

ANNEX IV

‘EC’ VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. GENERAL PRINCIPLES

“‘EC’ verification’ means a procedure carried out by the applicant within the meaning of Article 15 to demonstrate that the requirements of the relevant Union law and 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 to the obligations of the applicant to comply with the other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules.

2.2. Intermediate statement of verification (ISV)

2.2.1 Principles

At the request of the applicant 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 applicant. The ISV must provide reference to the TSIs with which the conformity has been assessed.

2.2.2 Parts of the subsystem

The applicant 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 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 point 2.2.2).

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

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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 file in accordance with Article 15(4) 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 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⁾.

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 applicant 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 applicant) throughout the service life of the subsystem. It must be sent to any Member State or the Agency, upon request.

The documentation submitted for an application for an authorisation for placing in service shall be submitted to the authority where the authorisation is sought. The national safety authority or the Agency 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

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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 applicant is established or in a Union official language accepted by the applicant

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 15(8), (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 14 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 applicant.

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. File

The 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 applicant is established or in a Union official language accepted by the applicant.

4. VERIFICATION OF PARTS OF SUBSYSTEMS IN ACCORDANCE WITH ARTICLE 15(7)

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.

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- (1) Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) ([OJ L 164, 30.4.2004, p. 44](#)).