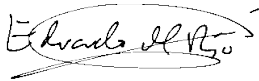
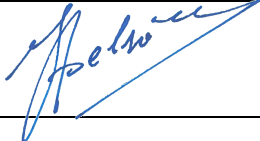



Making the railway system
work better for society.

Clarification note

Update of ERATV in case of changes impacting the type or design examination certificates

	<i>Drafted by</i>	<i>Validated by</i>	<i>Approved by</i>
<i>Name</i>	Eduardo del Rio	Hugues Delsoir	Thierry Breyne
<i>Position</i>	Project officer	Team leader	Head of Unit
<i>Date</i>	13/02/2020	14/02/2020	14/02/2020
<i>Signature</i>			

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0	13/02/2020	Initial version

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regards 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

When delivering an authorisation for placing on the market in conformity with an already authorised type, the Agency needs to check the consistency of the file accompanying the application for authorisation with the information available in ERATV and ERADIS. This file shall include, inter alia, the certificates issued by Notified Bodies and EC declarations of verification established by the manufacturers.

When the certificates referenced in the ERATV record are different than the certificates provided in the file accompanying the application in OSS and the certificates available in ERADIS, the Agency cannot verify that the original vehicle type authorisation, as described in ERATV, is still valid and that the vehicles are actually conforming to the authorised vehicle type.

A particular case of the issue above relates to the article 15 of Regulation (EU) 2018/545, that describes the different categories for the classification of a change. When the entity managing the change considers that the change belongs to category 15(1)(b), there is neither an obligation to apply for a new authorisation nor to request the creation of a version of the vehicle type in ERATV. However, and due to the fact that such changes may require new conformity assessments and therefore involve a Notified Body, there will be a need to update the type or design examination certificate(s) (and consequently, the certificate(s) of verification), which will then differ from the type or design examination certificates referred to in ERATV.

2. Line to take

The holder of the vehicle type authorisation, following its obligation to perform the configuration management of the vehicle type authorisation(s) it holds, should request to the authorising entity that issued the vehicle type authorisation the update of the concerned ERATV record whenever there is a change in the related type examination certificate(s) (e.g in case of changes according to article 15(1)(b) of Regulation (EU) 2018/545 when the change requires that a NoBo performs conformity assessments and issues a type or design examination certificate).

Notes

- *For changes classified as 15(1)(b), 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 is still considered to be conforming to the already authorised type, despite the changes brought by the holder.*
Nevertheless, the holder of the vehicle type authorisation shall perform its legal duties, including the configuration management of the type: 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:
 - *Document the change, the assessments performed and the rationale behind the decision for categorising the change;*
 - *Provide the documentation related to the change to the authorising entity upon request;*
 - *Inform the NoBo(s) that issued previous certificate(s).*
- *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 applicant for placing on the market of the mobile subsystems can decide whether there is a need or not for a new EC declaration of verification for the mobile subsystem(s) following a change. The NoBo that issued the type or design examination certificate is responsible to decide if the previously issued certificate remains valid after the change.*
- *If the references of the certificate(s) and/or the technical file accompanying the EC declaration(s) of verification change, it is expected that the EC declaration(s) of verification are updated as well, as they normally contain the references to the certificate(s) and to the accompanying technical file(s).*

- It should be noticed that ERATV provides the necessary traceability when changes are performed in an existing record. The details of changes performed throughout the life of a record are available by means of the “History of changes” section. ERADIS also provides the possibility to consult previous versions of the certificates.

3. Legal background

a) Regulation (EU) 2018/545

- › Article 2(3). Definitions. Configuration management

“ ‘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”

- › 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.”

- › 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.”

› 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.”

› Annex II. Aspects for assessment by the authorising entity

“[...]

11 Validity of the original vehicle type authorisation

12 Original vehicle type authorisation is valid for the concerned area of use

21 Declaration of conformity to the type and supporting documents (Article 24 Directive (EU) 2016/797)

[...]”

b) Directive (EU) 2016/797

› Article 15. Procedure for establishing the 'EC' declaration of verification

“[...]

5. In the event of the renewal or upgrading of a subsystem resulting in an amendment to the technical file and affecting the validity of the verification procedures already carried out, the applicant shall assess the need for a new 'EC' declaration of verification.

[...]”

c) Decision 2010/713/EU

› Module SB

“[...]

8. The applicant shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the

conformity of the subsystem with the requirements of the relevant TSI(s) or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.

[...]

10. The applicant shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities throughout the service life of the subsystem.

[...]”