II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 30 May 2002

concerning the technical specification for interoperability relating to the maintenance subsystem of the trans-European high-speed rail system referred to in Article 6(1) of Directive 96/48/EC

(Notified under document number C(2002) 1946)

(Text with EEA relevance)

(2002/730/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail network [1], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 2(c) of Directive 96/48/EC, the trans-European high-speed rail system is subdivided into structural or functional subsystems. These subsystems are described in Annex II to the Directive.

(2) In accordance with Article 5(1) of the Directive, each of the subsystems shall be covered by a technical specification for interoperability (TSI).

(3) In accordance with Article 6(1) of the Directive, draft TSIs shall be drawn up by the joint representative body.

(4) The Committee set up under Article 21 of Directive 96/48/EC has appointed the European Association for Railway Interoperability (AEIF) as the joint representative body in accordance with Article 2(h) of the Directive.

(5) The AEIF has been given a mandate to draw up a draft TSI for the maintenance subsystem in accordance with Article 6(1) of the Directive. This mandate has been established in accordance with the procedure laid down in Article 21(2) of the Directive.

(6) The AEIF has drawn up the draft TSI, together with an introductory report containing a cost-benefit analysis as provided for in Article 6(3) of the Directive.

(7) The draft TSI has been examined by the representatives of the Member States, in the framework of the Committee set up by the Directive, in the light of the introductory report.

(8) As specified in Article 1 of Directive 96/48/EC, the conditions for achieving interoperability of the trans-European high-speed rail system concern the design, construction, upgrading and operation of the infrastructures and rolling stock contributing to the functioning of the system to be put into service after the date of entry into force of the Directive. With regard to the infrastructures and rolling stock already in service at the time of entry into force of this TSI, the TSI should be applied from the time when work is envisaged on these infrastructures and rolling stock. However, the degree to which the TSI is applied will vary according to the scope and extent of the works foreseen and the costs and the benefits generated by the intended applications. In order for such partial works to concur into achieving full interoperability, they need to be underpinned by a coherent implementation strategy. In this context, a distinction should be made between upgrading, renewal and maintenance-related replacement.

[1] OJ L 235, 17.9.1996, p. 6.

(9) It is recognised that Directive 96/48/EC and the TSIs do not apply to renewals or maintenance-related replacement. It is desirable however that the TSIs should apply to renewals, as will be the case for the TSIs for the conventional rail system under Directive of the European Parliament and of its Council 2001/16/EC [2]. In the absence of a mandatory requirement and taking into account the extent of the renewal work, Member States are encouraged, where they are able to do so, to apply the TSIs to renewals and maintenance-related replacement.

(10) The TSI, which is the subject of this Decision, does not impose the use of specific technologies or technical solutions except where this is strictly necessary for the interoperability of the trans-European high-speed rail network.

(11) The TSI, which is the subject of this Decision, is based on best available expert knowledge at the time of preparation of the corresponding draft. Developments in technology or social requirements may make it necessary to amend or supplement this TSI. Where appropriate, a review or updating procedure will be initiated in accordance with Article 6(2) of Directive 96/48/EC.

(12) The provisions concerning maintenance specific to each subsystem and those concerning degraded modes are set out in the corresponding TSIs. The maintenance TSI therefore only concerns questions relating to logistics centres for train maintenance.

(13) In some cases, the TSI, which is the subject of this Decision, allows a choice between different solutions, making it possible to apply definitive or transitional interoperable solutions that are compatible with the existing situation. In addition, Directive 96/48/EC provides for special implementing provisions in certain specific cases. Furthermore, in the cases provided for in Article 7 of the Directive Member States must be allowed not to apply certain technical specifications. It is therefore necessary that the Member States ensure that an infrastructure register and a rolling stock register are published and updated each year. These registers will set out the main characteristics of the national infrastructure and rolling stock (e.g. the basic parameters) and their concordance with the characteristics prescribed by the applicable TSIs. To this end, the TSI, which is the subject of this Decision, indicates precisely which information must appear in the registers.

(14) The application of the TSI which is the subject of this Decision must take into account specific criteria relating to technical and operational compatibility between the infrastructures and the rolling stock to be placed in service and the network into which they are to be integrated. These compatibility requirements entail a complex technical and economical analysis that is to be done on a case by case basis. The analysis should take into account:

— the interfaces between the different subsystems referred to in Directive 96/48/EC,

— the different categories of lines and rolling stock referred to in that Directive, and

— the technical and operational environments of the existing network.

That is why it is essential to establish a strategy for the implementation of the TSI which is the subject of this Decision, which should indicate the technical stages to move from the present network conditions to a situation where the network is interoperable.

(15) The provisions of this Decision are in conformity with the opinion of the Committee set up by Directive 96/48/EC,

HAS ADOPTED THIS DECISION:

Article 1

The TSI relating to the 'maintenance' subsystem of the trans-European high-speed rail system referred to in Article 6(1) of Directive 96/48/EC is hereby adopted by the Commission. The TSI is set out in the Annex to this Decision. The TSI is fully applicable to the infrastructure and rolling stock of the trans-European high-speed rail system as defined in Annex I of Directive 96/48/EC, taking into account Article 2 hereunder.

Article 2

1. For the purposes of this Article:

— 'upgrading' means major work to modify a subsystem or part of a subsystem which changes the performance of the subsystem,

— 'renewal' means major work to replace a subsystem or part of a subsystem which does not change the performance of the subsystem,

[2] OJ L 110, 20.4.2001, p. 1.

— 'maintenance-related replacement' means replacement of components by parts of identical function and performances in the context of predictive or corrective maintenance.

2. In the case of upgrading, the contracting entity will submit a dossier describing the project to the Member State concerned. The Member State will examine the dossier and, taking into account the implementation strategy in Chapter 7 of the attached TSI, will (where appropriate) decide whether the application of the attached TSI is needed. If so, it will inform the Committee set up pursuant to Directive 96/48/EC.

3. In the case of renewal and maintenance-related replacement, application of the attached TSI is voluntary.

Article 3

The attached TSI shall enter into force six months after notification of this Decision.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 30 May 2002.

For the Commission

Loyola DE PALACIO

Vice-President

ANNEX

TECHNICAL SPECIFICATION FOR INTEROPERABILITY RELATING TO THE MAINTENANCE SUBSYSTEM

1. INTRODUCTION

1.1. TECHNICAL SCOPE

This TSI concerns the maintenance subsystem, which is one of the subsystems listed in Annex II.1 to Directive 96/48/EC.

This TSI is part of a set of six TSIs, which cover all the eight subsystems defined in the Directive. The specifications concerning the 'users' and 'environment' subsystems, which are necessary to ensure interoperability of the trans-European high-speed rail system in compliance with the essential requirements, are set out in the TSIs concerned.

More information about the maintenance subsystem is given in Chapter 2.

1.2. GEOGRAPHICAL SCOPE

The geographical scope of this TSI is the trans-European high-speed rail system as described in Annex I to Directive 96/48/EC.

Reference shall be made in particular to the lines of the trans-European rail network described in European Parliament and Council Decision No 1692/96/EC of 23 July 1996 on Community guidelines for the development of the trans-European transport network or in any update to the same Decision as a result of the revision provided for in Article 21 of that Decision.

1.3. CONTENT OF THIS TSI

In accordance with Article 5(3) and with Annex I, point 1(b) to Directive 96/48/EC, this TSI:

(a) specifies the essential requirements for the subsystems and their interfaces (Chapter 3);

(b) establishes the basic parameters described in Annex II, point 3 to that Directive, which are necessary to meet the essential requirements (Chapter 4);

(c) establishes the conditions to be complied with to achieve the specified performances for each of the following categories of line (Chapter 4):

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

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

— category III: specially upgraded high-speed lines which have special features as a result of topographical, relief or town-planning constraints, on which the speed must be adapted to each case.

(d) establishes implementing provisions in certain specific cases (Chapter 7);

(e) determines the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are needed in order to achieve interoperability within the trans-European high-speed rail system while meeting the essential requirements (Chapter 5):

(f) states, in each case under consideration, which of the modules defined in Decision 93/465/EEC or, where appropriate, which specific procedures are to be used in order to assess either the conformity or the suitability for use of the interoperability constituents, as well as 'EC' verification of the subsystems (Chapter 6).

2. SUBSYSTEM DEFINITION AND SCOPE

The aim of this technical specification is to define the technical and regulatory prescriptions together with the necessary and appropriate procedures for the constituents in the 'maintenance' subsystem and for the interfaces required to guarantee interoperability of the European high-speed network in compliance with the essential requirements of the 'maintenance' subsystem.

The definition of the domain concerned by the maintenance subsystem together with the field of application of the associated technical specification are derived from the maintenance or monitoring operations which should be applied as general practice in order to meet the requirements of interoperability.

In view of the geographical structure of the European high-speed network and the commercial speeds at which trains are operated, it will be possible to schedule rosters so that each train can return at staggered intervals to a designated base in its country of origin where the complex maintenance operations will be carried out at frequencies compatible with the design and reliability of high-speed trains. Indeed, the design of high-speed trains integrates highly reliable technical solutions and functional architecture incorporating redundancy with a very high level of availability which is far superior to a conventional rake of coaches with one or two locomotives. In addition, monitoring or testing devices which use automatic isolation equipment make it easier to identify the current functional status of the trainset so that it can be formed in such a way as to continue in commercial service until its return to the maintenance centre.

The conditions under which some repair work can be undertaken to allow the safe return of the rolling stock to the agreed maintenance depot and the special operating conditions for the rolling stock when it is in a degraded state, shall be agreed, case by case, between the infrastructure managers and the railway undertakings, according to particular characteristics of the rolling stock and to the circulation rules or regulations of the countries concerned.

In no event must any major corrective maintenance operation (except those required by specific situations, see Annex I to this TSI) or inspection be performed outside the dedicated trainset maintenance facilities. As a result, trainset maintenance logistics facilities covered by the present TSI shall be expressly restricted to operations ensuring interoperability. Such operations concern the restocking of consumable materials (water and sand), cleaning (the inside and outside of trainsets) and toilet emptying.

Generally speaking, maintenance arrangements specific to each subsystem covered by a TSI shall, if necessary at all, be set out in the corresponding TSI.

As regards the reliability and functional architecture of trainsets as well as the maintenance organisation used, maintenance is organised so as to be compatible with economically acceptable and profitable trainset operation.

From this standpoint, facilities falling within the field of application of the 'maintenance' technical specification for interoperability (TSI) are those required to:

— clean the inside and outside of the trainsets,

— deal with retention toilets,

— restock the water and sand supplies.

3. **ESSENTIAL REQUIREMENTS**

3.1. In accordance with Article 4(1) of Directive 96/48/EC, the trans-European high-speed rail system, its subsystems and their interoperability constituents must meet the relevant essential requirements as specified in Annex III to the Directive.

3.2. The essential requirements are related to:

— safety,

— reliability and availability,

— health,

— environmental protection,

— technical compatibility.

According to Directive 96/48/EC, the essential requirements may be general in scope and are applicable across the board to the entire trans-European high-speed rail system and may contain specific features for each subsystem and its constituents.

3.3. Requirements specific to the 'maintenance' subsystem (facilities and procedures used in maintenance centres handling interoperable high-speed trainsets) responding to and in addition to the considerations laid down in Annex III to the Directive are specified as follows:

— **Safety**

Essential requirement 1.1.1:

'The design, construction or assembly, maintenance and monitoring of safety-critical components, and more particularly of the components involved in train movements must be such as to guarantee safety at the level corresponding to the aims laid down for the network, including those for specific degraded situations.'

The fulfilment of this essential requirement may be considered as achieved when conformity to the prescriptions of point 4.2.2.2.5 (sand restocking equipment) of the present TSI is certified.

Essential requirement 1.1.2:

'The parameters involved in the wheel/rail contact must meet the stability requirements needed in order to guarantee safe movement at the maximum authorised speed.'

This essential requirement is not relevant to the maintenance subsystem.

Essential requirement 1.1.3:

'The components used must withstand any normal or exceptional stresses that have been specified during their period in service. The safety repercussions of any accidental failures must be limited by appropriate means.'

This essential requirement is not relevant to the maintenance subsystem.

Essential requirement 1.1.4:

'The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting the generation, propagation and effects of fire and smoke in the event of a fire.'

For the fixed installations of the maintenance subsystem, the fulfilment of this essential requirement may be considered as achieved when conformity of these installations with national regulations is demonstrated.

Essential requirement 1.1.5:

'Any devices intended to be handled by users must be so designed as not to impair their safety if used foreseeably in a manner not in accordance with the posted instructions.'

This essential requirement is not relevant to the 'maintenance' subsystem.

— **Reliability and availability**

Essential requirement 1.2:

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

High-speed trainsets incorporate high-reliability technical solutions and functional architectural features with built-in redundancy ensuring maximum trainset availability. In addition monitoring/control equipment combined with automatic-isolation systems makes easier the knowledge of the functional status of trainsets and enables them to be configured in a way that guarantees continued operation of the trainset in commercial service until its return to the maintenance depot.

Consequently no specific measure needs to be taken with regard to the 'maintenance' subsystem to ensure trainset reliability and availability in the context of this essential requirement.

— **Health**

Essential requirement 1.3.1:

'Materials likely, by virtue of the way they are used, to constitute a health hazard to those having access to them must not be used in trains and railway infrastructures.'

For the fixed installations of the maintenance subsystem, the fulfilment of this essential requirement may be considered as achieved when conformity of these installations with EC Directives and national regulations is demonstrated.

Essential requirement 1.3.2:

'Those materials must be selected, deployed and used in such a way as to restrict the emission of harmful and dangerous fumes or gases, particularly in the event of fire.'

For the fixed installations of the maintenance subsystem, the fulfilment of this essential requirement may be considered as achieved when conformity of these installations with national regulations is demonstrated.

Essential requirement 2.5.1:

'The technical installations and the procedures used in the maintenance centres must not constitute a danger to human health.'

For the fixed installations of the 'maintenance' subsystem, the fulfilment of this essential requirement may be considered as achieved when conformity of these installations with national regulations is demonstrated.

— **Environmental protection**

Essential requirement 1.4.1:

'The repercussions on the environment of the establishment and operation of the trans-European high-speed rail system must be assessed and taken into account at the design stage of the system in accordance with the Community provisions in force.'

This essential requirement is not relevant to the 'maintenance' subsystem.

Essential requirement 1.4.2:

'The materials used in the trains and infrastructures must prevent the emission of fumes or gas which are harmful and dangerous to the environment, particularly in the event of fire.'

For the fixed installations of the maintenance subsystem, the fulfilment of this essential requirement may be considered as achieved when conformity of these installations with national regulations is demonstrated.

Essential requirement 1.4.3:

'The rolling stock and energy-supply systems must be designed and manufactured in such way as to be electromagnetically compatible with the installations, equipment and public or private networks with which they might interfere.'

This essential requirement is not relevant to the maintenance subsystem.

Essential requirement 2.5.2:

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

For the fixed installations of the maintenance subsystem, the fulfilment of this essential requirement may be considered as achieved when conformity of these installations with national regulations is demonstrated.

— **Technical compatibility**

Essential requirement 1.5:

'The technical characteristics of the infrastructures and fixed installations must be compatible with each other and with those of the trains to be used on the trans-European high-speed rail system.

If adherence to these characteristics proves difficult on certain sections of the network, temporary solutions, which ensure compatibility in the future, may be implemented.'

The fulfilment of this essential requirement may be considered as achieved when conformity to the prescriptions of points 4.2.2.1, 4.2.2.2.1, 4.2.2.2.2 and 4.2.2.2.4 of Chapter 4, as well as points 5.3.1 and 5.3.5 of Chapter 5 of the present TSI is certified.

Essential requirement 2.5.3:

'The maintenance installations (handling) high-speed trains must be such as to enable safety, health and comfort operations to be carried out on all trains for which they have been designed.'

The fulfilment of this essential requirement may be considered as achieved when conformity to the prescriptions of points 4.2.2.1, 4.2.2.2.1, 4.2.2.2.2, 4.2.2.2.4, 4.2.2.2.5 and 4.2.2.2.6 of Chapter 4, as well as points 5.3.1 and 5.3.5 of Chapter 5 of the present TSI is certified.

3.4. Verification that the essential requirements governing the subsystem and its constituents have been complied with is established in accordance with the provisions laid down in Directive 96/48/EC.

4. **CHARACTERISATION OF THE SUBSYSTEM**

The high-speed trans-European rail system as covered by the provisions of Directive 96/48/EC and of which the maintenance subsystem forms a part, is an integrated system the coherence of which must be verified particularly regarding the basic parameters, the interfaces and the performance levels with a view to ensuring system interoperability in the respect of the essential requirements.

Regarding interoperability, the maintenance subsystem is characterised as follows:

4.1. BASIC PARAMETERS OF THE 'MAINTENANCE' SUBSYSTEM

The maintenance subsystem is not characterised by the basic parameters listed in Annex II (Section 3) to Directive 96/48/EC.

4.2. INTERFACES OF MAINTENANCE SUBSYSTEM

4.2.1. **Subsystem interface**

Regarding technical compatibility, the interfaces of the maintenance subsystem are concerned with:

— the infrastructure subsystem,

— the rolling stock subsystem.

4.2.2. **These interfaces are characterised by:**

4.2.2.1. *Interface with the infrastructure subsystem*

— Stabling tracks

  — Stabling tracks must have an overhead line to supply power to the train.

  — Their geometrical characteristics (including length) have to be in accordance with the prescriptions of point 4.3.3.5 of the infrastructure TSI.

  — If a toilet discharge trolley is used, the minimum distance between track centres must be 6 m and a running path for the trolleys shall be provided.

4.2.2.2. *Interface with the rolling stock subsystem*

4.2.2.2.1. Trainset exterior cleaning facilities

— It must be possible for the front windows of drivers' cabs to be cleaned both from the ground and from platform heights of 550 mm and 760 mm using suitable (with particular regard to health and safety aspects) cleaning equipment, in all stations and facilities at which the trains call or are stabled.

— When washing machines are used they shall be able to clean the outer sides of single or double-deck trainsets over a height of:

  — 1 000 to 3 500 mm for a single-deck trainset,

  — 500 to 4 300 mm for double-deck trainsets.

  It must be possible for the speed at which the trainset passes through the train washing plant to be adapted to suit each washing plant, i.e. between 4 and 6 km/h.

— Products used for washing trains must comply with local environmental-protection regulations.

4.2.2.2.2. Toilet discharge systems

— The technology of the trainset toilets shall allow the sealed toilets (using clear or recycled water) to be emptied at three-day intervals, so that the emptying operations can be performed on a scheduled basis at designated depots.

— Toilets discharge installation (fixed or mobile) shall be compatible with the characteristics either of one of the sealed system either with the other one.

— A mobile trolley may be provided to enable evacuation when needed thereby allowing the rolling stock to continue in commercial service until its return to the home depot.

— Any mobile discharge trolleys needed shall perform all of the following functions:

  — suction (the limit value for the suction vacuum is set at 0,2 bar),

  — rinsing (only applies to retention toilet discharge equipment),

  — pre-loading or filling with additive (only applies to retention toilet discharge equipment),

  — discharge.

4.2.2.2.3. Trainset interior cleaning equipment

— A 3 000 VA at 230 V, 50 Hz electrical power supply connection shall be provided in each coach for powering industrial cleaning equipment. This power must be available simultaneously in all the coaches of a trainset. Electric power sockets inside the train must be spaced such that no part of the coach that must be cleaned is more than 12 m from one of the sockets.

4.2.2.2.4. Water restocking equipment

— The new equipment for water supply on the interoperable network shall be supplied with drinking water in accordance with Directive 98/83/EC, and their mode of operation must ensure that water delivered at the last element of the fixed part of these installations complies with the quality specified by this same Directive for water intended for human consumption.

4.2.2.2.5. Sand restocking equipment

— Sandboxes are normally filled during scheduled maintenance operations in specialised workshops in charge of trainset maintenance. However, if required, sand meeting local specifications for this use shall be made available to fill sand boxes so that rolling stock can continue in commercial service until it returns to its maintenance centre.

4.2.2.2.6. Special requirements for stabling of trains

The trains must be designed so that:

— the trainsets respect, during their stabling, the level of noise stipulated in the rolling stock TSI,

— periodic monitoring is not necessary when they are stabled under voltage,

— they can be configured for different functional levels (standby, preparation, etc.),

— an absence of voltage does not damage any train constituents,

— stabled trains can be safely secured against all risks of unexpected movement.

They must in particular incorporate parking brakes to ensure that operating rules applicable locally can be observed whenever the use of such brakes is required.

4.2.3. **Regulatory and operational provisions**

To ensure coherence of the trans-European railway system, the abovementioned interfaces shall be subject to the following regulatory and operational requirements:

(None)

4.3. SPECIFIED PERFORMANCE OF THE MAINTENANCE SUBSYSTEM

The performance criteria which the maintenance subsystem must meet correspond to the performances specified for each of the following line categories of the trans-European high-speed rail system, as relevant:

— lines specially built for high-speed running,

— lines specially upgraded for high speed,

— lines specially upgraded for high speed which have special features.

In the case of the maintenance subsystem, the performance requirements are the same for all three categories of line.

5. **INTEROPERABILITY CONSTITUENTS**

5.1. In keeping with Article 2(d) of Directive 96/48/EC, interoperability constituents are 'any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the trans-European high-speed rail system depends either directly or indirectly'.

5.2. The interoperability constituents are subject to relevant provisions in Directive 96/48/EC and are the following as concerns this TSI:

— toilet discharge systems: connections,

— equipment for cleaning trainset interiors: electrical sockets,

— equipment for restocking of water and sand supplies: water filling (inlet) adapters.

5.3. These interoperability constituents are the subject of specifications in the form of performance requirements. Conformity assessment and/or fitness for use is focused through interoperability constituent interface requirements as a priority, with reference to design or descriptive characteristics being exceptional.

5.3.1. The specifications for the toilet discharge system connections interoperability constituent are the following:

— The connections (3" for emptying and 1" for rinsing) and their seals must comply with figures 1 and 2 respectively of Annex IV.

5.3.2. The interfaces of the toilet discharge system connections interoperability constituent are characterised as follows:

(None)

5.3.3. The specifications for the trainset interior cleaning equipment, electrical sockets interoperability constituent are the following:

— The interior sockets must comply with the dimensions laid down in EN Standard 60 309.1, and must fulfil the dimensional characteristics of the socket stated on page 22 of EN Standard 60 309.2 (socket with two poles + earth) and the characteristics specified in Sections 8.3.1 and 8.3.1.1 of Standard EN 50 153.

5.3.4. The interfaces of the trainset interior cleaning equipment, electrical sockets interoperability constituent are characterised as follows:

(None)

In as much as the specifications of the interoperability constituent trainset interior cleaning equipment, electrical sockets make reference to European specifications drawn up by the European standardisation bodies – CEN, CENELEC and ETSI – as instructed by the Commission, the latter specifications themselves must be drawn up on a performance basis and only exceptionally on a prescriptive basis.

The relevant European specifications are:

— Standard EN 60 309.1,

— Standard EN 60 309.2 (p. 22),

— Standard EN 50 153 (Section 8.3.1 and 8.3.1.1),

— Directive 98/83/EC (quality of the water).

5.3.5. The specifications of the interoperability constituent water filling adapters are the following:

— The water filling adapters shall be as shown in Figure 3 of Annex V.

5.3.6. The interfaces of the water filling adapters interoperability constituent are characterised as:

(None).

6. **ASSESSMENT OF CONFORMITY AND/OR SUITABILITY FOR USE**

6.1. INTEROPERABILITY CONSTITUENTS

6.1.1. **Conformity assessment procedures (modules)**

The assessment procedure for conformity of interoperability constituents as defined in Chapter 5 of this TSI shall be carried out by application of modules as specified in Annex III to this TSI.

Assessment procedures for conformity, descriptions of the testing methods for in the interoperability constituents: toilet discharge system connections, trainset interior cleaning equipment (electrical sockets) and water filling adapters, as defined in Chapter 5 of this TSI, are indicated in Annex II, Tables II.1, II.2 and II.3 to this TSI.

As far as required by the modules specified in Annex III to this TSI, the assessment of conformity of an interoperability constituent shall be appraised by a notified body, when indicated in the procedure, with which the manufacturer or his authorised representative established within the Community has lodged the application.

The manufacturer of an interoperability constituent or his authorised representative established within the Community shall draw up an EC declaration of conformity in accordance with Article 13(1) and Annex IV, Chapter 3, to Directive 96/48/EC before placing the interoperability constituent on the market. An EC declaration of suitability for use is not required for interoperability constituents of the maintenance subsystem.

6.1.2. **Application of modules**

Assessment of conformity

For the assessment procedure of each interoperability constituent of the maintenance subsystem, the manufacturer or his authorised representative established within the Community shall apply the internal control of production procedure (module A) indicated in Annex III (III.1) to this TSI.

Definition of assessment procedures

The assessment procedures are defined in Annex III to this TSI.

The conformity assessment shall cover the phases and characteristics as indicated by X in the Tables II.1, II.2 and II.3 of Annex II to this TSI.

6.2. MAINTENANCE SUBSYSTEM

6.2.1. **Assessment procedures (modules)**

At the request of the adjudicating entity or its authorised representative established within the Community, the notified body carries out the EC verification in accordance with Article 18(1) and Annex VI to Directive 96/48/EC and in accordance with the provisions of the relevant modules as specified in Annex III to this TSI.

If the adjudicating entity can demonstrate that tests or verifications for previous applications remain valid in the new application, then the notified body shall take them into account in the conformity assessment.

Assessment procedures for the EC verification of the maintenance subsystem, list of specifications and descriptions of the testing procedures are indicated in Annex II, Table II.4 to this TSI.

As far as specified in this TSI, the EC verification of the maintenance subsystem shall take account of its interfaces with other subsystems of the trans-European high-speed rail system.

The adjudicating entity shall draw up the EC declaration of verification for the maintenance subsystem in accordance with Article 18(1) and Annex V to Directive 96/48/EC.

6.2.2. **Application of modules**

6.2.2.1. *Fixed installations*

For the verification procedure of the maintenance subsystem (fixed installations), the adjudicating entity or its authorised representative established within the Community may choose either:

— the unit verification procedure (module SG) indicated in Annex III (III.5) to this TSI, or

— the full quality assurance with design examination procedure (module SH2) indicated in Annex III (III.6) to this TSI.

The module SH2 may be chosen only where all activities contributing to the subsystem project to be verified (design, manufacturing, assembling, installation) are subject to a quality system for design, production, final product inspection and testing, approved and surveyed by a notified body.

The assessment shall cover the phases and characteristics as indicated in Table II.4 of Annex II to this TSI.

6.2.2.2. *On-board installations*

For the verification procedure of the maintenance subsystem (on-board installations), the adjudicating entity or its authorised representative established within the Community may choose either:

— the type-examination procedure (module SB) indicated in Annex III (III.2) to this TSI, for the design and development phase, in combination with:

— either the production quality assurance procedure (module SD) indicated in Annex III (III.3), or the product verification procedure (module SF) indicated in Annex III (III.4) to this TSI, for the production phase, or

— the full quality assurance with design examination procedure (module SH2) indicated in Annex III (III.6) to this TSI, for all phases.

The module SD may be chosen only where all activities contributing to the subsystem project to be verified (manufacturing, assembling, installation) are subject to a quality system for production, final product inspection and testing, approved and surveyed by a notified body.

The module SH2 may be chosen only where all activities contributing to the subsystem project to be verified (design, manufacturing, assembling, installation) are subject to a quality system for design, production, final product inspection and testing, approved and surveyed by a notified body.

The assessment shall cover the phases and characteristics as indicated in Table II.5 of Annex II to this TSI.

7. **IMPLEMENTING THE MAINTENANCE TSI**

7.1. IMPLEMENTATION PROCEDURE AND TIMING

7.1.1. **Procedure**

The implementation of the specifications on maintenance equipment are based on the following general steps:

Step 1:

The rolling stock roster project is examined by both the infrastructure manager and the railway undertaking.

Step 2:

An economic study is carried out by both the infrastructure manager and the railway undertaking, on the basis of which the initial roster may be modified.

7.1.2. **Timing**

Because of:

— the time needed to build or modify the fixed installations, and to put into place the mobile toilet discharge trolleys,

— the principle by which compliance with interoperability requirements of the already existing fixed installations is only possible if incorporated into long-term renewal and repair schedules,

the timing of implementation will have to be negotiated between the infrastructure manager and the railway undertaking.

In particular, if the railway undertaking wishes to start to operate the interoperable route within a time not compatible with those constraints, then the infrastructure manager and the railway undertaking will negotiate temporary solutions (drawing up temporary rolling stock rosters for example).

7.1.3. **Implementation of maintenance equipment (lines of all categories)**

7.1.3.1. *Stabling tracks*

First step: the infrastructure manager and the railway undertaking examine together the rolling stock roster project proposed by the railway undertaking, and identify the areas of the interoperable network, on the route under consideration, where the trainsets should (according to this rolling stock roster project) have to be stabled and where there are not (or not enough) stabling tracks meeting the requirements of the TSI.

Second step: the infrastructure manager and the railway undertaking carry out together an economic study, possibly leading to modifications of the rolling stock roster. Those modifications, regarding the number and/or the location of the trainsets stabling areas, minimise the number of the new (complying with the maintenance TSI) stabling tracks that will have to be built, and also the number of already existing stabling tracks that will have to be brought into conformity with this TSI.

7.1.3.2. *Water supply facilities*

First step: the infrastructure manager and the railway undertaking examine together the rolling stock roster project proposed by the railway undertaking, and identify the areas of the interoperable network, on the route under consideration, where the trainsets should (according to this rolling stock roster project) be supplied with water, and where there are not (or not enough) water supply facilities meeting the requirements of the TSI.

Second step: the infrastructure manager and the railway undertaking carry out together an economic study possibly leading to modifications of the rolling stock roster. Those modifications, regarding the number and/or the location of the areas where the trainsets will be supplied with water, minimise the number of the new (complying with the maintenance TSI) water supply facilities that will have to be built, and also the number of already existing facilities that will have to be brought into conformity with this TSI.

7.1.3.3. *Mobile toilet discharge trolleys*

First step: the infrastructure manager and the railway undertaking examine together the rolling stock roster project proposed by the railway undertaking, and identify the areas of the interoperable network, on the route under consideration, where it should be possible (according to this rolling stock roster project) to discharge the trainsets toilets when needed, and where there are not (or not enough) toilet emptying fixed facilities allowing this operation on those trainsets.

Second step: the infrastructure manager and the railway undertaking carry out together an economic study leading to modifications of the rolling stock roster. Those modifications, regarding the number and/or the location of the areas where it will be possible to discharge the trainsets toilets when needed, minimise the number of mobile toilet discharge trolleys (complying with the maintenance TSI) that will have to be placed on those areas.

7.2. SPECIFIC CASES: DETAILS OF APPLICATION

(None).

7.3. RECOMMENDATION

With the aim of continually improving the water quality in the vehicles for high-speed traffic, it is recommended that installations dealt with in point 4.2.2.2.4 be employed in such a manner that the vehicles are filled with water of a quality complying with Directive 83/18/EC. In that case, the not fixed installations, the hoses and nozzles, should be handled with care in order to keep water quality.

ANNEX I

SPECIFIC SITUATIONS

As specified in the TSI, the redundancies incorporated into high-speed trainsets at the design stage should enable preventive and corrective maintenance work to be carried out mostly at the designated rolling stock maintenance depot.

However, certain types of damage, examples of which are listed below, can lead:

— either to degraded operating modes for the rolling stock and operating restrictions (speed restriction, coach shutdowns, etc.),

— or to the need for corrective maintenance at the train terminus.

As it is important for financial reasons not to equip every terminus with special facilities, nor to tie up supplies of little used spare parts, and in view of the difficulty of keeping staff trained for several types of rolling stock, corrective maintenance operations should be dealt with according to one of the following four arrangements:

— basic repairs that can be carried out by train staff without any specific knowledge of the type of rolling stock,

— repairs carried out with specialist support from the home depot via a phone link,

— repairs carried out by a team from the home depot sent immediately to the spot,

— isolation of the failed component and trainset returned to base in non-commercial service.

The specific operating conditions in degraded mode or following partial or temporary repairs must be approved on a case-by-case basis according to the specifics of the rolling stock and the rules or regulations governing the working of trains in the countries crossed (bilateral agreements required).

Examples of possible damage:

— evidence of wheel flats

— hot axle box

— seized axle

— entrance doors jammed

— air conditioning failure

— broken windows

— pantograph disabled

— toilets out of order

— faulty train control equipment (TVM, LZB, RS 4 codes…)

— horn or headlights failure

— damage to suspension spring

— damage to bogie

— damage to dampers

— damage to coupling

— trainset power supply failure

— lighting failure

— …

ANNEX II

ASSESSMENT OF CONFORMITY

ASSESSMENT OF INTEROPERABILITY CONSTITUENTS

II.1. **Scope**

This Annex indicates the assessment of conformity of interoperability constituents: toilet discharge system connections, trainset-interior cleaning equipment (electrical sockets) and water filling adapters of the maintenance subsystem.

II.2. **Characteristics**

The characteristics of the interoperability constituents to be assessed in the different phases of design and production are marked by X in Table II.1, Table II.2 and Table II.3.

Table II.1.

Assessment of the interoperability constituent: toilet discharge system connections

1		2	3	4	5	6
Characteristics to be assessed		Assessment in the following phase				
		Design and development phase				Production phase (series)
Characteristic	Clause	Design review	Review of manufacturing process	Type test	In service experience	
Type and dimensions	5.3.1	X	n.a.	n.a.	n.a.	X
n.a.: not applicable.						

Table II.2.

Assessment of the interoperability constituent: trainset-interior cleaning equipment (electrical sockets)

1		2	3	4	5	6
Characteristics to be assessed		Assessment in the following phase				
		Design and development phase				Production phase (series)
Characteristic	Clause	Design review	Review of manufacturing process	Type test	In service experience	
Type and dimensions	5.3.3	X	n.a.	n.a.	n.a.	X
n.a.: not applicable.						

Table II.3.

Assessment of the interoperability constituent: water filling adapters

1		2	3	4	5	6
Characteristics to be assessed		Assessment in the following phase				
		Design and development phase				Production phase (series)
Characteristic	Clause	Design review	Review of manufacturing process	Type test	In service experience	
Type and dimensions	5.3.5	X	n.a.	n.a.	n.a.	X
n.a.: not applicable.						

ASSESSMENT OF THE MAINTENANCE SUBSYSTEM

II.3. **Scope**

This Annex indicates the assessment of conformity of the maintenance subsystem.

II.4. **Characteristics**

The characteristics of the subsystem to be assessed in the different phases of design, installation and operation are marked by X in Tables II.4 (for fixed installations) and II.5 (for on-board installations).

Table II.4.

Assessment of the maintenance subsystem (fixed installations)

1		2	3	4	5
Characteristics to be assessed		Assessment in the following phase			
		Design and development phase	Production phase		
Characteristic	Clause	Design review	Construction, assembling, mounting	Assembled, before putting into service	Validation under full operation conditions
Washing machine					
Height to clean	4.2.2.2.1	X	n.a.	n.a.	X
Speed	4.2.2.2.1	X	n.a.	n.a.	X
Mobile emptying system					
Functions	4.2.2.2.2	X	n.a.	n.a.	X
Pressure	4.2.2.2.2	X	n.a.	n.a.	X
Compatibility with on-board toilets	4.2.2.2.2	X	n.a.	n.a.	X
Stabling tracks					
Length and geometrical characteristics		X	n.a.	n.a.	X
Water and sand supply facilities					
Quality of water	4.2.2.2.4	X	n.a.	n.a.	X
Availability of sand	4.2.2.2.5	X	n.a.	n.a.	X
Quality of sand	4.2.2.2.5	X	n.a.	n.a.	X

n.a.: not applicable.

Table II.5.

Assessment of the maintenance subsystem (on-board installations)

1		2	3	4
Characteristics to be assessed		Module for assessment in the following phase		
		Design and development phase		Production phase
Characteristic	Clause	Design review	Type test	Serial production quality
Toilet emptying				
Technology of trainset toilets allowing to be emptied at three-day intervals	4.2.2.2.2	X	n.a.	n.a.
Power supply for internal cleaning				
Power — Voltage	4.2.2.2.3	X	X	n.a.
Availability of electrical sockets	4.2.2.2.3	X	n.a.	n.a.
Spacing of sockets	4.2.2.2.3	X	n.a.	n.a.
Trainsets standby				
Stationary noise level	4.2.2.2.6	X	X	n.a.
Capability of being stabled with no crew aboard and with auxiliary power supply sustained	4.2.2.2.6	X	n.a.	n.a.
Parking brake	4.2.2.2.6	X	n.a.	n.a.

n.a.: not applicable

ANNEX III

ASSESSMENT PROCEDURES (MODULES)

III.1. Module A (Internal production control)

Conformity assessment of interoperability constituents

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the interoperability constituent concerned satisfies the requirements of the TSI that apply to it.

2. The manufacturer must establish the technical documentation described in point 3.

3. The technical documentation must enable the conformity of the interoperability constituent with the requirements of this TSI to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the interoperability constituent. So far as relevant for the assessment, the documentation must contain:

   — a general description of the interoperability constituent,

   — conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,

   — descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the interoperability constituent,

   — a list of the technical specifications (relevant TSI and/or European specifications with relevant clauses, referred to in the TSI), applied in full or in part,

   — descriptions of the solutions adopted to meet the requirements of this TSI, where the European specifications referred to in the TSI have not been applied in full,

   — results of design calculations made, examinations carried out, etc.,

   — test reports.

4. The manufacturer must take all the measures necessary in order that the manufacturing process ensures compliance of the manufactured interoperability constituent with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to it.

5. The manufacturer or his authorised representative established within the Community must draw up a written declaration of conformity. The content of this declaration has to include at least the information, indicated in Annex IV(3) to Directive 96/48/EC and in Article 13(3) thereof. The EC declaration of conformity and the accompanying documents must be dated and signed.

   The declaration must be written in the same language of the technical file and must contain the following:

   — the Directive reference (Directive 96/48/EC and other Directives to which the interoperability constituent may be subject),

   — the name and address of the manufacturer or his authorised representative established within the Community (give trade name and full address and in the case of authorised representative also give the trade name of the manufacturer or constructor),

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

   — description of the procedure (module) followed in order to declare conformity,

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

   — reference to this TSI and to any other applicable TSI, and where appropriate reference to European specifications,

   — identification of signatory having received power to engage the manufacturer or his authorised representative established within the Community.

6. The manufacturer or his authorised representative must keep a copy of the EC declaration of conformity with the technical documentation for a period of 10 years after the last interoperability constituent has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the interoperability constituent in the Community market.

7. If additional to the EC declaration of conformity, an EC declaration for suitability for use for the interoperability constituent is required by the TSI, this declaration has to be added after being issued by the manufacturer under the conditions of module V.

III.2. MODULE SB (EC Type-examination)

EC verification of maintenance subsystem

1. This module describes the part of EC verification procedure whereby a notified body checks and certifies at the request of an adjudicating entity or its authorised representative established within the Community, that a type of a maintenance subsystem, representative for the production envisaged,

— complies with this TSI and any other applicable TSI, which demonstrate that the essential requirements of Directive 96/48/EC have been met,

— complies with the other regulations deriving from the Treaty.

2. The adjudicating entity or its authorised representative established within the Community must lodge an application for EC verification (through type-examination) of the subsystem with a notified body of his choice.

The application includes:

— name and address of the adjudicating entity or its authorised representative,

— the technical documentation, as described in point 3.

3. The applicant must place at the disposal of the notified body a specimen of the subsystem, representative of the production envisaged and hereinafter called 'type'.

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

The notified body may request further specimens if needed for carrying out the test programme.

If so required for specific test or examination methods and specified in the TSI or in the European specifications referred to in Article 10 of Directive 96/48/EC, also a specimen or specimens of a subassembly or assembly or a specimen of the subsystem in a pre-assembled condition has to be delivered.

The technical documentation must enable the design, manufacture, installation and operation of the subsystem to be understood, and shall enable conformity with the provisions of Directive 96/48/EC and of the TSI to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the subsystem.

It must include:

— a general description of the subsystem, overall design and structure,

— conceptual design and manufacturing drawings and schemes of components, subassemblies, assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,

— the technical design specifications, including European specifications, that have been applied,

— the necessary supporting evidence for their adequacy, in particular where European specifications referred to in Article 10 of Directive 96/48/EC and the relevant clauses have not been applied in full,

— a list of the interoperability constituents, to be incorporated into the subsystem,

— technical documentation as regards the manufacturing and the assembling of the subsystem,

— a list of manufacturers, involved in the subsystem's design, manufacturing, assembling and installation,

— conditions for use and maintenance of the subsystem (restrictions of running time or distance, wear limits etc),

— a list of the European specifications referred to in Article 10 of Directive 96/48/EC or in the technical design specification,

— results of design calculations made, examinations carried out, etc.,

— test reports.

If the TSI is requiring further information for the technical documentation, this has to be included.

4. The notified body must:

4.1. examine the technical documentation,

4.2. if a design review is requested in the TSI, perform an examination of the design methods, the design tools and the design results to evaluate their capability to fulfil the requirements for conformity for the subsystem at the completion of the design process;

4.3. if type tests are requested in the TSI, verify that the specimen(s) of the subsystem or of assemblies or subassemblies of the subsystem, required for carrying out type tests, has (have) been manufactured in conformity with the technical documentation, and carry out or have carried out the type tests in accordance with the provisions of the TSI and the European specifications concerned;

4.4. identify the elements which have been designed in accordance with the relevant provisions of the TSI and the European Specifications referred to in Article 10 of Directive 96/48/EC, as well as the elements which have been designed without applying the relevant provisions of those European specifications;

4.5. perform or have performed the appropriate examinations and necessary tests in accordance with points 4.2 and 4.3 to establish whether, where the relevant European specifications have been chosen, these have actually applied;

4.6. perform or have performed the appropriate examinations and necessary tests in accordance with points 4.2 and 4.3 to establish whether, where the adjudicating entity or the manufacturer(s) have chosen to apply the relevant European specifications (standards), these have actually been applied;

4.7. agree with the applicant the location where the examinations and necessary tests will be carried out.

5. Where the type meets the provisions of Directive 96/48/EC and of the TSI, the notified body must issue a type-examination certificate to the applicant. The certificate must contain the name and address of the adjudicating entity and the manufacturer(s), conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

The time period of validity shall be no longer than three years.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the adjudicating entity or its authorised representative established within the Community is denied a type-examination certificate, the notified body must provide detailed reasons for such denial.

Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved subsystem which must receive additional approval where such changes may affect the conformity with the requirements of Directive 96/48/EC and the TSI or the prescribed conditions for use of the subsystem. This additional approval is given in the form of an addition to the original EC type-examination certificate, or a new certificate will be issued after withdrawal of the old certificate.

7. If no modifications as under point 6 have been made, the validity of an expiring certificate can be extended for another period of validity. The applicant applies for such a prolongation by a written confirmation that no such modifications have been made, and the notified body issues a prolongation for another period of validity as in point 5, if no contrary information is existent. This procedure can be reiterated.

8. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn or refused.

9. The other notified bodies may receive copies of the type-examination certificates issued and/or their additions on request. The annexes to the certificates must be kept at the disposal of the other notified bodies.

10. The adjudicating entity or its authorised representative established within the Community must keep with the technical documentation copies of type-examination certificates and their additions throughout the service life of the subsystem, it must be sent to any other Member State who so requests.

III.3. Module SD (Production quality assurance)

EC verification of maintenance subsystem

1. This module describes the EC verification procedure whereby a notified body checks and certifies, at the request of an adjudicating entity or its authorised representative established within the Community, that a maintenance subsystem, for which an EC type-examination certificate has already been issued by a notified body,

   — complies with this TSI and any other applicable TSI, which demonstrates that the essential requirements of Directive 96/48/EC have been met,

   — complies with the other regulations deriving from the Treaty and may be put into service.

   The notified body is carrying out the procedure, under the condition, that the adjudicating entity and the manufacturers involved are satisfying the obligations of point 2.

2. For the subsystem, being subject of the EC verification procedure, the adjudicating entity must contract only with manufacturers, whose activities contributing to the subsystem project to be verified (manufacturing, assembling, installation) are subject to an approved quality system for manufacture and final product inspection and testing as specified in point 3 and which shall be subject to surveillance as specified in point 4.

   The term 'manufacturer', in the sense of these provisions, also includes companies:

   — responsible for the whole subsystem project (including in particular responsibility for subsystem integration (main contractor)),

   — performing assembling (assemblers) and installation of the subsystem.

   The main contractor responsible for the whole subsystem project (including in particular responsibility for subsystem integration), must operate in any case an approved quality system for manufacture and final product inspection and testing, as specified in point 3 and which shall be subject to surveillance as specified in point 4.

   In the case, that the adjudicating entity is directly involved in the production (including assembling and installation), or that the adjudicating entity itself is responsible for the whole subsystem project (including in particular responsibility for subsystem integration), it has to operate an approved quality system for those activities, as specified in point 3 and subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer(s) involved and, if involved the adjudicating entity must lodge an application for assessment of their quality system with a notified body of their choice. The application must include:

   — all relevant information for the subsystem envisaged,

   — the quality system's documentation,

   — the technical documentation of the approved type and a copy of the type-examination certificate, issued after the completion of the type-examination procedure of module SB.

   For manufacturers, only involved in a part of the subsystem project, the information is only requested for that specific relevant part.

3.2. For the main contractor the quality system must ensure overall compliance of the subsystem with the type as described in the type-examination certificate and overall compliance of the subsystem with the requirements of the TSI. For other manufacturers (subsuppliers) the quality system has to ensure compliance of their relevant contribution to the subsystem with the type as described in the type-examination certificate and with the requirements of the TSI.

All the elements, requirements and provisions adopted by the applicants must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of the following items for all applicants:

— the quality objectives and the organisational structure,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations, the checking and tests that will be carried out before, during and after manufacture, assembling and installation and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc., and for the main contractor,

— responsibilities and powers of the management with regard to overall subsystem quality, including in particular the subsystem integration management.

The examinations, tests and checking shall cover all of the following stages:

— structure of subsystem, including, in particular, civil-engineering activities, constituent assembly, final adjustment,

— final testing of the subsystem,

— and, where specified in the TSI, the validation under full operation conditions.

3.3. The notified body referred to in point 3.1. must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard. This harmonised standard shall be EN ISO 9001 — December 2000, completed if necessary to take into consideration the specificity of the subsystem for which it is implemented.

The audit shall be specific for the subsystem concerned, taking into consideration the specific contribution of the applicant to the subsystem. The auditing team must have at least one member experienced as an assessor in the subsystem technology concerned. The evaluation procedure shall include an assessment visit to the applicant's premises.

The decision must be notified to the applicant. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer(s) and if involved the adjudicating entity must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

They must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 or whether a re-assessment is required.

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

4. Surveillance of the quality system(s) under the responsibility of the notified body(ies)

4.1. The purpose of surveillance is to make sure that the manufacturer(s) and, if involved the adjudicating entity duly fulfil the obligations arising out of the approved quality system.

4.2. The notified body as referred to in point 3.1 must have permanent access for inspection purposes to the locations of building sites, production workshops, locations of assembling and installation, storage areas and, where appropriate, prefabrication or testing facilities and, more general, to all premises which it considers necessary for its task, in accordance with the applicant's specific contribution to the subsystem project.

4.3. The manufacturer(s) and, if involved the adjudicating entity or its authorised representative established within the Community must send the notified body referred to point 3.1 (or have sent it) all the documents needed for that purpose and in particular the implementation plans and technical records concerning the subsystem (as far as relevant for the specific contribution of the applicant to the subsystem), in particular:

— the quality system documentation, including the particular means implemented to ensure that:

  — (for the main contractor) overall responsibilities and powers of the management for the compliance of the whole entire subsystem are sufficiently and properly defined,

  — the quality systems of each manufacturer are correctly managed for achieving integration at subsystem level,

— the quality records as foreseen by the manufacturing part (including assembling and installation) of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.4. The notified body(ies) must periodically carry out audits to make sure that the manufacturer(s) and, if involved the adjudicating entity maintain and apply the quality system and must provide an audit report to them.

The frequency of the audits shall be at least once a year, with at least one audit during the time period of performing relevant activities (manufacture, assembling or installation) for the subsystem being the subject of the EC verification procedure mentioned in point 6.

4.5. Additionally the notified body(ies) may pay unexpected visits to the sites mentioned in point 4.2. of the applicant(s). At the time of such visits, the notified body may conduct complete or partial audits and may carry out or cause to be carried out tests, in order to check the proper functioning of the quality system where necessary. It must provide the applicant(s) with an inspection report and also, if an audit has been carried out, with an audit report, and, if a test has been carried out with a test report.

5. The manufacturer(s) and, if involved the adjudicating entity must, for a period of 10 years after the last subsystem has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second subparagraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, points 4.4 and 4.5.

6. EC verification procedure

6.1. The adjudicating entity or its authorised representative established within the Community must lodge an application for EC verification of the subsystem (through production quality assurance), including coordination of the surveillance of the quality systems as in point 6.5, with a notified body of its choice. The adjudicating entity or his authorised representative within the Community must inform the manufacturers involved of this choice and of the application.

6.2. The application must enable the design, manufacture, assembling, installation and operation of the subsystem to be understood, and shall enable conformity with the requirements of Directive 96/48/EC and the TSI to be assessed.

It must include:

— the technical documentation regarding the approved type, including the type-examination certificate, as issued after completion of the procedure defined in module SB, and, if not included in this documentation,

  — the technical design specifications, including European specifications, that have been applied,

  — the necessary supporting evidence for their adequacy, in particular where the European specifications referred to in Article 10 of Directive 96/48 have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,

— the technical documentation as regards the manufacturing and the assembling of the subsystem,

— a list of the interoperability constituents, to be incorporated into the subsystem,

— a list of all manufacturers, involved in the subsystem's design, manufacturing, assembling and installation,

— the demonstration, that all stages, as mentioned in point 3.2, are covered by quality systems of the manufacturers and/or of the adjudicating entity involved and the evidence of their effectiveness,

— indication of the notified body(ies), responsible for the approval and surveillance of these quality systems.

6.3. The notified body must examine the application concerning the validity of the type-examination and the type-examination certificate.

6.4. The notified body must then examine, if all stages of the subsystem as mentioned in the last subparagraph of point 3.2 are sufficiently and properly covered by the approval and surveillance of the quality system(s) of the applicant(s).

If the conformity of the subsystem with the type as described in the EC type-examination certificate and the compliance of the subsystem with the requirements of Directive 96/48/EC and the TSI is based on more than one quality system, it has to examine in particular,

— if the relations and interfaces between the quality systems are clearly documented, and

— if overall responsibilities and powers of the management for the compliance of the whole entire subsystem for the main contractor are sufficiently and properly defined.

6.5. The notified body responsible for the EC verification, if not carrying out the surveillance of the quality system(s) concerned as in point 4, must coordinate the surveillance activities of any other notified body responsible for that task, in order to be ensured that correct management of interfaces between the different quality systems in view of subsystem integration has been performed. This coordination includes the right of the notified body responsible for the EC verification,

— to receive all documentation (approval and surveillance), issued by the other notified body(ies),

— to witness the surveillance audits as under point 4.4,

— to initiate additional audits as under point 4.5 under its responsibility and together with the other notified body(ies).

6.6. Where the subsystem meets the requirements of Directive 96/48/EC and the TSI, the notified body must then, based on the type-examination and the approval and surveillance of the quality system(s), draw up the certificate of EC verification intended for the adjudicating entity or its authorised representative established within the Community, which in turn draws up the EC declaration of verification intended for the supervisory authority in the Member State within which the subsystem is located and/or operates.

The EC declaration of verification and the accompanying documents must be dated and signed. The declaration must be written in the same language of the technical file and must contain at least the information included in Annex V to Directive 96/48/EC.

6.7. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification. The technical file has to include at least the information indicated in Article 18(3) of Directive 96/48/EC, and in particular as follows:

— all necessary documents relating to the characteristics of the subsystem,

— list of interoperability constituents incorporated into the subsystem,

— copies of the EC declarations of conformity and, where appropriate, of the EC declarations of suitability for use, which said constituents must be provided in accordance with Article 13 of the Directive, accompanied, where appropriate, by the corresponding documents (certificates, quality system approval and surveillance documents) issued by the notified bodies on the basis of the TSI,

— all elements relating to the conditions and limits for use,

— all elements relating to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance,

— the EC type-examination certificate for the subsystem and the accompanying technical documentation,

— certificate of EC verification of the notified body as mentioned in point 6.5, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with the Directive 96/48/EC and the TSI, and mentioning, where appropriate, reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up in connection with the verification, as mentioned under points 4.4 and 4.5 and in particular.

7. The complete records accompanying the certificate of EC verification must be lodged with the adjudicating entity or its authorised representative in support of the certificate of EC verification issued by the notified body and must be attached to the EC declaration of verification drawn up by the adjudicating entity intended for the supervisory authority.

8. The adjudicating entity or its authorised representative within the Community must keep a copy of the records throughout the service life of the subsystem; it must be sent to any other Member State who so requests.

III.4. Module SF (product verification)

EC verification of maintenance subsystem

1. This module describes the EC verification procedure whereby a notified body checks and certifies at the request of an adjudicating entity or its authorised representative established within the Community, that a maintenance subsystem, for which already a EC type-examination certificate has been issued by a notified body,

— complies with this TSI and any other applicable TSI, which demonstrates that the essential requirements of Directive 96/48/EC have been met,

— complies with the other regulations deriving from the Treaty and may be put into service.

2. The adjudicating entity or its authorised representative established within the Community must lodge an application for EC verification (through product verification) of the subsystem with a notified body of his choice.

The application includes:

— name and address of the adjudicating entity or its authorised representative,

— the technical documentation.

3. Within that part of the procedure the adjudicating entity or his authorised representative established within the Community checks and attests that the subsystem concerned is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the Directive 96/48/EC and the TSI that apply to them.

4. The adjudicating entity must take all measures necessary in order that the manufacturing process (including assembling and integration of interoperability constituents) ensures conformity of the subsystem with the type as described in the EC type-examination certificate and with the requirements of the TSI that apply to them.

5. The technical documentation must enable the design, manufacture, installation and operation of the subsystem to be understood, and shall enable conformity with the type as described in the type-examination certificate and the requirements of the Directive and the TSI to be assessed.

It must include:

— the type-examination certificate and its accompanying documents and additions, and, as far as not included in the documents accompanying the EC type-examination certificate,

— a general description of the subsystem, overall design and structure,

— conceptual design and manufacturing drawings and schemes of subassemblies, circuits, etc.,

— technical documentation as regards the manufacturing and the assembling of the subsystem,

— the technical design specifications, including European specification, that have been applied,

— the necessary supporting evidence for their adequacy, in particular where European specification have not been applied in full,

— a list of the interoperability constituents, to be incorporated into the subsystem,

— a list of manufacturers, involved in the subsystem's design, manufacturing, assembling and installation,

— a list of the European specification If the TSI is requiring further information for the technical documentation, this has to be included.

6. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the subsystem with the type as described in the EC type-examination certificate and with the requirements of Directive 96/48/EC and the TSI by examination and testing of every subsystem, manufactured as a serial product, as specified under Point 4.

7. Verification by examination and testing of every subsystem (as a serial product).

7.1. The notified body must carry out the tests, examinations and verifications, to ensure conformity subsystem as serial products with the essential requirements of the Directive and of the TSI. The examinations, tests and checking shall extend to the following stages as provided for in the TSI:

— structure of subsystem, including constituent assembly and overall adjustments,

— final testing of the subsystem,

— and, whenever specified in the TSI, the validation under full operational conditions.

7.2. All subsystems (as serial products) must be individually examined and appropriate tests and verifications as set out in the TSI and in the relevant European Specifications (or equivalent tests) shall be carried out in order to verify their conformity with the type as described in the type-examination certificate and the requirements of the TSI that apply to them.

8. The notified body may agree with the adjudicating entity the locations where the tests will be carried out and may agree that final testing of the subsystem and, whenever required in the TSI, tests or validation under full operating conditions, are carried out by the adjudicating entity under direct supervision and attendance of the notified body.

9. The notified body must have permanent access for testing and verification purposes to production workshops, locations of assembling and installations, and where appropriate, prefabrication and testing facilities in order to carry out its tasks as provided for in the TSI.

10. Where the subsystem meets the requirements of Directive 96/48/EC and the TSI, the notified body must then, based on the tests, verifications and checking carried out on all serial products as indicated in point 7, and required in the TSI and in the European specification referred to in Article 10 of Directive 96/48/EC, draw up the certificate of EC verification intended for the adjudicating entity or its authorised representative established within the Community, which in turn draws up the EC declaration of verification intended for the supervisory authority in the Member state where the subsystem is located and/or operates. The EC declaration of verification and the accompanying documents must be dated and signed. The declaration must be written in the same language of the technical file and must contain at least the information included in Annex V of Directive 96/48/EC.

11. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification. The technical file has to include at least the information indicated in Article 18(3) of Directive 96/48/EC, and in particular as follows:

— all necessary documents relating to the characteristics of the subsystem,

— list of interoperability constituents incorporated into the subsystem,

— copies of the EC declarations of conformity and, where appropriate, of the EC declarations of suitability for use, which said constituents must be provided in accordance with Article 13 of the Directive, accompanied, where appropriate, by the corresponding documents (certificates, quality system approval and surveillance documents) issued by the notified bodies on the basis of the TSI,

— all elements relating to conditions and limits for use,

— all elements relating to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance,

— EC type-examination certificate and accompanying technical documentation,

— certificate of EC verification of the notified body as mentioned under point 10, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with the Directive and the TSI, and mentioning, where appropriate, reservations recorded during performance of activities and not withdrawn; the certificate should also be accompanied, if relevant, by the inspection and audit reports drawn up in connection with the verification.

12. The complete records accompanying the certificate of EC verification must be lodged with the adjudicating entity or its authorised representative in support of the certificate of EC verification issued by the notified body and must be attached to the EC declaration of verification drawn up by the adjudicating entity intended for the supervisory authority.

13. The adjudicating entity or its authorised representative within the Community must keep a copy of the records throughout the service life of the subsystem; it must be sent to any other Member State who so requests.

III.5. Module SG (Unit verification)

EC verification of maintenance subsystem

1. This module describes the EC verification procedure whereby a notified body checks and certifies, at the request of an adjudicating entity or its authorised representative established within the Community, that a maintenance subsystem:

— complies with this TSI and any other applicable TSI, which demonstrates that the essential requirements of Directive 96/48/EC have been met,

— complies with the other regulations deriving from the Treaty and may be put into service.

2. The adjudicating entity or its authorised representative established within the Community must lodge an application for EC verification (through unit verification) of the subsystem with a notified body of his choice.

The application includes:

— name and address of the adjudicating entity or its authorised representative,

— the technical documentation.

3. The technical documentation must enable the design, manufacture, installation and operation of the subsystem to be understood, and shall enable conformity with the requirements of the TSI to be assessed.

It must include:

— a general description of the subsystem, overall design and structure,

— conceptual design and manufacturing drawings and schemes of subassemblies, circuits, etc.,

— technical documentation as regards the manufacturing and the assembling of the subsystem,

— the technical design specifications, including European specifications, that have been applied,

— the necessary supporting evidence for their adequacy, in particular where European specifications referred to in the TSI and the relevant clauses have not been applied in full,

— a list of the interoperability constituents, to be incorporated into the subsystem,

— a list of manufacturers, involved in the subsystem's design, manufacturing, assembling and installation,

— a list of the European specifications referred to in the TSI or in the technical design specification.

If the TSI is requiring further information for the technical documentation, this has to be included.

4. The notified body must examine the application, and carry out the appropriate tests and verifications as set out in the TSI and/or in the European specifications referred to in the TSI, to ensure conformity with the essential requirements of the Directive as provided for in the TSI. The examinations, tests and checking shall extend to the following stages as provided for in the TSI:

— overall design,

— structure of subsystem, including, in particular and when relevant, civil-engineering activities, constituent assembly, overall adjustments,

— final testing of the subsystem,

— and, whenever specified in the TSI, the validation under full operational conditions.

5. The notified body may agree with the adjudicating entity the locations where the tests will be carried out and may agree that final subsystem tests and, whenever required in the TSI, tests in full operating conditions, are carried out by the adjudicating entity under direct supervision and attendance of the notified body.

6. The notified body must have permanent access for testing and verification purposes to the locations of design, building sites, production workshops, locations of assembling and installations, and where appropriate, prefabrication and testing facilities in order to carry out its tasks as provided for in the TSI.

7. Where the subsystem meets the requirements of the TSI, the notified body must then, based on the tests, verifications and checking carried out as required in the TSI and in the European specifications referred to in the TSI, draw up the certificate of EC verification intended for the adjudicating entity or its authorised representative established within the Community, which in turn draws up the EC declaration of verification intended for the supervisory authority in the Member State where the subsystem is located and/or operates. The EC declaration of verification and the accompanying documents must be dated and signed. The declaration must be written in the same language of the technical file and must contain at least the information included in Annex V to Directive 96/48/EC.

8. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification. The technical file has to include at least the information indicated in Article 18(3) of Directive 96/48/EC, and in particular as follows:

— all necessary documents relating to the characteristics of the subsystem,

— list of interoperability constituents incorporated into the subsystem,

— copies of the EC declarations of conformity and, where appropriate, of the EC declarations of suitability for use, which said constituents must be provided in accordance with Article 13 of the Directive, accompanied, where appropriate, by the corresponding documents (certificates, quality system approval and surveillance documents) issued by the notified bodies on the basis of the TSI,

— all elements relating to conditions and limits for use,

— all elements relating to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance,

— certificate of EC verification of the notified body as mentioned in point 7, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with the Directive and the TSI, and mentioning, where appropriate, reservations recorded during performance of activities and not withdrawn; the certificate should also be accompanied, if relevant, by the inspection and audit reports drawn up in connection with the verification.

9. The complete records accompanying the certificate of EC verification must be lodged with the adjudicating entity or its authorised representative in support of the certificate of EC verification issued by the notified body and must be attached to the EC declaration of verification drawn up by the adjudicating entity intended for the supervisory authority.

10. The adjudicating entity or its authorised representative within the Community must keep a copy of the records throughout the service life of the subsystem; it must be sent to any other Member State who so requests.

III.6. Module SH2 (Full quality assurance with design examination)

EC verification of maintenance subsystem

1. This module describes the EC verification procedure whereby a notified body checks and certifies, at the request of an adjudicating entity or its authorised representative established within the Community, that a maintenance subsystem:

— complies with this TSI and any other applicable TSI, which demonstrates that the essential requirements of Directive 96/48/EC have been met,

— complies with the other regulations deriving from the Treaty and may be put into service.

The notified body is carrying out the procedure, including a design examination of the subsystem under the condition, that the adjudicating entity and the manufacturers involved are satisfying the obligations of point 2.

2. For the subsystem, being subject of the EC verification procedure, the adjudicating entity must contract only with manufacturers, whose activities contributing to the subsystem project to be verified (design, manufacturing, assembling, installation) are subject to an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and which shall be subject to surveillance as specified in point 4.

The term 'manufacturer' also includes companies:

— responsible for the whole subsystem project (including in particular responsibility for subsystem integration (main contractor),

— performing design services or studies (e.g. consultants),

— performing assembling (assemblers) and installation of the subsystem. For manufacturers, performing only assembling and installation, a quality system for manufacture and final product inspection and testing is sufficient.

The main contractor responsible for the whole subsystem project (including in particular responsibility for subsystem integration), must operate in any case an approved quality system for design, manufacture and final product inspection and testing, as specified in point 3 and which shall be subject to surveillance as specified in point 4.

In the case that the adjudicating entity is directly involved in the design and/or production (including assembling and installation), or that the adjudicating entity itself is responsible for the whole subsystem project (including in particular responsibility for subsystem integration), it has to operate an approved quality system for those activities, as specified in point 3 and subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer(s) involved and, if involved, the adjudicating entity must lodge an application for assessment of their quality system with a notified body of their choice.

The application must include:

— all relevant information for the subsystem envisaged,

— the quality system's documentation.

For manufacturers, only involved in a part of the subsystem project, the information is only requested for that specific relevant part.

3.2. For the main contractor the quality system must ensure overall compliance of the subsystem with the requirements of Directive 96/48/EC and the TSI. For other manufacturers (subsuppliers) the quality system has to ensure compliance of their relevant contribution to the subsystem with the requirements of the TSI.

All the elements, requirements and provisions adopted by the applicants must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of the following items for all applicants:

— the quality objectives and the organisational structure,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations, the checking and tests that will be carried out before, during and after manufacture, assembling and installation and the frequency with which they will be carried out,

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

for the main contractor and for the subsuppliers (only as far as relevant for their specific contribution to the subsystem project):

— the technical design specifications, including European specifications, that will be applied and, where the European specifications referred to in Article 10 of Directive 96/48/EC will not be applied in full, the means that will be used to ensure that the requirements of the TSI 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,

— the means to monitor the achievement of the required design and subsystem quality and the effective operation of the quality system,

and for the main contractor:

— responsibilities and powers of the management with regard to overall design and subsystem quality, including in particular the subsystem integration management.

The examinations, tests and checking shall cover all of the following stages:

— overall design,

— structure of subsystem, including, in particular, civil-engineering activities, constituent assembly, final adjustment,

— final testing of the subsystem,

— and, where specified in the TSI, the validation under full operation conditions.

3.3. The notified body referred to in point 3.1 must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard. This harmonised standard shall be EN ISO 9001 — December 2000, completed if necessary to take into consideration the specificity of the subsystem for which it is implemented.

For applicants, which are only involved in assembling and installation, the harmonised standard shall be EN ISO 9001 — December 2000, completed if necessary to take into consideration the specificity of the subsystem for which it is implemented.

The audit shall be specific for the subsystem concerned, taking into consideration the specific contribution of the applicant to the subsystem. The auditing team must have at least one member experienced as an assessor in the subsystem technology concerned. The evaluation procedure shall include an assessment visit to the applicant's premises.

The decision must be notified to applicant. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer(s) and, if involved the adjudicating entity must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

They must keep the notified body that has approved their quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

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

4. Surveillance of the quality system(s) under the responsibility of the notified body(ies)

4.1. The purpose of surveillance is to make sure that the manufacturer(s) and if involved the adjudicating entity duly fulfil the obligations arising out of the approved quality system.

4.2. The notified body(ies) as referred to in point 3.1 must have permanent access for inspection purposes to the locations of design, building sites, production workshops, locations of assembling and installation, storage areas and, where appropriate, prefabrication or testing facilities and, more general, to all premises which it considers necessary for its task, in accordance with the applicant's specific contribution to the subsystem project.

4.3. The manufacturer(s) and, if involved the adjudicating entity or its authorised representative established within the Community must send the notified body referred to under point 3.1. (or have sent it) all the documents needed for that purpose and in particular the implementation plans and technical records concerning the subsystem (as far as relevant for the specific contribution of the applicant to the subsystem), in particular:

— the quality system documentation, including the particular means implemented to ensure that:

  — (for the main contractor) overall responsibilities and powers of the management for the compliance of the whole entire subsystem are sufficiently and properly defined,

  — the quality systems of each manufacturer are correctly managed for achieving integration at subsystem level,

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

— the quality records as foreseen by the manufacturing part (including assembling and installation) of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.4. The notified body(ies) must periodically carry out audits to make sure that the manufacturer(s) and, if involved the adjudicating entity maintain and apply the quality system and shall provide an audit report to them.

The frequency of the audits shall be at least once a year, with at least one audit during the time period of performing relevant activities (design, manufacture, assembling or installation) for the subsystem being the subject of the EC verification procedure mentioned in point 6.

4.5. Additionally the notified body(ies) may pay unexpected visits to the sites mentioned in point 4.2. of the applicant(s). At the time of such visits, the notified body may conduct complete or partial audits. in order to check the proper functioning of the quality system where necessary; it must provide the applicant(s) with an inspection report and, if an audit has been carried out, with an audit report.

5. The manufacturer(s) and, if involved the adjudicating entity must, for a period of 10 years after the last subsystem has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second subparagraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, points 4.4 and 4.5.

6. EC verification procedure

6.1. The adjudicating entity or its authorised representative established within the Community must lodge an application for EC verification of the subsystem (through full quality assurance with design examination), including coordination of surveillance of the quality systems as in points 4.4 and 4.5, with a notified body of its choice. The adjudicating entity or its authorised representative established within the Community must inform the manufacturers involved of his choice and of the application.

6.2. The application must enable the design, manufacture, installation and operation of the subsystem to be understood, and shall enable conformity with the requirements of the TSI to be assessed.

It must include:

— the technical design specifications, including European specifications, that have been applied,

— the necessary supporting evidence for their adequacy, in particular where the European specifications referred to in the TSI have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

— the technical documentation as regards the manufacturing and the assembling of the subsystem,

— a list of the interoperability constituents, to be incorporated into the subsystem,

— a list of all manufacturers, involved in the subsystem's design, manufacturing, assembling and installation,

— the demonstration, that all stages, as mentioned under point 3.2, are covered by quality systems of the manufacturer(s) and/or of the adjudicating entity involved, and the evidence of their effectiveness,

— indication of the notified body(ies), responsible for the approval and surveillance of these quality systems.

6.3. The notified body must examine the application concerning the design examination and where the design meets the provisions of the Directive 96/48/EC and of the TSI that apply to it must issue a design examination report to the applicant. The report shall contain the conclusions of the design examination, conditions for its validity, the necessary data for identification of the design examined and, if relevant, a description of the subsystem's functioning.

6.4. The notified body must, concerning the other stages of the EC verification, examine if all stages of the subsystem as mentioned in point 3.2 are sufficiently and properly covered by the approval and surveillance of quality system(s).

If the compliance of the subsystem with the requirements of the TSI is based on more than one quality system, it has to examine in particular:

— if the relations and interfaces between the quality systems are clearly documented,

— and if overall responsibilities and powers of the management for the compliance of the whole entire subsystem for the main contractor are sufficiently and properly defined.

6.5. The notified body responsible for the EC verification, if not carrying out the surveillance of the quality system(s) concerned as in point 4, must coordinate the surveillance activities of any other notified body responsible for that task, in order to be ensured that correct management of interfaces between the different quality systems in view of subsystem integration has been performed. This coordination includes the right of the notified body responsible for the EC verification:

— to receive all documentation (approval and surveillance), issued by the other notified body(s),

— to witness the surveillance audits as in point 4.4,

— to initiate additional audits as in point 4.5 under its responsibility and together with the other notified body(s).

6.6. Where the subsystem meets the requirements of Directive 96/48/EC and the TSI, the notified body must then, based on the design examination and the approval and surveillance of the quality system(s), draw up the certificate of EC verification intended for the adjudicating entity or its authorised representative established within the Community, which in turn draws up the EC declaration of verification intended for the supervisory authority in the Member State within which the subsystem is located and/or operates.

The EC declaration of verification and the accompanying documents must be dated and signed. The declaration must be written in the same language of the technical file and must contain at least the information included in Annex V of Directive 96/48/EC.

6.7. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification. The technical file has to include at least the information indicated in Directive 96/48/EC, Article 18(3), and in particular as follows:

— all necessary documents relating to the characteristics of the subsystem,

— list of interoperability constituents incorporated into the subsystem,

— copies of the EC declarations of conformity and, where appropriate, of the EC declarations of suitability for use, which said constituents must be provided in accordance with Article 13 of the Directive, accompanied, where appropriate, by the corresponding documents (certificates, quality system approval and surveillance documents) issued by the notified bodies on the basis of the TSI,

— all elements relating to the conditions and limits for use,

— all elements relating to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance,

— certificate of EC verification of the notified body as mentioned in point 6.6, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with the Directive and the TSI, and mentioning, where appropriate, reservations recorded during performance of the activities and not withdrawn, the certificate should also be accompanied by the inspection and audit reports drawn up in connection with the verification, as mentioned in points 4.4 and 4.5.

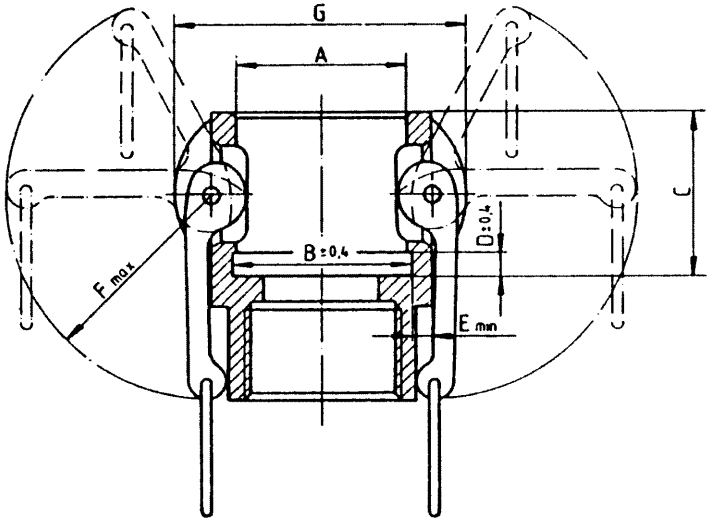
7. The complete records accompanying the certificate of EC verification must be lodged with the adjudicating entity or its authorised representative in support of the certificate of EC verification issued by the notified body and must be attached to the EC declaration of verification drawn up by the adjudicating entity intended for the supervisory authority.

8. The adjudicating entity or its authorised representative within the Community must keep a copy of the records throughout the service life of the subsystem; it must be sent to any other Member State who so requests.

ANNEX IV

CONNECTIONS FOR THE TOILET DISCHARGE SYSTEM

3″ Connection of evacuation and 1″ Connection for flushing (outer parts)

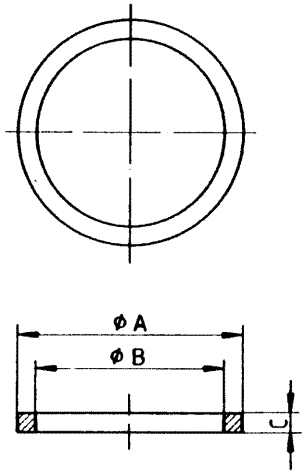


	A	B	C	D	E	F	G
3″ connection	92,20	104	55	7,14	4	82,55	133,3
1″ connection	37,24	40,5	37,5	7,14	2,4	44,45	65

Material: stainless steel General tolerances ± 0,1

Figure 1

Joints



	A	B	C
3″ joint	94,45	76,20	6,35
1″ joint	39,69	26,98	6,35

General tolerances ± 0,1

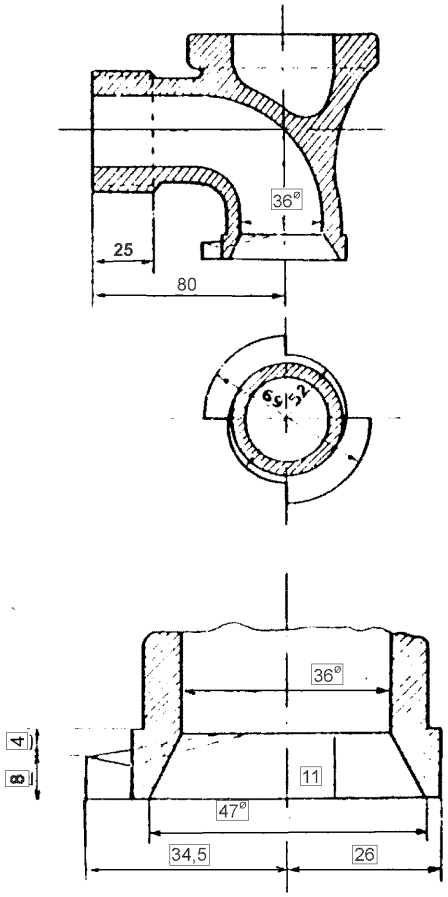
Material: Elastomer, faeces-resistant e.g. FPM (fluor rubber)

Figure 2

ANNEX V

INLET CONNECTIONS FOR WATER TANKS

Inlet connections for water tanks



□ = Obligatory

Figure 3