

ANNEX VI

‘EC’ VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. Introduction

‘EC’ verification is the procedure whereby a notified body checks and certifies that the subsystem:

- complies with the Directive,
- complies with the other regulations deriving from the Treaty, and may be put into operation.

2. Stages

The subsystem is checked at each of the following stages:

- overall design,
- production: construction of subsystem, including, in particular, civil-engineering activities, manufacturing, constituent assembly, overall adjustment,
- final testing of the subsystem.

For the design stage (including the type tests) and for the production stage the applicant may apply for an assessment as a first step.

In this case, this assessment or assessments lead to one or more intermediate statement verifications (ISV) issued by the notified body chosen by the applicant. The notified body in turn draws up an ‘EC’ declaration of intermediate subsystem conformity for the relevant stages.

3. Certificate

The notified body responsible for ‘EC’ verification assesses the design and production of the subsystem and draws up the certificate of verification intended for the applicant, which in turn draws up the ‘EC’ declaration of verification intended for the supervisory authority in the Member State in which the subsystem is located and/or operates.

If available, the notified body takes into account the ISVs, and, in order to issue the ‘EC’ certificate of verification, it:

- checks that the subsystem:
 - is covered by relevant design and production ISVs, if the applicant has asked the notified body for these two phases, or
 - corresponds as produced to all aspects covered by the design ISV delivered to the applicant, if it has asked the notified body only for the design phase,
- verifies that they cover correctly the requirement of the TSI and assesses the design and production elements that are not covered by the design and/or production ISV(s).

4. Technical file

The technical file accompanying the declaration of verification must be made up as follows:

- for infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete, etc.,
- for the other subsystems: general and detailed drawings in line with execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems, operating and maintenance manuals, etc.,
- list of interoperability constituents, as referred to in Article 3, incorporated into the subsystem,

- copies of the ‘EC’ declarations of conformity or suitability for use with which the abovementioned constituents must be provided in accordance with Article 13 of the Directive 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,
- if available, the ISV and, in such a case, the ‘EC’ declaration(s) of intermediate subsystem conformity, that accompany the ‘EC’ certificate of verification, including the result of verification by the notified body of their validity,
- certificate from the notified body responsible for ‘EC’ verification, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with this Directive and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in sections 5.3 and 5.4.

5. Monitoring

- 5.1. The aim of ‘EC’ monitoring is to ensure that the obligations deriving from the technical file have been met during production of the subsystem.
- 5.2. 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 applicant must send it or have sent to it all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.
- 5.3. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the Directive. It must provide those responsible for implementation with an audit report. It may need to be present at certain stages of the building operations.
- 5.4. 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.
- 5.5. With a view to deliver the ‘EC’ declaration of suitability for use referred to in section 2 of Annex IV, the notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where the corresponding TSI so requires, its suitability for use in its intended railway environment.

6. Submission

The complete file referred to in paragraph 4 must be lodged with the applicant in support of the ISV, if available, issued by the notified body responsible for this or in support of the certificate of conformity issued by the notified body responsible for verification of the subsystem in working order. The file must be attached to the ISV and/or to the ‘EC’ declaration of verification which the applicant sends to the supervisory authority in the Member State concerned.

A copy of the file must be kept by the applicant throughout the service life of the subsystem. It must be sent to any other Member States which so request.

7. Publication

Each notified body must periodically publish relevant information concerning:

- requests for ‘EC’ verification received,
- ISVs issued or refused,
- certificates of verification issued or refused,
- certificates of conformity refused.

8. Language

The files and correspondence relating to the ‘EC’ verification procedures must be written in an official language of the Member State in which the applicant is established or in a language accepted by the applicant.