#### STATUTORY INSTRUMENTS

# 2010 No. 000

# **TRANSPORT**

### **RAILWAYS**

# The Railways (Interoperability) Regulations 2010

Made	***
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The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972(a) and section 247 of the Transport Act 2000(b).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for the reference in Regulation 40(8) to the Annex to Commission Decision 2007/756/EC(c) to be construed as a reference to that Annex as amended from time to time.

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to railways and railway transport(**d**).

### PART 1

### Interpretation and Application

#### Citation and commencement

- 1.—(1) These Regulations may be cited as the Railways (Interoperability) Regulations 2010.
- (2) These Regulations come into force on 19th July 2010, but this is subject to regulation 39(7).

### **Interpretation**

- **2.**—(1) In these Regulations "the Directive" means Directive 2008/57/EC of the European Parliament and of the Council of 17th June 2008 on the interoperability of the rail system within the Community (Recast)(e).
- (2) Annexes I to VI, VIII and IX of the Directive are substantially reproduced in Schedules 1 to 8.

<sup>(</sup>a) 1972 c.68; section 2(2) is amended, and paragraph 1A of Schedule 2 is inserted, by the Legislative and Regulatory Reform Act 2006 (c.51, sections 27(1)(a) and 28) and both are amended by the European Union (Amendment) Act 2008 (c.7, Part I of the Schedule).

**<sup>(</sup>b)** 2000 c.38.

<sup>(</sup>c) O.J. No. L305, 23.11.2007, p30.

<sup>(</sup>d) S.I. 1996/266, to which there are amendments not relevant to these Regulations.

<sup>(</sup>e) O.J. No. L191, 18.7.2008, p1, as amended by Commission Directive 2009/131/EC (O.J. No. L273, 17.10.2009, p12).

#### (3) In these Regulations—

"the 1974 Act" means the Health and Safety at Work etc. Act 1974(a);

"Article 21 Committee" means the Committee set up pursuant to article 21 of the Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system(**b**);

"British standard implementing a European standard" means a European standard transposed into a British standard by the British Standards Institution;

"certificate of conformity with notified national technical rules" means a certificate issued by a body appointed under regulation 7(5) or regulation 16(1)(c) containing a statement from the body that in its opinion a subsystem conforms with the applicable notified national technical rules;

"certificate of verification" means a certificate drawn up by a notified body in relation to a structural subsystem as part of the verification assessment procedure for that structural subsystem;

"the Channel Tunnel system" has the meaning given by section 1(7) of the Channel Tunnel Act 1987(c) to the words "the tunnel system";

"the Commission" means the Commission of the EU;

"common technical specification" means a technical specification drawn up in accordance with a procedure recognised by the Member States with a view to uniform application in all Member States that has been published in the Official Journal and is in force, and includes a TSI;

"Competent Authority" means-

- (a) in Great Britain, the Secretary of State, except in relation to the Channel Tunnel system, where it means the Intergovernmental Commission; and
- (b) in Northern Ireland, the DRDNI;

"conformity or suitability for use assessment procedures" means the procedures specified in regulation 25;

"contracting entity" means the person in relation to a project who—

- (a) designs or manufactures or intends to design or manufacture the project on his own account;
- (b) contracts or intends to contract with another person for that other person to design or manufacture the project; or
- (c) is the keeper of a unit of rolling stock.

and includes an authorised representative established in the EU appointed by the contracting entity to act on the contracting entity's behalf;

"Conventional Directive" means Directive 2001/16/EC of the European Parliament and the Council of 19th March 2001 on the interoperability of the trans-European conventional rail system(d);

"CSM Regulation" means Commission Regulation 352/2009 of 24th April 2009 on the adoption of a common safety method on risk evaluation and assessment(e);

"designated body" means a person appointed under regulation 32 as a designated body;

"determination of type" means a determination made by the Safety Authority pursuant to regulation 8;

<sup>(</sup>a) 1974 c.37.

<sup>(</sup>b) O.J. No. L 235, 17.9.96, p6, corrected by O.J. No. L 262, 16.10.96, p8, and as amended by Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003 (O.J. L 284, 31.10.03, p1), Directive 2004/50/EC of the European Parliament and the Council of 29th April 2004 (O.J. No. L 164, 30.4.04. p114) and Commission Directive 2007/32/EC of 1 June 2007 (O.J. No. L 141, 2.6.07, p63).

<sup>(</sup>c) 1987 c.53.

<sup>(</sup>d) O.J. No. L 110, 20.4.2001, p.1. This Directive is repealed with effect from 19th July 2010 by the Directive.

<sup>(</sup>e) O.J. No. L. 108, 29.4.2009, p.4.

"DRDNI" means the Department for Regional Development established by article 3(1) of the Departments (Northern Ireland) Order 1999(a);

"EC declaration of conformity or suitability for use" has the meaning given in regulation 23;

"essential requirements" means all the conditions set out in Schedule 3 that must be met by the rail system, subsystems and interoperability constituents, including interfaces;

"European Railway Agency" means the agency for railway safety and interoperability established by Regulation (EC) No. 881/2004 of the European Parliament and the Council of 29th April 2004 establishing a European Railway Agency(**b**);

"European specification" means a common technical specification, a European technical approval or a British standard implementing a European standard;

"European standard" means a standard approved by the European Committee for Standardisation or by the European Committee for Electrotechnical Standardisation as a European Standard or a Harmonisation Document, according to the Common Rules of those organisations or by the European Telecommunications Standards Institute according to its own rules as a European Telecommunications Standard;

"European technical approval" means an approval of the fitness of a product for a particular use given by an approval body designated for the purpose by a Member State following a technical assessment of whether the product fulfils all essential requirements for such a product, having regard to the inherent characteristics of the product and any such defined conditions of application and use as are provided for in any Council Directive applicable to the product;

"European vehicle number" means a unique alphanumeric identification code;

"functional subsystem" means a functional subsystem as specified in paragraph 1(b) of Schedule 2:

"functional TSI" means a TSI applying to a functional subsystem;

"High-Speed Directive" means Council Directive 96/48/EC of 23rd July 1996 on the interoperability of the trans-European high-speed rail system( $\mathbf{c}$ );

"infrastructure register" means a register kept in accordance with regulation 39;

"Intergovernmental Commission" has the same meaning as in the Channel Tunnel Act 1987;

"interoperability" has the meaning given in article 2 of the Directive;

"interoperability constituent" means any elementary component, group of components, subassembly or complete assembly of equipment that is incorporated or intended to be incorporated into a subsystem upon which the interoperability of the rail system depends directly or indirectly; and the concept of a "constituent" covers both tangible objects and intangible objects such as software;

"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 accord with paragraph 2 of Schedule 6;

"keeper" means the person who, being the owner of a unit of rolling stock or having the right to use it, exploits the unit of rolling stock as a means of transport and is registered as such in the National Vehicle Register referred to in regulation 40;

"network" means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the rail system;

"notified body" has the meaning given in regulation 31;

"notified national technical rules" means the standards, technical specifications and technical rules in use in the United Kingdom which have been notified by the Secretary of State to the

<sup>(</sup>a) S.I. 1999/283 (N.I.1).

<sup>(</sup>**b**) O.J. No. L 164 of 30.04.04, p1.

<sup>(</sup>c) O.J. No. L 235 17.9.96, p. 6. This Directive is repealed with effect from 19th July 2010 by the Directive.

Commission pursuant to article 17(3) of the Directive or Article 16(3) of the High-Speed Directive or Article 16(3) of the Conventional Directive;

"Official Journal" means the Official Journal of the EU;

"operator", in relation to the use of an interoperability constituent or a project subsystem, means the infrastructure manager or railway undertaking having the management of that interoperability constituent or project subsystem for the time being;

"owner", in relation to a structural subsystem, means any person who has an estate or interest in, or right over that subsystem, and whose permission is needed before another may use it;

"placed in service" has the meaning given in regulation 4(2); and cognate expressions shall be construed accordingly;

"placed on the market" means making an interoperability constituent available for purchase with a view to its use on the rail system and cognate expressions shall be construed accordingly;

"project" means a discrete scheme for the construction or upgrading or renewal of the whole or part of any subsystem of the rail system, and where it is intended to carry out that construction, upgrading or renewal in parts, each of which are to be placed in service on a permanent basis independently of the other parts, it means any such part;

"project subsystem" means—

- (a) a structural subsystem which is subject to the requirement for authorisation under these Regulations, or
- (b) a structural subsystem in respect of which a person has voluntarily made an application for authorisation under these Regulations,

except if the subsystem is rolling stock part of which is being upgraded or renewed the "project subsystem" is that part of the subsystem;

"rail system" includes the trans-European rail system and has the same meaning as in the Directive;

"registration body" means the person designated under regulation 40(11);

"renewal" means any major substitution work on a subsystem or part subsystem which does not change the overall performance of the subsystem, and cognate expressions shall be construed accordingly;

"rolling stock" means a vehicle, or where a vehicle can only be operated as part of a fixed formation multiple unit the whole of that unit;

"safety assessment report" means a report provided in accordance with Article 7 of the CSM Regulation;

"Safety Authority" means the Office of Rail Regulation(a) except—

- (a) in relation to Northern Ireland, where it means the DRDNI; and
- (b) in relation to the Channel Tunnel system, where it means the Intergovernmental Commission;

"structural subsystem" means a structural subsystem as specified in paragraph 1(a) of Schedule 2;

"subsystem" means the whole, or, as the context requires, part of a subdivision of the rail system as specified in paragraphs 1(a) and 1(b) of Schedule 2, namely structural subsystems and functional subsystems;

"technical file" means a file relating to a structural subsystem which contains the matters required by regulations 17(2)(a) and 19(2) or, in the case of an application for an authorisation under regulation 5(1)(d), regulations 7(3)(b) and 19(2);

<sup>(</sup>a) Established under section 15 of the Railways and Transport Safety Act 2003 (c.20).

"trans-European rail system" means the trans-European conventional and high-speed rail systems as set out in paragraphs 1 and 2 of Schedule 1 and includes any extensions to the networks referred to in those paragraphs;

"TSIs" means technical specifications for interoperability adopted by an EU institution in accordance with the Directive or the Conventional Directive or the High Speed Directive and in force by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system;

"upgrading" means any major modification work on a structural subsystem or part of a structural subsystem which improves the overall performance of the subsystem, and cognate expressions shall be construed accordingly;

"verification assessment procedure" means—

- (a) the procedures specified in regulation 17(1) and the reference in Schedule 6 to "verification procedure" shall be construed as a reference to the verification assessment procedure, or
- (b) in the case of an application for an authorisation under regulation 5(1)(d), the procedure undertaken by a notified body in relation to the authorisation referred to in regulation 4(1)(c);

"vehicle" means a railway vehicle that runs on its own wheels on railway lines of a gauge of at least 350 millimetres, with or without traction and is composed of one or more structural and functional subsystems or parts of such subsystems;

"verification declaration" means-

- (a) an EC declaration of verification in relation to a structural subsystem drawn up by a contracting entity pursuant to regulation 16(3); or
- (b) in the case of an application for an authorisation under regulation 5(1)(d), the declaration made by a contracting entity under regulation 7(7);

"writing" includes any text transmitted using electronic communications that is received, or accessible by the person to whom it is sent, in legible form.

- (4) Other expressions used in these Regulations have the same meaning as in the Directive.
- (5) Except for the references to the EU in the definition of "the Commission" and in relation to the Official Journal, a reference to the EU includes a reference to the European Economic Area, and a reference to a Member State includes a reference to an EEA state.

#### **Application**

- 3.—(1) Subject to paragraphs (2) and (5), these Regulations apply to—
  - (a) the part of the rail system located in the United Kingdom;
  - (b) subsystems located, operated or intended to be operated in the United Kingdom; and
  - (c) interoperability constituents.
- (2) These Regulations do not apply to any part of the rail system that the Secretary of State determines falls within one or more of these categories—
  - (a) metros, trams and other light rail systems,
  - (b) networks that are functionally separate from the rest of the rail system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks,
  - (c) infrastructure and vehicles reserved for a strictly local, historical or touristic use.
- (3) A person may make an application to the Secretary of State for a determination under paragraph (2) and the Secretary of State must consider any such application.
- (4) The Secretary of State must publish and keep up to date a list of the parts of the rail system that are excluded from the scope of these Regulations by virtue of determinations made under paragraph (2).

- (5) These Regulations do not apply to—
  - (a) privately owned railway infrastructure and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its freight operations; or
  - (b) railways the lines of which have a gauge of less than 350 millimetres.
- (6) Paragraphs (2) and (5)(a) are subject to the voluntary arrangements provided for in regulation 5(1)(b) to (d).
- (7) References in this regulation to the Secretary of State shall in their application to Northern Ireland have effect as references to DRDNI.

#### PART 2

### Subsystems

### Requirement for authorisation

- **4.**—(1) No person shall place in service on the trans-European rail system, or if there is an applicable TSI, on any other part of the rail system, any structural subsystem which has been constructed, upgraded or renewed as a project unless—
  - (a) the Safety Authority has given an authorisation under these Regulations for the placing in service of that subsystem on that part of the rail system;
  - (b) the Competent Authority has decided under regulation 13 that for the upgrading or renewal of the subsystem, an authorisation is not required for the subsystem to be placed in service; or
  - (c) in the case of rolling stock, an authorisation given for placing in service on a part of the rail system located in another Member State is valid in accordance with the Directive for that part of the rail system.
- (2) A structural subsystem is placed in service in relation to a part of the rail system when, having been constructed, upgraded or renewed, it is first used on or as part of that part of the rail system in the transportation of passengers or freight or for the purpose for which it was designed.
- (3) For the purposes of paragraph (2) first use of a structural subsystem does not include any testing or trials conducted in the verification assessment procedure or for additional checks required by the Safety Authority.

### **Application for authorisation**

- **5.**—(1) A person may apply for an authorisation under these Regulations in respect of any structural subsystem to be placed in service wholly or partly on a part of the rail system if—
  - (a) the authorisation is required under regulation 4(1),
  - (b) an authorisation is not required under regulation 4(1) because the proposed placing in service is not within the scope of any TSIs, but the person nevertheless wants an authorisation,
  - (c) an authorisation is not required under regulation 4(1) because regulation 3(2) or (5)(a) applies, but the person nevertheless wants an authorisation, or
  - (d) an authorisation is not required under regulation 4(1) because regulation 4(1)(c) applies, but the person nevertheless wants an authorisation.
- (2) An application for an authorisation under these Regulations must be made in writing to the Safety Authority and be accompanied by—
  - (a) the complete technical file, including the certificate of verification, the safety assessment report and any certificate of conformity with notified national technical rules; and

- (b) the verification declaration.
- (3) Subject to paragraph (4), in considering an application the Safety Authority may not require checks carried out under the appropriate verification assessment procedure to be carried out again.
- (4) The Safety Authority may require an applicant to carry out any additional checks which the Safety Authority considers necessary in relation to the project subsystem if that subsystem appears to the Safety Authority not to meet the essential requirements in accordance with regulation 15.
  - (5) Where additional checks are required under paragraph (4) the Safety Authority must—
    - (a) inform the applicant that the application cannot be determined before the additional checks are carried out; and
    - (b) notify the Secretary of State in writing forthwith of the additional checks it requires and the reasons for requiring those checks.
  - (6) Paragraphs (2) and (4) are subject to regulations 7, 9 and 10.
  - (7) Paragraph (5)(b) does not apply to DRDNI.

#### **Authorisation decision**

- **6.**—(1) The Safety Authority must issue an authorisation under these Regulations for the placing in service of a structural subsystem on or as part of the rail system, where it is satisfied that—
  - (a) the verification declaration has been drawn up in accordance with Schedule 5 or, in the case of an application under regulation 5(1)(d), in accordance with regulation 7(7);
  - (b) the project subsystem has been so designed, constructed and installed as to meet the essential requirements in accordance with regulation 15 relating to that subsystem when placed in service on that rail system; and
  - (c) the project subsystem is compatible with the part of the rail system into which it is being placed in service.
  - (2) The Safety Authority must determine an application under these Regulations by—
    - (a) authorising the placing in service of the structural subsystem; or
    - (b) refusing the application for authorisation.
  - (3) The Safety Authority may include conditions in an authorisation under these Regulations.
  - (4) In this regulation "conditions" means—
    - (a) restrictions or limitations on the use of the structural subsystem; or
    - (b) requirements that must be met by a time specified in the authorisation.

### Authorisation for rolling stock already authorised for another Member State

- 7.—(1) This regulation applies when an application is made pursuant to regulation 5(1)(d).
- (2) When this regulation applies paragraph (3) applies instead of regulation 5(2) and paragraph (4) applies instead of regulation 5(4).
  - (3) The application must be made in writing to the Safety Authority and accompanied by—
    - (a) a copy of the authorisation referred to in regulation 4(1)(c) ("the first authorisation");
    - (b) a file containing—
      - (i) the items referred to in paragraph 4 of Schedule 6, including the certificate of verification;
      - (ii) for rolling stock equipped with a data recorder not required by an applicable TSI, information on the procedures for collecting and evaluating the data;
      - (iii) manuals and instructions relating to the servicing, constant or routine monitoring, adjustment, maintenance an configuration controls of the project subsystem;
      - (iv) the documentation relating to the maintenance history and any technical modifications undertaken after the first authorisation:

- (v) the safety assessment report;
- (vi) any certificate of conformity with notified national technical rules; and
- (c) a verification declaration from a contracting entity made under paragraph (7).
- (4) The Safety Authority may require an applicant to carry out any additional checks which the Safety Authority considers necessary in order to check compatibility with—
  - (a) the part of the network on which the vehicle is to be placed; and
  - (b) any notified national technical rules applicable to any specific case identified in any applicable TSIs.
- (5) If there are any applicable notified national technical rules, a contracting entity must appoint a designated body, or if the appointment is made before 19th July 2011 either a designated body or a notified body, to assess conformity with those rules.
- (6) A notified body appointed to assess conformity with notified national technical rules may only continue to carry out that function on and after 19th July 2011 if it has also been appointed as a designated body.
- (7) The contracting entity must draw up a declaration in relation to the project subsystem where—
  - (a) the contracting entity is satisfied the essential requirements are met in accordance with regulation 15 (including interfaces with the part of the rail system on which it will be placed in service);
  - (b) if there are applicable notified national technical rules, the body appointed under paragraph (5) has—
    - (i) assessed the subsystem as conforming with those rules in accordance with such procedures as are reasonably appropriate to make that assessment; and
    - (ii) issued a certificate of conformity with notified national technical rules.

### **Determination of type**

- **8.**—(1) If the Safety Authority has issued an authorisation under these Regulations for the placing in service of rolling stock, the Safety Authority must determine that the rolling stock is of a particular type.
- (2) If the Safety Authority has issued an authorisation under these Regulations for the placing in service of a structural subsystem that is not rolling stock, the Safety Authority may determine that the structural subsystem is of a particular type.
- (3) A contracting entity may make an application to the Safety Authority requesting the Safety Authority to make a determination of type under paragraph (2) and the Safety Authority must consider any such application.
- (4) A determination of type must describe the basic design characteristics of the structural subsystem in the same manner and to the same extent as an EC-type examination certificate issued in accordance with the procedures of Module B in Annex II to Decision 768/2008/EC of the European Parliament and of the Council of 9th July 2008 on a common framework for the marketing of products(a).
- (5) If the Safety Authority considers it necessary as a result of changes to TSIs or notified national technical rules it may modify, suspend or withdraw a determination of type.
- (6) The Safety Authority must notify the European Railway Agency of a determination of type for the placing in service of any rolling stock and of any modification, suspension or withdrawal of such a determination.
- (7) Following an authorisation under regulation 9 the Safety Authority is not required to make a further determination under this regulation.

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<sup>(</sup>a) O.J. No. L218, 13.8.2008, p82.

#### Type authorisation

- **9.**—(1) A person who proposes to place into service a structural subsystem that conforms to the description in a determination of type, as modified under regulation 8(5) if applicable, may make an application for an authorisation under this regulation to the Safety Authority.
  - (2) An application must be in writing and be accompanied by—
    - (a) a declaration by the applicant that the structural subsystem conforms to the description set out in the determination of type;
    - (b) a statement as to whether there have been any changes to the applicable TSIs or notified national technical rules since the Safety Authority made or modified the determination of type;
    - (c) if there are any such changes, a description of them; and
    - (d) the safety assessment report.
- (3) In this regulation "conforms" means conforms in all the respects which materially affect compliance with the applicable essential requirements.
- (4) The Safety Authority must consider any application made under and in accordance with paragraphs (1) and (2) and must issue an authorisation where it is satisfied that—
  - (a) the project subsystem conforms to the description set out in the determination of type;
  - (b) there have been no changes since the Safety Authority made or modified the determination of type which are material to the application;
  - (c) the project subsystem has been so designed, constructed and installed as to meet the essential requirements in accordance with regulation 15 relating to that subsystem when placed in service on that rail system; and
  - (d) the project subsystem is compatible with the part of the rail system into which it is being placed in service.
- (5) Subject to regulation 10, regulations 5(2) and (4) and 6(1) do not apply to an application for an authorisation under this regulation.

### Type authorisation: changes to TSIs etc.

- 10.—(1) If in the Safety Authority's opinion there have been changes to the applicable TSIs or notified national technical rules that are material to an application made under regulation 9 the Safety Authority must give a notice to the applicant specifying the changes that the Safety Authority considers to be material to the application.
- (2) If having received a notice issued by the Safety Authority under paragraph (1) the applicant wishes to continue with the application, the applicant must provide to the Safety Authority the documentation referred to in regulation 5(2)(a) and (b).
- (3) If the Safety Authority has received the further material referred to in paragraph (2), the Safety Authority may require the applicant to carry out additional checks in accordance with regulation 5(4) and (5).
  - (4) If paragraph (2) applies, regulation 6(1) applies.
- (5) For the purposes of paragraphs (2), (3) and (4) the documentation to be provided, the additional checks to be carried out and the authorisation to be issued may relate only to the changes to the applicable TSIs or notified national technical rules.

#### **Revocation of authorisations**

- 11.—(1) The Safety Authority may revoke an authorisation under these Regulations if it is satisfied that the holder no longer meets the conditions of that authorisation and that there is a significant safety risk arising as a result.
  - (2) Before revoking an authorisation the Safety Authority must notify the holder that—
    - (a) it is considering revoking that authorisation and the reasons why; and

- (b) within a period specified in the notice, which must be not less than 28 days, the holder may make representations in writing to the Safety Authority or, if the holder so requests, may make oral representations to the Safety Authority.
- (3) Where the Safety Authority revokes an authorisation, it must send to the holder with the notice of revocation a statement of the reasons why.

### List of projects for the renewal or upgrading of subsystems

- 12.—(1) The Competent Authority may publish an implementation plan for a TSI.
- (2) If such a plan is published under this regulation the Competent Authority must include in the plan a list (the "regulation 12 list") that names or describes each project or type of project that—
  - (a) deals with matters covered by the TSI to which the implementation plan relates, and
  - (b) is, in the opinion of the Competent Authority, a project or type of project for the renewal or upgrading of an existing structural subsystem.
- (3) In deciding whether a project or type of project is a renewal or upgrade factors to be taken into account by the Competent Authority must include—
  - (a) the scale of the project assessed by reference to its economic cost and benefits;
  - (b) the impact of the project on the rail system having regard to its effect on safety, reliability and availability, health, environmental protection and technical compatibility(a);
  - (c) the impact on the accessibility of the rail system to passengers of applying or not applying the TSI to the project; and
  - (d) the impact of the application of the TSI to the subsystem and any interfacing subsystems.
- (4) If the Competent Authority has published an implementation plan for a TSI, the Competent Authority must keep the regulation 12 list up to date and publish any changes to it.

### Authorisation requirements for the renewal or upgrading of subsystems

- 13.—(1) Subject to paragraph (2), in relation to a project for the renewal or upgrading of an existing structural subsystem that deals with matters covered by a TSI, a contracting entity must apply in writing to the Competent Authority for a decision as to whether an authorisation is required for that subsystem to be placed in service.
- (2) If the Competent Authority has published an implementation plan under regulation 12 for a TSI, paragraph (1) only applies in relation to that TSI if the project is named or is of a type described in the regulation 12 list.
- (3) An application made under paragraph (1) must be accompanied by the following information—
  - (a) a file setting out details of the project;
  - (b) the contracting entity's assessment of whether there are any new or changed safety risks resulting from the works envisaged and how any such risks will be managed;
  - (c) identification of any TSI, or parts thereof, for which derogations may or will be sought pursuant to regulation 14;
  - (d) an indication of any TSI, or parts thereof, which it is proposed should not apply if the Competent Authority determines that the subsystem requires authorisation.
- (4) The Competent Authority may give notice in writing to the applicant requiring the applicant to provide additional information that the Competent Authority considers necessary in order to make a decision.

<sup>(</sup>a) See the general requirements listed in Schedule 3.

- (5) The applicant must provide the Competent Authority with such additional information requested under paragraph (4) as the applicant is reasonably able to supply and the applicant must give a written explanation where the information requested is not supplied.
- (6) In making a decision as to the requirement for authorisation, factors to be taken into account by the Competent Authority must include—
  - (a) the implementation strategy provided in any applicable TSI; and
  - (b) the extent of the proposed works.
- (7) Except where the Competent Authority and the Safety Authority are the same person, the Competent Authority may only decide authorisation is not required if it has consulted the Safety Authority.
- (8) If it appears to the Competent Authority that the proposed works may adversely affect the overall safety of the subsystem the Competent Authority must decide that the subsystem requires authorisation to be placed in service.
  - (9) Where the Competent Authority determines that the subsystem requires an authorisation—
    - (a) the Competent Authority must, subject to any derogations under regulation 14, decide to what extent TSIs must apply to the project subsystem; and
    - (b) the Secretary of State must notify that decision to the Commission and other Member States.

### **Exemption from need to conform with TSIs (derogations)**

- **14.**—(1) The Competent Authority may determine that, in the circumstances or cases specified in paragraph (2), the whole or part of a relevant TSI shall not apply in relation to a subsystem ("a derogation").
  - (2) The cases are—
    - (a) for a proposed new subsystem, for the renewal or upgrading of an existing subsystem, or for any element referred to in Article 1(1) of the Directive at an advanced stage of development having regard to the impact that a change in technical specification would have on the project or the subject of a contract in the course of performance when the applicable TSI is published;
    - (b) for any project concerning the renewal or upgrading of an existing subsystem where the loading gauge, track gauge, space between tracks or electrification voltage in the applicable TSI is not compatible with those of the existing subsystem;
    - (c) for a proposed new subsystem or for the proposed renewal or upgrading of an existing subsystem where the rail network is separated or isolated by the sea or separated as a result of special geographical conditions from the rail network of the rest of the EU;
    - (d) for any proposed renewal, extension or upgrading of an existing subsystem when the application of an applicable TSI would compromise the economic viability of the project or the compatibility of the rail system;
    - (e) following an accident or natural disaster, where the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of an applicable TSI;
    - (f) for vehicles coming from or going to countries outside the EU the track gauge of which is different from that of the main rail network within the EU.
- (3) The Competent Authority shall not make a derogation from the application of a TSI or part of a TSI unless the Secretary of State has first forwarded a file to the Commission containing the information set out in Schedule 8.
- (4) Save for matters concerning the loading gauge and the track gauge, a derogation in relation to the circumstances or cases set out in paragraph (2)(b) shall have no effect unless the derogation has been permitted by the Commission.

- (5) In the circumstances or cases set out in paragraph (2)(d) and (f) a derogation shall have no effect unless the derogation has been permitted by the Commission.
- (6) For the purposes of paragraphs (5) and (6) the Commission shall be deemed to have permitted the derogation if it has made no decision within six months of receiving the file referred to in paragraph (3).

### Essential requirements for project subsystems

- **15.**—(1) For the purposes of regulations 5(4), 6(1), 9(4) and 18(1) the essential requirements for a project subsystem are deemed to be met by—
  - (a) conformity with—
    - (i) all applicable TSIs (if any); and
    - (ii) where paragraph (2) applies, the requirements of all applicable notified national technical rules (if any), and
  - (b) implementation of—
    - (i) any necessary measures identified by the risk management process undertaken in accordance with Article 5 of the CSM Regulation; and
    - (ii) any necessary measures identified in the safety assessment report.
- (2) This paragraph applies to a project subsystem (insofar as it is not subject to requirements by an applicable TSI) where—
  - (a) there are no applicable TSIs; or
  - (b) a relevant TSI does not govern all elements of the project subsystem; or
  - (c) a derogation from conformity with the whole or part of a relevant TSI has been granted under regulation 14 in respect of that subsystem; or
  - (d) the Competent Authority has determined under regulation 13(9) that the whole or part of an applicable TSI does not apply to that subsystem.

### **Duties on a contracting entity**

- **16.**—(1) A contracting entity in relation to a project subsystem must—
  - (a) appoint a notified body to act in carrying out the verification assessment procedure other than in relation to notified national technical rules;
  - (b) ensure that a notified body (whether that originally appointed or another) continues to be appointed until authorisation under these Regulations is given or refused; and
  - (c) if there are applicable notified national technical rules, appoint a designated body, or if the appointment is made before 19th July 2011 either a designated body or a notified body, to assess conformity with those rules.
- (2) The appointment of a notified body under paragraph (1) must be made—
  - (a) before completion of the design stage of the project subsystem; or
- (b) before commencement of the manufacture stage of the project subsystem,

### whichever is the earlier.

- (3) The contracting entity must draw up a verification declaration in relation to that project subsystem where—
  - (a) the contracting entity is satisfied the essential requirements are met in accordance with regulation 15, (including interfaces with the rail system on which it will be placed in service):
  - (b) the appropriate verification assessment procedure has been carried out by a notified body in accordance with regulation 17;
  - (c) a certificate of verification has been drawn up by a notified body in accordance with the procedures required by Schedule 6;

- (d) a technical file has been prepared containing the information and documents specified in regulation 17(2)(a)(i) to (vii); and
- (e) if there are applicable notified national technical rules, the body appointed under paragraph (1)(c) has—
  - (i) assessed the subsystem as conforming with those rules in accordance with such procedures as are reasonably appropriate to make that assessment; and
  - (ii) issued a certificate of conformity with notified national technical rules.
- (4) A notified body appointed to assess conformity with notified national technical rules may only continue to carry out that function on and after 19th July 2011 if it has also been appointed as a designated body.
- (5) This regulation and regulation 17 do not apply where an authorisation is being applied for under regulation 5(1)(d).
- (6) Where regulations 9 or 10 apply this regulation and regulation 17 only apply to the extent necessary to satisfy the Safety Authority that an authorisation must be granted under these Regulations.

### Project subsystems: verification assessment procedure

- 17.—(1) The appropriate verification assessment procedure in relation to a project subsystem is—
  - (a) in so far as that subsystem is required to conform with all or part of a TSI, the procedures specified in the TSI or part of the TSI with which that subsystem is required to conform; and
  - (b) the procedures set out in Schedule 6.
  - (2) The notified body must—
    - (a) compile a file containing:
      - (i) the items required by paragraph 4 of Schedule 6, including the certificate of verification;
      - (ii) documents relating to the conditions and limits of use of the project subsystem;
      - (iii) documents relating to the characteristics of the project subsystem;
      - (iv) manuals and instructions relating to the servicing, constant or routine monitoring, adjustment, maintenance and configuration controls of the project subsystem;
      - (v) documentation or records of notifications to the Commission pursuant to regulation 13(9) identifying to what extent TSIs apply to the project subsystem;
      - (vi) documentation or records of notifications to the Commission in relation to a derogation, pursuant to regulation 14; and
      - (vii) documents added to the file pursuant to regulation 19(2); and
    - (b) assess the interface between the project subsystem and the part of the rail system in which it will be placed in service to the extent that such an assessment is possible based on the available information referred to in paragraph (3).
- (3) The assessment under paragraph (2)(b) must be only based on information available in the relevant TSI and in any registers kept in accordance with Article 34 (European register of authorised types of vehicles) and Article 35 (register of infrastructure) of the Directive.

### Project subsystems: verification declaration

- **18.**—(1) A project subsystem in relation to which a verification declaration has been drawn up shall be taken to meet the essential requirements in accordance with regulation 15 unless there are reasonable grounds for believing that it does not so conform.
- (2) Paragraph (1) does not apply in relation to the Safety Authority where a person fails or refuses to make available to the Safety Authority the documentation which the person is required

to retain by the verification assessment procedure applying to the project subsystem or pursuant to regulation 19, or a copy of that documentation.

#### **Retention of documents**

- 19.—(1) From the time a project subsystem authorised under these Regulations is placed in service until it is permanently withdrawn from service (whether such service is in the United Kingdom or another Member State), a contracting entity must—
  - (a) keep the following documents—
    - (i) the technical file, including the certificate of verification;
    - (ii) the verification declaration; and
    - (iii) any declaration made in accordance with regulation 9(2)(a); and
  - (b) provide a copy of the technical file, including the certificate of verification, to any Member State that requests one.
  - (2) A contracting entity must ensure that—
    - (a) any alterations made to the project subsystem are documented;
    - (b) the documentation recording any alterations and any maintenance manuals in relation to the project subsystem are added to and kept as part of the technical file; and
    - (c) the safety assessment report and any certificate of conformity with notified national technical rules are added to and kept as part of the technical file.
- (3) Where a contracting entity is not the owner of the project subsystem when it is authorised under these Regulations, the contracting entity must within 60 days of the date of authorisation transfer the documents referred to in paragraphs (1) and (2) to the owner of the subsystem, and thereafter for the purpose of paragraphs (1) and (2) the owner shall be regarded as the contracting entity.
- (4) Where an owner of the project subsystem disposes of the owner's interest in it, the owner must within 60 days of the disposal transfer the documents referred to in paragraphs (1) and (2) to the person acquiring that interest, and thereafter for the purpose of paragraphs (1) and (2) and this paragraph, the person acquiring that interest shall be regarded as the contracting entity.
- (5) The contracting entity for the purpose of paragraphs (1) and (2) must make the technical file, or the documents kept in accordance with paragraph (7)(b), available to the Safety Authority on demand.
- (6) The duties of a contracting entity, or an owner of a project subsystem, under paragraphs (1), (2)(c) and (3) to (5) do not arise by virtue of an authorisation being deemed to be given under these Regulations by operation of regulation 47.
- (7) In respect of a project subsystem authorised under regulation 9 the duties of a contracting entity under paragraphs (1) and (2) are limited to keeping—
  - (a) the declaration made in accordance with regulation 9(2)(a); and
  - (b) documentation recording any alterations and any maintenance manuals in relation to the project subsystem.

### Duty on operator to ensure essential requirements are met

- **20.**—(1) This regulation applies where a project subsystem is in use on, or is part of, the rail system pursuant to an authorisation under these Regulations.
- (2) Subject to paragraphs (3) and (4), the operator of the project subsystem must ensure that the project subsystem is operated and maintained—
  - (a) in accordance with the essential requirements relevant to that subsystem;
  - (b) subject to paragraph (c), in conformity with the TSIs and notified national technical rules against which the subsystem was assessed for that authorisation;

- (c) where a TSI and notified national technical rule referred to in paragraph (b) has been varied and replacement parts which conform to the TSI or notified national technical rule against which it was assessed are no longer available, in conformity with that varied TSI or rule;
- (d) in conformity with any functional TSI applying to that subsystem; and
- (e) in a manner that ensures that—
  - (i) any necessary measures identified by the risk management process undertaken in accordance with Article 5 of the CSM Regulation; and
  - (ii) any necessary measures identified in the safety assessment report, continue to be implemented.

#### (3) Where—

- (a) the notified national technical rules against which a project subsystem was assessed for authorisation were the Rail Vehicle Accessibility Regulations 1998(a) as in force when the project was assessed; and
- (b) an exemption order has been made under section 47 of the Disability Discrimination Act 1995 in relation to that project subsystem;

the duty in paragraph (2)(b) to ensure that the project subsystem is operated and maintained in conformity with those Regulations is a duty to do so save to the extent the order exempted it from those Regulations, even though the order may include a provision for the expiry of such exemption.

- (4) Paragraph (2)(a) does not apply to rolling stock by virtue of an authorisation being deemed to be given under these Regulations by operation of regulation 47.
  - (5) Paragraph (2) is without prejudice to regulation 48.
  - (6) In this regulation—
    - (a) "project subsystem" includes a unit of rolling stock deemed to be authorised under these Regulations by operation of regulation 47; and
    - (b) the reference in paragraph (3)(a) to the Rail Vehicle Accessibility Regulations 1998 shall, in its application to Northern Ireland, have effect as a reference to the Rail Vehicle Accessibility Regulations (Northern Ireland) 2001(b).

### Fees payable to the Safety Authority

- **21.**—(1) A person applying to the Safety Authority for authorisation of a project subsystem under these regulations is liable to pay such fee to the Safety Authority as the Safety Authority may charge in respect of the Safety Authority's work in relation to the application.
  - (2) The fee payable under paragraph (1) must—
    - (a) not exceed the sum of the costs reasonably incurred by the Safety Authority in carrying out the work referred to in paragraph (1);
    - (b) be set out in an invoice that includes a statement of the work done and the costs reasonably incurred and specifies the period to which the statement relates; and
    - (c) be payable within 30 days from the date of the invoice that the Safety Authority has sent or given to the person who is required to pay the fees.
  - (3) A fee payable under this regulation shall be recoverable as a civil debt.
- (4) Failure to pay a fee under this regulation shall not constitute an offence under these Regulations.
- (5) This regulation shall not apply in relation to the Channel Tunnel system and the Intergovernmental Commission.

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<sup>(</sup>a) S.I. 1998/2456, amended by S.I. 2000/3215 and S.I. 2008/1746 and revoked by S.I. [ ].

 $<sup>\</sup>textbf{(b)} \quad S.R. \ (N.I.) \ 2001 \ No. \ 264$ 

#### Fees payable to the Competent Authority

- **22.**—(1) The Competent Authority may charge such reasonable fee in connection with, or incidental to, carrying out its functions under regulations 13 and 14, as it may determine.
- (2) This regulation shall not apply in relation to the Channel Tunnel system and the Intergovernmental Commission.

### PART 3

### **Interoperability Constituents**

### EC declaration of conformity or of suitability for use

- **23.**—(1) An EC declaration of conformity or an EC declaration of suitability for use is a declaration drawn up by the relevant person in accordance with the requirements of Schedule 4 that indicates that the interoperability constituent satisfies the requirements—
  - (a) of such European specifications as have been published in the Official Journal that are relevant to the interoperability constituent;
  - (b) of such TSIs that are relevant to the interoperability constituent;
  - (c) where a TSI relevant to the interoperability constituent requires compliance with a European specification that has not been published in the Official Journal, of the latest version of that draft European specification if so required by the TSI.
  - (2) In this regulation, "relevant person" means a person specified in regulation 26(2) or (3).

### Effect of conformity and suitability declarations

- **24.**—(1) An interoperability constituent in relation to which an EC declaration of conformity or suitability for use has been drawn up shall be taken to—
  - (a) meet such of the essential requirements as relate to an interoperability constituent of that type; and
  - (b) conform to such of the TSIs, European specifications or draft European specifications as required by regulation 23,

unless there are reasonable grounds for believing that it does not so conform.

(2) Paragraph (1) does not apply to the Safety Authority where a person fails or refuses to make available to the Safety Authority the documentation which the person is required to retain by any of the procedures for assessing the conformity or suitability for use of that interoperability constituent or a copy of that documentation.

# Assessment procedure for interoperability constituents

- **25.**—(1) The appropriate procedures for assessing the conformity or suitability for use of an interoperability constituent must be carried out by a notified body in accordance with—
  - (a) subject to paragraph (2), the procedures (if any) specified in any TSIs with which the interoperability constituent must comply;
  - (b) the procedures (if any) specified in any European specifications with which the interoperability constituent must comply;
  - (c) any relevant procedures set out in Schedule 7.
- (2) Spare parts for subsystems that were placed in service before the applicable TSI came into force are not subject to the procedures referred to in paragraph (1)(a).

### Prohibition on placing interoperability constituents on the market

- **26.**—(1) No person may place an interoperability constituent on the market with a view to its use on the trans-European rail system or, if there is an applicable TSI, on any other part of the rail system, unless—
  - (a) the interoperability constituent meets the essential requirements that are relevant to an interoperability constituent of that type;
  - (b) the appropriate procedure for assessing the conformity or suitability for use of the interoperability constituent has been carried out; and
  - (c) an EC declaration of conformity or suitability for use in relation to that interoperability constituent has been drawn up.
- (2) Subject to paragraph (3), an EC declaration of conformity or suitability for use must be drawn up by the manufacturer of the interoperability constituent or the manufacturer's authorised representative established in the EU.
- (3) Where an EC declaration of conformity or suitability for use has not been drawn up by the manufacturer or the manufacturer's authorised representative established in the EU, an EC declaration of conformity or suitability for use must be drawn up by any person who—
  - (a) places that interoperability constituent on the market; or
  - (b) uses that interoperability constituent, or any part of it, in any interoperability constituent that the person is manufacturing or assembling, or in any project subsystem that the person is constructing, upgrading or renewing.
- (4) Where a person draws up an EC declaration of conformity or suitability for use in relation to an interoperability constituent and the interoperability constituent is subject to other requirements pursuant to an EU Directive, the person who draws up the EC declaration of conformity or suitability for use must state in the declaration whether or not the interoperability constituent meets those other requirements.
- (5) Nothing in these Regulations shall preclude a person from placing an interoperability constituent on the market for a purpose other than use on the trans-European rail system or, if there is an applicable TSI, on any other part of the rail system.

### **Duties on operators**

- **27.** The operator of any interoperability constituent that is in use on, or is part of the trans-European rail system located in the United Kingdom or, if there is an applicable TSI, any other part of the rail system located in the United Kingdom, must ensure that while it is so in use it is—
  - (a) correctly installed for the purpose for which it is intended to be used;
  - (b) not used for any purpose other than the purpose for which it was designed; and
  - (c) maintained in effective working order and good repair.

# Position after placing on the market

**28.** Nothing in these Regulations precludes any person from drawing up an EC declaration of conformity or suitability for use at any time in relation to an interoperability constituent which has been placed on the market, provided that person has followed the requirements of these Regulations in relation to that interoperability constituent.

## Recognition of assessments of other Member States

**29.** Nothing in these Regulations shall preclude any person from placing on the market relating to the rail system an interoperability constituent that has successfully completed all the requirements of any scheme in force in another Member State for the purpose of implementing the Directive.

#### Notification to the Commission of incorrect declaration

- **30.**—(1) Where it appears to the Safety Authority that an interoperability constituent in relation to which an EC declaration of conformity or suitability for use has been drawn up fails to meet the essential requirements relating to it, it must forthwith give notice of that fact in writing to the Commission, and where appropriate other Member States.
  - (2) That notice must specify—
    - (a) whether the failure to comply was due to the inadequacy of a TSI,
    - (b) and if it was not—
      - (i) the steps taken to prohibit or restrict the use of that interoperability constituent or withdraw or recall the interoperability constituent;
      - (ii) the reasons for taking those steps; and
      - (iii) any measures taken against a person who drew up the declaration.

### PART 4

### Notified and Designated Bodies

### **Notified bodies**

- 31. For the purposes of these Regulations, a notified body is a body which has been—
  - (a) appointed by the Strategic Rail Authority(a) as a notified body and notified to the Commission and other Member States pursuant to regulation 5 of the Railways (Interoperability) (High-Speed) Regulations 2002(b); or
  - (b) appointed by the Secretary of State as a notified body and notified to the Commission and other Member States pursuant to regulation 25 of the Railways (Interoperability) Regulations 2006(c) or regulation 32 of these Regulations; or
  - (c) appointed by a Member State other than the United Kingdom, and notified by the Member State concerned to the Commission and the other Member States pursuant to Article 20(1) of the Conventional Directive and Article 20(1) of the High-Speed Directive; or
  - (d) appointed by a Member State other than the United Kingdom, and notified by the Member State concerned to the Commission and the other Member States pursuant to Article 28(1) of the Directive.

#### Appointment of notified bodies and designated bodies

- **32.**—(1) The Secretary of State may from time to time appoint such persons as the Secretary of State thinks fit to be a notified body or a designated body for the purposes of these Regulations.
- (2) The Secretary of State must not appoint any person as a notified body or a designated body in accordance with paragraph (1) unless the Secretary of State is satisfied that the person is capable of meeting the criteria specified in Schedule 7.
- (3) For the purposes of this regulation Schedule 7 applies to a designated body as it applies to a notified body.
  - (4) An appointment under this regulation—

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<sup>(</sup>a) Established under section 201 of the Transport Act 2000 c.38 and abolished by S.I. 2006/2925.

<sup>(</sup>b) S.I. 2002/1166, revoked with savings by S.I. 2006/397.

<sup>(</sup>c) S.I. 2006/397.

- (a) shall relate to such descriptions of structural subsystems and interoperability constituents of the rail system as the Secretary of State may specify; and
- (b) shall be made subject to such conditions as the Secretary of State may specify, including such conditions as are to apply upon or following termination of the appointment.
- (5) Subject to paragraphs (6)(b) and (c), (7) and (8), an appointment under this regulation shall be for such period as may be specified in the appointment.
  - (6) An appointment shall terminate—
    - (a) upon the expiry of any period specified in the appointment pursuant to paragraph (4);
    - (b) upon the expiry of 90 days notice in writing given by the notified body or the designated body to the Secretary of State; or
    - (c) on any date specified for the termination of the appointment in accordance with paragraphs (7) or (8),

#### whichever is the earliest.

- (7) If at any time it appears to the Secretary of State in relation to a notified body appointed by the Secretary of State or the Strategic Rail Authority or in relation to a designated body that—
  - (a) any of the conditions of the appointment of that body are not being complied with; or
  - (b) the body is not meeting the criteria specified in Schedule 7,

the Secretary of State may, by notice in writing to that body, specify a date on which the appointment of that person as a body shall terminate.

- (8) If at any time it appears to the Secretary of State in relation to a designated body that any of the conditions of the appointment of that designated body are not being complied with the Secretary of State may, by notice in writing to that designated body, specify a date on which the appointment of that person as a designated body shall terminate.
- (9) Before terminating the appointment of a person as a notified body or designated body pursuant to the grounds specified in paragraphs (7) or (8) the Secretary of State must—
  - (a) notify the notified body or designated body that—
    - (i) the Secretary of State is considering terminating the appointment and the reasons why;
    - (ii) the notified or designated body may make written representations within 14 days beginning with the day on which such notice is given;
  - (b) consider any representations made within that period by the notified body or the designated body before making a decision.
- (10) When the appointment of a notified body is terminated in accordance with paragraph (6) the Secretary of State may—
  - (a) give such directions as the Secretary of State considers appropriate, either to that notified body or to another notified body, for the purpose of making such arrangements as may be necessary or expedient for the determination of any matters which would, apart from the termination, have fallen to be determined by the notified body whose appointment has terminated; and
  - (b) without prejudice to the generality of sub-paragraph (a), authorise another notified body, to take over the functions of the notified body whose appointment has terminated, in respect of such matters as the Secretary of State may specify.
- (11) When the appointment of a designated body is terminated in accordance with paragraph (6) the Secretary of State may—
  - (a) give such directions as the Secretary of State considers appropriate, either to that designated body or to another designated body, for the purpose of making such arrangements as may be necessary or expedient for the determination of any matters which would, apart from the termination, have fallen to be determined by the designated body whose appointment has terminated; and

- (b) without prejudice to the generality of sub-paragraph (a), authorise another designated body, to take over the functions of the designated body whose appointment has terminated, in respect of such matters as the Secretary of State may specify.
- (12) The Secretary of State must notify in writing the Commission and other Member States of the appointment or termination of appointment, as the case may be, of a notified body.
- (13) Where it appears to the Secretary of State that a notified body appointed by another Member State fails to meet the criteria set out in Schedule 7, the Secretary of State must notify the Article 21 Committee of that fact forthwith.

### Requirement on notified bodies to carry out functions

- 33.—(1) Where a contracting entity, manufacturer or the manufacturer's authorised representative established in the EU, or other interested person so requests in writing, a notified body must carry out in relation to a structural subsystem or interoperability constituent the procedures and checks (including, where so provided as part of those procedures and checks, surveillance) required to ensure that the contracting entity, manufacturer or the manufacturer's authorised representative established in the EU, or other interested person, duly fulfils the obligations arising from the appropriate verification assessment procedure for a subsystem or the appropriate procedures for assessing the conformity or suitability for use of an interoperability constituent.
  - (2) A notified body shall not be required to comply with a request under paragraph (1) if—
    - (a) the request relates to a subsystem or interoperability constituent of a description to which the appointment of that body does not relate;
    - (b) to do so would place that body in breach of a condition of its appointment;
    - (c) the documents submitted to it in relation to carrying out such functions are not in a language acceptable to that body;
    - (d) the person making the request has not submitted with its request the amount of the fee which that body requires to be submitted with the request pursuant to regulation 37; or
    - (e) at the time of the request the notified body reasonably believes that it will be unable to commence the required work in relation to that request within 3 months of receiving it.
- (3) In this regulation "interested person" means a person who is or expects to be subject to the duties imposed by regulation 26(3).

#### Requirement on bodies to carry out functions relating to notified national technical rules

- **34.**—(1) Where a contracting entity has appointed a body under regulation 7(5) or regulation 16(1)(c) the body must, if requested by the contracting entity, assess conformity with the applicable notified national technical rules.
  - (2) A body shall not be required to comply with a request under paragraph (1) if—
    - (a) the request relates to a subsystem of a description to which the appointment of that body does not relate;
    - (b) to do so would place that body in breach of a condition of its appointment;
    - (c) the documents submitted to it in relation to carrying out such functions are not in a language acceptable to that body;
    - (d) the person making the request has not submitted with its request the amount of the fee which that body requires to be submitted with the request pursuant to regulation 37; or
    - (e) at the time of the request the body reasonably believes that it will be unable to commence the required work in relation to that request within 3 months of receiving it.

### Notified bodies and designated bodies: certificates etc.

- **35.**—(1) Where a notified body proposes to decline to draw up a certificate of verification or an ISV in relation to a project subsystem, or proposes to decline to confirm that an EC declaration of conformity or suitability for use can be drawn up in respect of an interoperability constituent, it must—
  - (a) give notice in writing to the applicant of the reasons why it proposes to do so;
  - (b) give the applicant the opportunity to make representations within a period of 28 days beginning with the day on which such notice is given; and
  - (c) consider any representations made within that period by the applicant before making its decision.
- (2) A notified body must not draw up a certificate of verification in relation to a project subsystem unless satisfied that the subsystem conforms to all applicable TSIs.
- (3) A notified body must not confirm that an EC declaration of conformity or suitability for use can be drawn up in respect of an interoperability constituent unless satisfied that that constituent conforms to such of the European specifications or TSIs as are required by regulation 23.
- (4) Where a body appointed under regulation 7(5) or regulation 16(1)(c) proposes to decline to issue a certificate of conformity with notified national technical rules in relation to a project subsystem it must—
  - (a) give notice in writing to the applicant of the reasons why it proposes to do so;
  - (b) give the applicant the opportunity to make representations within a period of 28 days beginning with the day on which such notice is given; and
  - (c) consider any representations made within that period by the applicant before making its decision.
- (5) A body must not draw up a certificate of conformity with notified national technical rules in relation to a project subsystem unless satisfied that the subsystem conforms to all applicable notified national technical rules.

#### Duties on notified bodies to consult

**36.** Notified bodies appointed by the Strategic Rail Authority or the Secretary of State must consult other notified bodies appointed pursuant to the High-Speed Directive, the Conventional Directive or the Directive throughout the EU in a notified bodies coordination group in relation to the procedures for assessing conformity or suitability for use of interoperability constituents and the verification assessment procedure for subsystems.

### Fees of notified bodies and designated bodies

- **37.**—(1) Subject to paragraph (2), a notified body or a designated body may charge such a fee in connection with, or incidental to, carrying out its functions under regulations 33 to 35 as it may determine.
  - (2) The fee charged pursuant to paragraph (1) must not exceed the sum of the following—
    - (a) the costs incurred or to be incurred by the notified body or the designated body in carrying out relevant work; and
    - (b) an amount of profit which is reasonable in the circumstances having regard to—
      - (i) the character and extent of the work carried out by the notified body or the designated body on behalf of the person commissioning the work; and
      - (ii) the commercial rate normally charged on account of profit for that work or similar work.
- (3) Subject to paragraph (4) the power in paragraph (1) includes the power to require the payment of a fee, or a reasonable estimate of the fee, in respect of the work commissioned in advance of carrying out that work.

(4) Unless the parties otherwise agree, an amount charged in accordance with paragraph (3) must not exceed a reasonable estimate of the fee for the work for the three months subsequent to the request for the advance payment.

### Fees of the Secretary of State

**38.** The Secretary of State may charge such reasonable fee in connection with, or incidental to, carrying out the Secretary of State's functions under regulation 32 as the Secretary of State may determine.

### PART 5

### Registers

### **Register of infrastructure**

- **39.**—(1) An infrastructure manager must keep a register of its infrastructure.
- (2) The infrastructure manager must ensure that the infrastructure register is available on a publicly accessible website.
  - (3) The particulars to be entered in an infrastructure register are—
    - (a) in the case of authorised infrastructure—
      - (i) its basic parameters;
      - (ii) the correlation of those basic parameters with the features laid down by any applicable TSI with which the infrastructure is required to comply;
      - (iii) any information required by any applicable TSI to be recorded in the infrastructure register;
    - (b) in the case of other infrastructure—
      - (i) a description of the features of the infrastructure that do not conform with any TSI against which the infrastructure would be assessed if an application were made under these Regulation for an authorisation; and
      - (ii) any information that would be required by any TSI referred to in paragraph (i) to be recorded in the infrastructure register.
  - (4) The infrastructure manager must update the particulars in the relevant register—
    - (a) each time a structural subsystem for which the infrastructure manager is responsible is authorised under these Regulations;
    - (b) each time authorised infrastructure is taken permanently out of use;
    - (c) each time work is carried out on the infrastructure which results in the registered particulars no longer being accurate;
    - (d) each time the infrastructure manager becomes responsible for infrastructure; or
    - (e) each time a new TSI is adopted or an existing TSI is amended which results in the registered particulars no longer being accurate.
- (5) Within 21 days of an event specified in paragraph (4)(a) to (d), and within 12 months of an event specified in paragraph (4)(e), the infrastructure manager must send to the Competent Authority a copy of the updated infrastructure register and ensure that it is available on a publicly available website.
  - (6) In this regulation—
    - (a) "infrastructure" means a structural subsystem, other than rolling stock; and
    - (b) "authorised infrastructure" means infrastructure authorised to be placed in service under these Regulations and in use on or as part of the rail system.

(7) In its application to infrastructure that is not authorised infrastructure this regulation comes into force on 19th July 2011.

### National vehicle register

- **40.**—(1) This regulation applies to a unit of rolling stock for which there is an authorisation under these Regulations for it to be placed in service.
- (2) A contracting entity in relation to a unit of rolling stock or its owner must apply to the registration body for it to assign a European vehicle number before the unit is placed in service.
- (3) The registration body must assign a European vehicle number to each unit of rolling stock for which an application is made and maintain a register of such rolling stock ("National Vehicle Register").
- (4) In the case of a unit of rolling stock first placed in service outside the United Kingdom and clearly identified by a different coding system, the registration body may assign to it a European vehicle number that is the same as that by which it is identified under the different coding system.
- (5) The registration body may reserve European vehicle numbers for rolling stock whether or not an application has been made.
- (6) Any person who places in service a unit of rolling stock must ensure it is marked with the European vehicle number assigned to it.
- (7) The contracting entity in relation to a unit of rolling stock or the owner of the unit must, no later than 14 days after the date of authorisation, provide particulars to the registration body sufficient to comply with paragraph (8), and such further information as the registration body may reasonably require.
- (8) In respect of each unit rolling stock authorised under these Regulations the registration body must ensure that the National Vehicle Register conforms to the common specifications as set out in the Annex to Commission Decision 2007/756/EC(a) as amended from time to time.
- (9) Where there is a material change to any of the particulars provided under paragraph (7), the owner of the unit of rolling stock must ensure that the registration body is given the particulars of the change and the registration body must alter the National Vehicle Register accordingly.
  - (10) The registration body must make the National Vehicle Register available for inspection—
    - (a) by any safety authority or investigating body designated in Articles 16 and 21 of Directive 2004/49/EC of the European Parliament and of the Council of 29th April 2004 on safety of the Community's railways(**b**);
    - (b) in response to a reasonable request—
      - (i) by any regulatory body designated in article 30 of Directive 2001/14/EC(c) of the European Parliament and of the Council of 21st February 2001 on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification;
      - (ii) by the European Railway Agency;
      - (iii) by railway undertakings;
      - (iv) by infrastructure managers; and
      - (v) by owners of project subsystems.
- (11) In Great Britain the Secretary of State and in Northern Ireland the DRDNI must designate a person to be the registration body from time to time provided that person is independent of any

<sup>(</sup>a) O.J. No. L305, 23.11.2007, p30.

<sup>(</sup>b) O.J. No. L164, 30.4.2004, p44. Directive as amended by Directive 2008/57/EC of the European Parliament and of the Council (O.J. L 191, 18.7.2008, p1), and by Directive 2008/110/EC of the European Parliament and of the Council (O.J. No. L345, 23.12.2008, p62).

<sup>(</sup>c) O.J. No. L75, 15.3.2001, p. 29. Directive as amended by Commission Decision 2002/844/EC (O.J. No. L289, 26.10.2002, p30, Directive 2004/49/EC of the European Parliament and of the Council (O.J. No. L164, 30.4 2004 and Directive 2007/58/EC of the European Parliament and of the Council (O.J. No. L315, 3.12.2007, p44).

railway undertaking; and different persons may be designated to maintain the register in different parts of the United Kingdom.

### PART 6

### Appeals and Enforcement

### **Appeals**

- **41.**—(1) A person who is aggrieved by a decision of the Safety Authority under regulations 5 to 11 may appeal to the Secretary of State.
- (2) For the purposes of paragraph (1) the Secretary of State may, in such cases as the Secretary of State considers it appropriate to do so, having regard to the nature of the questions which appear to the Secretary of State to arise, direct that an appeal under that paragraph shall be determined on the Secretary of State's behalf by a person appointed by the Secretary of State for that purpose.
- (3) Before the determination of an appeal the Secretary of State shall ask the appellant and the Safety Authority whether they wish to appear and be heard on the appeal and—
  - (a) the appeal may be determined without a hearing of the parties if both of them express a wish not to appear and be heard;
  - (b) the Secretary of State shall, if either of the parties expresses a wish to appear and be heard, afford to both of them an opportunity of doing so.
- (4) The Tribunals and Inquiries Act 1992(a) shall apply to a hearing held by a person appointed in pursuance of paragraph (2) to determine an appeal as it applies to a statutory inquiry held by the Secretary of State, but as if in section 10(1) of that Act (statement of reasons for decisions) the reference to any decision taken by the Secretary of State included a reference to a decision taken on the Secretary of State's behalf by that person.
- (5) A hearing held by a person appointed in pursuance of paragraph (2) shall be a statutory inquiry for the purposes of Schedule 7 to the Tribunals, Courts and Enforcement Act 2007(**b**) (functions etc of Administrative Justice and Tribunals Council).
- (6) A person who determines an appeal under this regulation on behalf of the Secretary of State and the Secretary of State, if the Secretary of State determines such an appeal, may give such directions as the person making the determination considers appropriate to give effect to the determination.
- (7) The Secretary of State may pay to any person appointed to hear or determine an appeal under paragraph (2) on the Secretary of State's behalf such remuneration and allowances as the Secretary of State may with the approval of the Treasury determine.
- (8) The Health and Safety Licensing Appeals (Hearing Procedure) Rules  $1974(\mathbf{c})$ , as respects England and Wales, and the Health and Safety Licensing Appeals (Hearing Procedure)(Scotland)( $\mathbf{d}$ ) Rules 1974, as respects Scotland, shall apply to an appeal under paragraph (1) as they apply to an appeal under section 44(1) of the 1974 Act, but with the modification that references to a licensing authority are to be read as references to the Safety Authority.
- (9) Where an appeal is made under paragraph (1), the decision in question shall be suspended pending the final determination of the appeal.
  - (10) This regulation does not apply to a decision of DRDNI under regulations 5 to 11.

<sup>(</sup>a) 1992 c.53.

**<sup>(</sup>b)** 2007 c.15.

<sup>(</sup>c) S.I. 1974/2040.

<sup>(</sup>d) S.I. 1974/2068.

#### **Enforcement in Great Britain**

- **42.**—(1) It is the duty of the Office of Rail Regulation to make adequate arrangements for the enforcement of these Regulations in Great Britain.
- (2) Subject to paragraph (5), the provisions of the 1974 Act specified in paragraph (3) (the "specified provisions") apply for the purposes of the enforcement of these Regulations in Great Britain as if in the specified provision—
  - (a) a reference to the "enforcing authority" was a reference to the Office of Rail Regulation;
  - (b) a reference to the "relevant statutory provisions" was a reference to these Regulations and to the specified provisions; and
  - (c) a reference to "health and safety regulations" was a reference to these Regulations.
  - (3) The provisions of the 1974 Act referred to in paragraph (2) are—
    - (a) sections 19 and 20 (appointment and powers of inspectors)(a), excluding section 20(3);
    - (b) sections 21 and 22 (improvement and prohibition notices)(b);
    - (c) section 23 (provisions supplementary to sections 21 and 22)(c), excluding section 23(3) and (6);
    - (d) section 24 (appeal against improvement and prohibition notices)(d);
    - (e) section 26 (power to indemnify inspectors);
    - (f) section 28 (restrictions on disclosure of information)(e);
    - (g) sections 33(1)(c), (e) to (h), (j) to (o), 34(2) to (4), 36(1) and (2), 37 to 41 and 42(1) to (3) (provision as to offences)(**f**); and
    - (h) section 46 (service of notices).
- (4) The mode of trial and maximum penalty applicable to each offence under section 33 of the 1974 Act so applied and listed in the first column of the following table are set out opposite that offence in the subsequent columns of the table.

Offence	Mode of trial	Penalty on summary conviction	Penalty on conviction on indictment
An offence under section 33(1)(c), (e), (f), (g), (j), (k), (l), (m) or (o).	Summarily or on indictment.	Imprisonment for a term not exceeding 3 months, or a fine not exceeding level 5 on the standard scale as it has effect from time to time (as if the offence was triable only summarily), or both.	Imprisonment for a term not exceeding two years, or a fine, or both.
An offence under section 33(1)(h).	Summarily only.	Imprisonment for a term not exceeding 3 months, or a fine not exceeding level 5 on the standard scale as it	

<sup>(</sup>a) Section 20(7) was amended by the Civil Partnership Act 2004 (c.33), Schedule 27, paragraph 49.

<sup>(</sup>b) Section 22(1) and (2) were amended by, and section 22(4) was substituted by, the Consumer Protection Act 1987 (c.43), Schedule 3.

<sup>(</sup>c) Section 23(4) was amended for England and Wales by the Fire and Rescue Services Act 2004 (c.21), Schedule 1, paragraph 44, and by S.I. 2005/1541. Corresponding amendments were made for Scotland by S.S.I. 2005/383 and S.S.I. 2006/475.

<sup>(</sup>d) Section 24(2) and (4) were amended by the Employment Rights (Dispute Resolution) Act 1998 (c. 8), section 1(2) (a).

<sup>(</sup>e) Section 28(4) was substituted by S.I. 2008/960. Section 28(5) was amended by S.I. 2004/3363. Section 28(9) was inserted by the Employment Protection Act 1975 (c.71), Schedule 15, paragraph 9. There are other amendments to section 28 not relevant to these Regulations.

<sup>(</sup>f) Section 33(1)(c) was amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraph 11, and Schedule 18. Section 33(1)(m) was amended by the Forgery and Counterfeiting Act 1981 (c.45), the Schedule, Part 1.

		has effect from time to time, or both.	
An offence under section 33(1)(n).	Summarily only.	A fine not exceeding level 5 on the standard scale as it has effect from time to time.	

(5) A failure to discharge a duty placed on the Office of Rail Regulation by these Regulations is not an offence under section 33(1)(c) of the 1974 Act.

#### **Enforcement in Northern Ireland**

- **43.**—(1) It is the duty of the Health and Safety Executive for Northern Ireland(a) to make adequate arrangements for the enforcement of these Regulations in Northern Ireland.
- (2) Subject to paragraph (5), the provisions of the Health and Safety at Work (Northern Ireland) Order 1978(b) ("the 1978 Order") specified in paragraph (3) (the "specified provisions") apply for the purposes of the enforcement in Northern Ireland of these Regulations as if the specified provision—
  - (a) a reference to the "enforcing authority" was a reference to the Health and Safety Executive for Northern Ireland;
  - (b) a reference to the "relevant statutory provisions" was a reference to these Regulations and to the specified provisions; and
  - (c) a reference to "health and safety regulations" was a reference to these Regulations.
  - (3) The provisions of the 1978 Order referred to in paragraph (2) are—
    - (a) articles 21 and 22 (appointment and powers of inspectors), excluding article 22(3);
    - (b) articles 23 and 24 (improvement and prohibition notices);
    - (c) article 25 (provisions supplementary to articles 23 and 24), excluding article 25(3);
    - (d) article 26 (appeal against improvement and prohibition notices);
    - (e) article 28 (power to indemnify inspectors);
    - (f) article 30 (restrictions on disclosure of information);
    - (g) articles 31(1)(c), (e) to (h), (j) to (o), 32(2) to (4), 34 (1) and (2), 34A to 38 and 39(1) to (3) (provision as to offences); and
    - (h) article 44(1) to (3) (application to Crown).
- (4) The mode of trial and maximum penalty applicable to each offence under article 31 of the 1978 Order so applied and listed in the first column of the following table are set out opposite that offence in the subsequent columns of the table.

Offence	Mode of trial	Penalty on summary conviction	Penalty on conviction on indictment
An offence under	Summarily or on	Imprisonment for a	Imprisonment for a
article 31(1)(c), (e),	indictment.	term not exceeding 3	term not exceeding

<sup>(</sup>a) Formerly known as the Health and Safety Agency for Northern Ireland which was established under Article 12 of the Health and Safety at Work (Northern Ireland) Order 1978 (S.I. 1978/1039 (N.I. 9)). Article 3(1) of the Health and Safety at Work (Amendment) (Northern Ireland) Order 1998 (S.I. 1998/2795 (N.I. 18)) changed its name to the Health and Safety Executive for Northern Ireland.

<sup>(</sup>b) S.I. 1978/ 1039 (N.I. 9). Article 24 was amended by S.I. 1987/2049 (N.I. 20), Article 28 and Schedule 2, paragraph 3. Article 26 was amended by S.I. 1984/1159 (N.I. 9), Article 35 and Schedule 4. Article 31 was amended by: S.I. 1987/2049 (N.I. 20), Article 28 and Schedule 2 paragraph 7; S.I. 1988/595 (N.I. 3), Article 10(1)(c); S.I. 1986/1883 (N.I. 15), Article 13(3) and Schedule 5; S.I. 1992/1728 (N.I. 17), article 6(1), (3), (4), (5), (7), Article 8 and Schedule 2; S.I. 1998/2795 (N.I. 18), Article 6 and Schedule 1, paragraph 15, and Schedule 2, Forgery and Counterfeiting Act 1981 (c. 45) section 30 and Schedule and the Health and Safety (Offences) Act 2008 (c.20) section 1(3). There are other amendments to the 1978 Order not relevant to these Regulations.

(f), (g), (j), (k), (l), (m) or (o).		months, or a fine not exceeding level 5 on the standard scale as it has effect from time to time (as if the offence was triable only summarily), or both.	two years, or a fine, or both.
An offence under article 31(1)(h).	Summarily only.	Imprisonment for a term not exceeding 3 months, or a fine not exceeding level 5 on the standard scale as it has effect from time to time, or both.	
An offence under article 31(1)(n).	Summarily only.	A fine not exceeding level 5 on the standard scale as it has effect from time to time.	

(5) A failure to discharge a duty placed on the Health and Safety Executive for Northern Ireland by these Regulations is not an offence under article 31(1)(c) of the 1978 Order.

### Notices relating to interoperability constituents not meeting the essential requirements

- **44.**—(1) If the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland is of the opinion that an interoperability constituent in relation to which an EC declaration of conformity or suitability for use has been drawn up does not meet the essential requirements relating to it, the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland may serve a notice on the person who is using or intending to use that interoperability constituent in a project subsystem in relation to which that person is a contracting entity—
  - (a) prohibiting the use of or restricting the area of use of that interoperability constituent, or,
  - (b) where there is a serious risk, requiring the recall or withdrawal of the interoperability constituent.
  - (2) The information to be contained in a notice served under paragraph (1) is—
    - (a) a statement that the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland is of the opinion referred to in paragraph (1);
    - (b) the reasons for that opinion;
    - (c) a direction that the interoperability constituent to which that notice relates must not be used, or that its area of use shall be restricted, or that it must be recalled or withdrawn; and
    - (d) the date by which the contracting entity must comply with the notice.
- (3) Any notice served under paragraph (1) may be withdrawn by the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland by serving written notice of the withdrawal on the contracting entity.
- (4) Where a notice has been served on the contracting entity in accordance with this regulation the contracting entity must—
  - (a) comply with that notice; and
  - (b) notify the person, (if any), who supplied the contracting entity with the interoperability constituent in relation to which the notice under paragraph (1) was served—
    - (i) that a notice under paragraph (1) has been served,
    - (ii) of what the notice says, and

(iii) that the contracting entity requires that person in turn to notify the supplier (if any) with the same information required by this paragraph.

# Notice of improper drawing up of the EC declaration of conformity for an interoperability constituent

- **45.**—(1) Where the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland has reasonable grounds for suspecting that the EC declaration of conformity has not been drawn up in accordance with the requirements of regulation 23 by the manufacturer of the interoperability constituent or the manufacturer's authorised representative established in the EU, it may give notice in writing to the manufacturer or the authorised representative established in the EU.
  - (2) A notice which is given under paragraph (1) shall—
    - (a) state that the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland considers that the EC declaration of conformity has not been properly drawn up in accordance with regulation 23;
    - (b) specify the respect in which it is so considered and give particulars;
    - (c) require the manufacturer or the manufacturer's authorised representative established in the EU—
      - (i) to secure that any interoperability constituent to which the notice relates conforms as regards the provisions concerning the proper drawing up of the declaration within such period as may be specified in the notice,
      - (ii) to provide evidence within that period, to the satisfaction of the Office of Rail Regulation or the Health and Safety Executive for Northern Ireland, as the case may be, that the declaration has been properly drawn up, or
      - (iii) where there is a serious risk, to recall or withdrawal of the interoperability constituent; and
    - (d) inform the manufacturer or the manufacturer's authorised representative established in the EU that if the non-conformity continues (or if satisfactory evidence of conformity has not been provided) within the period specified in the notice, further action may be taken in respect of that non-conformity under these Regulations.
- (3) Where a notice has been served on the manufacturer or the manufacturer's authorised representative established in the EU, the person served must comply or secure compliance with the notice.

### Defence of due diligence

- **46.**—(1) Subject to the following provisions of this regulation, in any proceedings against any person for an offence under these Regulations it shall be a defence for that person to show that the person took all reasonable steps and exercised all due diligence to avoid committing the offence.
- (2) Where in any proceedings against any person for such an offence the defence provided in paragraph (1) involves an allegation that the commission of the offence was due to—
  - (a) the act or default of another; or
  - (b) reliance on information given by another,

that person shall not, without the leave of the court, be entitled to rely on the defence unless, within a period ending 7 clear days before the commencement of the hearing of the proceedings (or in Scotland, the trial diet), the person has served a notice under paragraph (3) on the person bringing the proceedings.

(3) A notice under this paragraph must give such information identifying, or assisting in the identification of, the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time it is served.

- (4) A person shall not be entitled to rely on the defence provided by paragraph (1) by reason of the person's reliance on information supplied by another, unless he shows that it was reasonable in all the circumstances for the person to have relied on the information, having regard in particular—
  - (a) to the steps which the person took, and those which might reasonably have been taken, for the purpose of verifying the information; and
  - (b) to whether the person had any reason to disbelieve the information.

### PART 7

### Supplementary

#### **Deemed authorisation**

- **47.**—(1) A unit of rolling stock to which this paragraph applies is deemed—
  - (a) to have been authorised under these Regulations to be placed in service on the trans-European rail system located in the United Kingdom; and
  - (b) to have been assessed against Part 1 of Schedule 1 to the Rail Vehicle Accessibility Regulations  $2010(\mathbf{a})$ , as notified national technical rules, for that authorisation.
- (2) Paragraph (1) applies to a unit of rolling stock which—
  - (a) is constructed or adapted to transport passengers; and
  - (b) was first brought into use after 31st December 1998 and before 1st August 2006; and
  - (c) is used in the provision of a service for the carriage of passengers on the trans-European rail system located in the United Kingdom.
- (3) In its application to Northern Ireland the reference in paragraph (1)(b) to Part 1 of Schedule 1 of the Rail Vehicle Accessibility Regulations 2010 shall have effect as a reference to the Rail Vehicle Accessibility Regulations (Northern Ireland) 2001(b).
  - (4) Paragraph (2) does not apply to—
    - (a) a unit of rolling stock to the extent that immediately before 7th July 2008 the unit—
      - (i) was authorised under the Railways (Interoperability) Regulations 2006(c); and
      - (ii) had been assessed against the Rail Vehicle Accessibility Regulations 1998(**d**) as in force when the unit was assessed, or the Rail Vehicle Accessibility Regulations (Northern Ireland) 2001, for that authorisation; or
    - (b) a unit of rolling stock which belongs to a class of rolling stock first brought into use on or before 31<sup>st</sup> December 1998.
  - (5) Nothing in this regulation prejudices the application of—
    - (a) regulation 48; and
    - (b) regulation 4(1) to any upgrading or renewal of rolling stock to which paragraph (2) applies.

**(b)** S.R. (N.I.) 2001 No. 264.

(d) S.I. 1998/2456, amended by S.I. 2000/3215 and S.I. 2008/1746 and revoked by S.I. [].

<sup>(</sup>a) S.I. [ ]

<sup>(</sup>c) S.I. 2006/397, as amended by S.I. 2007/3386. S.I. 2006/397 was also amended by the Rail Vehicle Accessibility (Interoperable Rail System) Regulations 2008 (S.I. 2008/1746), but as those amendments came into force on 7th July 2008 they are not relevant to paragraph (4)(a)(i). Regulation 40(6) of S.I. 2006/397 provides for authorisations under the Railways (Interoperability)(High-Speed) Regulations 2002 (2002/1166) to be treated as an authorisation under S.I. 2006/397. Consequently the reference in paragraph (4)(a)(i) to a unit being authorised under the Railways (Interoperability) Regulations 2006 does not include a unit deemed to be authorised by virtue if regulation 4A of those Regulations, but does include a unit that was previously authorised under the Railways (Interoperability)(High-Speed) Regulations 2002.

#### Accessibility for people with reduced mobility

- **48.** No person shall use rolling stock in the provision of a service for the carriage of passengers on the trans-European rail system located in the United Kingdom on or after 1<sup>st</sup> January 2020 unless it has been constructed, renewed, upgraded or modified to comply with the technical standards, and is operated to comply with the operational standards, required by—
  - (a) the TSI relating to persons with reduced mobility set out in the Annex to Decision 2008/164/EC of the European Commission of 21<sup>st</sup> December 2007(**a**), or any amended version of it, or any TSI which replaces it; or
  - (b) Part 1 of Schedule 1 to the Rail Vehicle Accessibility Regulations 2010; or
  - (c) The Rail Vehicle Accessibility Regulations (Northern Ireland) 2001; or
  - (d) the TSI, or amended version of it or TSI replacing it, referred to in paragraph (a) except to the extent that—
    - (i) the rolling stock or its operation complies with the technical or operational standards required by the provisions referred to in paragraphs (b) or (c), and
    - (ii) a derogation from part of it has been granted under regulation 14, and
    - (iii) a determination that part of it does not apply has been made under regulation 13(9).

### Dispensation from notified national technical rule

- **49.**—(1) The Competent Authority may grant a conditional or unconditional dispensation from notified national technical rules.
- (2) This regulation does not apply to the Rail Vehicle Accessibility Regulations 2010 or the Rail Vehicle Accessibility regulations (Northern Ireland) 2001.

#### **Revocation and savings**

- **50.**—(1) The Railways (Interoperability) Regulations 2006, the Railways (Interoperability) (Amendment) Regulations 2007 and regulation 4 of the Rail Vehicle Accessibility (Interoperable Rail System) 2008(**b**) (together "the 2006 Regulations") are revoked.
- (2) Where immediately before 19th July 2010 an appointment of a notified body had effect under the 2006 Regulations it shall continue to have effect as if made as an appointment under regulation 32 of these Regulations for the period specified when appointed.
- (3) Where, under the 2006 Regulations, a structural subsystem has been authorised to be placed in service on the rail system or an interoperability constituent is placed on the market with a view to use on the rail system, it shall from 19th July 2010, be treated as authorised or placed on the market, as the case may be, under these Regulations.
- (4) Regulation 4(8), (9) and (9A) of the 2006 Regulations shall continue to have effect in relation to a contract made before 19th July 2010.
- (5) A derogation granted by the Secretary of State in accordance with the High-Speed Directive or a derogation granted by the Competent Authority in accordance with the Conventional Directive is treated under these Regulations as a derogation granted under regulation 13.

Signed by authority of the Secretary of State for Transport

Name
Parliamentary Under Secretary of State
Department for Transport

Date

<sup>(</sup>a) O.J. No. L64, 7.3.08, p72.

<sup>(</sup>b) S.I. 2006/397 was amended by S.I. 2007/3386 and by regulation 4 of S.I. 2008/1746

# Scope

### Trans-European conventional rail system

#### Network

**1.**—(1) The network of the trans-European conventional rail system will be that on the conventional lines of the trans-European transport network identified in Decision No 1692/96/EC(**a**).

For the purposes of the Directive, this network may be subdivided into the following categories—

lines intended for passenger services;

lines intended for mixed traffic (passengers and freight);

lines specially designed or upgraded for freight services;

passenger hubs;

freight hubs, including intermodal terminals;

lines connecting the abovementioned elements.

This network includes traffic management, tracking and navigation systems, technical installations for data processing and telecommunications intended for long-distance passenger services and freight services on the network in order to guarantee the safe and harmonious operation of the network and efficient traffic management.

#### Vehicles

(2) The trans-European conventional rail system shall comprise all the vehicles likely to travel on all or part of the trans-European conventional rail network, including—

self-propelling thermal or electric trains;

thermal or electric traction units;

passenger carriages;

freight wagons, including rolling stock designed to carry lorries.

Mobile railway infrastructure construction and maintenance equipment may be included.

Each of the above categories is subdivided into—

vehicles for international use;

vehicles for national use.

### Trans-European high-speed rail system

#### Network

**2.**—(1) The network of the trans-European high-speed rail system shall be that of the high-speed lines of the trans-European transport network identified in Decision No 1692/96/EC.

The high-speed lines shall comprise—

specially built high-speed lines equipped for speeds generally equal to or greater than 250 km/h,

specially upgraded high-speed lines equipped for speeds of the order of 200 km/h,

<sup>(</sup>a) O.J. No. L228, 9.9.1996, p1. Decision as amended by Decision No 1346/2001/EC (O.J. No. L185, 6.7.2001, p1), Decision 884/2004/EC (O.J. No. L167, 30.4.2004, p1) and Council Regulation (EC) No 1791/2006 (O.J. No. L363, 20.12.2006, p1).

specially upgraded high-speed lines which have special features as a result of topographical, relief or town-planning constraints, on which the speed must be adapted to each case. This category also includes interconnecting lines between the high-speed and conventional networks, lines through stations, accesses to terminals, depots, etc. travelled at conventional speed by "high speed" rolling stock.

This network includes traffic management, tracking and navigation systems, technical installations for data processing and telecommunications intended for services on these lines in order to guarantee the safe and harmonious operation of the network and efficient traffic management.

#### Vehicles

(2) The trans-European high-speed rail system shall comprise vehicles designed to operate—

either at speeds of at least 250 km/h on lines specially built for high speeds, while enabling operation at speeds exceeding 300 km/h in appropriate circumstances,

or at speeds of the order of 200 km/h on the lines of sub-paragraph(1), where compatible with the performance levels of these lines.

In addition, vehicles designed to operate with a maximum speed lower than 200 km/h which are likely to travel on all or part of the trans-European high-speed network, where compatible with the performance levels of this network, shall fulfil the requirements ensuring safe operation on this network. To this end, the TSIs for conventional vehicles shall also specify requirements for safe operation of conventional vehicles on high-speed networks.

### Compatibility of the railway system

**3.** The quality of rail services in Europe depends, inter alia, on excellent compatibility between the characteristics of the network (in the broadest sense, i.e. the fixed parts of all the subsystems concerned). Performance levels, safety, quality of service and cost depend upon that compatibility.

### Extension of the scope

Subcategories of network and vehicles

**4.**—(1) The scope of the TSIs shall be progressively extended to the whole rail system as referred to in Article 1(4) of the Directive. In order to deliver interoperability cost-effectively further subcategories of all categories of network and vehicles mentioned in this Schedule will, where necessary, be developed. If necessary, the functional and technical specifications mentioned in Article 5(3) of the Directive may vary according to the subcategory.

#### Cost safeguards

(2) The cost-benefit analysis of the proposed measures will take into consideration, among others, the following—

cost of the proposed measure,

benefits to interoperability of an extension of the scope to particular subcategories of networks and vehicles,

reduction of capital costs and charges due to economies of scale and better utilisation of vehicles,

reduction of investment and maintenance/operating costs due to increased competition between manufacturers and maintenance companies,

environmental benefits, due to technical improvements of the rail system,

increase of safety in operation.

In addition, this assessment will indicate the likely impact for all the operators and economic agents involved.

### **SCHEDULE 2**

# Subsystems

### List of subsystems

- **1.** For the purposes of the Directive, the system constituting the rail system may be broken down into the following subsystems, either:
  - (a) structural areas:

infrastructure,

energy,

control and command and signalling,

rolling stock, or

(b) functional areas:

traffic operation and management,

maintenance,

telematics applications for passenger and freight services.

### **Description of the subsystems**

**2.** For each subsystem or part of a subsystem, the list of constituents and aspects relating to interoperability is proposed by the European Railway 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, in particular:

#### 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.

### Energy

The electrification system, including overhead lines and on-board parts of the electric consumptions measuring equipment.

Control-command and signalling

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

Operation and traffic management

The procedures and related equipment enabling a coherent operation of the different structural subsystems, both during normal and degraded operation, including in particular training and train driving, traffic planning and management. The professional qualifications which may be required for carrying out cross-border services.

### Telematics applications

In accordance with Schedule 1, this subsystem comprises two elements:

(a) applications for passenger services, including systems providing 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 (real-time 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.

### Rolling stock

Structure, command and control system for all train equipment, current-collection devices, traction and energy conversion units, 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.

#### Maintenance

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

## Essential requirements

#### **General requirements**

#### Safety

- 1.—(1) The design, construction or assembly, maintenance and monitoring of safety-critical components and, more particularly, of the components involved in train movements must be such as to guarantee safety at the level corresponding to the aims laid down for the network, including those for specific degraded situations.
- (2) The parameters involved in the wheel/rail contact must meet the stability requirements needed in order to guarantee safe movement at the maximum authorised speed. The parameters of brake equipment must guarantee that it is possible to stop within a given brake distance at the maximum authorised speed.
- (3) The components used must withstand any normal or exceptional stresses that have been specified during their period in service. The safety repercussions of any accidental failures must be limited by appropriate means.
- (4) The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting the generation, propagation and effects of fire and smoke in the event of a fire
- (5) Any devices intended to be handled by users must be so designed as not to impair the safe operation of the devices or the health and safety of users if used in a foreseeable manner, albeit not in accordance with the posted instructions.

### Reliability and availability

**2.** The monitoring and maintenance of fixed or movable components that are involved in train movements must be organised, carried out and quantified in such a manner as to maintain their operation under the intended conditions.

#### Health

- **3.**—(1) Materials likely, by virtue of the way they are used, to constitute a health hazard to those having access to them must not be used in trains and railway infrastructures.
- (2) Those materials must be selected, deployed and used in such a way as to restrict the emission of harmful and dangerous fumes or gases, particularly in the event of fire.

#### Environmental protection

- **4.**—(1) The environmental impact of establishment and operation of the rail system must be assessed and taken into account at the design stage of the system in accordance with the Community provisions in force.
- (2) The materials used in the trains and infrastructures must prevent the emission of fumes or gases which are harmful and dangerous to the environment, particularly in the event of fire.
- (3) The rolling stock and energy-supply systems must be designed and manufactured in such a way as to be electromagnetically compatible with the installations, equipment and public or private networks with which they might interfere.
  - (4) Operation of the rail system must respect existing regulations on noise pollution.
- (5) Operation of the rail system must not give rise to an inadmissible level of ground vibrations for the activities and areas close to the infrastructure and in a normal state of maintenance.

#### Technical compatibility

**5.** The technical characteristics of the infrastructure and fixed installations must be compatible with each other and with those of the trains to be used on the rail system. If compliance with these characteristics proves difficult on certain sections of the network, temporary solutions, which ensure compatibility in the future, may be implemented.

#### Requirements specific to each subsystem

Infrastructure

Safety

**6.** Appropriate steps must be taken to prevent access to or undesirable intrusions into installations.

Steps must be taken to limit the dangers to which persons are exposed, particularly when trains pass through stations.

Infrastructure to which the public has access must be designed and made in such a way as to limit any human safety hazards (stability, fire, access, evacuation, platforms, etc.).

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels and viaducts.

#### Energy

Safety

7.—(1) Operation of the energy-supply systems must not impair the safety either of trains or of persons (users, operating staff, trackside dwellers and third parties).

#### Environmental protection

(2) The functioning of the electrical or thermal energy-supply systems must not interfere with the environment beyond the specified limits.

#### Technical compatibility

(3) The electricity/thermal energy supply systems used must:

enable trains to achieve the specified performance levels;

in the case of electricity energy supply systems, be compatible with the collection devices fitted to the trains.

## Control-command and signalling

Safety

**8.**—(1) The control-command and signalling installations and procedures used must enable trains to travel with a level of safety which corresponds to the objectives set for the network. The control-command and signalling systems should continue to provide for safe passage of trains permitted to run under degraded conditions.

## **Technical Compatibility**

(2) All new infrastructure and all new rolling stock manufactured or developed after adoption of compatible control-command and signalling systems must be tailored to the use of those systems. The control-command and signalling equipment installed in the train drivers' cabs must permit normal operation, under the specified conditions, throughout the rail system.

#### Rolling stock

Safety

**9.**—(1) The rolling stock structures and those of the links between vehicles must be designed in such a way as to protect the passenger and driving compartments in the event of collision or derailment.

The electrical equipment must not impair the safety and functioning of the control-command and signalling installations.

The braking techniques and the stresses exerted must be compatible with the design of the tracks, engineering structures and signalling systems.

Steps must be taken to prevent access to electrically-live constituents in order not to endanger the safety of persons.

In the event of danger devices must enable passengers to inform the driver and accompanying staff to contact him.

The access doors must incorporate an opening and closing system which guarantees passenger safety.

Emergency exits must be provided and indicated.

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels.

An emergency lighting system of sufficient intensity and duration is an absolute requirement on board trains.

Trains must be equipped with a public address system which provides a means of communication to the public from on-board staff.

#### Reliability and availability

(2) The design of the vital equipment and the running, traction and braking equipment and also the control and command system must, in a specific degraded situation, be such as to enable the train to continue without adverse consequences for the equipment remaining in service.

## Technical compatibility

(3) The electrical equipment must be compatible with the operation of the control-command and signalling installations.

In the case of electric traction, the characteristics of the current-collection devices must be such as to enable trains to travel under the energy-supply systems for the rail system.

The characteristics of the rolling stock must be such as to allow it to travel on any line on which it is expected to operate, taking account of relevant climatic conditions.

#### Controls

(4) Trains must be equipped with a recording device. The data collected by this device and the processing of the information must be harmonised.

#### Maintenance

#### Health and safety

**10.**—(1) The technical installations and the procedures used in the centres must ensure the safe operation of the subsystem and not constitute a danger to health and safety.

#### Environmental protection

(2) The technical installations and the procedures used in the maintenance centres must not exceed the permissible levels of nuisance with regard to the surrounding environment.

#### Technical compatibility

(3) The maintenance installations for rolling stock must be such as to enable safety, health and comfort operations to be carried out on all stock for which they have been designed.

#### Operation and traffic management

#### Safety

11.—(1) Alignment of the network operating rules and the qualifications of drivers and on-board staff and of the staff in the control centres must be such as to ensure safe operation, bearing in mind the different requirements of cross-border and domestic services.

The maintenance operations and intervals, the training and qualifications of the maintenance and control centre staff and the quality assurance system set up by the operators concerned in the control and maintenance centres must be such as to ensure a high level of safety.

#### Reliability and availability

(2) The maintenance operations and periods, the training and qualifications of the maintenance and control centre staff and the quality assurance system set up by the operators concerned in the control and maintenance centres must be such as to ensure a high level of system reliability and availability.

## Technical compatibility

(3) Alignment of the network operating rules and the qualifications of drivers, on-board staff and traffic managers must be such as to ensure operating efficiency on the rail system, bearing in mind the different requirements of cross-border and domestic services.

#### Telematics applications for freight and passengers

#### Technical compatibility

**12.**—(1) The essential requirements for telematics applications guarantee a minimum quality of service for passengers and carriers of goods, particularly in terms of technical compatibility.

#### Steps must be taken to ensure:

that the databases, software and data communication protocols are developed in a manner allowing maximum data interchange between different applications and operators, excluding confidential commercial data;

easy access to the information for users.

#### Reliability and availability

(2) The methods of use, management, updating and maintenance of these databases, software and data communication protocols must guarantee the efficiency of these systems and the quality of the service.

#### Health

(3) The interfaces between these systems and users must comply with the minimum rules on ergonomics and health protection.

#### Safety

(4) Suitable levels of integrity and dependability must be provided for the storage or transmission of safety related information.

## SCHEDULE 4

regulation 2(2)

# EC declaration of conformity and suitability for use of interoperability constituents

#### **Interoperability constituents**

The EC declaration applies to the interoperability constituents involved in the interoperability of the rail system, as referred to in article 3 of the Directive. These interoperability constituents may be:

#### Multiple-use constituents

(a) These are constituents that are not specific to the rail system and which may be used as such in other areas.

Multiple-use constituents having specific characteristics

(b) These are constituents which are not, as such, specific to the rail system, but which must display specific performance levels when used for railway purposes.

## Specific constituents

(c) These are constituents that are specific to railway applications.

#### Scope

The EC declaration covers:

- either the assessment by a notified body or bodies of the intrinsic conformity of an interoperability constituent, considered in isolation, to the technical specifications to be met;
- or the assessment/judgement by a notified body or bodies of the suitability for use of an interoperability constituent, considered within its railway environment and, in particular in cases where the interfaces are involved, in relation to the technical specifications, particularly those of a functional nature, which are to be checked.

The assessment procedures implemented by the notified bodies at the design and production stages will draw upon the modules defined in Decision 768/2008/EC(a), in accordance with the conditions referred to in the TSIs.

#### Contents of the EC declaration

The EC declaration of conformity or of suitability for use and the accompanying documents must be dated and signed.

That declaration must be written in the same language as the instructions and must contain the following:

the Directive references;

the name and address of the manufacturer or its authorised representative established within the EU (give trade name and full address, in the case of the authorised representative, also give the trade name of the manufacturer);

description of interoperability constituent (make, type, etc.);

description of the procedure followed in order to declare conformity or suitability for use (article 13 of the Directive);

all the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use;

name and address of the notified body or bodies involved in the procedure followed in respect of conformity or suitability for use and date of examination certificate together with, where appropriate, the duration and conditions of validity of the certificate;

where appropriate, reference to the European specifications;

identification of the signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative established within the EU.

## SCHEDULE 5

Regulation 2(2)

# EC declaration of verification of subsystems

The EC declaration of verification and the accompanying documents must be dated and signed. That declaration must be written in the same language as the technical file and must contain the following:

the Directive references;

name and address of the contracting entity or the manufacturer or its authorised representative established within the EU (give trade name and full address; in the case of the authorised representative, also give 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 of the Directive;

the references of the documents contained in the technical file;

all the relevant temporary or definitive 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.

## EC verification procedure for subsystems

#### Introduction

**1.** 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.

## **Stages**

**2.** 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.

#### Certificate

**3.** 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 account the ISVs, and, in order to issue the EC verification, it checks that the subsystem:

- (a) is covered by relevant design and production ISVs, if the applicant has asked the notified body for these two phases, or
- (b) 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 requirements of the TSI and assesses the design and production elements that are not covered by the design and /or production ISV(s).

#### **Technical file**

**4.** 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 of the Directive, 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 the 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).

#### **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.
- (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.
- (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.
- (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) With a view to deliver the EC declaration of suitability for use referred to in the section headed "Scope" in Schedule 4, 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.

#### **Submission**

**6.** 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 State which so requests.

#### **Publication**

**7.** 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.

## 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.

# Minimum criteria which must be taken into account by the Member States when Notifying Bodies

- 1. The body, its Director and the staff responsible for carrying out the checking operations may not become involved either directly or as authorised representatives in the design, manufacture, construction, marketing or maintenance of the interoperability constituents or subsystems or in their use. This does not exclude the possibility of an exchange of technical information between the manufacturer and that body.
- 2. The body and the staff responsible for the checks must carry out the checks with the greatest possible professional integrity and the greatest possible technical competence and must be free of any pressure and incentive, in particular of a financial type, which could affect their judgement or the results of their inspection, in particular from persons or groups of persons affected by the results of the checks.

In particular, the body and the staff responsible for the checks must be functionally independent of the authorities designated to issue authorisations for placing in service in the framework of the Directive, licences in the framework of Directive 95/18/EC(a) and safety certificates in the framework of Directive 2004/49/EC(b), and of the bodies in charge of investigations in the event of accidents.

- **3.** The body must employ staff and possess the means required to perform adequately the technical and administrative tasks linked with the checks; it should also have access to the equipment needed for exceptional checks.
  - **4.** The staff responsible for the checks must possess:
    - proper technical and vocational training;
    - a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks;
    - the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.
- **5.** The independence of the staff responsible for the inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.
- **6.** The body must take out civil liability insurance unless that liability is covered by the State under national law or unless the checks are carried out directly by that Member State.
- **7.** The staff of the body are bound by professional secrecy with regard to everything they learn in the performance of their duties (with the exception of the competent administrative authorities and accident investigation bodies in the State where they perform those activities as well as accident investigation bodies responsible for the investigation of accidents caused by the failure of the interoperability constituents or subsystems checked) in pursuance of the Directive or any provision of national law implementing the Directive.

<sup>(</sup>a) O.J. No. L143, 27.6.1995, p70. Directive as amended by Directive 2001/13/EC of the European Parliament and of the Council (O.J. L75, 15.3.2001, p26), and by Directive 2004/49/EC of the European Parliament and of the Council (O.J. No. L164, 30.4.2004, p44).

<sup>(</sup>b) O.J. No. L164, 30.4.2004, p44. Directive as amended by Directive 2008/57/EC of the European Parliament and of the Council (O.J. No. L191, 18.7.2008, p1), and by Directive 2008/110/EC of the European Parliament and of the Council (O.J. No. L345, 23.12.2008, p62).

## **SCHEDULE 8**

Regulation2(2)

## File for submitting a derogation

When submitting a request for a derogation, the Member State must supply the following documents:

- (a) A formal letter communicating the propose derogation to the Commission;
- (b) A file, annexed to the letter, comprising at least:
  - (i) a description of the work, goods and services subject to the derogation, specifying the key dates, the geographical location and the operational and technical area,
  - (ii) a precise reference to the TSIs (or their parts) for which a derogation is requested,
  - (iii) a precise reference to and details of the alternative provisions which will be applied,
  - (iv) for requests made under article 7(1)(a) of the Directive, justification of the advanced stage of development of the project,
  - (v) justification of the derogation, including the main reasons of a technical, economic, commercial, operational and/or administrative nature,
  - (vi) any other information justifying the request for a derogation,
  - (vii) a description of the measures that the Member State proposes to take in order to promote the final interoperability of the project. In the case of a minor derogation, this description is not required.

Documentation must be supplied in paper form and as electronic files so that it can be distributed among the members of the Committee.

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations implement the provisions of Directive 2008/57/EC (the "Directive") of the European Parliament and of the Council of 17th June 2008 (O.J. No. L191, 18.7.2008, p1, as amended by Commission Directive 2009/131/EC O.J. No. L273, 17.10.2009, p12) on the interoperability of the rail system within the Community (now the EU).

The Directive is a recast of two earlier rail interoperability Directives, which are repealed with effect from 19 July 2010. The two earlier Directives, defined in *regulation 2* as the Conventional Directive and the High-Speed Directive, were implemented in the United Kingdom by the Railways (Interoperability) Regulations 2006 (the "2006 Regulations") (S.I. 2006/397, as amended by S.I. 2007/3386 and S.I. 2008/1746). These Regulations in effect consolidate and where necessary, amend the 2006 Regulations. The 2006 Regulations are, therefore, revoked subject to appropriate savings being made (*regulation 50*). The substantive changes from the 2006 Regulations are explained in the Explanatory Memorandum, which is published on the Office of Public Sector Information website www.opsi.gov.uk.

Regulation 3 provides for the application of the Regulations, including provisions for parts of the of the United Kingdom rail system to be excluded from the scope of the Regulations. These exclusion provisions are subject to voluntary arrangements provided for in regulation 5.

Regulation 4 restricts the placing in service of structural subsystems (e.g. infrastructure, rolling stock) that are new or have undergone major renewal or upgrade. Only those authorised by the Safety Authority or ruled by the Competent Authority as not requiring authorisation (regulation 13) or, in the case of rolling stock, having a valid authorisation for another Member State may be placed in service. In Great Britain the Safety Authority is the Office of Rail Regulation, except in relation to the Channel Tunnel system where it is the Intergovernmental Commission. In Northern Ireland it is the Department for Regional Development in Northern Ireland ("DRDNI"). The Competent Authority means the Secretary of State in Great Britain, except in relation to the Channel Tunnel system where it is the Intergovernmental Commission, and the DRDNI in Northern Ireland. If the Competent Authority has published an implementation plan for a TSI, a project or type of project is deemed to be a project for the major renewal or upgrading of a subsystem if it is named or described in a list in the implementation plan (regulation 12).

Regulation 5 and regulations 16 to 19 set out the process for making an application to the Safety Authority for authorisation, the information that must be provided and the assessments that must be undertaken. These include assessments in relation to EU technical standards (TSIs) and, if any national technical rules have been notified to the Commission, assessments in relation to those rules. The Competent Authority may grant derogations from the application of TSIs in the circumstances set out in regulation 14.

Regulation 6 provides that in authorising the placing in service of a subsystem, the Safety Authority must be satisfied that the contracting entity (effectively the party procuring the work) has drawn up a verification declaration in accordance with regulation 16, and that the subsystem has been designed, constructed and installed so as to meet the essential requirements in accordance with regulation 15 when so placed into service and is compatible with the relevant part of the rail system.

If an authorisation is sought in respect of rolling stock that is authorised for use in another Member State the authorisation process is modified by *regulation* 7.

*Regulation 8* provides that the Safety Authority must make a determination of type that describes the basic design characteristics of a rolling stock subsystem for which an authorisation has been issued.

Where a determination of type has been made a potentially less onerous process for obtaining an authorisation of a subsystem that conforms to the determination is available under *regulations 9* and 10.

Regulation 11 provides that the Safety Authority may revoke an authorisation and the process for making a revocation decision.

Regulation 20 places obligations on the operator of an authorised subsystem that has been placed in service to continue to meet the essential requirements, TSIs and notified national technical rules.

Regulations 21 and 22 permit the Safety Authority and the Competent Authority to charge for certain work (but not in relation to the Channel Tunnel system).

Part 3 contains requirements for "interoperability constituents". These are components of a subsystem that must satisfy requirements to be placed on the railway market for use in the rail system.

Part 4 concerns the bodies responsible for assessing conformity of subsystems and interoperability constituents to the relevant standards, called "notified bodies", or, in the case of the assessment of notified national technical rules "designated bodies". Provision for the recovery of fees by notified bodies, designated bodies and the Secretary of State are contained in *regulations 37 and 38*.

Part 5 contains provisions for the keeping of registers of infrastructure (regulation 39) and a National Vehicle Register (regulation 40). Authorised rolling stock vehicles are issued with a vehicle number.

Enforcement and appeal provisions are set out in *Part 6*. The recall and withdraw notice powers in *regulations 44 and 45* give effect, in relation to the part that needs to be transposed for these Regulations, to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ No. L218 13/8/2008 p.30 – see Article 20(1)).

Part 7 contains supplementary provisions. Passenger rail vehicles falling under regulation 47 are to be authorised and assessed against notified national technical rules relating to rail vehicle accessibility. All passenger rail vehicles operated on the United Kingdom's part of the trans-European rail system must comply with accessibility standards by 2020 (regulation 48).

Regulation 49 enables dispensations from notified national technical rules to be granted.

A list of TSIs and of notified national technical rules applying in Great Britain can be obtained from the Department for Transport, Great Minster House, 76 Marsham Street, London SW1P 4DR and those applying in Northern Ireland can be obtained from the Department for Regional Development, River House, 48 High Street, Belfast, BT1 2AR.

A copy of the Impact Assessment and Transposition Note prepared in respect of these Regulations can be accessed on the Office of Public Information website at www.opsi.gov.uk.