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Line to take

Documents to be included in the file accompanying the application for authorisation pursuant to points 18.4 (declaration of conformity to type and the associated documentation) and 18.5 (technical file accompanying the EC Declaration of Verification) of Annex I of Regulation (EU) 2018/545

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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

According to point 18.4 of Annex I of Regulation (EU) 2018/545, for authorisations for placing on the market of vehicles in conformity to an already authorised type, the application file shall contain the declaration of conformity to type established by the applicant and the **associated documentation**. However, it is not clarified in the Regulation, nor in the guidelines to the Regulation, what is this associated documentation.

Similarly, according to point 18.5 of Annex I of Regulation (EU) 2018/545, the file accompanying the application for authorisation for the cases first, new, renewed and extension of the area of use shall contain the EC declarations of verification for the mobile subsystems and the **accompanying technical files**. There are doubts raised on what should be the mandatory content of the abovementioned accompanying technical files.

2. Line to take

a) File accompanying the application for authorisation in conformity to an authorised type (18.4 Annex I Regulation (EU) 2018/545)

The file accompanying the application for authorisation in conformity to an authorised vehicle type shall contain the following elements, pursuant to Annex I of Regulation (EU) 2018/545:

- 18.3: the relevant decisions for non-application of TSIs according to Article 7 of Directive (EU) 2016/797 (when applicable)
- 18.4: declaration of conformity to the type and 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 declaration shall include as annex(es) the EC declaration(s) of verification for the subsystem(s), see note (3) of the aforementioned Annex.

Pursuant to Article 15(4) of Directive 2016/797, the file that is to accompany the EC declaration(s) of verification shall also include all the necessary documents describing the subsystem. In addition, the Annex IV of Directive 2016/797 (section 2.4) states that the technical file accompanying the EC declaration(s) of verification shall contain the files referred to in Article 15(4), in particular:

- EC declaration(s) of conformity and suitability for use for interoperability constituents (including the relevant certificates where required);
- Certificate(s) of verification for the subsystem(s), accompanied by corresponding calculation notes and signed by the conformity assessment body(ies) responsible for the verification (NoBo/DeBo); and
- Certificates of verification issued in accordance with other legal acts of the Union.

However, in order to simplify the process for application for vehicle authorisation in conformity to an authorised vehicle type, the “associated documentation” referred to in point 18.4 of Annex I of Regulation (EU) 2018/545 should be understood as:

- EC declaration(s) of verification for the subsystem(s) (applicant);
- Certificate(s) of verification for the subsystems (NoBo/DeBo);
- EC declaration(s) of conformity and suitability for use of interoperability constituents (manufacturer or authorised representative);
- Certificate(s) of conformity and suitability for use of interoperability constituents (NoBo); and
- Certificate(s)/declaration(s) issued in accordance with other legal acts of the Union.

It is not necessary to include the technical file(s) accompanying the EC declaration(s) of verification nor the technical file(s) accompanying the EC certificate(s) of verification.

The applicant should include in the file accompanying the application for authorisation information about the interoperability constituents 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 interoperability constituents impacted by the change.

It should be noticed that under the 4th Railway Package, EC declarations of verification and certificates of verification/conformity/suitability for use shall be uploaded to ERADIS (otherwise, the vehicle authorisation for placing on the market and/or vehicle type authorisation would not 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 interoperability constituents to be updated in ERADIS are only those impacted by the change.

b) Technical file accompanying the EC declaration of verification (18.5 Annex I Regulation (EU) 2018/545)

Point 18.5 of Annex I of Regulation (EU) 2018/545 imposes the obligation to include the EC declaration(s) of verification for the mobile subsystem(s) composing the vehicle and the accompanying technical file(s) in the file accompanying the application for authorisation. The technical file accompanying an EC declaration of verification, to be compiled by the applicant, comprises at least the following elements, pursuant to Annex IV section 2.4 of Directive (EU) 2016/797:

1. All necessary documents describing the characteristics of the subsystem.

This includes the elements necessary to describe the design of the vehicle and to document to a sufficient level of detail the verification of conformity carried-out, 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 programme 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 to NB-Rail RFU-STR-011 and covering the scope of its activities.

This file should include calculation notes and records of the texts and examinations carried out by the notified body(ies), including inspection and audit report and the results of the verification regarding the validity of Intermediate Statement(s) of verification (ISVs) and the documentation related to Interoperability Constituent(s) (ICs):

- 3.2.1. Actors information (Applicant, NoBo)
- 3.2.2. NoBo Certificate(s) (including ISVs if any)

3.2.3. Conditions and limits of use

3.2.4. Project scope (project information, scope and interfaces, history, non-application or partial application of TSI(s), list of specific cases)

3.2.5. Project documentation, including

- Design evidence: for each TSI applicable requirements/parameters, reference to design evidence documents used during the EC verification (drawings, calculation notes, test reports, safety assessment report according to Regulation (EU) 402/2013 when required by TSIs)
- Evidence related to quality management system(s) or on production (depending on the modules used)
- List of manufacturers and main subcontractors
- Provisions for operation, maintenance,
- Interoperable constituents:
 - › EC declaration(s) of conformity or suitability for use of ICs
 - › EC certificate(s) of conformity or suitability for use of ICs (including technical documentation accompanying the declaration/certificates)

3.2.6. EC verification process information and results

3.2.7. For the CCS subsystem: template referred to in chapter 6.1.1.3 of the CCS TSI and included in the Application Guide

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 to 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):

4.2.1. Actors information (Applicant, DeBo)

4.2.2. DeBo Certificate(s) (including ISVs if any)

4.2.3. Conditions and limits of use

4.2.4. Project scope (project information, scope and interfaces, history, Non application or partial application of NR(s))

4.2.5. Project documentation including

- Design evidence: for each NR applicable requirements/parameters, reference to design evidence documents used during the EC verification (drawings, calculation notes, test reports, safety assessment report according to Regulation (EU) 402/2013 when required by NRs)
- Evidence related to quality management system(s) or on production (depending on the modules used)
- List of manufacturers and main subcontractors
- Provisions for operation, maintenance,

4.2.6. EC verification process information and results

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 aspects mentioned in §2.b) points 1 to 5 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.

It should be noticed that under the 4th Railway Package, EC declarations of verification and certificates of verification/conformity/suitability for use shall be uploaded to ERADIS (otherwise, the vehicle authorisation for placing on the market and/or vehicle type authorisation would not 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 interoperability constituents to be updated in ERADIS are only those impacted by the change.

Notes:

The file accompanying the application for authorisation of a vehicle and/or vehicle type is wider than the EC declaration(s) of verification for the subsystem(s) that compose the vehicle and the file(s) accompanying the EC declaration(s) of verification. 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 declaration of verification 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 assessors to find and assess the relevant information.

3. Legal background

a) Regulation (EU) 2018/545

- Annex I 18.4: “Declaration of conformity to the type and associated documentation (Article 24 Directive (EU) 2016/797)”
- Annex I 18.5: “EC Declarations of Verification for the mobile subsystems, including accompanying technical files (Article 15 Directive (EU) 2016/797)”

a) Directive (EU) 2016/797

- Article 15(4): “The applicant shall be responsible for compiling the technical file that is to accompany the ‘EC’ declaration of verification. That **technical file shall contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents**. It shall also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance”
- Article 15(9)(b): “The Commission may specify, by means of implementing acts: the templates for the ‘EC’ declaration of verification, including in the case of a modification of the subsystem or in the case of additional verifications, the intermediate statement of verification, and **templates for documents of the technical file that is to accompany those declarations as well as templates for the certificate of verification** [...]”.
- Annex IV 2.3. Certificate of verification
“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.

2.3.4 Each **notified body** involved in the verification of a subsystem shall draw up a file in accordance with Article 15(4) covering the scope of its activities”

- Annex IV 2.4. Technical file accompanying the ‘EC’ declaration of verification.

“The **technical file accompanying the ‘EC’ declaration of verification** shall be assembled by the applicant and **must contain the following**:

- (a) **technical characteristics linked to the design including general and detailed drawings** with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;
- (b) a **list of interoperability constituents**, referred to in point (d) of Article 4(3), incorporated into the subsystem;
- (c) the **files referred to in Article 15(4)**, compiled by each of the notified bodies involved in the verification of the subsystem, which shall include:
 - **copies of the ‘EC’ declarations of verification and, where applicable, ‘EC’ declarations of suitability for use established for interoperability. constituents** referred to in point (d) of Article 4(3) and **accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations** carried out by the notified bodies on the basis of the common technical specifications,
 - where available, the **ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,**
 - the **certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports** drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;
- (d) **certificates of verification issued in accordance with other legal acts of the Union;**
- (e) when verification of safe integration is required pursuant to in point (c) of Article 18(4) and in point (c) of Article 21(3), the relevant technical file shall include the **assessors’ report(s) on the CSMs on risk assessment** referred to in Article 6(3) of Directive 2004/49/EC (1)”

b) Regulation (EU) 2019/250

- Annex II template for ‘EC’ Declaration of Verification of subsystem

“[...]

In accordance with the following certificate(s) and or report(s):

[Certificate(s) number(s), report(s) number(s), date(s) of issue]

Identification of the technical file accompanying this declaration

[Reference to the technical file accompanying the ‘EC’ declaration of verification of subsystem in accordance with Article 15(4) of Directive (EU) 2016/797]

[...]”

- Annex III template for ‘EC’ declaration of verification of subsystem initially placed in service without an ‘EC’ declaration

“[...]

In accordance with the following certificate(s) and or report(s):

[Certificate(s) number(s), report(s) number(s), date(s) of issue]

Identification of the technical file accompanying this declaration

[Reference to the technical file accompanying the ‘EC’ declaration of verification of subsystem in accordance with Article 15(4) of Directive (EU) 2016/797]

[...]”

- Annex VI model of declaration of conformity to an authorised vehicle type

“[...]

List of annexes (3)

[Titles of the annexes]

[...]

(3) Annexes shall include copies of EC declaration(s) of verification of subsystem(s).

[...]”

c) Decision 2010/713

- Module SB

*“7. Where the type meets the requirements of the relevant TSI(s) that apply to the subsystem concerned, the notified body shall issue an EC-type examination certificate to the applicant. The certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. **The certificate may have one or more annexes attached. The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems with the examined type to be evaluated.**”*

- Module SD

“8. EC certificate of verification and EC declaration of verification

*8.2. The **applicant shall draw up a written EC declaration of verification** for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up.*

*The **EC declaration and the accompanying documents** shall be written in accordance with Annex V to Directive 2008/57/EC.*

The certificates to be referred to are:

- the quality management system approval indicated in point 3.3 and audit reports indicated in point 7.3, if any,
- the EC type examination certificate and its additions.

*8.3. The notified body shall be responsible for **compiling the technical file that has to accompany the EC declaration of verification** and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.”*

- Module SF

“4. EC verification

[...]

4.5. The notified body shall issue an EC certificate of verification in respect of the examinations and tests carried out.

[...]

5. EC declaration of verification

5.1. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities, throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up.

[...]

The EC declaration and the accompanying documents shall be written in accordance with Annex V to Directive 2008/57/EC.

A copy of the EC declaration of verification and EC ISV declarations, if any, shall be made available to the relevant authorities upon request

5.2. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.”

- Module SH1

“4. EC verification

4.4. The notified body shall examine the application, and where the design meets the requirements of the relevant TSI(s) that apply to the subsystem it shall issue an EC design examination certificate to the applicant. The certificate shall give the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of the subsystem with the examined design to be evaluated.

[...]

6. EC certificate of verification and EC declaration of verification

6.1. Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.

[...]

6.2. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up and shall mention the number of the design examination certificate.

[...]

6.3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.”

d) NB-Rail RFU-STR-011 content of the technical file

“The Applicant prepares and manages a **“Technical file accompanying the EC declaration of verification”** (in the following abbreviated as ECDV-TF) and the NoBo a Technical File accompanying the EC Certificate of Verification (in the following abbreviated as NoBoTF).

One or several individual NoBo-TF(s) form a part of the overall ECDV-TF.

[...]

Structure for the “Technical File accompanying the EC Certificate of Verification

1	Actors	(Heading only)
1.1	Notified Body(s)	Identification of NoBo(s) involved in the assessment and their respective scope of assessment (including ISVs).
1.2	Applicant	Identification of Applicant.
2	Notified Body Certificate(s)	This shall contain copies of all subsystem certificates issued by the NoBo(s) (including any ISV(s), if used).
3	Conditions and Limits of use	This shall contain references to the Conditions and Limits of use as declared by the Applicant to the NoBo. If necessary, the NoBo must state also any further Conditions and Limits of use, if these were identified during the EC verification. Individual TSIs may require further specific information to be provided by the Applicant (e.g. choice of environmental condition parameters in TSI CCS or L&P). Where defined in a TSI this shall include the ‘Area of Use’ information as far as this is to be evaluated by the NoBo.
4	Project Scope and Definition	(Heading only)
4.1	General Project information	Precise definition of the Product/ Installation under certification. Where relevant, this shall reference the precise Variant/Version of a type, line locations, etc.
4.1	General Project information	Precise definition of the Product/ Installation under certification. Where relevant, this shall reference the precise Variant/Version of a type, line locations, etc. Individual TSIs may require further specific information to be provided by the Applicant (e.g. choice of optional functions in TSI CCS). Additionally: in case of application for an ISV, detailed description of the part/stage under assessment is required.
4.2	Technical scope and interfaces	This shall define the scope of the verification clearly, e.g. the geographic and technical scope of assessment, interfaces to other subsystems, and special considerations.
4.3	Project History	Overview of relevant aspects of the project history and any phasing of activities. In particular for long lasting projects which started before a current TSI became applicable, this information of project history (e.g. date of application and amendments, date of derogations, start of construction works etc.) is indispensable to explain which TSI version is used for the project. This shall justify why a particular TSI version is used or why certain TSI’s are not applied or are applied only in parts and resulting in requirements or test methods to be different from a current TSI.
4.4	Derogations/ Limitation of TSI Application	Reference to documented evidence on any Derogations enjoyed or expected under 2008/57/EC Art 9 or Limitations to TSI application under Art 20 as agreed between the Applicant and the NSA(s).
4.5	List of specific cases	Reference listing on the Specific Cases declared by the Applicant to be present at this project (refer to ch.7 of the relevant TSIs).
5	Project documentation	(Heading only) The following sub-headings shall refer to all of the technical documentation supplied to the NoBo by the Applicant and used during verification activities. It is good practice to provide the information for 5.1 / 5.2 within a combined matrix.
5.1	Applied Standards/ Technical Specification/ Alternative Solutions	This shall contain for each applicable TSI Parameter/ Requirement the harmonized standards and/or other relevant technical specifications applied in full or in part, and descriptions of the alternative solutions adopted where those have not been applied. In the event of partly applied harmonized standards or technical specifications, state also which parts have been applied. This section also lists the applied RFUs and ERA TOs/TAs.

5.2	Design evidence	<p>This shall contain for each applicable TSI Parameter/ Requirement the references for the design evidence documents used during the EC verification. Documents which do not relate to the final EC certification should be avoided. Depending on the individual TSI Parameter/ Requirement, this may be one or several of the following: drawings, parts lists, functional/ technical descriptions, simulations, test procedures, test reports, etc. Individual TSIs/ Standards/ Technical Specifications may require further specific information to be provided by the Applicant (e.g. choice on specific tests in operational conditions in TSI CCS or L&P).</p>
5.3	Evidence related to quality management system(s) or on production (depending on the modules used)	<p>References to information on the applied quality management system. This may include references to:</p> <ul style="list-style-type: none"> • an ISO 9001 quality management system or • other relevant certificates on specific quality management systems (e.g. to EN15085) • quality management approvals from notified bodies, • information on relevant QM documents (e.g. procedures, quality planning, production related testing and inspection, etc.) <p>These References have typically been identified during the QMS audit activities. If no quality management system is used during the project (e. g. where Module SG or SF has been applied), then the production evidence required to demonstrate</p> <ul style="list-style-type: none"> • conformance of the installation or • conformance of the product with the type <p>shall be included. This may include installation or product inspections, test reports and other documentation as required by the module(s) used.</p>
5.4	List of manufacturers and main subcontractors	<p>In complex situations this shall also include an overview on roles and responsibilities.</p>
5.5	Provisions for operation	<p>This shall contain in accordance to the relevant TSIs the references to the Applicant documents which contain those provisions for operation which must be assessed by the NoBo. (e.g. operation manual)</p>
5.6	Provisions for maintenance	<p>This shall contain in accordance to the relevant TSIs the references to the Applicant documents which contain those provisions for maintenance which must be assessed by the NoBo. (e.g. maintenance file)</p>
5.7	Interoperability Constituents	<p>This shall include the reference to the Applicant’s list of ICs and to the associated EC Declarations of Conformity or Suitability for Use, associated Certificates and NoBo-TFs and the Applicant’s Technical Documentation. This shall include at least all information required to assure the correct integration of the IC into the subsystem e.g.</p> <ul style="list-style-type: none"> • interface definitions • conditions for use • maintenance & operation information.
6	EC verification process information and results	<p>This section includes the documents prepared by the NoBo(s). This shall include the reference to the NoBo Report(s) (and where existing, further supporting documentation) related to the applied Modules. (Note: If a NoBo does not issue separate reports, the respective information shall be provided in this section.)</p>

[...]”