “first authorisation” or a “new authorisation”;
- › A version of a vehicle type or of a variant of a vehicle type can only be the result of:
 - a change in the basic design characteristics within certain thresholds that do not require a new authorisation, or
 - an authorisation for the extension of the area of use.

This creates a few constraints:

- › Variants can be created only from a type, and not from a variant
- › Versions can be created from a type or from a variant
- › Extensions of the area of use, that always require an authorisation, do not completely fit into the definitions of variants nor versions:
 - The area of use is also a basic design characteristic, and any change in a basic design characteristic should be considered either a version (if it does not require a new authorisation) or a variant (if there is a need for a new authorisation).
 - An extension of the area of use requires an authorisation. It could be interpreted that an extension of the area of use is a change in a basic design characteristic that always requires an authorisation, and should result in the creation of a variant of the vehicle type
 - A variant can only be created as a result of either a first authorisation or a new authorisation due to the legal definitions in article 2 of the Regulation, excluding the possibility that an extension of the area of use results in the creation of a variant

Up until now, the interpretation of the legal text is that:

- › Variants of variants are not allowed
- › Versions of versions are not allowed
- › An extension of the area of use should result in the creation of either a new type or a version (of a type or of a variant).

This has an impact for the holders of vehicle type authorisations, as it limits the number of “children” that a “parent” type can have.

While a holder of a vehicle type authorisation can always decide to apply for a new type even in case of new authorisation and extension of the area of use, restarting anew the counter for possible subsequent configurations (variants and versions), there is a particular problem in case of the extensions of the area of use, where a given design of a vehicle (in terms of its technical characteristics) can correspond to different

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 (OJEU L138, 26.5.2016, p.44-101)

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.27-30)

³ 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.66-104)

⁴ 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 (OJ L 188, 15.6.2020, p.11-13)

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.

This creates problems when applying for the authorisation for placing on the market of vehicles in conformity to an already authorised type, because depending on the version selected, the effect is that the area of use is also automatically defined. Due to the fact that it is not possible to choose several 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 design would be de facto authorised in all the concerned MSs.

A similar problem occurs for versions created after the addition of an ETCS system compatibility (ESC) to an existing vehicle type or variant of a vehicle type, pursuant to section 7.2.1a.1 of Regulation (EU) 2016/919⁵ (CCS TSI), as amended by Regulations (EU) 2019/776⁶, 2020/387⁷ and 2020/420⁸, 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 or performing subsequent 15(1)(c) changes) of the newly created version would not be allowed (versions of versions).

⁵ 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 (OJ L 158, 15.6.2016, p. 1–79)

⁶ 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 (OJ L 139I, 27.5.2019, p. 108–311)

⁷ 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 (OJ L 73, 10.3.2020, p. 6–18)

⁸ 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 (OJ L 84, 20.3.2020, p. 5–6)

2. Line to take

2.1. Versions created following an extension of the area of use to another EU Member State

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, the Agency can create a new version compiling existing already authorised versions of a vehicle type or of a variant of a vehicle type. Each of the existing versions 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 versions is not an authorisation, but a service output that compiles already authorised versions created following an extension of the area of use of the same type/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 type/variant/version, while the same design is de facto authorised in all Member States of the area of use), without the need to provide the supporting documentation.

The result of the compilation will be a new entry in ERATV. The type ID will be assigned as if it was a new version of the parent type/variant. This new version will compile the values for the different parameters (including coded and non-coded restrictions) of the existing entries in ERATV corresponding to the versions that will be compiled. In the comments section, it will describe both the parent type/variant and the different versions compiled (including their type IDs).

The conditions that shall be met for compiling already authorised versions are:

- › The requestor shall be the holder of the vehicle type authorisation for the parent type/variant and for all the versions that will be compiled;
- › All versions shall derive from the same type/variant;
- › All the versions that will be compiled should have been authorised by the Agency following the procedure laid down in Regulation (EU) 2018/545 and should be registered in ERATV under Directive (EU) 2016/797;
- › The different versions should meet 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 design 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 those related to the:
 - Values for the ERATV parameters that can be different due to the fact that each version is authorised in a different area of use, such as:
 - area of use;
 - conditions for use of the vehicle and other restrictions of use 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, in particular coded and non-coded restrictions.
- › All the transitions between MSs in the area of use of the versions 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 versions, and no additional transitions can be included as a result of the compilation.

2.2. Versions created following the addition of an ETCS system compatibility (ESC)

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, the Agency can 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 to an authorised vehicle type or variant of a vehicle type. The existing versions will remain valid. The new entry in ERATV will have a type ID corresponding to a new version of the parent type/variant

In the comments section, the new entry will describe both the parent type/variant and the different existing versions from which the ESCs are taken (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 ESCs will be taken;
- › All versions shall derive from the same type/variant; All the versions that will be compiled should have been published in ERATV by the Agency;
- › There shall be no changes in the design 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;
 - 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.

2.3. Versions created following 15(1)(c) changes

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, the Agency can 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 entry in ERATV will have a type ID corresponding to a new version of the parent type/variant.

In the comments section, the new entry will describe both the parent type/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/variant;
- › All the versions that will be compiled should have been published in ERATV by the Agency;
- › 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/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.

2.4. Compilation of versions from different origins

Upon request and under the sole responsibility of the holder of the vehicle type authorisation, the Agency, can create new versions compiling existing versions even if the reasons for the creation of such versions are different, e.g.

- › Performing a 15(1)(c) change to a version authorised as a result of an extension of the area of use;
- › Adding an ESC type to a 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 entry in ERATV will have a type ID corresponding to a new version of the common parent type/variant

In the comments section, the new entry will describe both the parent type/variant and the different existing versions 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/variant and for all the versions that will be compiled;
- › All versions shall derive from the same type/variant;
- › All the versions that will be compiled should have been published in ERATV by the Agency;
- › 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:
 - Values for the ERATV parameters that can be different related to the fact that versions following extension of the area of use are authorised in different MSs (area of use, conditions for use, 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/variant from which all versions derive should be considered when analysing the thresholds allowed in the applicable TSIs;
 - ESCs;
 - 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.

2.5. Process to request the compilation of versions

The process to request the creation of a new version in the conditions described in sections 2.1, 2.2 and 2.3 above is described in the following FAQ in the website of the Agency:

<https://www.era.europa.eu/can-we-help-you/faq/575#faq1545>

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. Legal background

3.1. Regulation (EU) 2018/545 (as amended)

- › Article 2(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;”
- › Article 2(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;”
- › Article 2(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;”
- › 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). [...]”

- › 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.

[...]

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).

3.2. Regulation (EU) 2016/919 (as amended)

- › 4.2.17. *ETCS and Radio System Compatibility*

“Due to the different possible implementations and the status of the migration to fully compliant CCS Subsystems, checks shall be performed in order to demonstrate the technical compatibility between the on-board and trackside CCS Subsystems. The necessity of these checks shall be considered as a measure to increase the confidence on the technical compatibility between the CCS subsystems. It is expected that these checks will be reduced until the principle stated in 6.1.2.1 is achieved.”

- › 4.2.17.1. *ETCS System Compatibility*

“ETCS System Compatibility (ESC) shall be the recording of technical compatibility between ETCS on-board and the trackside parts ETCS of the CCS subsystems within an area of use.

ESC type shall be the value assigned to record the technical compatibility between an ETCS on-board and a section within the area of use. All sections of the Union network which require the same set of checks for the demonstration of ESC shall have the same ESC type.”

- › 7.2.1a.1. *Rules to manage changes in on-board CCS subsystems*

[...]

5. The changes impacting the Basic Design Characteristics of the on-board subsystem are defined in Table 7.1 Basic Design Characteristics and shall be classified as 15(1)(c) or 15(1)(d) of Implementing Regulation (EU) 2018/545, and in accordance with Table 7.1 Basic Design Characteristics changes not

impacting but related to the Basic Design Characteristics shall be classified by the entity managing the change as 15(1)(b) of Implementing Regulation (EU) 2018/545.

6. Changes not covered by point 7.2.1a.1(5) above are deemed not to have any impact on the basic design characteristics. They will be classified by the entity managing the change as 15(1)(a) or 15(1)(b) of Implementing Regulation (EU) 2018/545.

Note: The classification of the changes set out in points 7.2.1a.1(5) and 7.2.1a.1(6) above is performed by the entity managing the change without prejudice of the safety judgement mandated in Article 21(12)(b) of Directive (EU) 2016/797.

[...]"

Table 7.1 Basic Design Characteristics

1. TSI Point	2. Related basic design characteristic(s)	3. Changes not impacting the basic design characteristics according to 15(1)(b) of Regulation (EU) 2018/545	4. Changes impacting the basic design characteristic but inside the acceptable range of parameters therefore to be classified as Art 15.1(c) of Regulation (EU) 2018/545	5. Changes impacting the basic design characteristic and outside the acceptable range of parameters therefore to be classified as Art 15.1(d) of Regulation (EU) 2018/545
[...]				
4.2.17.1 ETCS System Compatibility	ETCS System Compatibility	Not applicable	Adding or removing ESC statements, after checking by a NoBo	Not applicable
[...]				

3.3. Guidelines for the practical arrangements for the vehicle authorisation process

› 3.2.2.15 Vehicle type

“Vehicles should belong to a vehicle type and the vehicle type should be authorised at the same time as the first vehicle of that vehicle type is authorised for placing on the market and before vehicles are authorised in conformity to 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. 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.

Any vehicle(s) that are produced and placed on the market and that are in conformity with an authorised vehicle type should receive an authorisation for placing on the market on the basis of a declaration of conformity to that authorised vehicle type submitted by the applicant, see chapter 3.3.2.1.

While railway infrastructure and projects for fixed installations tend to be specifically designed “one off” for a specific route or geographical location, individual vehicles are usually manufactured in series of identical vehicles of the same vehicle type.

Authorising entities issue the authorisation to a series of vehicles (set of identical vehicles) on the basis of a declaration of conformity to vehicle type submitted by the applicant, see chapter 3.3.2.1.

If a vehicle type is authorised and further vehicles are authorised for placing on the market on the basis of conformity to the vehicle type, and where applicable clearly specifying the vehicle type variant and vehicle type version, then all vehicles of that vehicle type can be considered to be compatible with networks that form the intended area of use.

The concept of vehicle type must not be confused with the concept of product type within the “new approach” or a subsystem type.

The concept of vehicle type applies to a vehicle design 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 design.

Because of the interaction between subsystems it cannot automatically be assumed that the characteristics of individual subsystems can be added together to become the characteristics of a vehicle.”

› 3.2.2.16 (13) Vehicle type variant

“A vehicle type can include variations of the design (e.g. platform).

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),so if the design of the vehicle type is changed to include a new variant it is still the same vehicle type.”

› 3.2.2.17 (14) Vehicle type version

“It is a configuration or a modification that constitutes a change to the basic design characteristics of the vehicle type or of a vehicle type variant and it is below the threshold for a new authorisation according to Articles 24(1) and 21(12) of Directive (EU) 2016/797, then a vehicle type version will have been created.

Vehicle type versions follow the stages of evolution of vehicle type over time i.e. the same vehicle type may have several different versions over time. So if a vehicle type is changed to a new vehicle type version it is still the same vehicle type. This should also apply to the documentation covering a vehicle type.

The extension of an area of use of an already authorised vehicle type should be considered as a new vehicle type version or as a version of a variant of a vehicle type,as:

- *The definition of vehicle type variant in article 2(13) of Commission Implementing Regulation (EU) 2018/545 limits the possibility to create variants to the authorisation cases first or new (pursuant to articles 14(1)(a) and 14(1)(d) of Commission Implementing Regulation (EU) 2018/545); and*
- *The area of use is part of the basic design characteristics of the vehicle type (see Article 48(c)(ii) of the Commission Implementing Regulation(EU) 2018/545).*

The extension of an area of use always requires an authorisation following article 21(13) of Directive 2016/797 and article 14(1)(c) of Commission Implementing Regulation (EU) 2018/545.

See also chapter 3.3.2.2 of this document for further guidance concerning changes to a vehicle type.”

› 3.3.2.2 Article 15: Changes to an already authorised vehicle type

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 categories of changes to an authorised vehicle type

Decisions made by a (potential) applicant/ entity managing the change concerning the changes to a vehicle and/ or vehicle type based on the four modification categories are different from the decision on the significance of a change to the railway system (in the meaning of Commission Implementing Regulation (EU) 402/2013) to be made by a railway undertaking or infrastructure manager contemplating a change to their part of the railway system (e.g. incorporating into the fleet a new design of vehicle to be operated on certain lines). The decisions involve different actors in different circumstances with different decision criteria; each actor is responsible for its part of the system.

The decision by the proposer on the categorisation of a change to a vehicle and/ or vehicle type may influence the scope of the responsibility. 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 declaration(s) of verification, 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 declaration(s) of verification; and/ or
- Is not the holder of the vehicle type authorisation;

it should establish the EC declaration(s) of verification 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.

This is further described in Annex XVIII, flowchart for Substage 1.1.

- a) Changes that do not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems.

This category of change has no impact on the verifications performed and consequently on the design 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 declaration(s) of verification 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).

- b) Changes that introduce 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 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.

This category of change has no impact on the design (basic design characteristics) and does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797 but it has an impact on the documentation that forms the basis for the issued vehicle type authorisation, therefore it is to be covered by the configuration management of the vehicle type.

This category of change may impact the conformity of the subsystems or the validity of certificates of conformity. The conformity assessment bodies perform the necessary verifications and issue the relevant certificates.

- 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.

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 design 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.**

- d) A change of the vehicle type that requires a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.

The changes trigger the criteria set out in Article 21(12) of Directive (EU) 2016/797 for when a new authorisation is required, see chapter 3.3.2.1. It is to be covered by the configuration management of the vehicle type. **The holder of the vehicle type authorisation can either add a new vehicle type variant to the authorised vehicle type or decide to create a new vehicle type. This is an administrative decision of the holder of the vehicle type authorisation.**

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

Extended (changed) area of use

An extension (change) of the area of use has an impact on the basic design characteristics i.e. the design (the area of use is a basic design characteristic specified in the issued vehicle type authorisation). However, for this type of change the case of authorisation should be for the **extended area of use** pursuant to Article 21(13) of Directive (EU) 2016/797. If this type of change is combined with other changes of the design requiring a new authorisation there should be two authorisation decisions but it can be combined in a single application, see chapter 3.3.2.1.

A change (extension) of the area of use is therefore a change to the design and it has an impact on the documentation that forms the basis for the issued vehicle type authorisation (it may be necessary to perform new conformity assessments according to the national rules for the extended area of use, which may also require updates on the technical files accompanying the EC declarations of verification, in the EC declarations of verification, in the evidence related to the requirements capture etc., even if there are no physical changes in the vehicle and/or vehicle type). It is to be covered by the configuration management of the vehicle type. The changes to the design require an authorisation for the extended area of use pursuant to Article 21(13) of Directive (EU) 2016/797, see chapter 3.3.2.1. **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.**

If the area of use is to be changed a new vehicle type version or a new vehicle type will have been created because the area of use is a part of the design (basic design characteristic) of a vehicle type and it requires an authorisation for the extended area of use pursuant to Article 21(13) of Directive (EU) 2016/797.

New vehicle type

If a new vehicle type is created it needs to be authorised. This applies irrespective of the change and whether the change would require an authorisation or not. For the applicable case of authorisation see chapter 3.3.2.1.

If the new vehicle type is based on an authorised vehicle type the applicant can apply for a new authorisation even if the applicant is not the holder of vehicle type authorisation for the authorised vehicle type. Only the changes and their interfaces with the unchanged parts should be assessed by the authorising entity and the concerned NSAs for the area of use. See also chapter 3.2.2.6 and 3.2.3.3.

In a case when a change requires a new authorisation according to the criteria set out in Article 24(1) and 21(12) 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.**

Changes managed by another entity than the holder of the vehicle type authorisation

Should an entity who is not the holder of the existing vehicle type authorisation wish to make a change to the design and/ or to the documentation that forms the basis for the 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 becomes the applicant and **creates a new vehicle type which should be authorised**. 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.

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. Those contractual arrangements are out of the scope of the practical arrangements for the vehicle authorisation process and the responsibilities assigned to the holder of the vehicle authorisation should not be transferred to another entity through contractual arrangements.

It is possible for another applicant to base its application for a vehicle type authorisation on an already authorised vehicle type in the event of introducing a change categorised as (b), (c) or (d) as specified in Article 16(1) of the Commission Implementing Regulation (EU) 2018/545 to that vehicle type even if this applicant is not the initial holder of the vehicle type authorisation. This applicant can apply for a new authorisation and become the holder of the vehicle type authorisation for a new vehicle type. In this case the applicant 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.*
- *It has sufficient information 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.*

When a new vehicle type is authorised the applicant for the authorisation of the new vehicle type becomes the holder of the vehicle type authorisation. This role cannot be transferred to another entity.

Whether creating a new vehicle type, a new vehicle type variant or a new vehicle type version the verification should cover only: the changes made to the design of the vehicle type, their interface with and their effect on the rest of the vehicle and its behaviour. The rest of the vehicle type design should not be re-checked.