

DIRECTIVES

COMMISSION DIRECTIVE 2011/18/EU

of 1 March 2011

amending Annexes II, 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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community⁽¹⁾, and in particular Article 30.3 thereof,

Whereas:

- (1) Measures designed to amend non-essential elements of Directive 2008/57/EC and relating to the adaptation of Annexes II to IX to that Directive are to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4) of Directive 2008/57/EC.
- (2) The control-command and signalling subsystem consist of trackside and on-board equipment, which should be considered as two separate subsystems. Annex II to Directive 2008/57/EC should therefore be amended accordingly.
- (3) The electricity consumption measuring equipment is physically integrated in the rolling stock. Annex II to Directive 2008/57/EC should therefore be amended accordingly.
- (4) In accordance with Article 17(3) of Directive 2008/57/EC, Member States should designate the bodies responsible for carrying out the verification procedures in the case of national rules. Annexes V and VI to Directive 2008/57/EC should therefore be amended to specify these procedures applied by these bodies.

(5) With regard to Section 2 of Annex VI to Directive 2008/57/EC and recourse to intermediate statements of verification (hereinafter 'ISV'), the notified body should first draw up an 'EC' certificate of intermediate statement of verification and then the applicant should draw up the related 'EC' declaration. Annexes V and VI to Directive 2008/57/EC should therefore be amended accordingly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee established pursuant to Article 29(1) of the Directive 2008/57/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, V and VI to Directive 2008/57/EC are replaced by the text set out in Annexes I, II and III to this Directive respectively.

Article 2

1. The Member States shall bring into force the laws, regulation and administrative provisions necessary to comply with this Directive by 31 December 2011 at the latest. They shall forthwith communicate the text of those provisions to the Commission.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. The obligations for transposition and implementation of this Directive shall not apply to the Republic of Cyprus and the Republic of Malta for as long as no railway system is established within their territories.

⁽¹⁾ OJ L 191, 18.7.2008, p. 1.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 1 March 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

ANNEX II

SUBSYSTEMS**1. List of subsystems**

For the purposes of this Directive, the system constituting the rail system may be broken down into the following subsystems, either:

(a) structural areas:

- infrastructure,
- energy,
- trackside control-command and signalling,
- on-board control-command and signalling,
- rolling stock,

(b) functional areas:

- operation and traffic management,
- maintenance,
- telematics applications for passenger and freight services.

2. Description of the subsystems

For each subsystem or part of a subsystem, the list of constituents and aspects relating to interoperability is proposed by the Agency at the time of drawing up the relevant draft TSI. Without prejudging the choice of aspects and constituents relating to interoperability or the order in which they will be made subject to TSIs, the subsystems include the following:

2.1. Infrastructure

The track, points, engineering structures (bridges, tunnels, etc.), associated station infrastructure (platforms, zones of access, including the needs of persons with reduced mobility, etc.), safety and protective equipment.

2.2. Energy

The electrification system, including overhead lines and the trackside of the electricity consumption measuring system.

2.3. Trackside control-command and signalling

All the trackside equipment required to ensure safety and to command and control movements of trains authorised to travel on the network.

2.4. On-board control-command and signalling

All the on-board equipment required to ensure safety and to command and control movements of trains authorised to travel on the network.

2.5. Operation and traffic management

The procedures and related equipment enabling coherent operation of the various structural subsystems, during both normal and degraded operation, including in particular train composition and train driving, traffic planning and management.

The professional qualifications which may be required for carrying out cross-border services.

2.6. *Telematics applications*

In accordance with Annex I, this subsystem comprises two elements:

- (a) applications for passenger services, including systems which provide passengers with information before and during the journey, reservation and payment systems, luggage management and management of connections between trains and with other modes of transport;
- (b) applications for freight services, including information systems (realtime monitoring of freight and trains), marshalling and allocation systems, reservation, payment and invoicing systems, management of connections with other modes of transport and production of electronic accompanying documents.

2.7. *Rolling stock*

Structure, command and control system for all train equipment, electric current collection devices, traction and energy conversion units, on-board equipment for electricity consumption measuring, braking, coupling and running gear (bogies, axles, etc.) and suspension, doors, man/machine interfaces (driver, on-board staff and passengers, including the needs of persons with reduced mobility), passive or active safety devices and requisites for the health of passengers and on-board staff.

2.8. *Maintenance*

The procedures, associated equipment, logistics centres for maintenance work and reserves providing the mandatory corrective and preventive maintenance to ensure the interoperability of the rail system and guarantee the performance required.'

ANNEX II

ANNEX V

DECLARATION OF VERIFICATION OF SUBSYSTEMS**1. "EC" declaration of verification of subsystems**

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

The said declaration must be based on the information resulting from the "EC" verification procedure for subsystems as defined in Section 2 of Annex VI. It must be written in the same language as the technical file and must contain at least the following:

- the Directive references,
- name and address of the contracting entity or the manufacturer, or its authorised representative established within the European Union (specify the trade name and full address; in the case of the authorised representative, specify also the trade name of the contracting entity or the manufacturer),
- a brief description of the subsystem,
- name and address of the notified body which conducted the "EC" verification referred to in Article 18,
- the references of the documents contained in the technical file,
- all the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,
- if temporary: duration of validity of the "EC" declaration,
- identity of the signatory.

Where reference is made in Annex VI to the "EC" ISV declaration, the provisions of this Section shall apply to this declaration.

2. Declaration of verification of subsystems in the case of national rules

Where reference is made in Annex VI to the declaration of verification of subsystems in the case of national rules, the provisions of Section 1 shall apply *mutatis mutandi* to that declaration.

ANNEX III

'ANNEX VI

VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. GENERAL PRINCIPLES

The verification procedure for a subsystem involves checking and certifying that a subsystem:

- is designed, constructed and installed in such a way as to meet the essential requirements concerning it, and
- may be authorised to be placed in service.

2. "EC" VERIFICATION PROCEDURE

2.1. **Introduction**

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

- complies with the relevant TSI(s),
- complies with the other regulations deriving from the Treaty.

2.2. **Parts of the subsystem and stages**2.2.1 *Intermediate statement of verification (ISV)*

If specified in the TSIs or, where appropriate, at the applicant's request, the subsystem could be divided into certain parts or checked at certain stages of the verification procedure.

The intermediate statement of verification (ISV) is the procedure whereby a notified body checks and certifies certain parts of the subsystem or certain stages of the verification procedure.

Each ISV leads to the issuing of an "EC" ISV certificate by the notified body chosen by the applicant, which in turn, where applicable, draws up an "EC" ISV declaration. The ISV certificate and ISV declaration 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 each part. And each part shall be checked at each stage as described in Section 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:

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

The applicant may apply for an ISV for the design stage (including the type tests) and for the production stage.

2.3. **Certificate of verification**

- 2.3.1. The notified body responsible for "EC" verification assesses the design, production and final testing of the subsystem and draws up the "EC" certificate of verification intended for the applicant, who in turn draws up the "EC" declaration of verification. The "EC" verification certificate 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 "EC" certificate shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the "EC" verification procedure.

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

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

2.4. **Technical file**

The technical file accompanying the “EC” declaration of verification must contain the following:

- 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, documentation on operation and maintenance, etc., relevant for the subsystem concerned,
- list of interoperability constituents, as referred to in Article 5(3)(d), 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,
- where available, the “EC” ISV certificate(s) and, in such a case, where relevant, the “EC” ISV declaration(s), that accompany the “EC” certificate of verification, including the result of verification by the notified body of the certificates validity,
- “EC” certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the “EC” 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 “EC” 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 Sections 2.5.3 and 2.5.4,
- “EC” certificates issued in accordance with other legislation deriving from the Treaty,
- when safe integration is required pursuant Commission Regulation (EC) No 352/2009 ⁽¹⁾, the applicant shall include in the technical file the assessor's report on the Common Safety Methods (CSM) on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

2.5. **Monitoring**

2.5.1. The aim of “EC” monitoring is to ensure that the obligations deriving from the technical file have been met during the production of the subsystem.

2.5.2. 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 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.

2.5.3. 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.

2.5.4. 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.

⁽¹⁾ OJ L 108, 22.4.2009, p 4.

2.5.5. With a view to delivering 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 required by the corresponding TSI so requires, its suitability for use in its intended railway environment.

2.6. **Submission**

The complete file referred to in paragraph 2.4 must be lodged with the applicant in support of the “EC” ISV certificate(s), if available, issued by the notified body responsible for this or in support of the certificate of verification issued by the notified body responsible for “EC” verification of the subsystem. The file must be attached to the “EC” declaration of verification which the applicant sends to the competent authority with which he lodges the application for authorisation for placing in service.

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.

2.7. **Publication**

Each notified body must periodically publish relevant information concerning:

- requests for “EC” verification and ISV received,
- request for assessment of conformity and/or suitability for use of ICs,
- “EC” ISV certificates issued or refused,
- “EC” certificates of conformity and/or suitability for use issued or refused,
- “EC” certificates of verification issued or refused.

2.8. **Language**

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

3. VERIFICATION PROCEDURE IN THE CASE OF NATIONAL RULES

3.1. **Introduction**

The verification procedure in the case of national rules is the procedure whereby the body designated pursuant to Article 17(3) (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 17(3).

3.2. **Certificate of verification**

The designated body responsible for the verification procedure in the case of national rules 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, including those related to parts subject to derogation from a TSI, upgrade or renewal.

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 accompanying the certificate of verification in the case of national rules must be included in the technical file referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the sub-system with the national rules.
