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From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Uwe CORSEPIUS, Secretary-General of the Council of the European
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Subject: ANNEXES to the Commission Directive amending Annexes V and VI to
Directive 2008/57/EC of the European Parliament and of the Council on
the interoperability of the rail system within the Community

Delegations will find attached document D031394/04 Annexes 1 to 2.

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ANNEXES 1 to 2

ANNEXES

to the

Commission Directive

**amending Annexes V and VI to Directive 2008/57/EC of the European Parliament and
of the Council on the interoperability of the rail system within the Community**

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ANNEX I

"ANNEX V

'EC' DECLARATION OF VERIFICATION OF SUBSYSTEMS

1. EC' DECLARATION OF VERIFICATION OF SUBSYSTEMS

The 'EC' declaration of verification of a subsystem is a declaration established by the "applicant" within the meaning of Article 18 in which he declares on his sole responsibility that the subsystem concerned, which has been subject to the relevant verifications procedures, satisfies the requirements of the relevant Union legislation, including any relevant national rules.

The 'EC' declaration of verification and the accompanying documents must be dated and signed.

The 'EC' declaration of verification must be based on the information resulting from the 'EC' verification procedure for subsystems set out in Annex VI. It must be written in the same language as the technical file accompanying the 'EC' declaration of verification and must contain at least the following:

- (a) the reference to this Directive, TSIs and applicable national rules,
- (b) the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure and to the national technical rules which have been applied in case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case,
- (c) name and address of the "applicant" within the meaning of Article 18 (specifying the trade name and full address; in the case of the authorised representative, specifying also the trade name of the contracting entity or the manufacturer),
- (d) a brief description of the subsystem,
- (e) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the 'EC' verification(s) referred to in Article 18,

- (f) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the assessment of conformity with other regulations deriving from the Treaty,
- (g) name(s) and address(es) of the designated body(ies) which conducted the verification(s) of conformity with national rules referred to in Article 17(3),
- (h) name and address of the assessment body(ies) which established the safety assessment reports related to the use of the CSM on risk assessment where required by this Directive,
- (i) the references of the documents contained in the technical file accompanying the 'EC' declaration of verification,
- (j) all the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,
- (k) the identity of the signatory (i.e. the physical person or persons authorised to sign the declaration)

Where reference is made in Annex VI to the "intermediate statement of verification" (ISV), the provisions of this Section shall apply to that declaration.

2. 'EC' DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF MODIFICATIONS

In a case of a modification, which is not a substitution in the framework of maintenance, of a subsystem covered by an 'EC' declaration of verification, without prejudice to Article 20, the following provisions apply.

- 2.1. If the entity introducing the modification demonstrates that the modification does not affect the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning the basic parameters:
 - (a) the entity introducing the modification shall update the references of the documents contained in the technical file accompanying the 'EC' declaration of verification;
 - (b) no new 'EC' declaration of verification needs to be established.
- 2.2. If the entity introducing the modification demonstrates that the modification affects the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning some basic parameters:
 - (a) the entity introducing the modification shall establish a complementary 'EC' declaration of verification with reference to the basic parameters concerned;
 - (b) the complementary 'EC' declaration of verification shall be accompanied by a list of documents of the original technical file accompanying the original 'EC' declaration of verification that are no more valid;

- (c) the technical file accompanying the 'EC' declaration of verification shall include a demonstration that the impact of modifications is limited to the basic parameters referred to in point a);
- (d) provisions of Section 1 of this Annex shall apply mutatis mutandis to this complementary 'EC' declaration of verification;
- (e) the original 'EC' declaration of verification shall be considered valid for the basic parameters not concerned by the modification.

3. 'EC' DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF ADDITIONAL VERIFICATIONS

An 'EC' declaration of verification of a subsystem may be complemented in the case of additional verifications carried out, in particular when such additional verifications are necessary for an additional authorisation for placing in service. In this case the scope of the complementary declaration shall be limited to the scope of the additional verifications.

ANNEX II

"ANNEX VI

'EC' VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. GENERAL PRINCIPLES

"'EC' verification" means a procedure carried out by the applicant within the meaning of Article 18 to demonstrate that the requirements of the relevant Union legislation including any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.

2. CERTIFICATE OF VERIFICATION ISSUED BY A NOTIFIED BODY

2.1. Introduction

For the purpose of this Directive, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI).

This is without prejudice of the obligations of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18) to comply with the other applicable legislation deriving from the Treaty, including any verifications by the assessment bodies required by the other legislation.

2.2. Intermediate statement of verification (ISV)

2.2.1. Principles

At the request of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an "intermediate statement of verification" (ISV) issued by the notified body chosen by the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18).

The ISV must provide reference to the TSIs with which the conformity has been assessed.

2.2.2. Parts of the subsystem

The applicant within the meaning of Article 18 may apply for an ISV for any part into which he decides to split the subsystem. Each part shall be checked at each stage as set out in point 2.2.3.

2.2.3. Stages of the verification procedure

The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages:

- (a) overall design,
- (b) production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment,
- (c) final testing.

The applicant (within the meaning of Article 18) may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the applicant decided to split it (see paragraph 2.2.2).

2.3. Certificate of verification

2.3.1. The notified bodies responsible for the verification assesses the design, production and final testing of the subsystem and draw up the certificate of verification intended for the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), 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.

Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case), the certificate of verification shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the verification procedure.

2.3.2. Where ISV have been issued, the notified body responsible for the verification of the subsystem takes these ISV into account, and, before issuing its certificate of verification:

- (a) verifies that the ISV cover correctly the relevant requirements of the TSI(s),
- (b) checks all aspects that are not covered by the ISV, and
- (c) checks the final testing of the subsystem as a whole.

2.3.3. In the case of a modification to a subsystem already covered by a certificate of verification, the notified body shall perform only those examinations and tests that are relevant and necessary, i.e. assessment shall relate only to the parts of the subsystem that are changed and their interfaces to the unchanged parts of the subsystem.

2.3.4. Each notified body involved in the verification of a subsystem shall draw up a technical file in accordance with Article 18(3) covering the scope of its activities.

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 (in the meaning of Article 18) 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 Article 5(3)(d), incorporated into the subsystem,
- (c) the technical files referred to in Article 18(3), compiled by each of the notified bodies involved in the verification of the sub-system, 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 Article 5(3)(d) 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 legislation deriving from the Treaty,
- (e) when verification of safe integration is required pursuant to Article 15, the relevant technical file shall include the assessors’ report(s) on the common safety methods (CSM) on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

2.5. Surveillance by notified bodies

- 2.5.1. The notified body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The notified body must receive from the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.

- 2.5.2. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the relevant TSI(s). It must provide those responsible for implementation with an audit report. Its presence may be required at certain stages of the building operations.
- 2.5.3. In addition, the notified body may pay unexpected visits to the worksite or to the production workshops. At the time of such visits the notified body may conduct complete or partial audits. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.
- 2.5.4. The notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where required by the corresponding TSI, its suitability for use in its intended railway environment.

2.6. Submission

A copy of the technical file accompanying the EC declaration of verification must be kept by the manufacturer or contracting entity (i.e. by the applicant in the meaning of Article 18) throughout the service life of the subsystem. It must be sent to any Member State which so requests.

The documentation submitted for an application for an authorisation for placing in service shall be submitted to the national safety authority of the Member State where the authorisation is sought. The national safety authority may request that part(s) of the documents submitted together with the authorisation is/are translated into its own language.

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.

2.8. Language

The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) is established or in a Union official language accepted by the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

3. CERTIFICATE OF VERIFICATION ISSUED BY A DESIGNATED BODY

3.1. Introduction

In the case where national rules apply, the verification shall include a procedure whereby the body designated pursuant to Article 17(3), third sub-paragraph, (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 17(3) for each Member State in which the subsystem is intended to be authorised to be placed in service.

3.2. Certificate of verification

The designated body draws up the certificate of verification intended for the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the designated body in the verification process.

In the case of national rules related to the subsystems composing a vehicle, the designated body shall divide the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

3.3. Technical file

The technical file compiled by the designated body and accompanying the certificate of verification in the case of national rules must be included in the technical file accompanying the 'EC' declaration of verification referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the subsystem with those national rules.

3.4. Language

The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) is established or in a Union official language accepted by the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

4. VERIFICATION OF PARTS OF SUBSYSTEMS IN ACCORDANCE WITH ARTICLE 18(5)

If a certificate of verification is to be issued for certain parts of a subsystem, provisions for this Annex shall apply *mutatis mutandis* for those parts.