Organisation intergouvernementale pour les transports internationaux ferroviaires
Zwischenstaatliche Organisation für den internationalen Eisenbahnverkehr
Intergovernmental Organisation for International Carriage by Rail

Commission d'experts techniques
Fachausschuss für technische Fragen
Committee of Technical Experts

TECH-16013-CTE9-6.2

01.04.2016

Original: DE

EXPLANATORY DOCUMENT UTP GEN-D "ASSESSMENT PROCEDURES"

Practical information on applying the modules for the procedures for assessment of conformity, suitability for use and UTP verification

Tel. +41 (0) 31 359 10 10 Fax +41 (0) 31 359 10 11 info@otif.org Gryphenhübeliweg 30 CH - 3006 Berne/Bern

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1. Introduction

Uniform Technical Prescriptions (UTP) are adopted specifications and as such are a part of COTIF. In principle, each subsystem is subject to one UTP. Where relevant, a subsystem may be covered by several UTP and one UTP may cover several subsystems.

All the conditions that subsystems like vehicles must meet and the procedures to be complied with in assessing conformity are set out in UTPs. This explanatory document deals with the UTP GEN-D which sets out the procedures for assessing conformity with UTPs.

2. Definition of terms

a. Subsystem

According to the legal definition, a subsystem is the result of the division of the rail system, as shown in the UTP; these subsystems, for which essential requirements must be laid down, may be structural or functional.

In other words, a subsystem is a component of the railway system and in order that the railway system can function as a whole, it must be compatible with other subsystems. For this reason, the requirements applicable to subsystems also contain provisions concerning the interfaces with other subsystems. The subsystems are defined in the UTP GEN-B.

Structural subsystems include:

- Infrastructure,
- Energy,
- Trackside control, command and signalling,
- On-board control, command and signalling,
- Vehicles.

Functional subsystems are:

- Operation and traffic management,
- Maintenance,
- Telematics applications for passenger and freight transport.

In order to be admitted to international traffic, the vehicle must meet all the technical requirements applicable according to APTU, ATMF and the UTPs.

b. Elements of construction (IC)

According to the legal definition, Elements of Construction, also referred to as interoperability constituents (ICs) are construction elements, groups of construction elements, sub-assemblies or complete groups of materials which are or which will be built into a subsystem and on which the

interoperability of the railway system depends directly or indirectly. The concept of an IC includes both material and non-material products (e.g. software).

In other words, an IC is a product that can be developed, manufactured and sold independently of a subsystem. Examples of ICs for rail vehicles are: the wheels, the pantograph and the automatic coupling. At least one parameter of the IC can be assessed and certified separately from the subsystem; subsequent assessments and certifications concern the correct integration of the IC into the subsystem.

A list of constituents considered as an IC integrated into a subsystem is contained in the UTP that applies to the subsystem. Chapter 5 of each structural UTP specifies the requirements for ICs.

c. Assessing entity

Before a structural subsystem is used in international operation, the assessing entity checks its conformity with the applicable UTP. Either the competent national authority itself or any other body recognised or accredited by a Contracting State in accordance with Article 5 of ATMF may act as an assessing entity. In the EU Member States and States that apply EU law, the function of assessing entity is carried out by the so-called notified body.

The assessing entity must comply with the procedures of the assessment modules in UTP GEN-D. The module used depends firstly on the provisions of the relevant structural UTP and secondly on the agreements between the applicant and the assessing entity. Checks begin during the design phase of a project and continue until the last production unit is completed. The assessing entity should therefore be involved from the start of a project. In accordance with Article 6a of ATMF, the results of the checks should apply and be recognised in all other Contracting States for future approvals.

d. Conformity assessment procedures for ICs

The conformity assessment procedures for ICs covered by the UTP are selected from the modules described in the UTP based on the following criteria:

a) Suitability of the module concerned for the type of IC;

b) Type of risks linked to the IC and relevance of the conformity assessment in terms of the type and level of risk;

c) Need for the manufacturer to have the opportunity to choose between quality management systems and product certification modules in accordance with the UTP GEN-D;

d) Need to avoid prescribing modules which cause an excessive burden in proportion to the risks.

The modules to be used for the conformity assessment of ICs are set out in the UTPs. If necessary, they can be made more specific and supplemented in the UTPS on the basis of the specific features of the subsystem concerned. Although ICs can be assessed separately from the subsystem, separate assessment is not obligatory under COTIF, cf. Chapter 2 of UTP GEN-D. In the EU however, separate assessments of ICs is obligatory.

e. Assessment procedure for suitability for use

Insofar as the UTPs so require, the procedure for assessing the suitability for use of ICs is carried out in accordance with the instructions in the modules in the UTPs.

f. UTP Verification procedure for subsystems

The procedures for UTP verification of the subsystems covered by the UTPs are selected according to the following criteria:

a) Suitability of the module concerned for the type of subsystem;

b) Type of risks linked to the subsystem and relevance of the UTP verification in terms of the type and level of risk;

c) Need for the manufacturer to have the opportunity to choose between quality management systems and product certification modules in accordance with the UTP GEN-D;

d) Need to avoid prescribing modules which cause an excessive burden in proportion to the risks.

The modules to be used for the UTP verification of subsystems are set out in the UTP. If necessary, they can be made more specific and supplemented in the UTPS on the basis of the specific features of the subsystem concerned.

3. General sequence

The following diagram shows the general sequence of a UTP verification procedure:

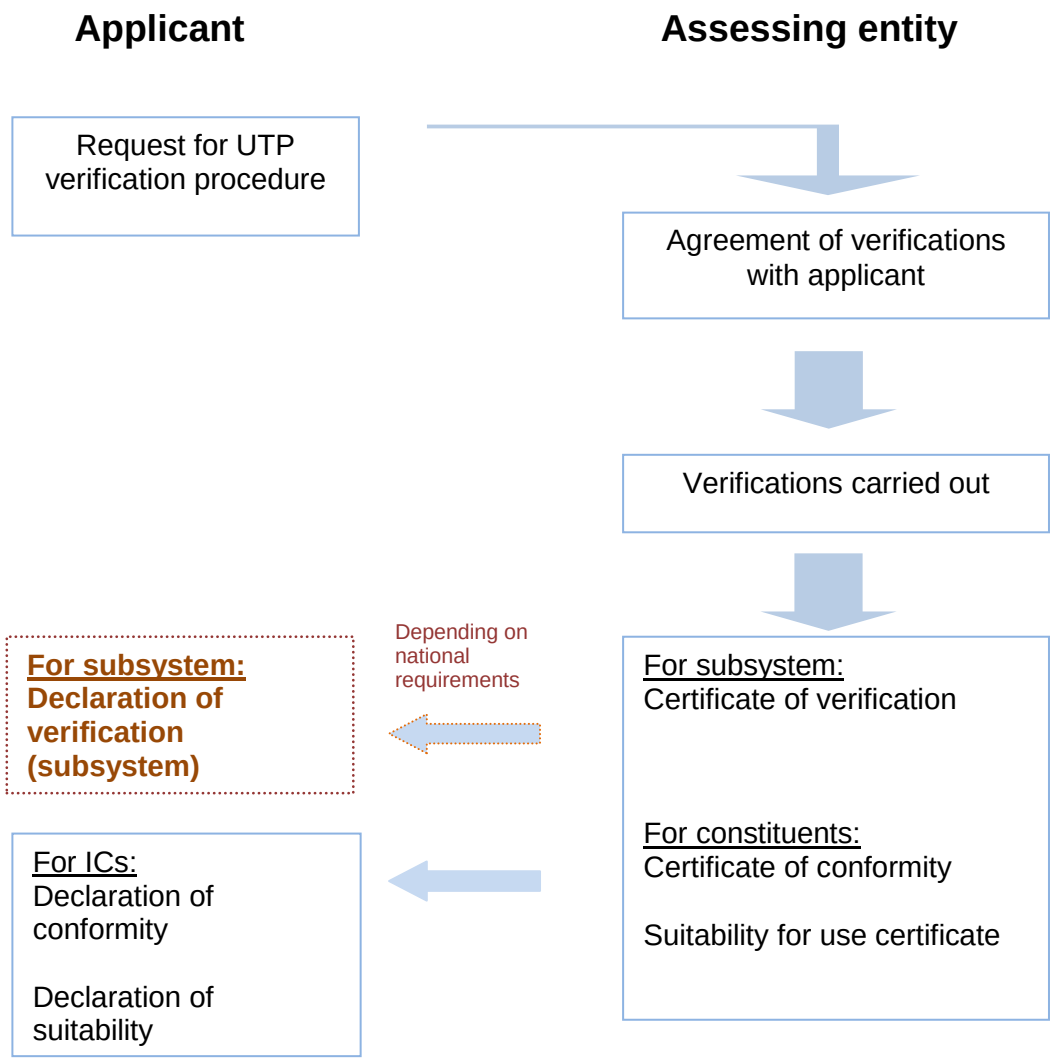

Diagram 1 General overview

The principles for the recognition and accreditation of assessing entities are described in Article 5 of the ATMF Appendix to COTIF as complemented by the provisions of UTP GEN-E

4. Conformity assessment of structural subsystems

The following diagram shows the structure of the verification modules that apply to subsystems, such as vehicles. The table should be read from top to bottom, meaning the following combinations are possible: SB+SD, SB+SF, or the use of only SH1.

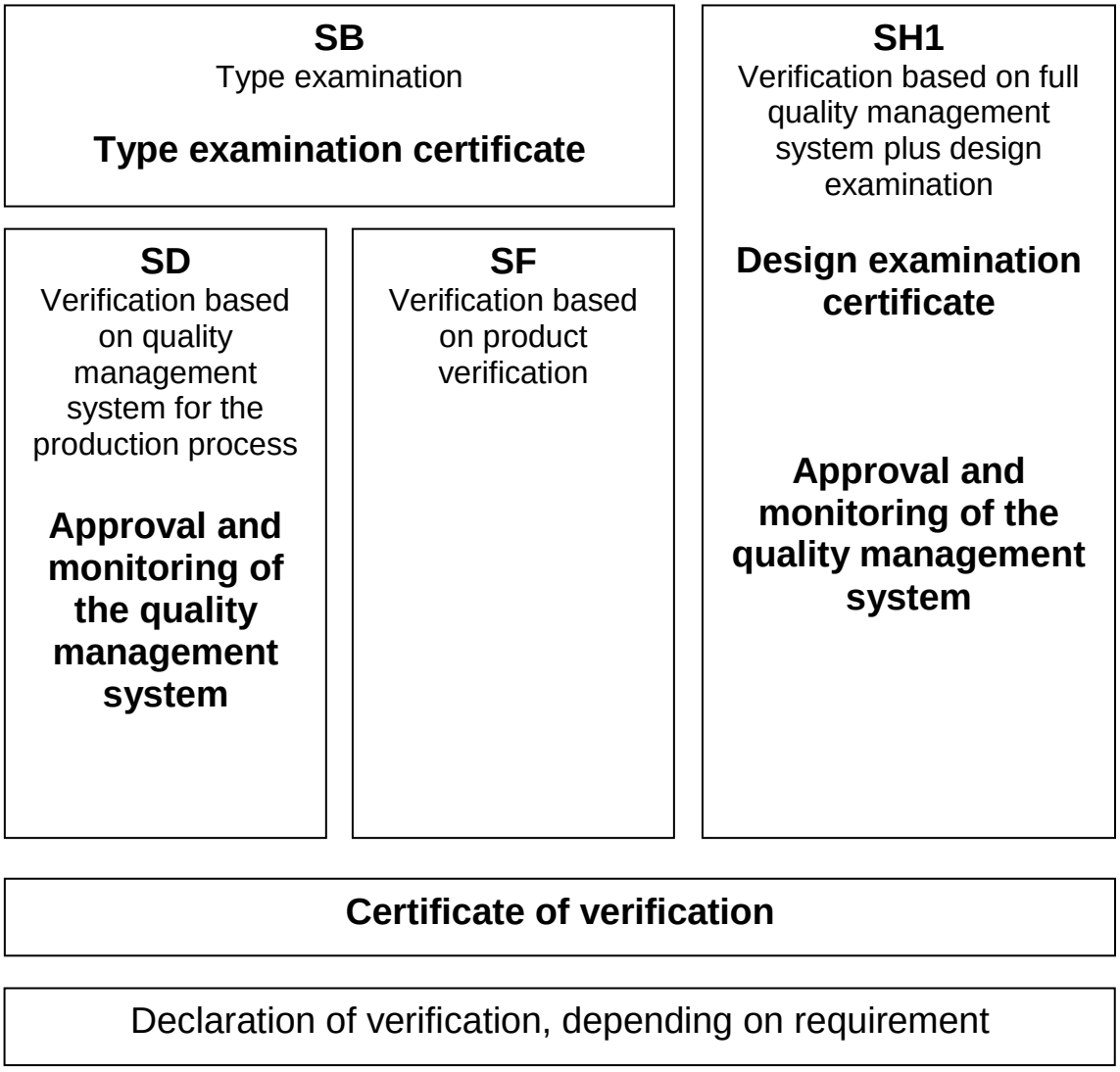

Diagram 2 Overview of verification modules by subsystem[1]

[1] Source: http://www.era.europa.eu/Document-Register/Documents/IU-TSI-Guide-Annex02.pdf
Documents issued by assessing entities

The “S” in front of each module description stands for “subsystem”, i.e. applicable to subsystems.
The sequence behind each module is described in the UTP GEN-D.

Module SH1 may be used for the verification of a subsystem on its own.
Modules SD and SF may only be used following the application of module SB.
Verification concludes with a certificate of verification or a declaration of verification.
A UTP declaration of verification may be drawn up on a voluntary or mandatory basis (if it is required by law in the Contracting State where the application for assessment according to this module has been made). In this case the provisions of the UTP relating to a UTP declaration of verification apply.
Contracting States which are also members of the European Union apply European law concerning EC declarations of verification.

5. Conformity assessment of ICs

According to UTP GEN-D, the certification of ICs is not mandatory.

However, in those cases where certification is desired, the provisions that apply are that the ICs integrated into a subsystem are assessed together with the subsystem.

The following diagram shows the verification modules that apply to the certification of ICs.

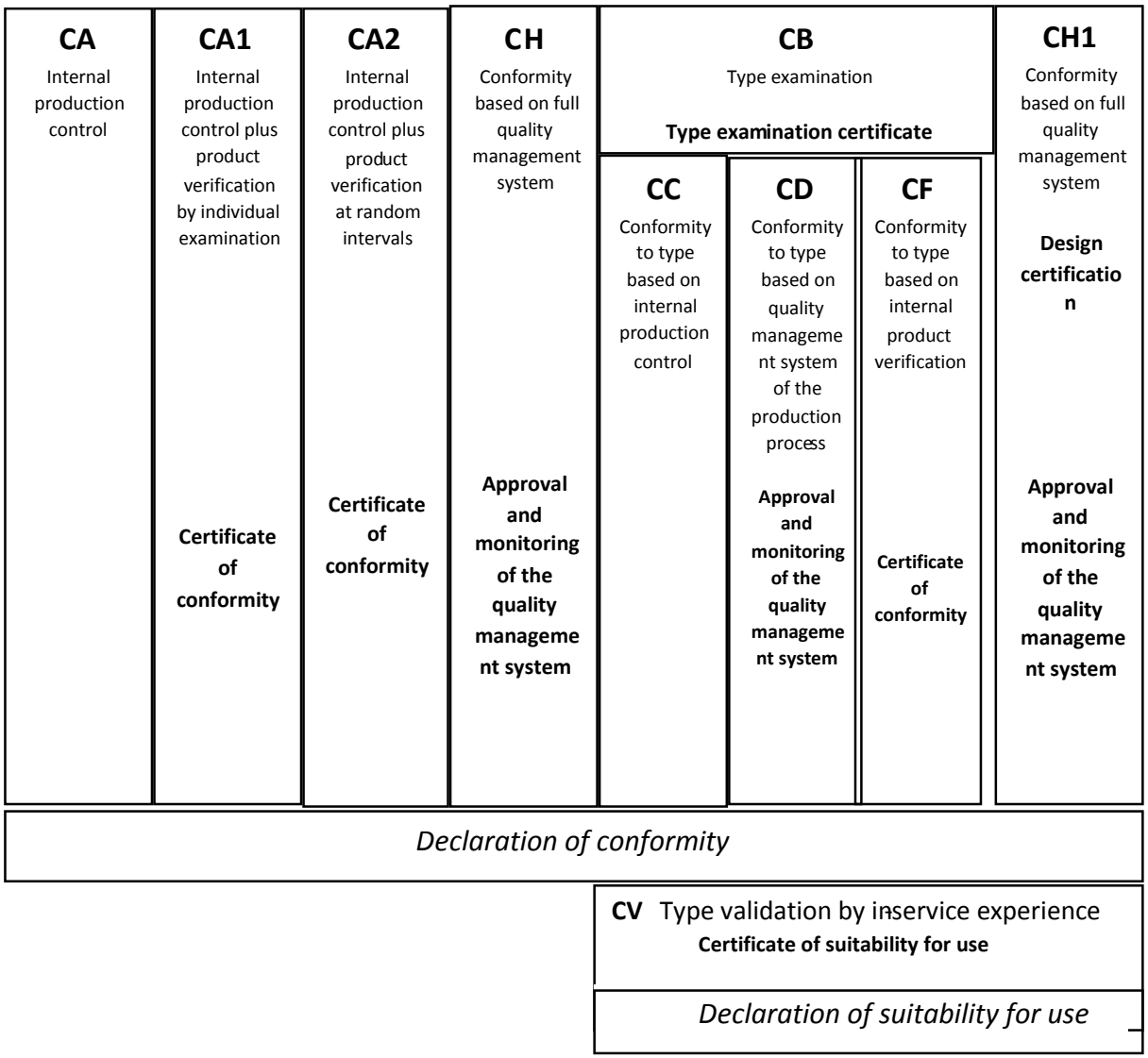

Diagram 3 Structure of verification modules for ICs[2]

[2] Source: http://www.era.europa.eu/Document-Register/Documents/IU-TSI-Guide-Annex02.pdf
Documents issued by assessing entities;
Documents issued by manufacturers or by their authorised representatives

The “C” in front of each module description stands for “component”; i.e. applicable to components.

The following combinations are possible for certification:

- Modules CA, CA1, CA2, CH and CH1 may be used for the conformity assessment of an IC on their own
- Modules CC, CD and CF may only be used following the application of module CB
- Module CV is always complementary to application of modules CB+CC, CB+CD, CB+CF or CH1

Modules CA1, CA2 or CH may be used only in the case of products manufactured according to a design developed and already used to place products on the market before the entry into force of relevant UTPs applicable to those products, provided that the manufacturer demonstrates to the assessing entity that design review and type examination were performed for previous applications under comparable conditions, and are in conformity with the requirements of this UTP.
This demonstration shall be documented, and is considered as providing the same level of proof as module CB or design examination according to module CH1.

6. Intermediate statements of verification

If the applicant so requests, the assessing entity tasked with the verification may issue an intermediate statement of verification relating to certain phases of the verification procedure or certain parts of the subsystem.
The intermediate statement of verification must specify the UTP with which compliance has been assessed.

According to the European interoperability directive 2008/57, the intermediate statement of verification may also lead to a "provisional declaration of conformity".

Within module SB, an intermediate statement of verification might be useful if the design, for a platform for instance, is to continue to be used.
With the help of an intermediate statement of verification, it can be ensured that for each new design type, only the modifications are assessed.

In certain circumstances, an intermediate statement of verification might become necessary if the product to be verified is in itself neither a complete subsystem, nor an IC. It may be the case here that the parameters of the product are described in a subsystem or IC or that an intermediate statement of verification becomes necessary because the independent assessing entity has integrated the product into the subsystem or IC.

Internally, suppliers can provide intermediate statements of verification and the results of the designs or manufacture can then continue to be used by the assessing entity.

7. Overview of modules

a. Type examination "SB"

Covers design. Here, the manufacturer issues the technical documents and ensures that the model/models comply with the legal requirements. The manufacturer or his authorised representative lodges an application for the type examination.

Module SB is always followed by another module. Therefore, it is always a conformity assessment procedure with two modules by means of which the conformity of the products to the approved type is demonstrated.

In some cases (mass production based on a type/a model "representative of the planned production") and/or if the design of the product concerned is of a more complex nature, verification of conformity can take place in two steps. Firstly, the conformity of the type/model with the requirements of the legislative instrument that apply to it (module SB) is verified.

This method not only reduces costs and the work involved, but is also more efficient than the usual direct verification that products are in conformity with the legal requirements. As soon as the type is approved (and this happens only once for a specific model), it just has to be checked whether the products to be brought into service are in conformity with the approved type.

An assessing entity examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing a type examination certificate.

If the applicant so requests, the assessing entity tasked with the verification can issue an intermediate statement of verification.

b. Verification based on quality management system of the production process "SD"

This module follows "SB" and includes the design and quality management for manufacturing and inspection of final product. The manufacturer operates an approved quality system for production, final product inspection and testing of the products in order to ensure compliance of the manufactured products with the approved (under module SB) type and the legislative requirements.
The quality system must include the following elements and has to be documented:

- quality objectives,
- organisational structure,
- manufacturing techniques,

- quality control,
- tests (carried out before, during and after manufacturing),
- quality records,
- monitoring methods

The manufacturer fulfils the obligations arising out of the quality system and ensures compliance of the manufactured products with the approved (under module SB) type and the legislative requirements.

The manufacturer himself or his authorised representative lodges an application for the assessment of the quality system with a single assessing entity of his choice. This assessing entity performs periodic audits in order to assess and survey the quality system.

c. Verification based on product verification "SF"

This module follows "SB" and includes manufacture, product verification (testing a single product or statistical controls) in order to ensure conformity with the design type.

The manufacturer ensures compliance of the manufactured products with the type and with the legislative requirements. In the case of testing using statistical means, the manufacturer also takes all the necessary measures to ensure that the manufacturing process and the monitoring of this process guarantee that all the lots produced are uniform, and submits his products for testing in homogeneous lots.

The tasks of the manufacturer or his authorised representative are to apply for the tests to be carried out by a single notified assessing entity, to issue a written declaration of conformity and to make this available to the national authorities, together with the technical documents for the approved design type, the assessing entity's certificate of conformity and other relevant information.

The notified assessing entity issues the certificate of conformity on the basis of the examinations required. In so doing, the entity takes the technical documentation into account, but does not check it, as this has already been done as part of module SB.

d. Verification based on a full quality management system plus design examination "SH1"

This module includes verification of the design and manufacturing and a full quality management system with a design examination in order to ensure compliance with the legislative requirements. This module does not include a design type test if the assessing entity also has to issue a design examination certificate.

The manufacturer draws up the technical documentation for this and operates an approved quality management system for production, final product inspection and testing of the products.

The quality system must include the following elements and has to be documented:

- quality objectives,

- organisational structure,
- manufacturing techniques,
- quality control,
- techniques for testing the product design,
- tests (carried out before, during and after manufacturing),
- quality records,
- monitoring methods

The manufacturer fulfils the obligations arising out of the quality system and ensures compliance of the manufactured products with the approved (under module SB) design type and the legislative requirements.

The manufacturer himself or his authorised representative then lodges an application for a design examination with the same notified assessing entity that is to assess the quality system.
At the same time, an application for assessment of the quality system is lodged with a single notified assessing entity of his choice.
He is also responsible for keeping the contracted assessing entity informed of any modifications to the quality management system.
As in module SF, this module also gives the manufacturer or his authorised representative the task of issuing a written declaration of conformity and to make this available to the national authorities, together with the technical documents for the approved design type, the assessing entity's certificate of conformity and other relevant information.

The contracted assessing entity again examines the product design, issues a design examination certificate and carries out periodic audits.
These audits include a review of the technical documentation, control of the quality system, inspections and product tests. It is also the assessing entity which notifies the manufacturer of its decision about the quality management system.

e. Internal production control "CA"

This module includes design and production. The manufacturer carries out himself all checks in order to ensure the conformity of the products with the legislative requirements (no design type). On the basis of these, he draws up the technical documentation and ensures compliance of the manufactured products with the legislative requirements.

The manufacturer himself or his authorised representative draws up a written declaration of conformity and keeps it together with the technical documentation and other relevant information at the disposal of the national authorities.
No assessment body is involved in this module. The manufacturer carries out himself all the checks that a notified assessing entity would carry out. The module is therefore only used for non-complex products such as toilet discharge connections and inlet connections for water tanks.

f. Internal production control plus product verification by individual examination "CA1"
This module includes design and production. The manufacturer carries out himself all checks in order to ensure the conformity of the products with the legislative requirements and checks specific aspects of the product. Supplementary to module "CA", the manufacturer checks specific aspects of the product or has tests carried out on his behalf.
In this respect and at his choice tests are carried out either by an accredited in-house body or under the responsibility of an assessing entity chosen by the manufacturer.

Here too, it is up to the manufacturer himself or his authorised representative to draw up a written declaration of conformity and to keep it together with the technical documentation and other relevant information at the disposal of the national authorities. Supplementary to "CA", the decision of the assessing entity or in-house accredited body must be attached to the declaration of conformity.

Depending on whether the manufacturer chooses an assessing entity or accredited in-house body to check the product, their tasks differ as follows:
Accredited in-house body:

- carries out tests on one or more specific aspects of the product,
- keeps record of its decisions and other relevant information,
- informs authorities and the other bodies about the examinations it has performed

Notified assessing entity:

- supervises and assumes responsibility for tests carried out by the manufacturer or on his behalf on one or more specific aspects of the product,
- keeps record of its decisions and other relevant information,
- informs authorities and the other bodies about the examinations it has performed

g. Internal production control plus product verification at random intervals "CA2"

This module includes design and production. The manufacturer carries out himself all checks in order to ensure the conformity of the products with the legislative requirements, and production controls at random intervals. Supplementary to module "CA", the manufacturer lodges an application for product checks with an assessing entity of his choice.

In terms of the documentation to be made available, the tasks of the manufacturer or his authorised representative are the same as for module "CA1", i.e. to issue a written declaration of conformity and to make this available to the national authorities, together with the technical documents, the decision of the assessing entity or the accredited, in-house body and other relevant information.

h. Conformity to type based on internal production control "CC"

This module follows "CB" and includes manufacture and all the checks to be carried out by the manufacturer himself to ensure conformity with the design type. The manufacturer therefore ensures compliance of the manufactured products with the approved type and with the legislative requirements.

The manufacturer himself or his authorised representative draws up a written declaration of conformity and keeps it together with the technical documentation for the approved type and other relevant information at the disposal of the national authorities.

No assessing entity is involved in this module. The manufacturer carries out himself all the checks that an assessing entity would carry out.

i. Type validation by in-service experience (suitability for use) "CV"

Module "CV" is part of the assessment procedure in which a notified assessing entity confirms and attests that a representative type intended for production meets the suitability for use requirements of the relevant UTP.

This module is intended to validate "usability" and is synonymous with the quality of the suitable product.

The manufacturer lodges an application for type validation by in-service experience with a notified assessing entity of his choice.

Among other things, the application includes the type examination certificate, insofar as module CB was used in the development phase. If module CH1 was used for the development phase, the UTP design examination certificate must be attached.

8. Obligation for the notified assessing entity to provide information in the event of certificates that have been refused, suspended, withdrawn or otherwise qualified

Each assessing entity must inform the other assessing entities of type examination certificates and/or any additions, as well as approvals of quality management systems which they have refused, suspended, withdrawn or otherwise restricted, and must inform them, upon request, of all certificates it has issued and/or additions thereto.

The competent national authorities must take measures to enforce conformity if they ascertain that a product does not meet the requirements of the applicable harmonisation provisions.
The corrective measure depends on the degree of non-compliance and must therefore be proportionate.
ATMF Article 10a contains the high level provisions on this subject.

9. UTP declaration of verification, UTP certificate of verification, suitability for use and quality management system

For modules SD, SF, SG and SH1, the assessing entity issues the UTP certificate of verification to the applicant.
Subsequently, a UTP declaration of verification is to be drawn up by the applicant on a voluntary or mandatory basis (if it is required by law in the Contracting State where the application for assessment according to this module has been made). If a declaration of verification is mandatory, the provisions of the UTP relating to a UTP declaration of verification apply.
Contracting States which are also members of the European Union apply European law concerning EC declarations of verification.

For modules CD, CH, CH1, SD and SH1, the quality management system is approved by the assessing entity.

For ICs subject to module CV, the assessing entity issues the certificate of suitability for use in the framework of module verification CV and subsequently the manufacturer issues the Declaration of suitability for use.
As already mentioned at the beginning, according to UTP GEN-D the certification of ICs is not mandatory.
However, in those cases where certification is desired, the provisions that apply are that the ICs integrated into a subsystem are assessed together with the subsystem. In the case of ICs subject to

module CV, assessment as part of the subsystem is not possible and therefore this module can only be used for the separate assessment of the IC. In practise, the module CV is only used for the assessment of friction elements for wheel tread brakes (break blocks).

10. Notified national provisions and open points

Neither of these aspects are usually dealt with in the context of UTP verification, but in accordance with national guidelines. Where no applicable rules for assessing conformity are in force in a Contracting State, UTP GEN-D part 4 applies. The principle is that the conformity is assessed by applying mutatis mutandis an appropriate combination of modules as described in UTP GEN-D. In some cases, a CSM-RA[3] might be necessary (including for innovative solutions).

They mostly relate to the technical compatibility between the vehicle and the rail network or alternatively are needed because no (harmonised) technical solution is available.

National provisions are national requirements which apply in addition to the UTP verification. For open points, the corresponding national requirements also apply, because with regard to the basic requirements in the UTP, it was not possible to describe any technical aspects. Therefore, these also have to be complied with in addition to the national provisions and the UTP itself.

11. Choice of modules

Each UTP indicates which modules may be used for the conformity assessment of an IC or verification of a subsystem. It is up to the manufacturer of the IC or applicant for the verification of the subsystem to choose, from those indicated in the UTPs, the module or combination of modules.

Some of the modules have higher fixed costs[4] (e.g. application of SB+SD or SH1 implies costs before the first unit is produced) and smaller marginal costs for each new unit. The bigger the size of serial production, the more suitable these modules are.

The choice of the module may have an important impact from the cost and time points of view. It is not possible to give a general straightforward rule on which module to select. The choice depends on the particular situation of each company and specific characteristics of the products.

[3] CSM-RA: UTP GEN-G on the common safety method for risk evaluation and assessment.

[4] Extract from: http://www.era.europa.eu/Document-Register/Documents/IU-TSI-Guide-Annex02.pdf

12. Source

1. UTP GEN-D of 1.10.2012

2. Decision of the European Commission of 9 November 2010 “2010/713/EU”

3. OTIF Bulletin article, “Procedures for assessing conformity and the suitability for use of structural subsystems and ICs in accordance with COTIF”

4. Guidelines on applying the TSI, Annex 2, “Verification of conformity and EC verification” of 30.11.2012

5. “Blue Guide" on the implementation of EU product rules 2014