

Making the railway system  
work better for society.

## Line to take

*Clarification on the responsibilities for the population of ERADIS database prior to the delivery of vehicle authorisation by the Authorising Entity in the framework of Article 50 (2) of Regulation (EU) 2018/545*

	<i>Drafted by</i>	<i>Validated by</i>	<i>Approved by</i>
<i>Name</i>	E.DEL RIO	H.DELSOIR	T.BREYNE
<i>Position</i>	Project Officer	Team Leader	Head of Unit
<i>Date</i>			
<i>Signature</i>			

### *Document History*

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0	05/06/2019	Initial version
1.1	05/07/2019	§2 added clarification in case of new authorisation

*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 Railway Agency. 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 Regulation (EU) 2018/545 imposes the obligation for authorising entities to ensure that ERADIS is adequately populated before delivering an authorisation.

The Directive (EU) 2016/797 imposes the obligation for notified bodies to provide to the Agency with the documents for which they are responsible within the EC verification procedure:

- › ‘EC’ certificates of verification of subsystems;
- › ‘EC’ certificates of conformity of interoperability constituents; and
- › ‘EC’ certificates of suitability of use of interoperability constituents.

This independently of any authorisation process. Notified bodies are also responsible for publishing those documents periodically.

The Regulation (EU) 2016/796 obliges the Agency to make publicly available the above-mentioned documentation and also:

- › ‘EC’ declarations of verification of subsystems;
- › ‘EC’ declarations of conformity of interoperability constituents; and
- › ‘EC’ declarations of suitability of use of interoperability constituents.

In order to allow the different parties involved to fulfil the legal obligations, the Agency has set up the ERADIS database to store and publish the above-mentioned information.

However, the stakeholders express doubts about:

- › who bears the responsibility of performing the actions required by the legal texts;
- › the mandatory character of populating ERADIS, and
- › the documents that need to be uploaded to ERADIS.

## 2. Line to take

The notified bodies have the legal obligation to establish, publish and provide the Agency with the ‘EC’ certificates. The applicant for the mobile subsystem and the manufacturer (or its authorised representative) of Interoperability Constituents have the legal obligation to establish the relevant ‘EC’ declarations. The Agency has the legal obligation to make those documents publicly available. Authorising entities shall check that ERADIS is adequately populated before delivering any authorisation.

According to a systematic interpretation of the legal framework, population of ERADIS is considered by the Agency as the only legally compliant, logical, adequate and suitable way for the different parties involved to effectively deliver their legal duties. As a consequence:

- › Applicants for the placing on the market of the mobile subsystems should upload the ‘EC’ declarations of verification of subsystems in ERADIS;
- › Manufacturers (or their authorised representatives) of Interoperability Constituents should upload the ‘EC’ declarations of conformity of interoperability constituents the ‘EC’ declarations of suitability of use of interoperability constituents in ERADIS;
- › Notified Bodies shall upload ‘EC’ certificates of verification of subsystems, ‘EC’ certificates of conformity of interoperability constituents and ‘EC’ certificates of suitability of use of interoperability constituents in ERADIS; and
- › The Agency shall make publicly available the documentation uploaded by applicants for the mobile subsystems, manufacturers (or authorised representatives) of Interoperability Constituents and notified bodies through ERADIS.

The requirement for notified bodies to publish information is not a new one. It was present in the Directive 2008/57/EC, and it has been reinforced in Directive (EU) 2016/797. Similarly, the obligation for the Agency to make public documentation related to the EC verification procedure is not a new one, and was already present in the former Regulations of the Agency (EC) 881/2004 and (EC) 1335/2008.

The obligation of notified bodies to publish relevant information in ERADIS has been further emphasized by the Agency in front of the Member States and the European Commission in its presentation given at the 85th meeting of the Railway Interoperability and Safety Committee (RISC) in April 2019. This presentation is now the part of the RISC documents and is mentioned in the minutes of the meeting.

In case of new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, the certificates and declarations related to the interoperability constituents to be updated in ERADIS are only those impacted by the change.

### 3. Legal background

#### a) Directive (EU) 2016/797

- Article 20. Placing on the market of mobile subsystems  
*“1. Mobile subsystems shall be placed on the market by the applicant only if they are designed, constructed and installed in such a way as to meet the essential requirements.  
2. In particular, the applicant shall ensure that the relevant declaration of verification has been provided.”*
- Article 42. Obligation of notified bodies to provide information  
*“3. Notified bodies shall provide the Agency with ‘EC’ certificates of verification of subsystems, ‘EC’ certificates of conformity of interoperability constituents and ‘EC’ certificates of suitability of use of interoperability constituents.”*
- Annex IV. EC verification procedure for subsystems  
*“2.3.1. The notified bodies responsible for the verification assess the design, production and final testing of the subsystem and draw up the certificate of verification intended for the applicant who in turn draws up the ‘EC’ declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.  
[...]  
“2.7. Publication  
Each notified body must periodically publish relevant information concerning:  
(a) requests for verification and ISV received;  
(b) request for assessment of conformity and suitability for use of ICs;  
(c) ISV issued or refused;  
(d) certificates of verification and ‘EC’ certificates for suitability for use issued or refused;  
(e) certificates of verification issued or refused.”*

#### b) Regulation (EU) 2018/545

- Article 50. Registration in ERATV and ERADIS  
*“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.”*

### c) Regulation (EU) 2016/796

- Article 37. Registers and their accessibility

*“3. The Agency shall make the following documents and registers provided for in Directive (EU) 2016/797 and Directive (EU) 2016/798 publicly available :*

*(a) The ‘EC’ declarations of verification of subsystems;*

*(b) The ‘EC’ declarations of conformity of interoperability constituents and ‘EC’ declarations of suitability of use of interoperability constituents;*

*[...]*

*7. The Agency may include any public document or link relevant to the objectives of this Regulation in the public database, taking into account applicable Union legislation on data protection.”*

### d) Regulation (EU) 2019/250

- Article 2. Definitions

*[...]*

*(b) “‘EC’ declaration of suitability for use’ means the supplementary declaration to the ‘EC’ declaration of conformity of the interoperability constituent established for an interoperability constituent by the manufacturer or its authorised representative in which the manufacturer or its authorised representative declares on its sole responsibility that the interoperability constituent concerned, which has been subject to the relevant verification procedures, satisfies the requirements for suitability for use specified in the relevant TSI;*

*(c) “‘EC’ declaration of verification’ means the declaration established for a subsystem by the applicant in which the applicant declares on its sole responsibility that the subsystem concerned, which has been subject to the relevant verification procedures, satisfies the requirements of the relevant Union law and any relevant national rules;*

*(d) ‘Subsystem placed in service without an “EC” declaration of verification’ means a subsystem, fixed or mobile, that has been placed in service before ‘EC’ verification procedure was applicable to it in accordance with Council Directive 96/48/EC (4), Directive 2001/16/EC of the European Parliament and of the Council (5) or Directive 2008/57/EC, and thus without an ‘EC’ declaration of verification.*

*[...]*

*(f) ‘ “EC” certificate of conformity ’ means the certificate delivered for an interoperability constituent by the notified body of the conformity of an interoperability constituent, considered in isolation, with the Union technical specifications to be met;*

*(g) ‘ “EC” certificate of suitability for use ’ means the certificate delivered for an interoperability constituent by the notified body of the suitability for use of an interoperability constituent considered within its railway environment;*

*(h) ‘certificate of verification’ means the certificate delivered for a subsystem either by the notified body or by the designated body regarding the verification of conformity respectively with relevant TSIs or with relevant national rules from the design stage to the acceptance stage before the subsystem is placed on the market or in service and which covers verification of the interfaces of the subsystem in question with the system into which it is incorporated;*

*(i) ‘ “EC” certificate of verification ’ means the certificate delivered for a subsystem by the notified body regarding solely the verification of conformity with relevant TSIs;*

*[...]*

(k) 'ERADIS ID' means the alphanumeric code used to identify an 'EC' declaration of conformity or suitability for use of interoperability constituent or an 'EC' declaration of verification of subsystem and which is established in accordance with Annex VII.

- Article 3. 'EC' declaration of conformity or 'EC' declaration of suitability for use

*"1. The manufacturer or its authorised representative shall establish 'EC' declaration of conformity of interoperability constituent or 'EC' declaration of suitability for use of interoperability constituent in accordance with the template set out in Annex I."*

- Article 5. 'EC' declaration of verification

*"2. The applicant shall establish 'EC' declaration of verification in accordance with the template set out in Annex II, and in accordance with the template set out in Annex III when it relates to a subsystem initially placed in service without an 'EC' declaration of verification."*

#### e) Directive 2008/57/EC

- Annex VI. EC verification procedure for subsystems

*"2.7. Publication*

*Each notified body must periodically publish relevant information concerning:*

- (a) requests for verification and ISV received,*
- (b) request for assessment of conformity and suitability for use of ICs,*
- (c) ISV issued or refused,*
- (d) certificates of conformity and 'EC' certificates for suitability for use issued or refused;*
- (e) certificates of verification issued or refused."*

#### f) Regulation (EC) 881/2004

- Article 19. Register of documents on interoperability

*"1. The Agency shall keep a public list of the following documents provided for by Directives 2001/16/EC and 96/48/EC:*

- (a) the EC declarations of verification of subsystems;*
- (b) the EC declarations of conformity of constituents;*
- (c) the authorisations for putting into service, including the corresponding registration numbers;*
- (d) the registers of infrastructure and rolling stock.*

*2. The bodies concerned shall submit these documents to the Agency, which shall determine in agreement with Member States the practical procedures for submitting them.*

*[...]*

*4. The Agency shall set up an electronic database for the documents, taking full account of paragraph 3. This database shall be accessible to the public through a website."*

#### g) Regulation (EC) 1335/2008

- Article 19. Accessibility of documents and registers

*"1. The Agency shall make publicly accessible the following documents and registers provided for by the Railway Interoperability Directive and the Railway Safety Directive:*

- (a) the EC declarations of verification of subsystems;  
 (b) the EC declarations of conformity of constituents available to the national safety authorities;  
 [...]
2. The practical arrangements for transmitting the documents referred to in paragraph 1 shall be discussed and agreed by Member States and the Commission on the basis of a draft of the Agency.  
 [...]
5. The Agency may add to this public database any public document or link relevant to the objectives of this Regulation.”

#### *h) Guidelines for the practical arrangements for the vehicle authorisation process ERA-PRG-005/02-361*

- **3.2.3.1. Responsibilities of the applicant**

“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; vehicle type authorisation as specified in Article 24 of Directive (EU) 2016/797).
- › The second part of the definition refers to the applicant that establishes the EC Declaration for Verification for subsystems as specified in Article 15 of Directive (EU) 2016/797.
- › 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.

[...]

#### **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 declaration of verification 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.

[...]”

- **3.5.4. Perform verifications and establish evidence**

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

- › Choose the EC verification modules to be used;
- › 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; and
- › Establish the relevant declarations for the subsystem(s) and the vehicle.

[...]

Declaration(s) made by applicant (EC declaration of verification, declaration of conformity to a type):

- › The EC declaration of verification of a subsystem is drawn up by the applicant and is transmitted with the technical file. The information to be provided on the EC declaration of verification is currently specified in Annex V of the Directive 2008/57/EC. However, the

*planned Implementing Regulation on EC declaration of verification will replace this annex and together with its guideline will provide more detailed provisions.*

- › *EC declarations of verification of subsystems are stored in ERADIS, see chapter 3.8.4.*

*[...]*

*“*

- **3.8.4. Registration in ERATV and ERADIS**

**“ERADIS**

*The Regulation (EU) 2016/796 imposes the obligation to make publicly available the following documents:*

- › *‘EC’ declarations of verification of subsystems;*
- › *‘EC’ declarations of conformity of interoperability constituents; and*
- › *‘EC’ declarations of suitability of use of interoperability constituents.*

*The Directive (EU) 2016/797 imposes on the NoBos the obligation to provide the Agency with:*

- › *‘EC’ certificates of verification of subsystems;*
- › *‘EC’ certificates of conformity of interoperability constituents; and*
- › *‘EC’ certificates of suitability of use of interoperability constituents.*

*The Agency has set up the ERADIS register to store these certificates and declarations. This register should be used by:*

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

*There is no legal basis to impose on the DeBos the obligation to provide their certificates for national rules to the Agency. However, the principle of “mutatis mutandis” could be applied; therefore, DeBos should upload the certificates in ERADIS when the relevant feature in ERADIS has been developed and is available.”*