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STATUTORY INSTRUMENTS

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**2007 No. 3386**

**TRANSPORT**

**RAILWAYS**

**The Railways (Interoperability) (Amendment) Regulations 2007**

*Made* - - - - *29th November 2007*  
*Laid before Parliament* *5th December 2007*  
*Coming into force* - - *8th January 2008*

The Secretary of State for Transport makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(1) and section 247 of the Transport Act 2000(2).

She is a Minister designated for the purposes of section 2(2) of that Act in relation to measures relating to railways and railway transport (3).

**Citation and commencement**

1. These Regulations may be cited as the Railways (Interoperability) (Amendment) Regulations 2007 and come into force on 8th January 2008.

**Amendments to the Railways (Interoperability) Regulations 2006**

2.—(1) The Railways (Interoperability) Regulations 2006(4) are amended as follows.

(2) In regulation 2 (interpretation)—

(a) for paragraph (1) substitute—

“(1) In these Regulations—

“Conventional Directive” means Directive 2001/16/EC(5) of the European Parliament and of the Council on the interoperability of the trans-European

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(1) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a). The enabling powers of section 2(2) were extended by virtue of the amendment of section 1(2) of the 1972 Act by section 1 of the European Economic Area Act 1993 (c.51).

(2) 2000 c.38.

(3) S.I. 1996/266, to which there are amendments not relevant to these Regulations.

(4) S.I. 2006/397.

(5) O.J. No. L 110, 20.4.2001, p.1.

conventional rail system, as amended by Directive 2004/50/EC<sup>(6)</sup> of the European Parliament and of the Council; and

“High-Speed Directive” means Council Directive 96/48/EC<sup>(7)</sup> on the interoperability of the trans-European high-speed rail system, as amended by Regulation (EC) No. 1882/2003<sup>(8)</sup> of the European Parliament and of the Council and by Directive 2004/50/EC of the European Parliament and of the Council.”;

- (b) in paragraph (2) for the words from “Annexes I to III to the High-Speed Directive” to the end of the sentence substitute—

“The Annexes to both the High-Speed Directive and the Conventional Directive are reproduced in Schedules to these Regulations as follows—

- (a) Annexes I to III are reproduced in the Schedules indicated in the table;
- (b) Annexes IV, V and VII are substantially reproduced in the Schedules indicated in the table; and
- (c) Annex VI, as replaced by Directive 2007/32/EC of the Commission <sup>(9)</sup>, is substantially reproduced, with minor modifications, in Schedule 9 as indicated in the table.”;

- (c) in paragraph (3)—

- (i) for the definition of “certificate of conformity” substitute—

““certificate of verification” means a certificate drawn up by the notified body in relation to a structural subsystem as part of the verification assessment procedure for that structural subsystem, and the reference in Schedule 9 to certificate shall be construed as a reference to the certificate of verification;”;

and

- (ii) after the definition of “interoperability constituent” insert—

““ISV” means an intermediate statement of verification issued by a notified body in relation to the design stage or the production stage of a subsystem in accordance with Part 2 of Schedule 9;”;

and

- (d) in paragraph (5)—

- (i) insert “and” at the end of sub-paragraph (a); and
- (ii) for sub-paragraphs (b) and (c) substitute—

“(b) “EEA State” has the same meaning as in Schedule 1 to the Interpretation Act 1978<sup>(10)</sup>.”.

(3) In regulation 4 (2) (a) (requirement for authorisation), for “conformity” substitute “verification”.

(4) In regulation 8 (3) (c) (duties on a contracting entity), for “conformity” substitute “verification”.

- (5) In regulation 11 (technical file and retention of documents)—

- (a) in sub-paragraph (1) (a)—

- (i) for “paragraph” substitute “Part”; and
- (ii) for “conformity” substitute “verification”; and

<sup>(6)</sup> O.J. No. L 164, 30.4.2004, p.114. Corrected version published at O.J. No. L 220, 21.6.2004, p.40.

<sup>(7)</sup> O.J. No. L 235, 17.9.1996, p.6. Corrected by corrigendum published at O.J. No. L 262, 16.10.1996, p.18.

<sup>(8)</sup> O.J. No. L 284, 31.10.2003, p.1.

<sup>(9)</sup> O.J. No. L 141, 2.6.07, p. 63.

<sup>(10)</sup> 1978 c. 30. The definition of “EEA state” in Schedule 1 was inserted by section 26(1) of the Legislative and Regulatory Reform Act 2006 (c.51).

- (b) in paragraph (2) for the words from “shall keep the following documents” to the end of the paragraph substitute—
  - “shall—
    - (a) keep the following documents—
      - (i) the technical file, including the certificate of verification; and
      - (ii) the verification declaration; and
    - (b) provide a copy of the technical file, including the certificate of verification, to any Member State that requests one.”.
- (6) In regulation 27 (notified bodies: certificates of conformity etc.)—
  - (a) in the heading to the regulation, for “conformity” substitute “verification”;
  - (b) in paragraph (1), for “certificate of conformity” substitute “certificate of verification or an ISV”; and
  - (c) in paragraph (2), for “certificate of conformity” substitute “certificate of verification”.
- (7) In Schedule 8 (declaration of verification of subsystems)—
  - (a) for the heading substitute “VERIFICATION DECLARATION OF SUBSYSTEMS”;
  - (b) in the first paragraph, for “EC declaration of verification” substitute “verification declaration”; and
  - (c) in the penultimate entry in the list set out in the second paragraph, for “EC declaration” substitute “verification declaration”.
- (8) For Schedule 9 (verification procedure for subsystems) substitute—

“SCHEDULE 9

Regulation 2(2)

VERIFICATION PROCEDURE FOR SUBSYSTEMS

*(This Schedule substantially reproduces, with minor modifications, the provisions of Annex VI to the High-Speed Directive and to the Conventional Directive as replaced by Commission Directive 2007/32/EC)*

PART 1. INTRODUCTION

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

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

ART 2. STAGES

The subsystem is checked at each of the following stages:

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

For the design stage (including the type tests) and for the production stage the main contractor (or the manufacturer) or its authorised representative established within the Community may apply for an assessment as a first step.

In such a case, the assessment leads to an “intermediate statement of verification” (“ISV”) for the relevant stage issued by a notified body chosen by the main contractor (or the manufacturer). The

main contractor (or the manufacturer) in turn draws up an “EC declaration of intermediate subsystem conformity” for the relevant stage.

### PART 3. CERTIFICATE

The notified body responsible for EC verification draws up the certificate of verification intended for the contracting entity, or its authorised representative established within the Community, which in turn draws up the verification declaration intended for the Safety Authority.

The notified body responsible for EC verification assesses the design and production of the subsystem.

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

- checks that the subsystem:
- is covered by relevant design and production ISVs delivered to the main contractor (or the manufacturer) if it had asked a notified body for ISVs for these two stages,
- or corresponds as produced to all aspects covered by any design ISV delivered to the main contractor (or the manufacturer) if it had asked a notified body for an ISV for only the design stage, and
- verifies that the ISVs cover correctly the requirements of the TSIs and assesses the design and production elements that are not covered by the ISVs delivered to the main contractor (or the manufacturer).

### PART 4. TECHNICAL FILE

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

- for the 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, descriptions of data processing and automatic systems, operating and maintenance manuals, etc.,
- list of interoperability constituents, as referred to in Article 3 of the High-Speed Directive or Article 3 of the Conventional Directive, incorporated into the subsystem,
- copies of the EC declarations of conformity or suitability for use with which the above mentioned constituents must be provided in accordance with Article 13 of the High-Speed Directive or Article 13 of the Conventional 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, any ISV and in such a case the “EC declaration of intermediate subsystem conformity” that accompanies the certificate of verification, including the result of verification by the notified body of their validity,
- certificate from and signed by the notified body responsible for EC verification, accompanied by corresponding calculation notes, stating that the project complies with the applicable 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 paragraphs 5.3 and 5.4 of Part 5 of this Schedule.

### PART 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 contracting entity or its authorised representative within the Community 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 High-Speed Directive or the Conventional Directive. It must provide those responsible for implementation with an audit report. It may require 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.

#### PART 6. SUBMISSION

The complete file referred to in Part 4 of this Schedule must be lodged with the contracting entity or its authorised agent established with the Community in support of the certificate of verification issued by the notified body responsible for verification of the subsystem in working order. The file must be attached to the verification declaration which the contracting entity sends to the Safety Authority.

#### PART 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.

#### PART 8. LANGUAGE

The files and correspondence relating to the EC verification procedures must be written in English or in a language accepted by the contracting entity.”.

Signed by authority of the Secretary of State for Transport

29th November 2007

*Tom Harris*  
Parliamentary Under Secretary of State  
Department for Transport

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## EXPLANATORY NOTE

*(This note is not part of the Order)*

These Regulations amend the Railways (Interoperability) Regulations 2006 (S.I. 2006/397) in order to implement Directive 2007/32/EC of the European Commission of 1<sup>st</sup> June 2007 (O.J. No. L 141, 2.6.07, p. 63). This Directive substitutes a new text for Annex VI to Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and also for Annex VI to Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system. Annex VI sets out a verification procedure for railway subsystems, to check they comply with technical requirements.

The previous Annex VI was substantially reproduced, with minor modifications, in Schedule 9 (verification procedure for subsystems) to the Railways (Interoperability) Regulations 2006.

These Regulations substitute for Schedule 9 to the 2006 Regulations a new Schedule 9 in which the new Annex VI is substantially reproduced, with minor modifications, and make consequential amendments to the 2006 Regulations.

The key change is to enable main contractors or manufacturers, or their authorised representatives, to seek an “intermediate statement of verification” (“ISV”) in relation to the design stage, or the production stage, of subsystems, certifying compliance with essential requirements. The expression “certificate of conformity” is replaced by “certificate of verification”. Otherwise the new provisions largely repeat the existing ones.

Apart from this the 2006 Regulations are amended by updating the definition of “EEA State”, (*regulation 2 (2) (c)*), and substituting the expression “verification declaration” for “declaration of verification” in Schedule 8 because the former expression is defined in regulation 2(3) and used in regulation 4(6)(a), (*regulation 2(7)*).

A full impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.