

## II

(Non-legislative acts)

## DECISIONS

## COMMISSION DECISION

of 9 November 2010

**on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council**

(notified under document C(2010) 7582)

(Text with EEA relevance)

(2010/713/EU)

THE EUROPEAN COMMISSION,

‘control-command and signalling’ of the trans-European conventional rail system.

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

Having regard to Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community <sup>(1)</sup>, and in particular Article 5(3)(e) and Article 6(1) thereof,

Whereas:

(1) Technical specifications for interoperability (TSIs) are specifications adopted in accordance with Directive 2008/57/EC. TSIs set all the conditions with which interoperability constituents and subsystems must conform, and the procedures to be followed in assessing conformity and suitability for use of interoperability constituents and EC verification of subsystems.

(2) Commission Decision 2006/66/EC <sup>(2)</sup> established the modules to be used for conformity assessment of interoperability constituents and EC verification of subsystems of the technical specification for interoperability (TSI) ‘rolling stock-noise’, Commission Decision 2006/861/EC <sup>(3)</sup> did the same for the TSI ‘rolling stock-freight wagons’ and Commission Decision 2006/679/EC <sup>(4)</sup> established modules for the TSI

(3) Commission Decisions 2008/217/EC <sup>(5)</sup>, 2008/284/EC <sup>(6)</sup>, 2008/232/EC <sup>(7)</sup> and 2006/860/EC <sup>(8)</sup> established the modules to be used for conformity assessment of interoperability constituents and EC verification of subsystems of the TSI ‘infrastructure’, the TSI ‘energy’, the TSI rolling stock and the TSI ‘control-command and signalling’ of the trans-European high-speed rail system respectively.

(4) Commission Decisions 2008/163/EC <sup>(9)</sup> and 2008/164/EC <sup>(10)</sup> established the modules to be used for conformity assessment of interoperability constituents and EC verification of subsystems for the TSI ‘safety in railway tunnels’ and for the TSI ‘people with reduced mobility’ of the trans-European conventional and high-speed rail system respectively.

(5) In accordance with Article 5(3)(e) of Directive 2008/57/EC, TSIs have to refer to modules set out in Council Decision 93/465/EEC <sup>(11)</sup>. That Decision has been repealed by Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products <sup>(12)</sup>, and lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for drawing up, revision or recasts of that legislation.

<sup>(1)</sup> OJ L 191, 18.7.2008, p. 1.

<sup>(2)</sup> OJ L 37, 8.2.2006, p. 1.

<sup>(3)</sup> OJ L 344, 8.12.2006, p. 1.

<sup>(4)</sup> OJ L 284, 16.10.2006, p. 1.

<sup>(5)</sup> OJ L 77, 19.3.2008, p. 1.

<sup>(6)</sup> OJ L 104, 14.4.2008, p. 1.

<sup>(7)</sup> OJ L 84, 26.3.2008, p. 132.

<sup>(8)</sup> OJ L 342, 7.12.2006, p. 1.

<sup>(9)</sup> OJ L 64, 7.3.2008, p. 1.

<sup>(10)</sup> OJ L 64, 7.3.2008, p. 72.

<sup>(11)</sup> OJ L 220, 30.8.1993, p. 23.

<sup>(12)</sup> OJ L 218, 13.8.2008, p. 82.

- (6) However, a specific comprehensive legal framework is already in place for the railway sector which necessitates specific adaptation of the modules of Decision No 768/2008/EC. In particular, the provisions of Directive 2008/57/EC related to conformity assessment and suitability for use of interoperability constituents and EC verification of subsystems require specific adaptation of the modules set out in Annex II to Decision No 768/2008/EC.
- (7) As specific features of rail must be taken into account to ensure consistency of all legislative acts concerning interoperability constituents and subsystems, it is appropriate to lay down modules which are specific for railways.
- (8) To establish a common set of modules for all TSIs it is necessary to introduce them in one legislative act. This Decision should provide such a common set of modules which should enable the legislator to choose the appropriate procedures for conformity assessment, suitability for use and EC verification when drafting or revising TSIs.
- (9) The TSIs which are in force on the date this Decision becomes applicable, should not apply the modules provided for in this Decision until their revision and should be allowed to continue to apply the modules for conformity assessment and suitability for use of interoperability constituents and EC verification of subsystems as defined in the relevant annexes to those TSIs. However, when those TSIs will be revised they should fall within the scope of this Decision.
- (10) In order to provide a better comprehension, a list of terms used in the conformity assessment modules specific for railways and their equivalent in generic modules defined in Decision No 768/2008/EC should be attached to this Decision. Furthermore, a correlation table of the modules used in the TSIs referred to in recitals 2 to 4, the modules used in Decision No 768/2008/EC and the specific modules for railways set out in Annex I to this Decision should be set up.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 29(1) of Directive 2008/57/EC,

verification of subsystems, as set out in Annex I, are hereby adopted.

A list of terms used in the conformity assessment modules specific for railways and their equivalent in generic modules defined in Decision No 768/2008/EC is set out in Annex II.

A correlation table of the modules used is attached in Annex III.

#### Article 2

##### Scope

The modules shall be applicable to all TSIs which enter in force on or after the date referred to in Article 8.

#### Article 3

##### Definitions

For the purposes of this Decision, the following definitions shall apply:

1. 'technical specification for interoperability' (TSI) means a specification adopted in accordance with Directive 2008/57/EC by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system;
2. 'vehicle' means a railway vehicle that runs on its own wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems or parts of such subsystems;
3. 'subsystems' means the result of the division of the rail system, as shown in Annex II to Directive 2008/57/EC;
4. 'interoperability constituents' means any elementary component, group of components, sub-assembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly. The concept of a 'constituent' covers both tangible objects and intangible objects such as software;
5. 'applicant' means contracting entity or manufacturer;
6. 'contracting entity' means any entity, whether public or private, which orders the design and/or construction or the renewal or upgrading of a subsystem. This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for carrying out a project;

HAS ADOPTED THIS DECISION:

#### Article 1

##### Subject matter

The modules for procedures for assessment of conformity and suitability for use of the interoperability constituents and for EC

7. 'notified bodies' means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the 'EC' procedure for verification of the subsystems;
8. 'harmonised standard' means any European standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services <sup>(1)</sup> in connection with a mandate by the Commission drawn up in accordance with the procedure referred to in Article 6(3) of that Directive, which, by itself or together with other standards, provides a solution as regards compliance with a legal provision;
9. 'placing in service' means all the operations by which a subsystem or a vehicle is put into its design operating state;
10. 'placing on the market' means the first making available of an interoperability constituent on the Union market;
11. 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;
12. 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer or a contracting entity to act on their behalf in relation to specified tasks;
13. 'conformity assessment' means the process demonstrating whether requirements specified in the relevant TSI relating to an interoperability constituent have been fulfilled;
14. 'assessment of suitability for use' means the process demonstrating whether requirements for suitability for use specified in the relevant TSI relating to an interoperability constituent have been fulfilled;
15. 'EC verification' means the procedure referred to in Article 18 of Directive 2008/57/EC whereby a notified body checks and certifies that the subsystem complies with Directive 2008/57/EC, relevant TSI(s) and with the other regulations deriving from the Treaty, and may be put into operation.

#### Article 4

##### Conformity assessment procedures

1. The procedures for conformity assessment for the interoperability constituents covered by the TSIs shall be chosen among the modules set out in Annex I, in accordance with the following criteria:
- whether the module concerned is appropriate to the type of interoperability constituent;
  - the nature of the risks entailed by the interoperability constituent and the extent to which conformity assessment corresponds to the type and degree of risk;
  - the need for the manufacturer to have a choice between quality management system and product certification modules set out in Annex I;
  - the need to avoid imposing modules which would be too burdensome in relation to the risks.
2. The TSI(s) shall specify the modules for conformity assessment to be applied for the interoperability constituents. Where necessary, the TSI(s) may clarify and complement them due to the specificity of the sub system concerned.

#### Article 5

##### Procedure for assessment of suitability for use

Where the TSIs so require, the procedure for assessment of suitability for use of the interoperability constituents shall be done in accordance with the instructions set out in the module CV set out in Annex I.

#### Article 6

##### EC verification procedures

1. The EC verification procedures for the subsystems covered by the TSIs shall be chosen among the modules set out in Annex I, in accordance with the following criteria:
- whether the module concerned is appropriate to the type of the subsystem;
  - the nature of the risks entailed by the subsystem and the extent to which EC verification corresponds to the type and degree of risk;

<sup>(1)</sup> OJ L 204, 21.7.1998, p. 37.

(c) the need for the manufacturer to have a choice between quality management system and product certification modules set out in Annex I;

(d) the need to avoid imposing modules which would be too burdensome in relation to the risks.

2. The TSI(s) shall specify the modules for EC verification to be applied for the subsystems. Where necessary, the TSI(s) may clarify and complement them due to the specificity of the sub system concerned.

#### *Article 7*

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or EC verification or has recourse to a subsidiary, it shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

2. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the applicant.

#### *Article 8*

##### **Application**

This Decision shall apply from 1 January 2011.

#### *Article 9*

##### **Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 9 November 2010.

*For the Commission*

Siim KALLAS

*Vice-President*

## ANNEX I

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**MODULES FOR CONFORMITY ASSESSMENT OF INTEROPERABILITY CONSTITUENTS****Module CA. Internal production control**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the TSI. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance and operation of the interoperability constituent.

Wherever applicable, the technical documentation shall give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the interoperability constituent has been used in service in the same area of use.

The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the TSI where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to them.

4. EC declaration of conformity

- 4.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

4.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### **Module CA1. Internal production control plus product verification by individual examination**

1. Internal production control plus product verification by individual examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the TSI.

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance and operation of the interoperability constituent.

Wherever applicable, the technical documentation shall also give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the interoperability constituent has been used in service in the same area of use.

The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the TSI where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to them.

#### 4. Product checks

For each individual product manufactured, one or more tests on one or more specific aspects of the interoperability constituent shall be carried out in order to verify conformity with the type described in the technical documentation and the requirements of the TSI. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body or under the responsibility of a notified body chosen by the manufacturer.

#### 5. EC certificate of conformity

The notified body shall issue an EC certificate of conformity in respect of the examinations and tests carried out.

The manufacturer shall keep the EC certificates of conformity available for inspection by the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.

#### 6. EC declaration of conformity

- 6.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 6.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

#### 7. Authorised representative

The manufacturer's obligations set out in point 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### **Module CA2. Internal production control plus product verification at random intervals**

1. Internal production control plus product verification at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.

#### 2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the TSI. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance and operation of the interoperability constituent.

Wherever applicable, the technical documentation shall also give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the interoperability constituent has been used in service in the same area of use.

The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,



- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the TSI where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

### 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to them.

### 4. Product checks

- 4.1. At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals.
- 4.2. The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.
- 4.3. All interoperability constituents shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. All interoperability constituents in a sample shall be individually examined and appropriate tests shall be carried out to ensure the product conformity with the type described in the technical documentation and the requirements of the TSI that apply to it and to determine whether the lot is accepted or rejected.

### 5. EC certificate of conformity

The notified body shall issue an EC certificate of conformity in respect of the examinations and tests carried out.

The manufacturer shall keep the EC certificates of conformity available for inspection by the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.

### 6. EC declaration of conformity

- 6.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 6.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

7. Authorised representative

The manufacturer's obligations set out in point 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**Module CB. EC-type examination**

1. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an interoperability constituent and verifies and attests that the technical design of the interoperability constituent meets the requirements of the technical specification for interoperability (TSI) that apply to it.

2. EC-type examination may be carried out in either of the following manners:

- examination of a specimen, representative of the production envisaged, of the interoperability constituent (production type),
- assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the interoperability constituent (combination of production type and design type),
- assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EC-type examination with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The technical documentation shall make it possible to assess the interoperability constituent's conformity with the applicable requirements of the TSI. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance and operation of the interoperability constituent. The technical documentation shall contain, wherever applicable, at least the following elements:
  - a general description of the interoperability constituent,
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
  - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation (including conditions for use) and maintenance of the interoperability constituent,
  - conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
  - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the TSI where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc., and
  - test reports,
  - the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,
  - the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
4. The notified body shall:
- For the interoperability constituent:
- 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the interoperability constituent with the requirements of the relevant TSI.
- For the specimen(s):
- 4.2. verify that the specimen(s) have been manufactured in conformity with the requirements of the TSI and the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;
- 4.3. carry out appropriate examination and test, or have them carried out, to check whether requirements of the TSI have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;
- 4.5. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the TSI;
- 4.6. agree with the manufacturer on a location where the examinations and tests will be carried out.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of the TSI that apply to the interoperability constituent concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituents with the examined type to be evaluated.

Where the type does not satisfy the requirements of the TSI, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the interoperability constituent with the requirements of the TSI or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate. Only those examinations and tests that are relevant and necessary to the changes shall be performed.
8. Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

#### **Module CC. Conformity to type based on internal production control**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his sole responsibility that the interoperability constituents concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.
2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the interoperability constituents with the approved type described in the EC-type examination certificate and with the requirements of the TSI that apply to them.
3. EC declaration of conformity
  - 3.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 3.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificate to be referred to is:

- the EC type-examination certificate and its additions.

#### 4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### **Module CD. Conformity to type based on quality management system of the production process**

1. Conformity to type based on quality management system of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the interoperability constituent concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the technical specification for interoperability (TSI) that apply to it.

#### 2. Manufacturing

The manufacturer shall operate an approved quality management system for production, final product inspection and testing of the interoperability constituents concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

#### 3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with the notified body of his choice, for the interoperability constituents concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information for the interoperability constituent category envisaged,
- the documentation concerning the quality management system,
- the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality management system shall ensure that the interoperability constituents are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the TSI that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
- the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required product quality and the effective operation of the quality management system.

3.3. The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard, harmonised standard and/or technical specification.

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the manufacturing of the relevant interoperability constituent, the notified body shall take this into account in the assessment. In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. The notified body shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the TSI. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second paragraph, fifth indent, to verify the manufacturer's ability to identify the requirements of the TSI and to carry out the necessary examinations with a view to ensuring compliance of the interoperability constituent with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision. Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the notified body shall issue a quality management system approval to the applicant.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.

The notified body shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### 4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.

4.2. The manufacturer shall, for periodic audits purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- the quality management system documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the manufacturer operates a certified quality management system, the notified body shall take this into account during the periodic audits.

- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out interoperability constituent tests, or have them carried out, in order to verify that the quality management system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. EC declaration of conformity

- 5.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 5.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificates to be referred to are:

— the quality management system approval indicated in point 3.3 and audit reports indicated in point 4.3, if any,

— the EC type-examination certificate and its additions.

6. The manufacturer shall, for the period defined in the relevant TSI and, where the TSI does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality management system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality management system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**Module CF. Conformity to type based on product verification**

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the interoperability constituents with the approved type described in the EC-type examination certificate and with the requirements of the TSI that apply to them.

3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the interoperability constituents with the approved type described in the EC-type examination certificate and with the requirements of the TSI.

The examinations and tests to check the conformity of the interoperability constituents with the requirements of the TSI shall be carried out, at the choice of the manufacturer either by examination and testing of every interoperability constituent as specified in point 4 or by examination and testing of the interoperability constituents on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every interoperability constituent.

4.1. All interoperability constituents shall be individually examined and appropriate tests set out in the relevant TSI, harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the requirements of the TSI. When a test is not set out in the TSI, harmonised standard(s) and technical specification(s), the appropriate tests to be carried out shall be decided between the manufacturer and the notified body concerned.

4.2. The notified body shall issue an EC certificate of conformity in respect of the examinations and tests carried out.

The manufacturer shall keep the EC certificates of conformity available for inspection by the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his interoperability constituents for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of the TSI. All interoperability constituents in a sample shall be individually examined and appropriate tests set out in the relevant TSI, harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the requirements of the TSI and to determine whether the lot is accepted or rejected. When a test is not set out in the relevant TSI, harmonised standard(s) and/or technical specification(s), the appropriate tests to be carried out shall be decided between the manufacturer and the notified body concerned.

5.3. If a lot is accepted, all interoperability constituents of the lot shall be considered approved, except for those interoperability constituents from the sample that have been found not to satisfy the tests.

The notified body shall issue an EC certificate of conformity in respect to the examinations and tests carried out.



The manufacturer shall keep the EC certificates of conformity at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.

- 5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot is being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. EC declaration of conformity

- 6.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities, for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 6.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificates to be referred to are:

- the EC type-examination certificate and its additions,
- the EC certificate of conformity referred to in point 4.2 or point 5.3.

7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2, 5.1 and 5.2.

**Module CH. Conformity based on full quality management system**

1. Conformity based on full quality management system is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality management system for design, manufacture and final product inspection and testing of the interoperability constituents concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality management system

- 3.1. The manufacturer shall lodge an application for assessment of his quality management system with the notified body of his choice, for the interoperability constituents concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- the technical documentation for one model of each category of interoperability constituents intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
  - a general description of the interoperability constituent,

- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the TSI where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports,
- the documentation concerning the quality management system, and
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality management system shall ensure compliance of the interoperability constituents with the requirements of the TSI that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the requirements of the TSI that apply to the interoperability constituents will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the interoperability constituents pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

- 3.3. The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard, harmonised standard and/or technical specification.

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, the notified body shall take this into account in the assessment. In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. The notified body shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the TSI. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the requirements of the TSI and to carry out the necessary examinations with a view to ensuring compliance of the interoperability constituent with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision. Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the notified body shall issue a quality management system approval to the applicant.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.

The notified body shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### 4. Surveillance under the responsibility of the notified body

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.
- 4.2. The manufacturer shall, for periodic audits purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality management system documentation,

— the quality records as provided for by the design part of the quality management system, such as results of analyses, calculations, tests, etc., and

— the quality records as provided for by the manufacturing part of the quality management system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the manufacturer operates a certified quality management system, the notified body shall take this into account during the periodic audits.

- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out interoperability constituent tests, or have them carried out, in order to check the proper functioning of the quality management system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. EC declaration of conformity

- 5.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 5.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificate to be referred to is:

— the quality management system approval indicated in point 3.3 and audit reports indicated in point 4.3, if any.

6. The manufacturer shall, for the period defined in the relevant TSI and, where the TSI does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:

— the technical documentation referred to in point 3.1,

— the documentation concerning the quality management system referred to in point 3.1,

— the change referred to in point 3.5, as approved, and

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality management system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**Module CH1. Conformity based on full quality management system plus design examination**

1. Conformity based on full quality management system plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality management system for design, manufacture and final product inspection and testing of the interoperability constituents concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the interoperability constituents shall have been examined in accordance with point 4.

3. Quality management system

- 3.1. The manufacturer shall lodge an application for assessment of his quality management system with the notified body of his choice, for the interoperability constituents concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- all relevant information for the interoperability constituent category envisaged,
- the documentation concerning the quality management system, and
- a written declaration that the same application has not been lodged with any other notified body.

- 3.2. The quality management system shall ensure compliance of the interoperability constituents with the requirements of the TSI that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the requirements of the TSI that apply to the interoperability constituents will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the interoperability constituents pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

3.3. The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard, harmonised standard and/or technical specification.

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, the notified body shall take this into account in the assessment. In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. The notified body shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the TSI. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision. Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the notified body shall issue a quality management system approval to the applicant.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.

The notified body shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.6. Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality management system approvals which it has issued.

#### 4. Design examination

- 4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

4.2. The application shall make it possible to understand the design, manufacture, maintenance and operation of the interoperability constituent, and to assess the conformity with the requirements of the TSI that apply to it. It shall include:

- the name and address of the manufacturer,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The technical documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the relevant TSI. The technical documentation shall specify the requirements and cover, as far as relevant for the assessment, the design and operation of the interoperability constituent. The technical documentation shall, wherever applicable, contain at least the following elements:
  - a general description of the interoperability constituent,
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
  - descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
  - conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
  - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the TSI where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
  - results of design calculations made, examinations carried out, etc., and
  - test reports,
- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the requirements of the TSI that apply to the interoperability constituent it shall issue an EC design examination certificate to the manufacturer. The certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design and if relevant, a description of the product's functioning. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituent s with the examined design to be evaluated.

Where the design does not satisfy the requirements of the TSI, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

4.4. The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the TSI or the conditions for validity of the certificate until the expiry of the validity of the certificate. Such modifications shall require additional approval — from the notified body that issued the EC design examination certificate — in the form of an addition to the original EC design examination certificate. Only those examinations and tests that are relevant and necessary to the changes shall be performed.

- 4.5. Each notified body shall inform its notifying authorities of the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EC design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EC design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

- 4.6. The manufacturer shall keep a copy of the EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.

5. Surveillance under the responsibility of the notified body

- 5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.

- 5.2. The manufacturer shall, for periodic audits purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality management system documentation,

— the quality records as provided for by the design part of the quality management system, such as results of analyses, calculations, tests, etc.,

— the quality records as provided for by the manufacturing part of the quality management system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the manufacturer operates a certified quality management system, the notified body shall take this into account during the periodic audits.

- 5.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out interoperability constituent tests, or have them carried out, in order to check the proper functioning of the quality management system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.



6. EC declaration of conformity
- 6.1. The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of conformity shall identify the interoperability constituent for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.

- 6.2. The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificates to be referred to are:

- the quality management system approval indicated in point 3.3 and audit reports indicated in point 5.3, if any,
  - the EC design examination certificate indicated in point 4.3 and its additions.
7. The manufacturer shall, for the period defined in the relevant TSI and, where the TSI does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:
- the documentation concerning the quality management system referred to in point 3.1,
  - the change referred to in point 3.5, as approved, and
  - the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### **MODULES FOR SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS**

##### **Module CV. Type validation by in-service experience (suitability for use)**

1. Type validation by in-service experience is the part of assessment procedure in which a notified body ascertains and attests that a specimen, representative of the production envisaged meets the requirements for suitability for use of the technical specification for interoperability (TSI) that apply to it.
2. The manufacturer shall lodge an application for type validation by in-service experience with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation referred to in point 3,
- the programme for validation by in-service experience, as described in point 4,

- the name and address of the company(ies) (infrastructure managers and/or railway undertaking), with which the applicant has obtained an agreement to contribute to a suitability for use assessment by in-service experience:
  - by operating the interoperability constituent in service,
  - by monitoring the in-service behaviour, and
  - by issuing a report about in-service experience,
- the name and the address of the company undertaking the maintenance of the interoperability constituent during the time period or running distance required for in-service experience, and
- the EC type examination certificate when module CB was used for design phase, or EC design examination certificate when module CH1 was used for design phase.

The manufacturer shall place at the disposal of the company(ies), undertaking the operation of the interoperability constituent in service, a specimen or a sufficient number of specimens, representative of the production envisaged and hereinafter called 'type'. A type may cover several versions of the interoperability constituent provided that the differences between the versions are all covered by EC certificates as mentioned above.

The notified body may request further specimens if needed for carrying out the validation by in-service experience.

3. The technical documentation shall make it possible to assess the interoperability constituent's conformity with the requirements of the TSI. The technical documentation shall cover the design, manufacturing, maintenance and operation of the interoperability constituent.

The technical documentation shall contain the following elements:

- the technical documentation specified in point 9 of Module CB or in point 4.6 of Module CH1,
- conditions for use and maintenance of the interoperability constituent (e.g. restrictions of running time or distance, wear limits, etc.).

If the TSI requires further information for the technical documentation, this shall be included.

4. The programme for the validation by in-service experience shall include:
  - the required performance or behaviour in service of the interoperability constituent under trial,
  - the installation arrangements,
  - the duration of the programme — either time or distance,
  - the operating conditions and the service programme expected,
  - the maintenance programme,
  - the special in-service tests, if any, to be performed,
  - the batch size of the specimens — if more than one,
  - the inspection programme (nature, number and frequency of inspections, documentation),

- criteria for tolerable defects and their impact on the programme,
- the information to be included in the report of the company(ies) operating the interoperability constituent in service (see point 2, fifth indent).

5. Type validation by in-service experience

The notified body shall:

- 5.1. examine the technical documentation and the programme for validation by in-service experience;
  - 5.2. verify that the type is representative and has been manufactured in conformity with the technical documentation;
  - 5.3. verify that the programme for validation by in-service experience is well adapted to assess the required performance and in-service behaviour of the interoperability constituents;
  - 5.4. agree with the applicant and the company(ies) undertaking the operation of the interoperability constituent referred to in point 2 the programme and the location where the inspections will be carried out and if necessary, the test(s) and the body performing the test(s);
  - 5.5. monitor and inspect the progress of in-service running, operation and maintenance of the interoperability constituent;
  - 5.6. assess the report, to be issued by the company(ies) undertaking the operation the interoperability constituent referred to in point 2, and all other documentation and information, collected during the procedure (test reports, maintenance experience etc.);
  - 5.7. evaluate whether the in-service behaviour results meet the requirements of the TSI.
6. Where the type meets the requirements of the TSI that apply to the interoperability constituent concerned, the notified body shall issue an EC certificate of suitability for use to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the validation, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

A list of the relevant parts of the technical documentation shall be annexed to the EC certificate of suitability for use and a copy kept by the notified body.

Where the type does not satisfy the requirements of the TSI, the notified body shall refuse to issue an EC certificate of suitability for use and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The manufacturer shall inform the notified body that holds the technical documentation relating to the EC certificate of suitability for use of all modifications to the approved type that may affect the suitability for use of the interoperability constituent or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC certificate of suitability for use. Only those examinations and tests that are relevant and necessary to the changes shall be performed.
8. Each notified body shall inform its notifying authorities concerning the EC certificate of suitability for uses and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.
9. Each notified body shall inform the other notified bodies concerning the EC certificate of suitability for uses and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

10. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC certificate of suitability for uses and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC certificate of suitability for use, its annexes and additions, until the expiry of the validity of the certificate.

11. EC declaration of suitability for use

11.1. The manufacturer shall draw up a written EC declaration of suitability for use for an interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. The EC declaration of suitability for use shall identify the interoperability constituent for which it has been drawn up.

A copy of the EC declaration of suitability for use shall be made available to the relevant authorities upon request.

11.2. The EC declaration of suitability for use shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificate to be referred to is:

— EC certificate of suitability for use.

11.3. The interoperability constituent may be placed on the market only after the following EC declarations have been drawn up:

— EC declaration of suitability for use referred to in point 11.1, and

— EC declaration of conformity.

12. Authorised representative

The manufacturer's obligations set out in points 2, 7 and 11.1 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## MODULES FOR EC VERIFICATION OF SUBSYSTEMS

### Module SB. EC-type examination

1. EC-type examination is the part of an EC verification procedure whereby a notified body examines the technical design of a subsystem and verifies and attests that the technical design of the subsystem meets the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.

2. EC-type examination shall be carried out by:

— assessment of the adequacy of the technical design of the subsystem through examination of the technical documentation and supporting evidence referred to in point 3 (design type), and

— examination of a specimen, representative of the production envisaged, of the complete subsystem (production type).

A type may cover several versions of the subsystem provided that the differences between the versions do not affect the provisions of the relevant TSI(s).

3. The applicant shall lodge an application for EC-type examination with a notified body of his choice.

The application shall include:

- the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The technical documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s). The technical documentation shall specify the requirements of the relevant TSI(s) and cover, as far as relevant for the EC-type examination procedure, the design, manufacture and operation of the subsystem. The technical documentation shall contain the following elements:
  - a general description of the subsystem, its overall design and structure,
  - documents necessary for the compilation of the technical file as described in point 4 of Annex VI to Directive 2008/57/EC,
  - a separate file with the set of data required by the TSI(s) for each relevant register provided for in Articles 34 and 35 of Directive 2008/57/EC,
  - copy of EC declaration(s) of intermediate statement of verification (hereinafter referred to as ISV) issued for the subsystem according to point 2 of Annex VI to Directive 2008/57/EC, if any,
  - if relevant, descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
  - conditions of integration of the subsystem in its system environment and the necessary interface conditions,
  - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
  - results of design calculations made, examinations carried out, etc.,
  - test programme and reports,
  - evidence of conformity with other regulations deriving from the Treaty (including certificates, if any),
  - supporting documentation regarding the manufacture and the assembly of the subsystem,
  - a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation,
  - conditions for use of the subsystem (restrictions of running time or distance, wear limits etc.),
  - conditions for maintenance and technical documentation on maintenance of the subsystem,
  - any technical requirement specified in the relevant TSI(s) that shall be taken into account during production, maintenance or operation of the subsystem,
  - all other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies, and

- any further information, if required by the relevant TSI(s),
- the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,
- a specimen or specimens of a sub-assembly or assembly or a specimen of the subsystem in a pre-assembled condition shall be provided, if so required for specific test or examination methods and specified in the relevant TSI(s),
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate testing body of the applicant, or by another testing body on his behalf and under his responsibility.

4. The notified body shall

For the design type:

- 4.1. examine the technical documentation and supporting evidence to assess whether the technical design of the subsystem is adequate to fulfil the requirements of the relevant TSI(s);
- 4.2. where a design review is requested in the relevant TSI(s), examine design methods, the design tools and the design results to assess compliance with the requirements of the relevant TSI(s).

For the production type:

- 4.3. verify that the specimen(s) have been manufactured in conformity with the requirements of the relevant TSI(s) and with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant TSI(s), harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;
  - 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the applicant has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;
  - 4.5. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the relevant TSI(s);
  - 4.6. agree with the applicant on a location where the examinations and tests will be carried out.
5. When the subsystem referred to in point 3 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.

The applicant shall also provide the notified body with a precise reference to the TSI(s) (or their parts) for which the derogation is requested.

The applicant shall communicate to the notified body the outcome of the derogation procedure.

6. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the applicant.

7. Where the type meets the requirements of the relevant TSI(s) that apply to the subsystem concerned, the notified body shall issue an EC-type examination certificate to the applicant. The certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems with the examined type to be evaluated.

Where the type does not satisfy the requirements of the relevant TSI(s), the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

Where the subsystem referred to in point 3 is subject to derogation, upgrade, renewal or specific case, the EC-type examination certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

If only certain parts of the subsystem are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.

The applicant shall draw up a written EC ISV declaration according to section 2 of Annex VI to Directive 2008/57/EC.

8. The applicant shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the subsystem with the requirements of the relevant TSI(s) or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.
9. Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, including the documentation intended for the technical file submitted by the applicant, until the expiry of the validity of the certificate.

10. The applicant shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities throughout the service life of the subsystem.
11. The applicant's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 5, 8 and 10, provided that they are specified in the mandate.

#### **Module SD. EC verification based on quality management system of the production process**

1. EC verification based on quality management system of the production process is the part of a EC verification procedure whereby the applicant fulfils the obligations laid down in points 2 and 8, and ensures and declares on his sole responsibility that the subsystem concerned is in conformity with the type described in the EC-type examination certificate and satisfies the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.

2. Manufacturing

The production, final subsystem inspection and testing of the subsystem concerned shall be covered by approved quality management system(s) as specified in point 3, and shall be subject to surveillance as specified in point 7.

3. Quality management system

- 3.1. The applicant shall lodge an application for assessment of the quality management system with the notified body of his choice, for the subsystem concerned.

The application shall include:

- the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the breakdown structure of the project management and the name and address of each involved entity,
- all relevant information for the subsystem envisaged,
- the documentation concerning the quality management system,
- copy of EC ISV declaration(s) issued for the subsystem, if any,
- the technical documentation of the approved type and a copy of the EC-type examination certificate and its annexes.

- 3.2. The quality management system shall ensure that the subsystem is in conformity with the type described in the EC-type examination certificate and comply with the requirements of the relevant TSI(s) that apply to it.

All the elements, requirements and provisions adopted by the applicant shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to subsystem quality,
- the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required subsystem quality and the effective operation of the quality management system.



- 3.3. The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard, harmonised standard and/or technical specification.

If the compliance of the subsystem with the requirements of the relevant TSI(s) is based on more than one quality management system, the notified body shall examine in particular:

- whether the relations and interfaces between the quality management systems are clearly documented, and
- whether overall responsibilities and powers of the management for the compliance of the whole entire subsystem are clearly assigned to and acknowledged by each entity involved in the project.

The audit shall be specific for the subsystem concerned, taking into consideration the specific contribution of the applicant to the subsystem.

When the applicant operates a certified quality management system certified by an accredited certification body, for the manufacturing and final testing of the relevant subsystem, the notified body shall take this into account in the assessment. In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the subsystem only. The notified body shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant TSI(s). The audit shall include an assessment visit to the premises of the relevant entities concerned. The auditing team shall review the technical documentation referred to in point 3.1, second paragraph, seventh indent, to verify the ability of the relevant entities concerned to identify the requirements of the relevant TSI(s) and to carry out the necessary examinations with a view to ensuring compliance of the subsystem with those requirements.

The decision shall be notified to the applicant. The notification shall contain the conclusions of the audit and the reasoned assessment decision. Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the notified body shall issue a quality management system approval to the applicant.

- 3.4. The applicant shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The applicant shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any changes of quality management system certificate.

The notified body shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the applicant of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality management system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality management system approvals which it has issued.

5. EC verification

5.1. The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice.

The application shall include:

- name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,
- the technical documentation, regarding the approved type, including the EC type examination certificate, as issued after completion of the procedure defined in module SB,

and, if not included in this documentation:

- a general description of the subsystem, its overall design and structure,
- the documents necessary for the compilation of the technical file as described in point 4 of Annex VI to Directive 2008/57/EC,
- a separate file with the set of data required by the relevant TSI(s) for each relevant register provided for in Articles 34 and 35 of Directive 2008/57/EC,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),
- descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- conditions for maintenance and technical documentation regarding the maintenance of the subsystem,
- any technical requirement specified in the relevant TSI(s) that shall be taken into account during production, maintenance or operation of the subsystem,
- other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,
- results of design calculations made, examinations carried out, etc.,
- test reports, if any,
- documentation regarding the manufacture and the assembly of the subsystem,
- a list of manufacturers involved in the subsystem's manufacturing, assembly and installation,

- the demonstration, that the manufacturing and final testing as mentioned under point 2, are covered by quality management system of the applicant and the evidence of its effectiveness,
- indication of the notified body, responsible for the approval and surveillance of the quality management system, and
- evidence of conformity with other regulations deriving from the Treaty (including certificates, if any),
- any further information, if required by the relevant TSI(s).

- 5.2. The notified body chosen by the applicant shall first examine the application concerning the validity of the EC type examination certificate and its annexes.

If the notified body considers the EC type examination certificate no longer remains valid or is not appropriate and that a new EC type examination is necessary, the notified body shall refuse to assess the quality management system of the applicant and shall justify its refusal.

6. When the subsystem referred to in point 5.1 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.

The applicant shall also provide the notified body with a precise reference to the TSI(s) (or their parts) for which the derogation is requested.

The applicant shall communicate to the notified body the outcome of the derogation procedure.

7. Surveillance under the responsibility of the notified body

- 7.1. The purpose of surveillance is to make sure that the applicant duly fulfils the obligations arising out of the approved quality management system.

- 7.2. The applicant shall, for periodic audits purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- the quality management system documentation,

- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 7.3. The notified body shall carry out periodic audits to make sure that the applicant maintains and applies the quality management system and shall provide the applicant with an audit report.

The frequency of the periodic audits shall be at least once every 2 years.

When the applicant operates a certified quality management system, the notified body shall take this into account during the periodic audits.

- 7.4. In addition, the notified body may pay unexpected visits to the applicant. During such visits the notified body may, if necessary, carry out subsystem tests, or have them carried out, in order to verify that the quality management system is functioning correctly. The notified body shall provide the applicant with a visit report and, if tests have been carried out, with a test report.

7.5. The notified body responsible for the EC verification of the subsystem, if not carrying out the surveillance of all the quality management systems concerned as under point 3, shall coordinate the surveillance activities of any other notified bodies responsible for that task, in order:

- to be ensured that correct management of interfaces between the different quality management systems relating to subsystem integration has been performed,
- to collect, in liaison with the applicant, the necessary elements for the assessment to guarantee the consistency and the overall supervision of the different quality management systems.

This coordination includes the right of the notified body:

- to receive all documentation (approval and surveillance), issued by the other notified body(ies),
- to witness the surveillance audits as in point 7.3, and
- to initiate additional audits as in point 7.4 under its responsibility and together with the other notified body(ies).

8. EC certificate of verification and EC declaration of verification

8.1. Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.

Where the subsystem referred to in point 5.1 is subject to derogation, upgrade, renewal or specific case, the EC certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.

8.2. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up.

Where the subsystem referred to in point 5.1 is subject to derogation, upgrade, renewal or specific case, the EC declaration for the subsystem shall also indicate the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

In case of ISV procedure the applicant shall draw up a written EC ISV declaration.

The EC declaration and the accompanying documents shall be written in accordance with Annex V to Directive 2008/57/EC.

The certificates to be referred to are:

- the quality management system approval indicated in point 3.3 and audit reports indicated in point 7.3, if any,
- the EC type examination certificate and its additions.

A copy of the EC declaration of verification and EC ISV declaration(s), if any, shall be made available to the relevant authorities upon request.

- 8.3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.
9. The applicant shall, throughout the service life of the subsystem, keep at the disposal of the national authorities:
- the documentation referred to in point 3.1,
  - the change(s) referred to in point 3.5, as approved,
  - the decisions and reports of the notified body referred to in points 3.5, 7.3 and 7.4, and
  - the technical file referred to in point 8.3.
10. Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of EC certificates of verification it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of EC certificates of verification which it has issued.

11. Authorised representative

The applicant's obligations set out in points 3.1, 3.5, 6, 8.2 and 9 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### **Module SF. EC verification based on product verification**

1. EC verification based on product verification is the part of an EC verification procedure whereby the applicant fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the subsystem concerned, which have been subject to the provisions of point 4, is in conformity with the type described in the EC-type examination certificate and satisfies the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.
2. Manufacturing
- The manufacturing process and its monitoring shall ensure conformity of the manufactured subsystem with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s) that apply to it.
3. The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice. The application shall include:
- name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,
  - the technical documentation, regarding the approved type, including the EC type examination certificate and its annexes, as issued after completion of the procedure defined in module SB.

It shall also include the following if it is not already included in the technical documentation:

- a general description of the subsystem, its overall design and structure,
- the documents necessary for the compilation of the technical file as described in point 4 of Annex VI to Directive 2008/57/EC,

- a separate file with the set of data required by the relevant TSI(s) for each relevant register provided for in Articles 34 and 35 of Directive 2008/57/EC,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),
- descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- conditions for maintenance and technical documentation regarding the maintenance of the subsystem,
- any technical requirement specified in the relevant TSI(s) that shall be taken into account during production, maintenance or operation of the subsystem,
- other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,
- evidence of conformity with other regulations deriving from the Treaty (including certificates, if any),
- results of design calculations made, examinations carried out, etc.,
- test reports,
- documentation regarding the manufacture and the assembly of the subsystem,
- a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation, and
- any further information, if required by the relevant TSI(s).

#### 4. EC verification

- 4.1. The notified body chosen by the applicant shall first examine the application concerning the validity of the EC type examination certificate.

If the notified body considers the EC type examination certificate no longer remains valid or is not appropriate and that a new EC type examination is necessary, the notified body shall refuse to carry out EC verification of the subsystem and shall justify its refusal.

The notified body shall carry out appropriate examinations and tests in order to check the conformity of the subsystem with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s).

- 4.2. All subsystems shall be individually examined and appropriate tests set out in the relevant TSI(s), harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s). In the absence of such a harmonised standard, the appropriate tests to be carried out shall be decided between the applicant and the notified body concerned.

- 4.3. The notified body shall agree with the applicant the locations where the tests will be carried out and shall agree that final testing of the subsystem and, whenever required in the relevant TSI(s), tests or validation under full operating conditions, are carried out by the applicant under direct supervision and attendance of the notified body.

The notified body shall have entrance for testing and verification purposes to production workshops, locations of assembly and installations, and where appropriate, prefabrication and testing facilities in order to carry out its tasks as provided for in the relevant TSI(s).

- 4.4. When the subsystem referred to in point 3 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.

The applicant shall also provide the notified body with a precise reference to the TSI(s) (or their parts) for which the derogation is requested.

The applicant shall communicate to the notified body the outcome of the derogation procedure.

- 4.5. The notified body shall issue an EC certificate of verification in respect of the examinations and tests carried out.

Where the subsystem referred to in point 3 is subject to derogation, upgrade, renewal or specific case the EC certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.

The applicant shall keep the EC certificate of verification available for inspection by the national authorities throughout the service life of the subsystem.

## 5. EC declaration of verification

- 5.1. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities, throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up.

Where the subsystem referred to in point 3 is subject to derogation, upgrade, renewal or specific case, the EC declaration for the subsystem shall also indicate the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

In case of ISV procedure the applicant shall draw up a written EC ISV declaration.

The EC declaration and the accompanying documents shall be written in accordance with Annex V to Directive 2008/57/EC.

A copy of the EC declaration of verification and EC ISV declarations, if any, shall be made available to the relevant authorities upon request.

- 5.2. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.

6. Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of EC certificates of verification it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of EC certificates of verification which it has issued.

7. Authorised representative

The applicant's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the applicant's obligations set out in point 2.

**Module SG. EC verification based on unit verification**

1. EC verification based on unit verification is the EC verification procedure whereby the applicant fulfils the obligations laid down in points 2, 3, 4, 6.2 and 6.4, and ensures and declares on his sole responsibility that the subsystem concerned, which has been subject to the provisions of point 5, satisfies the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.

2. The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice.

The application shall include:

- name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well, and
- the technical documentation.

3. Technical documentation

The applicant shall establish the technical documentation and make it available to the notified body referred to in point 5. The documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s). The technical documentation shall specify the requirements and cover, as far as relevant for the assessment, the design, manufacture, installation/construction and operation of the subsystem.

The technical documentation shall, wherever applicable, contain the following elements:

- a general description of the subsystem, its overall design and structure,
- the documents necessary for the compilation of the technical file as described in point 4 of Annex VI to Directive 2008/57/EC,
- a separate file with the set of data required by the relevant TSI(s) for each relevant register provided for in Articles 34 and 35 of Directive 2008/57/EC,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),
- descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- conditions for maintenance and technical documentation regarding the maintenance of the subsystem,
- any technical requirement specified in the relevant TSI(s) that shall be taken into account during production, maintenance or operation of the subsystem,
- other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,



- conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,
- evidence of conformity with other regulations deriving from the Treaty (including certificates, if any),
- conceptual design and manufacturing and construction drawings and schemes of components, sub-assemblies, circuits,
- descriptions and explanations necessary for the understanding of those drawings,
- results of design calculations made, examinations carried out, etc.,
- test reports,
- documentation regarding the manufacture and the assembly of the subsystem,
- a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation, and
- any further information, if required by the relevant TSI(s).

The applicant shall keep the technical documentation at the disposal of the relevant national authorities throughout the service life of the subsystem.

#### 4. Manufacturing

The applicant shall take all measures necessary so that the manufacturing and/or installation/construction process and its monitoring ensure conformity of the subsystem with the requirements of the relevant TSI(s).

#### 5. EC verification

- 5.1. A notified body chosen by the applicant shall carry out appropriate examinations and tests, set out in the relevant TSI(s), harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the subsystem with the requirements of the relevant TSI(s), or have them carried out. In the absence of such a harmonised standard and/or technical specification the appropriate tests to be carried out shall be decided between the applicant and the notified body concerned.

The examinations, tests and checks shall be carried out at the stages provided in point 2 of Annex VI to Directive 2008/57/EC.

The notified body may take into account evidence of examinations, checking or tests that have been successfully performed, under comparable conditions by other bodies <sup>(1)</sup> or, when this is specified by the relevant TSI(s), by (or on the behalf of) the applicant. The notified body will then decide as to whether it shall use the results of these checks or tests.

The evidences gathered by the notified body shall be suitable and sufficient to show the conformity with the requirement of the relevant TSI(s) and that all required and appropriate checks and tests have been carried out.

The extent to which the evidence originating from other parties is taken into account by the notified body shall be justified by documented analysis using the factors listed in the following paragraph.

#### 5.2. The notified body shall examine:

- the use of existing equipment and systems:

<sup>(1)</sup> The conditions to entrust checking and test must be similar to the conditions, respected by a notified body to subcontract activities (see §6.5 of the Blue Guide on the New Approach).

- used identically as before,
- used before but adapted for use in the new work,
- the use of existing designs, technologies, materials and production techniques,
- the arrangements for design, production, testing and commissioning,
- previous approvals from other competent bodies,
- the accreditations of other involved bodies:
  - it is permissible for the notified body to take account of valid accreditation to relevant European standards, provided that no conflict of interest exists, that accreditation covers the testing being performed and that accreditation is current,
  - where no formal accreditation exists, the notified body shall confirm that the systems for control of competence, independence, testing and material handling processes, facilities and equipment and other processes relevant to the contribution to the subsystem are controlled,
  - in all cases, the notified body shall consider the appropriateness of the arrangements and decide the level of witnessing required.

In all cases, the notified body keeps the responsibility of final results of the examinations, tests and checks.

- 5.3. The notified body shall agree with the applicant the locations where the tests will be carried out and shall agree that final subsystem tests and, whenever required in the TSI, tests under full operating conditions, are carried out by the applicant under direct supervision and attendance of the notified body.
- 5.4. When the subsystem referred to in point 2 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.

The applicant shall also provide the notified body with a precise reference to the TSI(s) (or their parts) for which the derogation is requested.

The applicant shall communicate to the notified body the outcome of the derogation procedure.

## 6. EC declaration of verification

- 6.1. Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.

Where the subsystem referred to in point 2 is subject to derogation, upgrade, renewal or specific case the EC certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.

- 6.2. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up.

Where the subsystem referred to in point 2 is subject to derogation, upgrade, renewal or specific case, the EC declaration for the subsystem shall also indicate the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

In case of ISV procedure the applicant shall draw up a written EC ISV declaration.

The EC declaration and the accompanying documents shall be written in accordance with Annex V to Directive 2008/57/EC.

A copy of the EC declaration of verification and/or EC ISV declarations, if any, shall be made available to the relevant authorities upon request.

6.3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.

6.4. The technical file accompanying the EC certificate of verification shall be lodged with the applicant. A copy of the EC certificate of verification and the technical file shall be made available to the Commission, the Member States and the relevant authorities upon request.

The applicant shall keep a copy of the technical file throughout the service life of the subsystem; it shall be sent to any other Member State which so requests.

7. Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of EC certificates of verification it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of EC certificates of verification which it has issued.

8. Authorised representative

The applicant's obligations set out in points 2, 3, 5.3, 5.4, 6.2 and 6.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### **Module SH1. EC verification based on full quality management system plus design examination**

1. EC verification based on full quality management system plus design examination is the EC verification procedure whereby the applicant fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the subsystem concerned satisfies the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.

2. Manufacturing

The design, manufacture and final subsystem inspection and testing of the subsystem concerned shall be covered by approved quality management system(s) as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the subsystem shall have been examined in accordance with point 4.

3. Quality management system

3.1. The applicant shall lodge an application for assessment of the quality management system with the notified body of his choice, for the subsystem concerned.

The application shall include:

— the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,

— the breakdown structure of the project management and the name and address of each involved entity,

- all relevant information for the subsystem envisaged,
- the documentation concerning the quality management system,
- copy of EC ISV declaration(s) issued for the subsystem, if any, and
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality management system shall ensure compliance of the subsystem with the requirements of the relevant TSI(s) that apply to it.

All the elements, requirements and provisions adopted by the applicant shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and subsystem quality,
- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the requirements of the relevant TSI(s) that apply to the subsystem will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the subsystem pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required design and subsystem quality and the effective operation of the quality management system.

3.3. The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standards that implements the relevant quality management standard, harmonised standard and/or technical specifications.

If the compliance of the subsystem with the requirements of the relevant TSI(s) is based on more than one quality management system, the notified body shall examine in particular:

- whether the relations and interfaces between the quality management systems are clearly documented, and
- whether overall responsibilities and powers of the management for the compliance of the whole entire subsystem are clearly assigned to and acknowledged by each entity involved in the project.

The audit shall be specific for the subsystem concerned, taking into consideration the specific contribution of the applicant to the subsystem.

When the applicant operates a certified quality management system certified by an accredited certification body for the design, manufacturing and final testing of the relevant subsystem, the notified body shall take this into account in the assessment. In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the subsystem only. The notified body shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant TSI(s). The audit shall include an assessment visit to the premises of the relevant entities concerned.

The applicant or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision. Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the notified body shall issue a quality management system approval to the applicant.

- 3.4. The applicant shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The applicant shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any changes of quality management system certificate.

The notified body shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the applicant of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.6. Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality management system approvals which it has refused, suspended or withdrawn, and, upon request, of quality management system approvals which it has issued.

#### 4. EC verification

- 4.1. The applicant shall lodge an application for EC verification of the subsystem (through full quality management system plus examination of the design) with the notified body referred to in point 3.1.

- 4.2. The application shall make it possible to understand the design, manufacture, maintenance and operation of the subsystem, and to assess the conformity with the requirements of the TSI(s) that apply to it. It shall include:

— the name and address of the applicant,

— a written declaration that the same application has not been lodged with any other notified body,

— the technical documentation. The documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s). The technical documentation shall specify the requirements of the relevant TSI(s) and cover, as far as relevant for the assessment, the design and operation of the subsystem. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of subsystem, its overall design and structure,
  - documents necessary for the compilation of the technical file as described in point 4 of Annex VI to Directive 2008/57/EC,
  - a separate file with the set of data required by the relevant TSI(s) for each relevant register provided for in Articles 34 and 35 of Directive 2008/57/EC,
  - if relevant, descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
  - conditions of integration of the subsystem in its system environment and the necessary interface conditions,
  - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
  - results of design calculations made, examinations carried out, etc.,
  - test programme and reports,
  - evidence of conformity with other regulations deriving from the Treaty (including certificates, if any),
  - documentation regarding the manufacture and the assembly of the subsystem,
  - a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation,
  - conditions for use of the subsystem (restrictions of running time or distance, wear limits etc.),
  - conditions for maintenance and technical documentation on maintenance of the subsystem,
  - any technical requirement specified in the relevant TSI(s) that shall be taken into account during production, maintenance or operation of the subsystem,
  - all other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies, and
  - any further information, if required by the relevant TSI(s),
- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests (including those in operational conditions) carried out by the appropriate testing body of the applicant, or by another testing body on his behalf and under his responsibility.
- 4.3. When the subsystem referred to in point 4.1 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.

The applicant shall also provide the notified body with a precise reference to the TSI(s) or their parts for which the derogation is requested.

The applicant shall communicate to the notified body the outcome of the derogation procedure.

- 4.4. The notified body shall examine the application, and where the design meets the requirements of the relevant TSI(s) that apply to the subsystem it shall issue an EC design examination certificate to the applicant. The certificate shall give the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of the subsystem with the examined design to be evaluated.

Where the subsystem referred to in point 4.1 is subject to derogation, upgrade, renewal or specific case, the EC design examination certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

If only certain parts are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.

Where the design does not satisfy the requirements of the relevant TSI(s), the notified body shall refuse to issue an EC design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

The applicant shall draw up a written EC ISV declaration according to section 2 of Annex VI to Directive 2008/57/EC.

- 4.5. The applicant shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the relevant TSI(s) or the conditions for validity of the certificate until the expiry of the validity of the certificate. Such modifications shall require additional approval — from the notified body that issued the EC design examination certificate — in the form of an addition to the original EC design examination certificate. Only those examinations and tests that are relevant and necessary to the changes shall be performed.

- 4.6. Each notified body shall inform its notifying authorities of the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EC design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EC design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the applicant until the expiry of the validity of the certificate.

- 4.7. The applicant shall keep a copy of the EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities throughout the service life of the subsystem.

5. Surveillance under the responsibility of the notified body

- 5.1. The purpose of surveillance is to make sure that the applicant duly fulfils the obligations arising out of the approved quality management system.

5.2. The applicant shall, for periodic audits purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality management system documentation,
- the quality records as provided for by the design part of the quality management system, such as results of analyses, calculations, tests, etc.,
- the quality records as provided for by the manufacturing part of the quality management system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.3. The notified body shall carry out periodic audits to make sure that the applicant maintains and applies the quality management system and shall provide the applicant with an audit report.

The frequency of the periodic audits shall be at least once every 2 years, with at least one audit during the time period of performing the relevant activities (design, manufacture, assembly or installation) for the subsystem being the subject of the EC design examination referred to in point 4.4.

When the manufacturer operates a certified quality management system, the notified body shall take this into account during the periodic audits.

5.4. In addition, the notified body may pay unexpected visits to the applicant. During such visits, the notified body may, if necessary, carry out subsystem tests, or have them carried out, in order to check the proper functioning of the quality management systems. It shall provide the applicant with a visit report and, if tests have been carried out, with a test report.

5.5. The notified body responsible for the EC verification of the subsystem, if not carrying out the surveillance of all the quality management systems concerned as under point 3, shall coordinate the surveillance activities of any other notified bodies responsible for that task, in order:

- to be ensured that correct management of interfaces between the different quality management systems relating to subsystem integration has been performed,
- to collect, in liaison with the applicant, the necessary elements for the assessment to guarantee the consistency and the overall supervision of the different quality management systems.

This coordination includes the right of the notified body:

- to receive all documentation (approval and surveillance), issued by the other notified body(ies),
- to witness the surveillance audits referred to in point 5.2,
- to initiate additional audits referred to in point 5.3 under its responsibility and together with the other notified body(ies).

6. EC certificate of verification and EC declaration of verification

6.1. Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.

Where the subsystem referred to in point 4.1 is subject to derogation, upgrade, renewal or specific case, the EC certificate shall also indicate the precise reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant TSI(s), the notified body shall issue an EC ISV certificate in compliance with Article 18(4) of Directive 2008/57/EC.



- 6.2. The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem. The EC declaration of verification shall identify the subsystem for which it has been drawn up and shall mention the number of the design examination certificate.

Where the subsystem referred to in point 4.1 is subject to derogation, upgrade, renewal or specific case, the EC declaration for the subsystem shall also indicate the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure.

In case of ISV procedure the applicant shall draw up a written EC ISV declaration.

The EC declaration and the accompanying documents shall be written in accordance with Annex V to Directive 2008/57/EC.

The certificates to be referred to are:

- the quality management system approval referred to in point 3.3 and audit reports indicated in point 5.3, if any,
- the EC design examination certificate referred to in point 4.4 and its additions.

A copy of the EC declaration of verification and EC ISV declarations, if any, shall be made available to the relevant authorities upon request.

- 6.3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.

7. The applicant shall, throughout the service life of the subsystem, keep at the disposal of the national authorities:

- the documentation concerning the quality management system referred to in point 3.1,
- the change referred to in point 3.5, as approved,
- the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4, and
- the technical file referred to in 6.3.

8. Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of EC certificates of verification it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of EC certificates of verification which it has issued.

9. Authorised representative

The applicant's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.3, 4.5, 4.7, 6.2 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX II

**List of terms used in the conformity assessment modules specific for railways and their equivalent in generic modules defined in Decision No 768/2008/EC**

Decision No 768/2008/EC	This Decision	Module in this Decision
product	interoperability constituent	CA, CA1, CA2, CB, CC, CD, CF, CH, CH1
product	subsystem	SB, SD, SF, SG, SH1
legislative instrument	technical specification for interoperability	CA, CA1, CA2, CB, CC, CD, CF, CH, CH1
legislative instrument	relevant TSI(s) as well as any other regulations deriving from the Treaty;relevant TSI(s)	SB, SD, SF, SG, SH1
quality system	quality management system	CD, CH, CH1, SD, SH1
quality assurance	quality management system	CD, CH, CH1, SD, SH1
conformity (assessment)	EC verification	SB, SD, SF, SG, SH1
manufacturer	applicant	SB, SD, SF, SG, SH1
certificate of conformity	EC certificate of verification	SD, SF, SG, SH1
declaration of conformity	EC declaration of verification	SD, SF, SG, SH1

## ANNEX III

## CORRELATION TABLE

Decisions 2008/164/EC, 2008/163/EC, 2008/217/EC, 2008/284/EC, 2006/860/EC, 2008/232/EC, 2006/679/EC, 2006/66/EC, 2006/861/EC	Decision No 768/2008/EC	This Decision
Module A. Internal production control	Module A. Internal production control	Module CA. Internal production control
Module A1. Internal design control with product verification	Module A1. Internal production control plus supervised product testing	Module CA1. Internal production control plus product verification by individual examination
	Module A2. Internal production control plus supervised product checks at random intervals	Module CA2. Internal production control plus product verification at random intervals
Module B. Type examination	Module B. EC-type examination	Module CB. EC-type examination
Module C. Conformity to type	Module C. Conformity to type based on internal production control	Module CC. Conformity to type based on internal production control
	Module C1. Conformity to type based on internal production control plus supervised product testing	
	Module C2. Conformity to type based on internal production control plus supervised product checks at random intervals	
Module D. Production quality management system	Module D. Conformity to type based on quality assurance of the production process	Module CD. Conformity to type based on quality management system of the production process
	Module D1. Quality assurance of the production process	
	Module E. Conformity to type based on product quality assurance	
	Module E1. Quality assurance of final product inspection and testing	
Module F. Product verification	Module F. Conformity to type based on product verification	Module CF. Conformity to type based on product verification
	Module F1. Conformity based on product verification	
	Module G. Conformity based on unit verification	
Module H1. Full quality management system	Module H. Conformity based on full quality assurance	Module CH. Conformity based on full quality management system
Module H2. Full quality management system with design examination	Module H1. Conformity based on full quality assurance plus design examination	Module CH1. Conformity based on full quality management system plus design examination

Decisions 2008/164/EC, 2008/163/EC, 2008/217/EC, 2008/284/EC, 2006/860/EC, 2008/232/EC, 2006/679/EC, 2006/66/EC, 2006/861/EC	Decision No 768/2008/EC	This Decision
Module V. Type validation by in-service experience (suitability for use)		Module CV. Type validation by in-service experience (suitability for use)
Module SB. Type examination		Module SB. EC-type examination
Module SD. Product(ion) quality management system		Module SD. EC verification based on quality management system of the production process
Module SF. Product verification		Module SF. EC verification based on product verification
Module SG. Unit verification		Module SG. EC verification based on unit verification
Module SH2. Full quality management system with design examination		Module SH1. EC verification based on full quality management system plus design examination