APTU Uniform Rules (Appendix F to COTIF 1999)

Uniform Technical Prescriptions (UTP)
General Provisions –

ASSESSMENT PROCEDURES (MODULES)

These regulations have been developed in accordance with the provisions of APTU, particularly Article 8, in the version as amended by the OTIF Revision Committee in 2009, which entered into force on 1 December 2010.

For definitions and terms, see also Article 2 of ATMF (Appendix G) and Article 2 of APTU (Appendix F), both Appendices to the 1999 version of the COTIF Convention as applicable from 1 December 2010.

Footnotes are not part of the regulations; they are only included as explanatory information.

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Explanatory note:

The texts of this UTP which appear across two columns are identical to corresponding texts of the European Union regulations. Texts which appear in two columns differ; the left-hand column contains the UTP regulations, the right-hand column shows the text in the corresponding EU regulations. The text in the right-hand column is for information only and is not part of the OTIF regulations.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
With reference to Article 8 § 8 of Appendix F (APTU) to the Convention, the following regulations shall apply:		

0. EQUIVALENCE

Following their adoption by the Committee of Technical Experts, the OTIF regulations included in this document are declared equivalent (with the exception of chapter 4 [3]) to the corresponding EU regulations within the meaning of Article 13 of APTU and Article 3a of ATMF.

See conversion table in Annex 3.

1. GENERAL PROVISIONS

1.1 SCOPE AND CONTENT OF THIS UTP

This UTP applies to the assessment of conformity with provisions of the UTPs applicable[4] to structural subsystems and of applicable national technical requirements (rules) notified in accordance with Article 12 of APTU.

In addition to the General Provisions in **Chapter 1** applicable to all assessments of conformity, it contains specific provisions for the assessment of

INTEROPERABILITY CONSTITUENTS

(Referred to as “elements of construction” in APTU and ATMF.

Chapter 2:

Assessment of the ICs’ conformity with applicable requirements of UTPs or of their suitability for use; for this task the applicant may choose any authorised “assessing entity” (see definition).

(See the provisions of Article 11 and 13 of 2008/57/EC).

[1] Commission Decision 2010/713/EU on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council, published in the EU Official Journal L319 on 4 December 2010.

[2] If no EU reference is indicated, it means that the chapter/section number is the same as in the OTIF text.

[3] Chapter 4 needs no declaration of equivalence as the chapter concerns assessment of a Contracting State’s national requirements/rules.

[4] This also includes UTP Noise as those UTP apply to (conventional) rolling stock.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
SUBSYSTEMS The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages: - overall design, - production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment, - final testing.		2011/18/EC Annex VI, 2.2.3
The assessment of a subsystem's conformity with the applicable regulations falls into three parts:		
Chapter 3 (part 1): The assessment of conformity with the provisions included in applicable UTPs; for this task the applicant may choose any authorised "assessing entity" (see definition).	(See the provisions of Article 18 of 2008/57/EC).	
Chapter 4 (part 2): The assessment of conformity with the applicable national technical requirements notified in accordance with APTU Article 12, including, where appropriate, open points and specific cases, as they require the application of technical rules not included in the relevant UTP(s).	(See the provisions of the Articles 15 and 17 of 2008/57/EC).	
Chapter 5 (part 3): The assessment of the safe integration of a subsystem into its environment.		
Guidelines **(Not part of the legal provisions).** **Annex 4:** A flow diagram of the assessment procedures (modules) to be carried out for a subsystem. **Annex 5:** Assessment of the safe integration of a subsystem into its environment.		

1.2 DEFINITIONS AND TERMINOLOGY

The definitions included in Article 2 of ATMF and APTU are valid for this UTP.

Furthermore,

a) RID means the "Regulation concerning the International Carriage of Dangerous Goods by Rail" (RID – Appendix C to the Convention).

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
b) a "Validated Standard" [5] is a standard which has been validated in accordance with APTU Article 5 by the Committee of Technical Experts and published as such on the OTIF website;		
c) "assessing entity" see definition in UTP GEN-E.		
d) "Interoperability Constituent" (IC) is an "Element of construction" (see the definition in ATMF Article 2 g)). The Interoperability Constituents are listed in (Chapter 5 of) the UTPs.	(same definition of IC in 2008/57/EC Article 2 (f))	
e) "National technical requirements" means those requirements of which the Secretary General has been informed and which have been made public in accordance with Article 12 of APTU.		
f) "Technical admission" and "Technical Certificate", see ATMF Article 2 cc) and dd).		
g) "Applicant" for assessment:	(see Article 18(1) of Directive 2008/57/EC).	
Subsystem: In ATMF the procedures for technical admission include the assessments of conformity with applicable regulations. Thus, the applicant for assessment(s) of a subsystem may only be one of those indicated in ATMF Article 10 § 2, which are: 1. the manufacturer, 2. a rail transport undertaking, 3. the keeper of the vehicle, 4. the owner of the vehicle, 5. the infrastructure manager.		
Interoperability constituent: As assessments of ICs are voluntary, ATMF does not specify who may apply for an assessment of an interoperability constituent. In the IC modules the applicant may only be the manufacturer of the interoperability constituent or his authorised representative as indicated in the modules.		
h) "authorised representative" means any natural or legal person established within a Contracting State	the Union	2010/713/ EC Art 3, 12.

[5] In COTIF, a "Validated Standard" has the same function and must fulfil the same criteria as a "Harmonised Standard" in the European Union, cf. Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards", as published in the EU Official Journal C 136, 04/06/1985 pages 0001 – 0009.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
who has received a written mandate from a manufacturer or a contracting entity to act on their behalf in relation to specified tasks.		
i) "contracting entity" see definition in ATMF Article 2 point da).	see Directive 2008/57/EC Article 2 (r).	2008/57/EC Art 2 (r)
j) "manufacturer" means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.		2008/57/EC Art 3, 11.
k) "Intermediate statement of verification (ISV)" means a statement issued by the assessing entity which covers verification of compliance with the UTP(s) <u>only</u> for certain stages of an assessment procedure or certain parts of the subsystem.	The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem. In such a case, the procedure set out in Annex VI shall apply.	2008/57/EC Art 18, 4
1.3 PROVISIONS RELATING TO ASSESSING ENTITIES		
1.3.1 The Secretary General shall publish and update a list of notified authorised assessing entities (including authorities and NoBos) on the Organisation's website, indicating their area of responsibility (professional competence).	The Commission shall publish in the *Official Journal of the European Union* the list of bodies, their identification numbers and areas of responsibility, and shall keep this list updated.	2008/57/EC, Art. 28 (1)
1.3.2 A "Notified Body" (NoBo) notified to the EU by a Contracting State in accordance with EU Directive 2008/57/EC, thus meeting the provisions of that Directive, in particular the criteria set out in Annex VIII, and insofar as the body is registered in the EU's public, so-called Nando database[6], shall be considered as a "Suitable Body" with the competence to carry out assessments and shall be included in the list mentioned above.		
1.3.3 A Contracting State	A Member State	2008/57/EC, Art. 28 (3)
shall withdraw approval from an assessing entity	a body	
which no longer meets the criteria referred to in ATMF Article 5 § 2 and/or this UTP GEN-D.	Annex VIII.	
It shall forthwith inform the Committee of Technical Experts	Commission	
and the other Contracting States	Member States	
thereof.		
1.3.4 If a Contracting State (competent national authority) has evidence or reasoned arguments that an assessing entity does not comply [7] with the criteria of ATMF Article 5 § 2 or with this UTP GEN-D, the infringement procedure in ATMF Article 5 § 7 shall	Should a Member State or the Commission consider that a body notified by another Member State does not meet the criteria referred to in Annex VIII, the Commission shall consult the parties concerned. The Commission shall inform	2008/57/EC, Art. 28 (4)

[6] http://ec.europa.eu/enterprise/newapproach/nando

[7] This includes if an assessing entity carries out assessments which do not fall within its published area of responsibility (professional competence).

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
be initiated. In this case, all Contracting States shall be informed without delay.	the latter Member State of any changes that are necessary for the notified body to retain the status conferred upon it.	
1.3.5 The Committee of Technical Experts shall set up an assessing entity coordination group which shall discuss any matter relating to the application of the procedures for assessing conformity or suitability for the use of interoperability constituents (chapter 2) and the procedures for assessing conformity of subsystems with the applicable UTP(s) (chapter 3).	The Commission shall set up a notified bodies coordination group (hereinafter referred to as the Coordination Group) which shall discuss any matter relating to the application of the procedures for assessing conformity or suitability for the use referred to in Article 13 and the verification procedure referred to in Article 18, or to application of the relevant TSIs. Member States' representatives may take part in the work of the Coordination Group as observers. The Commission and the observers shall inform the committee referred to in Article 29 of the work carried out in the framework of the Coordination Group. The Commission, when appropriate, will propose the measures needed to remedy the problems. Where necessary, coordination of the notified bodies shall be implemented in accordance with Article 30(4).	2008/57/EC, Art. 28 (5)

1.4 NON-COMPLIANCE WITH ESSENTIAL REQUIREMENTS

1.4.1 INTEROPERABILITY CONSTITUENTS

1.4.1.1 According to Article 3 § 3 of ATMF, the subsequent ATMF Articles apply “mutatis mutandis” to “Elements of construction”, i.e. Interoperability Constituents. Therefore, ATMF Article 10a concerning suspensions and withdrawals shall apply in an adapted form as below:

1.4.1.2 Where a

Contracting State	Member State	2008/57/EC Art 14 [8] ↓↓
finds that an interoperability constituent covered by the		
Declaration of conformity or a Declaration of suitability for use	EC declaration of conformity or suitability	
is unlikely, when used as intended, to meet the essential requirements, it shall take all necessary steps to restrict its field of application and shall prohibit its use.		
	… or withdraw it from the market.	
The Contracting State shall inform the Secretary General without delay	The Member State shall forthwith inform the Commission	
of the measures taken and give the reasons for its decision, stating in particular whether failure to conform is due to:		
(a) failure to meet the essential requirements;		
(b) incorrect application of		
UTP, Validated Standards or other COTIF regulations (e.g. RID)	European specifications	

[8] EU Interoperability Directive 2008/57/EC, published in the EU Official Journal L191 on 18.07.2008.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
where application of such regulations is relied upon;	specifications	
(c) inadequacy of UTP or Validated Standards.	European specifications.	
1.4.1.3. The Secretary General shall consult the parties concerned as quickly as possible. Where, following that consultation, the	The Commission	
Secretary General establishes that the measure is justified	Commission	
he shall immediately inform the	it	
Contracting State that has taken the initiative, as well as the other	Member State	
Contracting States thereof.	Member States	
Where, after that consultation, the Secretary General establishes that the measure is unjustified,	Commission	
he shall immediately inform the	it	
Contracting State that has taken the initiative and the manufacturer.	Member State	
	or his authorised representative established within the Community thereof.	
Where the decision referred to in paragraph 1 is justified by the existence of a gap in UTP or Validated Standards	European specifications	
the procedure set out in APTU Article 8a shall apply.	Article 12 (of EU Directive 2008/57/EC)	
1.4.1.4 Where an interoperability constituent bearing the Declaration of conformity (including the EC declaration of conformity)	EC declaration of conformity	
fails to comply with the regulations applicable to it, the Contracting State where manufacture takes place	the competent Member State	
shall take appropriate measures against whomsoever has drawn up the declaration and shall inform the Secretary General and the other Contracting States thereof. The Secretary General shall also inform the European Commission.	Commission and the other Member States thereof.	
If the manufacture does not take place in a Contracting State, the Contracting States informed by the Secretary General shall immediately take all necessary steps to restrict the field of application of the interoperability constituent in question or shall prohibit its use.	…where non-conformity persists, the Member State shall take all appropriate steps to restrict or prohibit the placing on the market of the interoperability constituent in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 14.	2008/57/EC Art 13 (5) b)
The Secretary General shall ensure that the	The Commission	
Contracting States and the European Commission	Member States	

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

are kept informed of the course and results of that procedure.

1.4.2 SUBSYSTEMS

With regard to non-compliance with essential requirements, see ATMF Article 7 § 1, Article 10 § 11, Article 19 § 1 and Article 10a.

1.5 LANGUAGE

Unless otherwise specified in the modules in chapter 2 and 3 of this UTP, the following rules shall apply:

Certificates shall be printed in one of the official working languages of the Organisation (see ATMF Article 11 § 6 and Article 1 § 6 of the Convention). In addition, a duplicate may be printed in one of the official national languages of the Contracting State of the issuing party.

Applications, including the associated documentation, **documentation annexed to Certificates** (including the Technical File) and **Reports** shall be made in a language agreed between the applicant and the assessing entity.

User manuals, labels, markings and **Declarations of conformity** shall be available in the official national language(s) of the Contracting States where the interoperability constituent is to be used and/or the subsystem admitted.

That declaration (of conformity) must be written in the same language as the instructions and must contain the following: ……

2008/57/EC, Annex IV, point 3

Declarations of verifications (if issued) for a subsystem shall be written in the same language as the technical file

2008/57/EC, Annex V

1.6 USE OF THE MODULES

1.6.1 The assessment modules included in chapters 2 and 3 shall be combined according to the specification in the applicable UTP.

Modules CA1, CA2 or CH may be used only in the case of products placed on the market, and therefore developed, before the entry into force of
the UTP in question, | this TSI,
provided that the manufacturer demonstrates to the
assessing entity | NoBo
that design review and type examination were performed for previous applications under comparable conditions, and are in conformity with the requirements of
the UTP in question; | this TSI;
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.

see footnote [9]

[9] Preliminary draft 1.0 of the revised TSI WAG, section 6.1.2 note *

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

2. MODULES FOR THE PROCEDURES FOR ASSESSMENT OF INTEROPERABILITY CONSTITUENTS' CONFORMITY WITH THE TECHNICAL REQUIREMENTS

Note: The assessment of Interoperability Constituents as components and the manufacturer's issue of Declarations of conformity are **not** mandatory in COTIF. Such assessments may be carried out on a voluntary basis, in which case the provisions in this UTP shall apply.

Interoperability Constituents which have been integrated into a subsystem shall normally be assessed together with the subsystem.

Contracting States which are also members of the European Union shall apply European law concerning assessment of Interoperability Constituents as components. Other Contracting States may require the mandatory assessment and declaration of Interoperability Constituents placed on the market of their territory, in which case chapter 2 shall be applied in full.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

MODULE CA. INTERNAL PRODUCTION CONTROL

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

Uniform Technical Prescriptions (UTP)	technical specification for interoperability (TSI)

that apply to them.

2. Technical documentation

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

UTP	TSI

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

Wherever applicable, the technical documentation shall also give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable

UTP	TSI

is in accordance with the

UTP	TSI

and that the interoperability constituent has been used in service in the same area of use.

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

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the

"Validated Standards" [10] and/or other relevant technical specifications which have been	harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,

applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the

UTP	TSI

where those

Validated Standards	harmonised standards

have not been applied. In the event of partly applied

Validated Standards,	harmonised standards,

the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc., and

[10] See definition in section 1.2 b).

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
test reports.		
3. Manufacturing		
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the UTP that apply to them.	TSI	
4. Declaration of conformity	EC declaration of conformity	
4.1 The manufacturer shall draw up a written Declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant UTP and, where the UTP does not define this period, for 10 years after the last interoperability constituent has been manufactured. The Declaration of conformity shall identify the interoperability constituent for which it has been drawn up.	EC declaration of conformity TSI TSI EC declaration of conformity	
A copy of the Declaration of conformity shall be made available to the relevant authorities upon request.	EC declaration of conformity	
4.2 The Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	
5. Authorised representative		
The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.		

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

MODULE CA1. INTERNAL PRODUCTION CONTROL PLUS PRODUCT VERIFICATION BY INDIVIDUAL EXAMINATION

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

2. Technical documentation

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

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

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

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

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the
"Validated Standards" [11] and/or other relevant technical specifications which have been | harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,
applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the
UTP | TSI
where those
Validated Standards | harmonised standards
have not been applied. In the event of partly applied
Validated Standards, | harmonised standards,
the technical documentation shall specify the parts which have been applied,

[11] See section 1.2 b).

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

- results of design calculations made, examinations carried out, etc., and
- test reports.

3. Manufacturing

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

4. Product checks

For each individual product manufactured, one or more tests on one or more specific aspects of the interoperability constituent shall be carried out in order to verify conformity with the type described in the technical documentation and the requirements of the
UTP. | TSI.

At the choice of the manufacturer, the tests are carried out either by an
in-house body accredited by the national accreditation organisation in the State where manufacture takes place | accredited in-house body
or under the responsibility of
an assessing entity [12] | a notified body
chosen by the manufacturer.

5. Certificate of conformity | EC Certificate of conformity

The assessing entity shall issue a Certificate of conformity | The notified body shall issue an EC Certificate of conformity
in respect of the examinations and tests carried out.

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

6. Declaration of conformity | EC declaration of conformity

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

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

6.2 The

[12] See section 1.2 b).

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	

7. Authorised representative

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

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

MODULE CA2. INTERNAL PRODUCTION CONTROL PLUS PRODUCT VERIFICATION AT RANDOM INTERVALS

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

2. Technical documentation

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

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

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

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

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the
"Validated Standards" [13] and/or other relevant technical specifications which have been | harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,
applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the
UTP | TSI
where those
Validated Standards | harmonised standards
have not been applied. In the event of partly applied
Validated Standards, | harmonised standards,

[13] In COTIF regulations, a "Validated Standard" has the same function and must fulfil the same criteria as a "Harmonized Standard" in the European Union, cf. "Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards" as published in the EU Official Journal C 136, 04/06/1985 pages 0001 – 0009.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
the technical documentation shall specify the parts which have been applied,		
☐ results of design calculations made, examinations carried out, etc., and		
☐ test reports.		
3. Manufacturing		
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the		
UTP	TSI	
that apply to them.		
4. Product checks		
4.1 At the choice of the manufacturer, either an		
in-house body accredited by the national accreditation organisation in the State where the manufacture takes place or	accredited in-house body	
by the responsibility of		
an assessing entity	a notified body	
chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals.		
4.2 The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.		
4.3 All interoperability constituents shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. All interoperability constituents in a sample shall be individually examined and appropriate tests shall be carried out to ensure the product conformity with the type described in the technical documentation and the requirements of the		
UTP(s)	TSI	
that apply to it and to determine whether the lot is accepted or rejected.		
5. Certificate of conformity	EC Certificate of conformity	
The assessing entity shall issue a Certificate of conformity	The notified body shall issue an EC Certificate of conformity	
in respect of the examinations and tests carried out.		
The manufacturer shall keep the		
Certificate of conformity	EC Certificate of conformity	
available for inspection by the national authorities for the period defined in the relevant		
UTP	TSI	
and where the		
UTP	TSI	
does not define this period, for 10 years after the last interoperability constituent has been manufactured.		
6. Declaration of conformity	EC declaration of conformity	
6.1 The manufacturer shall draw up a written		
Declaration of conformity	EC declaration of conformity	
for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant		
UTP	TSI	
and, where the		
UTP	TSI	
does not define this period, for 10 years after the last interoperability constituent has been manufactured. The		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Declaration of conformity shall identify the interoperability constituent for which it has been drawn up.	EC declaration of conformity	
A copy of the Declaration of conformity shall be made available to the relevant authorities upon request.	EC declaration of conformity	
6.2 The Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	

7. Authorised representative

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
MODULE CB. TYPE EXAMINATIONS	EC-TYPE EXAMINATION	

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

2. The Type examination | EC-type examination
may be carried out in either of the following manners:
   - examination of a specimen, representative of the production envisaged, of the interoperability constituent (production type),
   - assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the interoperability constituent (combination of production type and design type),
   - assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

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

   The application shall include:
   - the name and address of the manufacturer, and, if the application is lodged by the authorised representative, his name and address as well,
   - a written declaration that the same application has not been lodged with any other
assessing entity, | notified body,
   - the technical documentation. The technical documentation shall make it possible to assess the interoperability constituent's conformity with the applicable requirements of the
UTP. | TSI.

     The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance and operation of the interoperability constituent. The technical documentation shall contain, wherever applicable, at least the following elements:
     - a general description of the interoperability constituent,
     - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
     - descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
     - conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
     - a list of the

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Validated Standards [14] and/or other relevant technical specifications which have been	harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,	

applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the
UTP | TSI
where those
Validated Standards | harmonised standards
have not been applied. In the event of partly applied
Validated Standards, | harmonised standards,
the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc., and
- test reports.

- the specimens representative of the production envisaged. The
assessing entity | notified body
may request further specimens if needed for carrying out the test programme,
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant
Validated Standards | harmonised standards
and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The assessing entity shall: | The notified body shall:

For the interoperability constituent:

4.1 examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the interoperability constituent with the requirements of the relevant
UTP. | TSI.

For the specimen(s):

4.2 verify that the specimen(s) have been manufactured in conformity with the requirements of the
UTP | TSI
and the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant
Validated Standards | harmonised standards
and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3 carry out appropriate examinations and tests, or have them carried out, to check whether requirements of the
UTP | TSI
have been applied correctly;

4.4 carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant
Validated Standards | harmonised standards
and/or technical specifications, these have been applied correctly;

4.5 carry out appropriate examinations and tests, or have them carried out, to check

[14] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
whether, where the solutions in the relevant		
Validated Standards	harmonised standards	
and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the		
UTP;	TSI;	
4.6 agree with the manufacturer on a location where the examinations and tests will be carried out.		
5. The assessing entity	The notified body	
shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcome.		
Without prejudice to its obligations vis-à vis the		
authority that has authorised it to perform assessments (cf. section 1.2 c) and 1.3), the assessing entity	the notifying authorities, the notified body	
shall release the content of that report, in full or in part, only with the agreement of the manufacturer.		
6. Where the type meets the requirements of the		
UTP	TSI	
that apply to the interoperability constituent concerned, the		
assessing entity shall issue a Type examination certificate	notified body shall issue an EC-Type examination certificate	
to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.		
The certificate may have one or more annexes attached.		
The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituents with the examined type to be evaluated.		
Where the type does not satisfy the requirements of the		
UTP, the assessing entity	TSI, the notified body	
shall refuse to issue		
A Type examination certificate	an EC-Type examination certificate	
and shall inform the applicant accordingly, giving detailed reasons for its refusal.		
7. The manufacturer shall inform the		
assessing entity	notified body	
that holds the technical documentation relating to the		
Type examination certificate	EC-Type examination certificate	
of all modifications to the approved type that may affect the conformity of the interoperability constituent with the requirements of the		
UTP	TSI	
or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original		
Type examination certificate.	EC-Type examination certificate.	
Only those examinations and tests that are relevant and necessary to the changes shall be performed.		
8. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any Type-examination certificates	Each notified body shall inform its notifying authorities concerning the EC-type examination certificates	
and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
the competent authority	its notifying authorities	

the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each assessing entity shall ensure that the other assessing entities are informed of the Type-examination certificates	Each notified body shall inform the other notified bodies concerning the EC-type examination certificates	

and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Secretary General, the Contracting States and the other assessing entities	The Commission, the Member States and the other notified bodies	

may upon request, obtain a copy of the

Type examination certificate	EC-Type examination certificate.	

and/or additions thereto.

Upon request,

the Secretary General and the Contracting States may also similarly	the Commission and the Member States may	

obtain a copy of the technical documentation and the results of the examinations carried out by the

assessing entity.	notified body.	
The assessing entity	The notified body	

shall keep a copy of the

Type examination certificate,	EC-Type examination certificate.	

its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the

Type examination certificate,	EC-Type examination certificate,	

its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant

UTP	TSI	

and where the

UTP	TSI	

does not define this period, for 10 years after the last interoperability constituent has been manufactured.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

MODULE CC. CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his sole responsibility that the interoperability constituents concerned are in conformity with the type described in the

Type examination certificate	EC-Type examination certificate.

and satisfy the requirements of the

Uniform Technical Prescriptions (UTP)	technical specification for interoperability (TSI)

that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the interoperability constituents with the approved type described in the

Type examination certificate	EC-type examination certificate

and with the requirements of the

UTP	TSI

that apply to them.

3. Declaration of conformity	EC declaration of conformity

3.1 The manufacturer shall draw up a written

Declaration of conformity	EC declaration of conformity

for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant

UTP	TSI

and, where the

UTP	TSI

does not define this period, for 10 years after the last interoperability constituent has been manufactured. The

Declaration of conformity	EC declaration of conformity

shall identify the interoperability constituent for which it has been drawn up.

A copy of the

Declaration of conformity	EC declaration of conformity

shall be made available to the relevant authorities upon request.

4.2 The

Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

The certificate to be referred to is:

☐ the Type examination certificate and its additions.	☐ the EC-type examination certificate and its additions.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

4. Authorised representative

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

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

MODULE CD. CONFORMITY TO TYPE BASED ON QUALITY MANAGEMENT SYSTEM OF THE PRODUCTION PROCESS

1. Conformity to type based on quality management system of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the interoperability constituents concerned are in conformity with the type described in the 1.

Type examination certificate | EC-Type examination certificate.

and satisfy the requirements of the

Uniform Technical Prescriptions (UTP) | technical specification for interoperability (TSI)

that apply to it.

2. Manufacturing 2.

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

3. Quality management system

3.1 The manufacturer shall lodge an application for assessment of his quality management system with

an assessing entity | the notified body

of his choice, for the interoperability constituents concerned.

The application shall include:

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

3.2 The quality management system shall ensure that the interoperability constituents are in conformity with the type described in the

Type examination certificate | EC-Type examination certificate

and comply with the requirements of the

UTP | TSI

that apply to them.

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

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

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

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

- the means of monitoring the achievement of the required product quality and the effective operation of the quality management system.

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

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard,
Validated Standards [15] | harmonised standard
and/or technical specification.

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

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the
UTP. | TSI.

The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second paragraph, fifth indent, to verify the manufacturer's ability to identify the requirements of the
UTP | TSI
and to carry out the necessary examinations with a view to ensuring compliance of the interoperability constituent with those requirements.

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

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

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

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

[15] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.		
4. Surveillance under the responsibility of the assessing entity	notified body	
4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.		
4.2 The manufacturer shall, for periodic audit purposes, allow the assessing entity access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular: - the quality management system documentation, - the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.	notified body	
4.3 The assessing entity shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be at least once every two years. When the manufacturer operates a certified quality management system, the assessing entity shall take this into account during the periodic audits.	notified body	
4.4 In addition, the assessing entity may pay unexpected visits to the manufacturer. During such visits the assessing entity may, if necessary, carry out interoperability constituent tests, or have them carried out, in order to verify that the quality management system is functioning correctly. The assessing entity shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	notified body notified body	
5. Declaration of conformity	EC declaration of conformity	
5.1 The manufacturer shall draw up a written Declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant UTP and, where the UTP does not define this period, for 10 years after the last interoperability constituent has been manufactured. The Declaration of conformity shall identify the interoperability constituent for which it has been drawn up. A copy of the Declaration of conformity shall be made available to the relevant authorities upon request.	EC declaration of conformity TSI TSI EC declaration of conformity EC declaration of conformity	
5.2 The Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability	EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.		

The certificate to be referred to is:

- the "quality management system approval" indicated in point 3.3 and audit reports indicated in point 4.3, if any,
- the Type examination certificate and its additions. | the EC-type examination certificate and its additions.

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

- the documentation referred to in point 3.1,
- the change referred to in point 3.5, as approved,
- the decisions and reports of the assessing entity | notified body referred to in points 3.5, 4.3 and 4.4.

7. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any | Each notified body shall inform its notifying authorities of
"quality management system approvals" issued or withdrawn, and shall, periodically or upon request, make available to
the competent authority | its notifying authorities
the list of "quality management system approvals" refused, suspended or otherwise restricted.

Each assessing entity shall ensure that the other assessing entities are informed of the | Each notified body shall inform the other notified bodies of
"quality management system approvals" which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of "quality management system approvals" which it has issued.

8. Authorised representative

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

MODULE CF. CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

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

2. Manufacturing

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

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

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

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

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

4.2 The assessing entity | The notified body
shall issue

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
a Certificate of conformity	an EC certificate of conformity	

in respect of the examinations and tests carried out.

The manufacturer shall keep the

Certificate of conformity	EC certificate of conformity	

available for inspection by the national authorities for the period defined in the relevant

UTP	TSI	

and, where the

UTP	TSI	

does not define this period, for 10 years after the last interoperability constituent has been manufactured.

5. Statistical verification of conformity

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

5.2 A random sample shall be taken from each lot according to the requirements of the

UTP.	TSI.	

All interoperability constituents in a sample shall be individually examined and appropriate tests set out in the relevant

UTP, Validated Standard(s)	TSI, harmonised standard(s)	

and/or technical specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the requirements of the

UTP	TSI	

and to determine whether the lot is accepted or rejected. When a test is not set out in the relevant

UTP, Validated Standard(s)	TSI, harmonised standard(s)	

and/or technical specification(s), the appropriate tests to be carried out shall be decided between the manufacturer and the

assessing entity	notified body	

concerned.

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

The

assessing entity	notified body	

shall issue

a Certificate of conformity	an EC certificate of conformity	

in respect of the examinations and tests carried out.

The manufacturer shall keep the

Certificate of conformity	EC certificate of conformity	

at the disposal of the national authorities for the period defined in the relevant

UTP	UTP	

and, where the

UTP	TSI	

does not define this period, for 10 years after the last interoperability constituent has been manufactured.

5.4 If a lot is rejected, the

assessing entity or the competent authority in the Contracting State where the production of the constituent takes place	notified body or the competent authority	

shall take appropriate measures to prevent that the lot is being placed on the market. In the event of the frequent rejection of lots the

assessing entity	notified body	

may suspend the statistical verification and take appropriate measures.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
6. Declaration of conformity		
6.1 The manufacturer shall draw up a written Declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant UTP and, where the UTP does not define this period, for 10 years after the last interoperability constituent has been manufactured. The Declaration of conformity shall identify the interoperability constituent for which it has been drawn up.	EC declaration of conformity TSI TSI EC declaration of conformity	
A copy of the Declaration of conformity shall be made available to the relevant authorities upon request.	EC declaration of conformity	
6.2 The Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	
The certificate to be referred to is: ☐ the Type examination certificate and its additions. ☐ the Certificate of conformity referred to in point 4.2 and point 5.3	☐ the EC-type examination certificate and its additions. ☐ the EC Certificate of conformity	
7. Authorised representative		
The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2, 5.1 and 5.2.		

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

MODULE CH. CONFORMITY BASED ON FULL QUALITY MANAGEMENT SYSTEM

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

2. Manufacturing

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

3. Quality management system

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

The application shall include:

- the name and address of the manufacturer, and, if the application is lodged by the authorised representative, his name and address as well,
- the technical documentation for one model of each category of interoperability constituents intended to be manufactured.

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

  - a general description of the interoperability constituent,
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
  - descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
  - conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
  - a list of the
    Validated Standards [16] and/or other relevant technical specifications which have been | harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,
    applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the
    UTP | TSI
    where those
    Validated Standards | harmonised standards
    have not been applied. In the event of partly applied
    Validated Standards, | harmonised standards,

[16] See section 1.2 c)

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc., and
- test reports.

- the documentation concerning the quality management system, and
- a written declaration that the same application has not been lodged with any other assessing entity. | notified body.

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

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

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

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

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

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

When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, the
assessing entity | notified body
shall take this into account in the assessment. In this case, the
assessing entity | notified body
will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. The

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

assessing entity | notified body
shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the
UTP. | TSI.

The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the requirements of the
UTP | TSI
and to carry out the necessary examinations with a view to ensuring compliance of the interoperability constituent with those requirements.

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

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

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

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

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

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

4. Surveillance under the responsibility of the
assessing entity | notified body

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

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

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

4.3 The assessing entity | The notified body

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality management system and shall provide the manufacturer with an audit report.		
The frequency of the periodic audits shall be at least once every two years.		
When the manufacturer operates a certified quality management system, the assessing entity shall take this into account during the periodic audits.	notified body	
4.4 In addition, the assessing entity may pay unexpected visits to the manufacturer. During such visits, it may, if necessary, carry out interoperability constituent tests, or have them carried out, in order to check the proper functioning of the quality management system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	notified body	
5. Declaration of conformity		
5.1 The manufacturer shall draw up a written Declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant UTP and, where the UTP does not define this period, for 10 years after the last interoperability constituent has been manufactured. The Declaration of conformity shall identify the interoperability constituent for which it has been drawn up.	EC Declaration of conformity TSI TSI EC Declaration of conformity	
A copy of the Declaration of conformity shall be made available to the relevant authorities upon request.	EC Declaration of conformity	
5.2 The Declaration of conformity shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	
The certificate to be referred to is: - the quality management system approval indicated in point 3.3 and audit reports indicated in point 4.3, if any.		
6. The manufacturer shall, for the period defined in the relevant UTP and, where the UTP does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:	TSI TSI	
- the technical documentation referred to in point 3.1,		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

- the documentation concerning the quality management system referred to in point 3.1,
- the change referred to in point 3.5, as approved, and
- the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any

Each notified body shall inform its notifying authorities of

"quality management system approvals" issued or withdrawn, and shall, periodically or upon request, make available to

the competent authority

its notifying authorities

the list of "quality management system approvals" refused, suspended or otherwise restricted.

Each assessing entity shall ensure that the other assessing entities will be informed

Each notified body shall inform the other notified bodies

of "quality management system approvals" which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of "quality management system approvals" which it has issued.

8. Authorised representative

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

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

MODULE CH1. CONFORMITY BASED ON FULL QUALITY MANAGEMENT SYSTEM PLUS DESIGN EXAMINATION

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

2. Manufacturing

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

3. Quality management system

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

The application shall include:

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

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

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

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

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where the relevant
Validated Standards | harmonised standards
and/or technical specifications will not be applied in full, the means that will be used to ensure that the requirements of the
UTP | TSI
that apply to the interoperability constituents will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the interoperability constituents pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality management system

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

techniques, processes and systematic actions that will be used,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

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

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

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

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the
UTP. | TSI.

The audit shall include an assessment visit to the manufacturer's premises.

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

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

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

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

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

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

3.6. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any

	Each notified body shall inform its notifying authorities of

"quality management system approvals" issued or withdrawn, and shall, periodically or upon request, make available to

the competent authority	its notifying authorities

the list of "quality management system approvals" refused, suspended or otherwise restricted.

Each assessing entity shall ensure that the other assessing entities are informed of the

	Each notified body shall inform the other notified bodies of

"quality management system approvals" which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of "quality management system approvals" which it has issued.

4. Design examination

4.1 The manufacturer shall lodge an application for examination of the design with the

assessing entity	notified body

referred to in point 3.1.

4.2 The application shall make it possible to understand the design, manufacture, maintenance and operation of the interoperability constituent, and to assess the conformity with the requirements of the

UTP	TSI

that apply to it.

It shall include:

- the name and address of the manufacturer
- a written declaration that the same application has not been lodged with any other

assessing entity,	notified body,

- the technical documentation. The technical documentation shall make it possible to assess the interoperability constituent's conformity with the applicable requirements of the

UTP.	TSI.

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, maintenance and operation of the interoperability constituent. The technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the interoperability constituent,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation (including conditions for use) and maintenance of the interoperability constituent,
- conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- a list of the

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Validated Standards [17] and/or other relevant technical specifications which have been	harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,	

applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the

UTP	TSI	

where those

Validated Standards	harmonised standards	

have not been applied. In the event of partly applied

Validated Standards,	harmonised standards,	

the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc., and
- test reports.

- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant

Validated Standards	harmonised standards	

and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

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

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

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

4.4 The manufacturer shall keep the
assessing entity | notified body
that has issued the
Design examination certificate | EC design examination certificate
informed of any modification to the approved design that may affect the conformity with the requirements of the
UTP | TSI
or the conditions for validity of the certificate until the expiry of the validity of the certificate. Such modifications shall require additional approval — from the
assessing entity | notified body
that issued the
Design examination certificate | EC design examination certificate
— in the form of an addition to the original
Design examination certificate. | EC design examination certificate.

[17] see section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Only those examinations and tests that are relevant and necessary to the changes shall be performed.		
4.5 Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any Design examination certificates	Each notified body shall inform its notifying authorities concerning the EC design examination certificates	
and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	its notifying authorities	
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities are informed of the Design examination certificates	Each notified body shall inform the other notified bodies concerning the EC design examination certificates	
and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.		
The Secretary General, the competent authorities of the other Contracting States and the other assessing entities	The Commission, the Member States and the other notified bodies	
may, upon request, obtain a copy of the Design examination certificate.	EC design examination certificate.	
and/or additions thereto.		
Upon request, the Secretary General and the other Contracting States	Commission and the Member States	
may obtain a copy of the technical documentation and the results of the examinations carried out by the assessing entity.	notified body.	
The assessing entity	The notified body	
shall keep a copy of the Design examination certificate,	EC design examination certificate.	
its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.		
4.6 The manufacturer shall keep a copy of the Design examination certificate,	EC design examination certificate,	
its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant UTP	TSI	
and, where the UTP	TSI	
does not define this period, for 10 years after the last interoperability constituent has been manufactured.		
5. Surveillance under the responsibility of the assessing entity	notified body	
5.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.		
5.2 The manufacturer shall, for periodic audit purposes, allow the assessing entity	notified body	
access to the manufacture, inspection, testing and storage sites and shall provide it with		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

all necessary information, in particular:

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

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

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

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

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

6. Declaration of conformity | EC declaration of conformity

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

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

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

a) meet the requirements set out in Annex 1 to this UTP, and
b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
state that the interoperability constituents meet the requirements of those EU directives.		

The certificates to be referred to are:

- the "quality management system approval" indicated in point 3.3 and audit reports indicated in point 5.3, if any,
- the Design examination certificate indicated in point 4.3 and its additions.

the Design examination certificate indicated in point 4.3 and its additions.	the EC design examination certificate

7. The manufacturer shall, for the period defined in the relevant

UTP	TSI
and, where the	
UTP	TSI

does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the competent national authorities:

- the documentation concerning the quality management system referred to in point 3.1,
- the change referred to in point 3.5, as approved, and
- the decisions and reports of the assessing entity referred to in points 3.5, 5.3 and 5.4.

the decisions and reports of the assessing entity referred to in points 3.5, 5.3 and 5.4.	notified body

8. Authorised representative

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

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

MODULES FOR THE PROCEDURES FOR ASSESSMENT OF SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS

MODULE CV. TYPE VALIDATION BY IN-SERVICE EXPERIENCE (SUITABILITY FOR USE)

1. Type validation by in-service experience is the part of the assessment procedure in which
an assessing entity | a notified body
ascertains and attests that a specimen, representative of the production envisaged meets the requirements for suitability for use of the
Uniform Technical Prescriptions (UTP) | technical specification for interoperability (TSI)
that apply to it.

2. The manufacturer shall lodge an application for Type validation by in-service experience with
an assessing entity | a notified body
of his choice.

The application shall include:

- the name and address of the manufacturer, and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other assessing entity, | notified body,
- the technical documentation referred to in point 3,
- the programme for validation by in-service experience, as described in point 4,
- the name and address of the company(ies) (infrastructure managers and/or railway undertaking), with which the applicant has obtained an agreement to contribute to a suitability for use assessment by in-service experience:
  - by operating the interoperability constituent in service,
  - by monitoring the in-service behaviour, and
  - by issuing a report about in-service experience,
- the name and the address of the company undertaking the maintenance of the interoperability constituent during the time period or running distance required for in-service experience, and
- the Type examination certificate | the EC type examination certificate
  when module CB was used for the design phase, or
  the Design examination certificate | the EC design examination certificate
  when module CH1 was used for the design phase.

The manufacturer shall place at the disposal of the company(ies), undertaking the operation of the interoperability constituent in service, a specimen or a sufficient number of specimens, representative of the production envisaged and hereinafter called ‘type’. A type may cover several versions of the interoperability constituent provided that the differences between the versions are all covered by the certificates as mentioned above.
The assessing entity | The notified body
may request further specimens if needed for carrying out the validation by in-service experience.

3. The technical documentation shall make it possible to assess the interoperability constituent’s conformity with the requirements of the
UTP. | TSI.

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

The technical documentation shall cover the design, manufacturing, maintenance and operation of the interoperability constituent.

The technical documentation shall contain the following elements:

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

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

4. The programme for the validation by in-service experience shall include:
   - the required performance or behaviour in service of the interoperability constituent under trial,
   - the installation arrangements,
   - the duration of the programme — either time or distance,
   - the operating conditions and the service programme expected,
   - the maintenance programme,
   - the special in-service tests, if any, to be performed,
   - the batch size of the specimens — if more than one,
   - the inspection programme (nature, number and frequency of inspections, documentation),
   - criteria for tolerable defects and their impact on the programme,
   - the information to be included in the report of the company(ies) operating the interoperability constituent in service (see point 2, fifth indent).

5. Type validation by in-service experience

The assessing entity shall: | The notified body shall:

5.1 examine the technical documentation and the programme for validation by in-service experience;

5.2 verify that the type is representative and has been manufactured in conformity with the technical documentation;

5.3 verify that the programme for validation by in-service experience is well adapted to assess the required performance and in-service behaviour of the interoperability constituents;

5.4 agree with the applicant and the company(ies) undertaking the operation of the interoperability constituent referred to in point 2 the programme and the location where the inspections will be carried out and if necessary, the test(s) and the body performing the test(s);

5.5 monitor and inspect the progress of in-service running, operation and maintenance of the interoperability constituent;

5.6 assess the report, to be issued by the company(ies) undertaking the operation the interoperability constituent referred to in point 2, and all other documentation and information, collected during the procedure (test reports, maintenance experience etc.);

5.7 evaluate whether the in-service behaviour results meet the requirements of the
UTP. | TSI.

6. Where the type meets the requirements of the
UTP | TSI
that apply to the interoperability constituent concerned,

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
the assessing entity shall issue a Certificate of suitability for use to the manufacturer.	the notified body an EC certificate of suitability for use	
The certificate shall contain the name and address of the manufacturer, the conclusions of the validation, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.		
A list of the relevant parts of the technical documentation shall be annexed to the Certificate of suitability for use and a copy kept by the assessing entity.	EC certificate of suitability for use notified body.	
Where the type does not meet the requirements of the UTP, the assessing entity shall refuse to issue a Certificate of suitability for use and shall inform the applicant accordingly, giving detailed reasons for its refusal.	TSI, the notified body an EC certificate of suitability for use	
7. The manufacturer shall inform the assessing entity that holds the technical documentation relating to the Certificate of suitability for use of all modifications to the approved type that may affect the suitability for use of the interoperability constituent or the conditions for the validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original Certificate of suitability for use.	notified body EC certificate of suitability for use EC certificate of suitability for use.	
Only those examinations and tests that are relevant and necessary to the changes shall be performed.		
8. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any Certificate of suitability for use and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the competent authority the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.	Each notified body shall inform its notifying authorities concerning the EC certificate of suitability for use its notifying authorities	
9. Each assessing entity shall ensure that the other assessing entities are informed of the Certificates of suitability for use and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.	Each notified body shall inform the other notified bodies concerning the EC Certificates of suitability for use	
10. The Secretary General, the competent authorities of the other Contracting States and the other assessing entities may, upon request, obtain a copy of the Certificate of suitability for use and/or additions thereto.	The Commission, the Member States and the other notified bodies EC Certificate of suitability for use	
Upon request, the Secretary General and the Contracting States	Commission and the Member States	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
may obtain a copy of the technical documentation and the results of the examinations carried out by the		
assessing entity.	notified body.	
The assessing entity	The notified body	
shall keep a copy of the		
Certificate of suitability for use,	EC Certificate of suitability for use	
its annexes and additions, until the expiry of the validity of the certificate.		
11. Declaration of suitability for use	EC declaration of suitability for use	
11.1 The manufacturer shall draw up a written		
Declaration of suitability for use	EC declaration of suitability for use	
for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant		
UTP	TSI	
and, where the		
UTP	TSI	
does not define this period, for 10 years after the last interoperability constituent has been manufactured. The		
Declaration of suitability for use	EC declaration of suitability for use	
shall identify the interoperability constituent for which it has been drawn up.		
A copy of the		
Declaration of suitability for use	EC declaration of suitability for use	
shall be made available to the relevant authorities upon request.		
11.2 The		
Declaration of suitability for use	EC declaration of suitability for use	
shall a) meet the requirements set out in Annex 1 to this UTP, and b) in cases where the interoperability constituent is intended for the EU market and if the constituent is also the subject of EU directives covering other aspects than those covered by COTIF regulations (including the applicable UTPs) e.g. environmental pollution, also state that the interoperability constituents meet the requirements of those EU directives.	shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.	
The certificate to be referred to is:		
☐ the Certificate of suitability for use.	☐ the EC certificate of suitability for use.	
11.3 The interoperability constituent may be placed on the market only after the following		
declarations have been drawn up:	EC declarations have been drawn up:	
☐ Declaration of suitability for use referred to in point 11.1, and	☐ EC declaration of suitability for use referred to in point 11.1, and	
☐ Declaration of conformity.	☐ EC declaration of conformity.	
12. Authorised representative		
The manufacturer's obligations set out in points 2, 7 and 11.1 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
3. MODULES FOR THE PROCEDURES FOR ASSESSMENT OF A SUBSYSTEM'S CONFORMITY WITH THE TECHNICAL REQUIREMENTS	**Modules for EC Verification of Subsystems**	
MODULE SB. TYPE EXAMINATION	**EC TYPE EXAMINATION**	
1. Type examination is the procedure whereby an assessing entity examines the technical design of a subsystem and verifies and attests that the technical design of the subsystem meets the requirements of the relevant UTP(s) and other applicable regulations [18] that apply to it.	EC-type examination is the part of an EC verification procedure whereby a notified body examines the technical design of a subsystem and verifies and attests that the technical design of the subsystem meets the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.	
2. Type examination shall be carried out by:	EC-type examination shall be carried out by:	
☐ assessment of the adequacy of the technical design of the subsystem through examination of the technical documentation and supporting evidence referred to in point 3 (design type), and	☐ assessment of the adequacy of the technical design of the subsystem through examination of the technical documentation and supporting evidence referred to in point 3 (design type), and	
☐ examination of a specimen, representative of the production envisaged, of the complete subsystem (production type).	☐ examination of a specimen, representative of the production envisaged, of the complete subsystem (production type).	
A type may cover several versions of the subsystem provided that the differences between the versions do not affect the provisions of the relevant UTP(s).	A type may cover several versions of the subsystem provided that the differences between the versions do not affect the provisions of the relevant TSI(s).	
3. The applicant shall lodge an application for Type examination with an assessing entity of his choice.	The applicant shall lodge an application for EC-type examination with a notified body of his choice.	
The application shall include:	The application shall include:	
☐ the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,	☐ the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,	
☐ a written declaration that the same application has not been lodged with any other assessing entity,	☐ a written declaration that the same application has not been lodged with any other notified body,	
☐ the technical documentation.[19] The technical documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant UTP(s).	☐ the technical documentation.[19] The technical documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s).	
The technical documentation shall specify the requirements of the relevant UTP(s) and cover, as far as relevant for the	The technical documentation shall specify the requirements of the relevant TSI(s) and cover, as far as relevant for the	

[18] The assessing entity will request evidence of conformity with all "other applicable regulations" from the applicant. The applicant must provide such evidence of conformity as is relevant and the assessing entity will include this evidence without further assessments in its compilation of the Technical File.
UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

[19] The technical documentation includes descriptions and explanations necessary for understanding the functioning and possible risks/failures in safety-related software used in the subsystem, if appropriate.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
assessment,	EC-type examination procedure,	

the design, manufacture and operation of the subsystem. The technical documentation shall contain, at least the following elements:

- a general description of the subsystem, its overall design and structure,
- documents necessary for the compilation of the technical file

according to the provisions of UTP GEN-B "Technical File"	as described in point 4 of Annex VI to Directive 2008/57/EC,

- a separate file with the set of data required by the

UTP(s)	TSI(s)

for each relevant register

set up by the Committee of Technical Experts according to ATMF Article 13,	provided for in Articles 34 and 35 of Directive 2008/57/EC,

- copy of

UTP declarations of	EC declarations of

intermediate statements of verification (ISV) issued for the subsystem,

	issued for the subsystem according to point 2 of Annex VI to Directive 2008/57/EC,

if any,

- if relevant, descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- conditions of integration of the subsystem in its system environment and the necessary interface conditions,
- a list of the

Validated Standards [20] and/or other relevant technical specifications which have been	harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,

applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the

UTP(s)	TSI(s)

where those

Validated Standards	harmonised standards

have not been applied. In the event of partly applied

Validated Standards,	harmonised standards,

the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc.,
- test programme and reports,
- evidence of conformity with other

applicable COTIF regulations	regulations deriving from the Treaty (including certificates, if any),

- supporting documentation regarding the manufacture and the assembly of the subsystem,
- a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation,
- conditions for use of the subsystem (restrictions of running time or distance, wear limits etc.),
- conditions for maintenance and technical documentation on maintenance of the subsystem,
- any technical requirement specified in the relevant

[20] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
UTP(s)	TSI(s)	

that shall be taken into account during production, maintenance or operation of the subsystem,

- all other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- any further information, if required by the relevant

UTP(s),	TSI(s),

- the specimens representative of the production envisaged. The

assessing entity	notified body

may request further specimens if needed for carrying out the test programme,

- a specimen or specimens of a sub-assembly or assembly or a specimen of the subsystem in a pre-assembled condition shall be provided, if so required for specific test or examination methods and specified in the relevant

UTP(s),	TSI(s),

- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant

Validated Standards	harmonised standards

and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate testing body of the applicant, or by another testing body on his behalf and under his responsibility.

4.	The assessing body shall	The notified body shall

For the design type:

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

For the production type:

4.3	verify that the specimen(s) have been manufactured in conformity with the requirements of the relevant	
	UTP(s)	TSI(s)
	and with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant	
	UTP(s), Validated Standards	TSI(s), harmonised standards
	and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;	
4.4	carry out appropriate examinations and tests, or have them carried out, to check whether, where the applicant has chosen to apply the solutions in the relevant	
	Validated Standards	harmonised standards
	and/or technical specifications, these have been applied correctly;	
4.5	carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant	
	Validated Standards	harmonised standards
	and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the relevant	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
UTP(s);	TSI(s);	
4.6 agree with the applicant on a location where the examinations and tests will be carried out.		
5. When the subsystem referred to in point 3 is subject to derogation(s) procedure according to		
Article 7a of ATMF and the regulations/ guidelines adopted by the Committee of Technical Experts in pursuance of that Article,	Article 9 of Directive 2008/57/EC,	
the applicant shall inform the assessing entity thereof.	notified body	
The applicant shall also provide the assessing entity with a precise reference to the UTP(s) (or their parts) for which the derogation is requested.	notified body TSI(s)	
When the assessing entity is the competent authority, it shall analyse whether the derogation complies with the essential requirements and follow the procedure set out by the Committee of Technical Experts according to Article 7a of ATMF.		
The applicant shall be informed of the result of the analysis and the outcome of the derogation procedure.		
If the assessing entity is not the competent authority,		
the applicant shall communicate to the assessing entity the outcome of the derogation procedure.	notified body	
6. The assessing entity shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes.	The notified body	
The evaluation report shall be given to the applicant and, on request, to the competent authority in the Contracting State which has authorised the assessing entity.		
Without prejudice to its obligations vis-à-vis the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3), the assessing entity shall release the content of that report, in full or in part, only with the agreement of the applicant.	notifying authorities, the notified body	
7. Where the type meets the requirements of the relevant UTP(s) that apply to the subsystem concerned, the	TSI(s)	
assessing entity shall issue	notified body	
a UTP Type-examination certificate to the applicant.	an EC-type examination certificate	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
The certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.		
The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems with the examined type to be evaluated.		
Where the type does not satisfy the requirements of the relevant		
UTP(s), the assessing entity	TSI(s), the notified body	
shall refuse to issue		
a UTP Type-examination certificate	an EC-type examination certificate	
and shall inform the applicant accordingly, giving detailed reasons for its refusal.		
Where the subsystem referred to in point 3 is subject to derogation, upgrade, renewal or specific case, the		
UTP Type-examination certificate	EC-type examination certificate	
shall also indicate the precise reference to the		
UTP(s)	TSI(s)	
or their parts to which conformity has not been examined during		
the assessments carried out.	EC verification procedure.	
If only certain parts of the subsystem are covered and they meet the requirements of the relevant		
UTP(s), the assessing entity	TSI(s), the notified body	
shall issue an intermediate statement of verification (ISV)		
clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	in compliance with Article 18(4) of Directive 2008/57/ EC.	
Based on the ISV, the applicant may draw up a written UTP declaration of intermediate statement of verification (ISV).	The applicant shall draw up a written EC ISV declaration of intermediate subsystem conformity according to section 2 of Annex VI to Directive 2008/57/EC.	
8. The applicant shall inform the		
assessing entity	notified body	
that holds the technical documentation relating to the		
UTP Type-examination certificate	EC-type examination certificate	
of all modifications to the approved type that may affect the conformity of the subsystem with the requirements of the relevant		
UTP(s)	TSI(s)	
or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original		
UTP Type-examination certificate.	EC-type examination certificate.	
9. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any UTP Type-examination certificates	Each notified body shall inform its notifying authorities concerning the EC-type examination certificates	
and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to		
the competent authority	its notifying authorities	
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities are informed of the UTP Type-examination certificates	Each notified body shall inform the other notified bodies concerning the EC-type examination certificates	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.		
The Secretary General, the Contracting States and the other assessing entities	The Commission, the Member States and the other notified bodies	
may upon request, obtain a copy of the UTP Type-examination certificate and/or additions thereto.	EC-Type examination certificate.	
Upon request, the Secretary General and the Contracting States may also	the Commission and the Member States may	
obtain a copy of the technical documentation and the results of the examinations carried out by the assessing entity.	notified body.	
The assessing entity	The notified body	
shall keep a copy of the UTP Type-examination certificate,	EC-Type examination certificate.	
its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.		
10. The applicant shall keep a copy of the UTP Type-examination certificate,	EC-type examination certificate,	
its annexes and additions together with the technical documentation at the disposal of the national authorities throughout the service life of the subsystem.		
11. The applicant's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 5, 8 and 10, provided that they are specified in the mandate.		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
MODULE SD. QUALITY MANAGEMENT SYSTEM OF THE PRODUCTION PROCESS	**EC VERIFICATION BASED ON QUALITY MANAGEMENT SYSTEM OF THE PRODUCTION PROCESS**	
1. This assessment based on quality management system of the production process is the part of the procedure for assessment of a subsystem's conformity with the requirements of the applicable UTP(s)	EC verification a EC verification procedure	
whereby the applicant fulfils the obligations laid down in points 2 5, 7 and 9, in order that assessments can be carried out to verify	and 8, and ensures and declares on his sole responsibility	
that the subsystem concerned is in conformity with the type described in the UTP Type-examination Certificate and thereby	EC type examination certificate and	
satisfies the requirements of the relevant UTP(s) and other applicable regulations [21]	TSI(s) as well as any other regulations deriving from the Treaty	
that apply to it.		
2. Manufacturing		
The production, final subsystem inspection and testing of the subsystem concerned shall be covered by approved quality management system(s) as specified in point 3, and shall be subject to surveillance as specified in point 7.		
3. Quality management system		
3.1 The applicant shall lodge an application for assessment of the	his	
quality management system to be used with an assessing entity of his choice, for the subsystem concerned.	with the notified body	
The application shall include:		
☐ the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,		
☐ a written declaration that the same application has not been lodged with any other assessing entity,	notified body,	
☐ the breakdown structure of the project management and the name and address of each involved entity,		
☐ all relevant information for the subsystem envisaged,		
☐ the documentation concerning the quality management system,	☐ copy of EC declaration(s) of intermediate subsystem conformity (ISV) issued for the subsystem, if any	
☐ the technical documentation of the approved type and a copy of the UTP Type-examination certificate	EC-type examination certificate	

[21] The assessing entity will request evidence of conformity with all "other applicable regulations" from the applicant. The applicant must provide such evidence of conformity as is relevant and the assessing entity will include this evidence without further assessments in its compilation of the Technical File.
UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

and its annexes.

3.2 The quality management system shall ensure that the subsystem is in conformity with the type described in the

UTP Type-examination certificate | EC-type examination certificate

and comply with the requirements of the relevant

UTP(s) | TSI(s)

that apply to it.

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

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

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

3.3 The assessing entity | The notified body

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

It shall presume conformity with those requirements in respect of the elements of the quality management system that comply with the corresponding specifications of the national standard that implements the relevant quality management standard,

Validated Standard | harmonised standard

and/or technical specification.

If the compliance of the subsystem with the requirements of the relevant

UTP(s) | TSI(s)

is based on more than one quality management system, the

assessing entity | notified body

shall examine in particular:

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

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

When

| the applicant operates

a certified quality management system certified by an accredited certification body,

is used |

for the manufacturing and final testing of the relevant subsystem, the

assessing entity | notified body

shall take this into account in the assessment. In this case, the

assessing entity | notified body

will make a detailed assessment of quality management system specific documents and

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
records of the subsystem only. The assessing entity shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.	notified body	
In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant UTP(s).	TSI(s).	
The audit shall include one or more assessment visits to the premises of the relevant entities concerned. The auditing team shall review the technical documentation referred to in point 3.1, second paragraph, sixth indent, to verify the ability of the relevant entities concerned to identify the requirements of the UTP(s) and to carry out the necessary examinations with a view to ensuring compliance of the subsystem with those requirements.	an assessment visit seventh indent, TSI(s)	
The decision shall be notified to the applicant, who shall forward a copy to the manufacturer.	applicant.	
The notification shall contain the conclusions of the audit and the reasoned assessment decision.		
Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the assessing entity shall issue a “quality management system approval” to the applicant.	notified body	
3.4 The applicant and the manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.	The applicant	
3.5 The manufacturer shall keep the applicant informed and the applicant shall keep the assessing entity that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture, and final inspection, testing and operation, as well as of any changes of quality management system certificate.	notified body	
The assessing entity shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	The notified body	
It shall notify the applicant of its decision, and the applicant shall forward the notification to the manufacturer if the quality management system is operated by the manufacturer.		
The notification shall contain the conclusions of the examination and the reasoned assessment decision.		
4. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assess-	Each notified body shall inform its notifying authorities of	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
ments (cf. sections 1.2 c) and 1.3) of any "quality management system approvals" issued or withdrawn, and shall, periodically or upon request, make available to the competent authority the list of "quality management system approvals" refused, suspended or otherwise restricted.	its notifying authorities	
Each assessing entity shall ensure that the other assessing entities are informed of "quality management system approvals" which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of "quality management system approvals" which it has issued.	Each notified body shall inform the other notified bodies of	
5. Verification of conformity with applicable UTP(s)	EC verification	
5.1 The applicant shall lodge an application for verification of conformity with applicable UTP(s) with an assessing entity of his choice.	the EC verification of the subsystem with a notified body	

The application shall include:

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

and if **not** included in this documentation:

- a general description of the subsystem, its overall design and structure
- the documents necessary for the compilation of the technical file according to the provisions of UTP GEN-B "Technical File" | as described in point 4 of Annex VI to Directive 2008/57/EC,
- a separate file with the set of data required by the relevant UTP | TSI for each relevant register set up by the Committee of Technical Experts according to ATMF Article 13, | provided for in Articles 34 and 35 of Directive 2008/57/EC,
- a list of Validated Standards [22] and/or other relevant technical specifications which have been | harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the UTP | TSI where those Validated Standards have not been applied. In the event of partly applied Validated Standards, | harmonised standards have not been applied. In the event of partly applied Validated Standards, the technical documentation shall specify the parts which have been applied,
- conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),

[22] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

- descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- conditions for maintenance and technical documentation regarding the maintenance of the subsystem,
- any technical requirement specified in the relevant
  UTP(s) | TSI(s)
  that shall be taken into account during production, maintenance or operation of the subsystem,
- other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,
- results of design calculations made, examinations carried out, etc.,
- test reports, if any,
- documentation regarding the manufacture and the assembly of the subsystem,
- a list of manufacturers involved in the subsystem's manufacturing, assembly and installation,
- the demonstration, that the manufacturing and final testing as mentioned under point 2, are covered by the quality management system of the applicant and the evidence of its effectiveness,
- indication of the notified body responsible for the approval and surveillance of the quality management system,
- evidence of conformity with other
  applicable COTIF regulations, | regulations deriving from the Treaty (including certificates, if any),
- any further information, if required by the relevant
  UTP(s). | TSI(s).

5.2 The assessing entity | The notified body
chosen by the applicant shall first examine the application concerning the validity of the
UTP Type-examination certificate. | EC type examination Certificate.

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

6. When the subsystem referred to in point 3 is subject to derogation(s) procedure according to
Article 7a of ATMF and the regulations/ guidelines adopted by the Committee of Technical Experts in pursuance of that Article, | Article 9 of Directive 2008/57/EC,
the applicant shall inform the
assessing entity | notified body
thereof.

The applicant shall also provide the
assessing entity | notified body

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
with a precise reference to the UTP(s) (or their parts) for which the derogation is requested.	TSI(s)	
When the assessing entity is the competent authority, it shall analyse whether the derogation complies with the essential requirements and follow the procedure set out by the Committee of Technical Experts according to Article 7a of ATMF.		
The applicant shall be informed of the result of the analysis and the outcome of the derogation procedure.		
If the assessing entity is not the competent authority, the applicant shall communicate to the assessing entity the outcome of the derogation procedure.	notified body	
7. Surveillance under the responsibility of the assessing entity	notified body	
7.1 The purpose of surveillance is to make sure that the applicant duly fulfils the obligations arising out of the approved quality management system.		
7.2 The applicant shall, for periodic audit purposes, allow the assessing entity access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:	notified body	
☐ the quality management system documentation,		
☐ the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.		
7.3 The assessing entity shall carry out periodic audits to make sure that the applicant maintains and applies the quality management system and shall provide the applicant with an audit report.	The notified body	
The frequency of the periodic audits shall be at least once every two years.		
When the applicant operates a certified quality management system, the assessing entity shall take this into account during the periodic audits.	notified body	
7.4 In addition, the assessing entity may pay unexpected visits to the applicant. During such visits the assessing entity may, if necessary, carry out subsystem tests, or have them carried out, in order to verify that the quality management system is functioning correctly. The assessing entity shall provide the applicant with a visit report and, if tests have been carried out, with a test report.	notified body notified body notified body	
7.5 The assessing entity responsible for the assessment of conformity of the manufactured subsystems with the approved type of the subsystem, if not carrying out the surveillance of all the quality management systems concerned as under point 3, shall coordinate the surveillance activities of any	The notified body EC verification	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
other assessing entity responsible for that task, in order:	notified body	
☐ to be ensured that correct management of interfaces between the different quality management systems relating to subsystem integration has been performed,		
☐ to collect, in liaison with the applicant, the necessary elements for the assessment to guarantee the consistency and the overall supervision of the different quality management systems.		
This coordination includes the right of the assessing entity	notified body	
☐ to receive all documentation (approval and surveillance), issued by the other assessing entity(ies),	notified body(ies),	
☐ to witness the surveillance audits as in point 7.3, and		
☐ to initiate additional audits as in point 7.4 under its responsibility and together with the other assessing entity(ies).	notified body(ies).	
8. **UTP Certificate of verification**	EC certificate of verification and EC declaration of verification	
8.1 Where the subsystem meets the requirements of the relevant TSI(s), the assessing entity shall issue a UTP Certificate of verification.	notified body an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.	
The certificate shall include in an annex the assessing entity's compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [23] "Technical File". The certificate shall be given to the applicant.		
Where the subsystem referred to in point 5.1 is subject to derogation, upgrade, renewal or specific case, the UTP Certificate of verification shall also indicate the precise reference to the UTP(s) or their parts to which conformity has not been examined during the assessments carried out.	EC certificate TSI(s) EC verification procedure.	
If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant UTP(s), the assessing entity shall issue an intermediate statement of verification (ISV) clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body in compliance with Article 18(4) of Directive 2008/57/ EC.	
Based on the ISV, the applicant may draw up a written UTP declaration of intermediate statement of verification (ISV) in accordance with Annex 2.	The applicant shall draw up a written EC ISV declaration of intermediate subsystem conformity according to section 2 of Annex VI to Directive 2008/57/EC.	
8.2 A UTP declaration of verification may be drawn up on a voluntary or mandatory basis		

[23] Formerly named APTU Annex 1-C

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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 in this UTP relating to the UTP Declaration of verification shall apply. A Contracting State which is also a member of the European Union shall apply European law concerning EC Declarations of verification.		

The applicant shall

keep the UTP Certificate of verification and, if issued, the UTP Declaration of verification	draw up a written EC declaration of verification for the subsystem and keep it

at the disposal of the national authorities throughout the service lifetime of the subsystem.

Where the subsystem referred to in point 3 is subject to a derogation, upgrade, renewal or specific case(s), the

UTP Certificate of verification and, if issued, the UTP Declaration of verification	EC declaration

for the subsystem shall also indicate the references to the

UTP(s)	TSI(s)

or their parts to which conformity has not been examined during the

verification	EC verification

procedure.

[covered by last sentence of 8.1]	In case of ISV procedure the applicant shall draw up a written EC ISV declaration.	
If a UTP declaration of verification is drawn up, it	The EC declaration	

and the accompanying documents shall be written in accordance with

Annex 2 to this UTP.	Annex V to Directive 2008/57/EC.

The certificates to be referred to are:

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

	the EC type examination certificate and its additions.
A copy of the UTP declaration of verification and UTP declaration(s) of intermediate statement of verification (ISV), if any,	A copy of the EC declaration of verification and EC ISV declarations, if any,

shall be made available to the relevant authorities upon request.

(see 8.1) The Technical File referred to in point 8.1 shall also be annexed to the UTP Declaration of verification.	The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.	8.3

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

- the documentation referred to in point 3.1,
- the change(s) referred to in point 3.5, as approved,

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
the decisions and reports of the notified body referred to in points 3.5, 7.3 and 7.4, and		
the Technical File referred to in point 8.1 (and 8.3).	point 8.3.	
10. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any UTP Certificates of verification	Each notified body shall inform its notifying authorities concerning the EC Certificates of verification	
issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	its notifying authorities	
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities are informed of the UTP Certificates of verification	Each notified body shall inform the other notified bodies concerning of EC certificates of verification	
which it has refused, suspended, withdrawn, or otherwise restricted, and, upon request, of		
UTP Certificates of verification	EC certificates of verification	
which it has issued.		

11. Authorised representative

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
MODULE SF. VERIFICATION BASED ON PRODUCT VERIFICATION	**EC VERIFICATION BASED ON PRODUCT VERIFICATION**	
1. This assessment	EC verification	
based on product verification is the part of the procedure for assessment of a subsystem's conformity with the requirements of the applicable UTP(s)	a EC verification procedure	
whereby the applicant fulfils the obligations laid down in point 2		
in order that assessments can be carried out to verify	and 5, and ensures and declares on his sole responsibility	
that the subsystem concerned, which has been subject to the provisions of point 4, is in conformity with the type described in the		
UTP Type-examination certificate and thereby	EC type examination certificate and	
satisfies the requirements of the relevant UTP(s) and other applicable regulations [24]	TSI(s) as well as any other regulations deriving from the Treaty	
that apply to it.		
2. Manufacturing		
The manufacturing process and its monitoring shall ensure conformity of the manufactured subsystem with the approved type described in the		
UTP Type-examination certificate	EC-type examination certificate	
and with the requirements of the relevant UTP(s)	TSI(s)	
that apply to it.		
3. The applicant		
shall lodge an application for verification of conformity with applicable UTP(s) with an assessing entity	the EC verification of the subsystem with a notified body	
of his choice.		
The application shall include:		
☐ the name and address of the applicant, and, if the application is lodged by the authorised representative, his name and address as well,		
☐ name and address of the manufacturer(s), if not the applicant himself,		
☐ the technical documentation regarding the approved type, including the		
UTP Type-examination certificate	EC type examination certificate	
and its annexes, as issued after completion of the procedure defined in module SB.		
It shall also include the following if it is not already included in the technical documentation:		
☐ a general description of the subsystem, its overall design and structure,		
☐ the documents necessary for the compilation of the technical file		
according to the requirements set out in UTP GEN-C Technical File	as described in point 4 of Annex VI to Directive 2008/57/EC,	

[24] The assessing entity will request evidence of conformity with all "other applicable regulations" from the applicant. The applicant must provide such evidence of conformity as is relevant and the assessing entity will include this evidence without further assessments in its compilation of the Technical File.
UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
a separate file with the set of data required by the relevant UTP(s) for each relevant register set up by the Committee of Technical Experts according to ATMF Article 13,	TSI(s) provided for in Articles 34 and 35 of Directive 2008/57/EC,	
a list of the Validated Standards [25] and/or other relevant technical specifications which have been applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant UTP where those Validated Standards have not been applied. In the event of partly applied Validated Standards, the technical documentation shall specify the parts which have been applied,	harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, TSI harmonised standards harmonised standards,	
conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),		
descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,		
conditions for maintenance and technical documentation regarding the maintenance of the subsystem,		
any technical requirement specified in the relevant UTP(s) that shall be taken into account during production, maintenance or operation of the subsystem,	TSI(s)	
other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,		
conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,		
evidence of conformity with other applicable COTIF regulations,	regulations deriving from the Treaty (including certificates, if any),	
results of design calculations made, examinations carried out, etc.,		
test reports,		
documentation regarding the manufacture and the assembly of the subsystem,		
a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation, and		
any further information, if required by the relevant UTP(s) and Validated Standards.	TSI(s).	
4. Verification of conformity with applicable UTP(s)	EC verification	
4.1 The assessing entity chosen by the applicant shall first examine the application concerning the validity of the UTP Type-examination certificate.	The notified body EC type examination Certificate.	
If the		

[25] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
assessing entity	notified body	
considers the		
UTP Type-examination certificate	EC type examination Certificate	
no longer remains valid or is not appropriate and that a new		
UTP Type-examination certificate	EC type examination Certificate	
is necessary, the		
assessing entity	notified body	
shall refuse to assess the quality management system of the applicant and shall justify its refusal.		
The assessing entity	The notified body	
shall carry out appropriate examinations and tests in order to check the conformity of the subsystem with the approved type described in the		
UTP Type-examination certificate	EC-type examination certificate	
and with the requirements of the relevant		
UTP(s).	TSI(s).	
4.2 All subsystems shall be individually examined and appropriate tests set out in the relevant		
UTP(s), Validated Standards	TSI(s), harmonised standard(s)	
and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the		
UTP Type-examination certificate	EC-type examination certificate	
and with the requirements of the relevant		
UTP(s).	TSI(s).	
In the absence of such a		
Validated Standard,	harmonised standard,	
the appropriate tests to be carried out shall be decided between the applicant and the		
assessing entity	notified body	
concerned.		
4.3 The assessing entity	The notified body	
shall agree with the applicant the locations where the tests will be carried out and shall agree that final testing of the subsystem and, whenever required in the relevant		
UTP(s),	TSI(s),	
tests or validation under full operating conditions, are carried out by the applicant under direct supervision and attendance of the		
assessing entity.	notified body.	
The assessing entity	The notified body	
shall have entrance for testing and verification purposes to production workshops, locations of assembly and installations, and where appropriate, prefabrication and testing facilities in order to carry out its tasks as provided for in the relevant TSI(s).		
UTP(s).	TSI(s).	
4.4 When the subsystem referred to in point 3 is subject to derogation(s) procedure according to		
Article 7a of ATMF and the regulations/ guidelines adopted by the Committee of Technical Experts in pursuance of that Article,	Article 9 of Directive 2008/57/EC,	
the applicant shall inform the		
assessing entity	notified body	
thereof.		
The applicant shall also provide the		
assessing entity	notified body	
with a precise reference to the		
UTP(s)	TSI(s)	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
(or their parts) for which the derogation is requested.		
When the assessing entity is the competent authority, it shall analyse whether the derogation complies with the essential requirements and follow the procedure set out by the Committee of Technical Experts according to Article 7a of ATMF. The applicant shall be informed of the result of the analysis and the outcome of the derogation procedure.		
If the assessing entity is not the competent authority, the applicant	The applicant	
shall communicate to the		
assessing entity	notified body	
the outcome of the derogation procedure.		
4.5. **UTP Certificate of verification**	EC certificate of verification and EC declaration of verification	
The		
assessing entity	notified body	
shall issue		
a UTP Certificate of verification if the subsystem meets the requirements of the relevant UTPs, and	an EC certificate of verification in	
in respect of the examinations and tests carried out.		
The certificate shall include in an annex the assessing entity's compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [26] "Technical File".		
The certificate shall be given to the applicant.		
Where the subsystem referred to in point 3 is subject to derogation, upgrade, renewal or specific case, the		
UTP Certificate of verification	EC certificate	
shall also indicate the precise reference to the		
UTP(s)	TSI(s)	
or their parts to which conformity has not been examined during		
the assessments carried out.	EC verification procedure.	
If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant		
UTP(s), the assessing entity	TSI(s), the notified body	
shall issue an intermediate statement of verification (ISV)		
clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	in compliance with Article 18(4) of Directive 2008/57/ EC.	
Based on the ISV, the applicant may draw up a written UTP declaration of intermediate statement of verification (ISV) in accordance with Annex 2.	The applicant shall draw up a written EC ISV declaration of intermediate subsystem conformity according to section 2 of Annex VI to Directive 2008/57/EC.	
The applicant shall keep the		

[26] Formerly named APTU Annex 1-C

OTIF UTP		*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	UTP Certificate of verification and the documentation referred to in point 3.	EC certificate of verification	
	available for inspection by the national authorities throughout the service lifetime of the subsystem.		
5.	**UTP declaration of verification**	EC declaration of verification	
	A UTP declaration of verification may be drawn up on a voluntary or mandatory basis as 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 in this UTP relating to the UTP declaration of verification shall apply. A Contracting State which is also a member of the European Union shall apply European law concerning EC declarations of verification.		
5.1	The applicant		
	shall, if applicable, draw up a written UTP declaration of verification	shall draw up a written EC declaration of verification	
	for the subsystem and keep it at the disposal of the national authorities throughout the service lifetime of the subsystem.		
	Where the subsystem referred to in point 3 is subject to a derogation, upgrade, renewal or specific case(s), the		
	UTP declaration of verification	EC declaration	
	for the subsystem shall also indicate the references to the		
	UTP(s)	TSI(s)	
	or their parts to which conformity has not been examined during the		
	assessment procedure.	EC verification procedure.	
	[covered by 4.5]	In case of ISV procedure the applicant shall draw up a written EC ISV declaration.	
	If a UTP declaration of verification is drawn up, it	The EC declaration	
	and the accompanying documents shall be written in accordance with		
	Annex 2 to this UTP.	Annex V to Directive 2008/57/EC.	
	A copy of the UTP declaration of verification and UTP declaration(s) of intermediate statement of verification (ISV), if any,	A copy of the EC declaration of verification and EC ISV declarations, if any,	
	shall be made available to the relevant authorities upon request.		
5.2	(see point 4.5) The Technical File referred to in point 4.5 shall also be annexed to the UTP Declaration of verification.	The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.	
6.	Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State	Each notified body shall inform its notifying authorities concerning the EC declarations of verification	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any UTP Certificates of verification		
issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	its notifying authorities	
the list of certificates refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities are informed of the UTP Certificates of verification	Each notified body shall inform the other notified bodies concerning of EC-certificates of verification	
which it has refused, suspended, withdrawn, or otherwise restricted, and, upon request, of		
UTP Certificates of verification	EC certificates of verification	
which it has issued.		

7. Authorised representative

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

An authorised representative may NOT fulfil the applicant's obligations set out in point 2.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
MODULE SH1 VERIFICATION BASED ON FULL QUALITY MANAGEMENT SYSTEM PLUS DESIGN EXAMINATION	**EC VERIFICATION BASED ON FULL QUALITY MANAGEMENT SYSTEM PLUS DESIGN EXAMINATION**	
1. This assessment	EC verification	1.
based on full quality management system of the design and the production process is		
the part of the procedure for assessment of a subsystem's conformity with the requirements of the applicable UTP(s)	EC verification procedure	
whereby the applicant fulfils the obligations laid down in points 2		
5 and 7, in order that assessments can be carried out to verify	and 6, and ensures and declares on his sole responsibility	
that the subsystem concerned satisfies the requirements of the relevant		
UTP(s) and other applicable regulations [27]	TSI(s) as well as any other regulations deriving from the Treaty	
that apply to it.		

2. Manufacturing

The design, manufacture and the inspection and testing of the subsystem concerned shall be covered by approved quality management system(s) as specified in point 3, and shall be subject to surveillance as specified in point 5.

The adequacy of the technical design of the subsystem shall have been examined in accordance with point 4.

3. **Quality management system**

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

The application shall include:

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

3.2 The quality management system shall ensure compliance of the subsystem with the

[27] The assessing entity will request evidence of conformity with all "other applicable regulations" from the applicant. The applicant must provide such evidence of conformity as is relevant and the assessing entity will include this evidence without further assessments in its compilation of the Technical File.
UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

requirements of the relevant
UTP(s) | TSI(s)
that apply to it.

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

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

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and subsystem quality,
- the technical design specifications, including standards, that will be applied and, where the relevant
  Validated Standards [28] and/or other relevant technical specifications | harmonised standards and/or technical specifications
  will not be applied in full, the means that will be used to ensure that the requirements of the relevant
  UTP(s) | TSI(s)
  that apply to the subsystem will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the subsystem pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

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

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

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

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

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

[28] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
When		
	the applicant operates	
a certified quality management system certified by an accredited certification body,		
is used		
for the manufacturing and final testing of the relevant subsystem, the		
assessing entity	notified body	
shall take this into account in the assessment. In this case, the		
assessing entity	notified body	
will make a detailed assessment of quality management system specific documents and records of the subsystem only. The		
assessing entity	notified body	
shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.		
In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant		
UTP(s).	TSI(s).	
The audit shall include		
one or more assessment visits	an assessment visit	
to the premises of the relevant entities concerned.		
The applicant		
	or his authorised representative	
shall be notified of the decision.		
The notification shall contain the conclusions of the audit and the reasoned assessment decision. Where the assessment of the quality management system provided satisfying evidence that the requirements referred to in point 3.2 are met, the		
assessing entity	notified body	
shall issue a “quality management system approval” to the applicant.		
3.4 The applicant shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.		
3.5 The applicant shall keep the		
assessing entity	notified body	
that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture, and final inspection, testing and operation, as well as of any changes of quality management system certificate.		
The assessing entity	The notified body	
shall evaluate any proposed changes and decide whether the modified quality management system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.		
It shall notify the applicant of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.		
The applicant shall forward the notification to the manufacturer if the quality management system is operated by the manufacturer.		
3.6 Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any	Each notified body shall inform its notifying authorities of	
“quality management system approvals” issued or withdrawn, and shall, periodically or		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
upon request, make available to the competent authority	its notifying authorities	
the list of "quality management system approvals" refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities are informed of the	Each notified body shall inform the other notified bodies of	
"quality management system approvals" which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of "quality management system approvals" which it has issued.		
4. **Verification of conformity with applicable UTP(s)**	EC verification	
4.1 The applicant shall lodge an application for verification of the subsystems' conformity with the applicable UTP(s)	the EC verification of the subsystem	
(through full quality management system plus examination of the design) with the the assessing entity	the notified body	
referred to in point 3.1 (assessing the QMS).		
4.2 The application shall make it possible to understand the design, manufacture, maintenance and operation of the subsystem, and to assess the conformity with the requirements of the UTP(s)	TSI(s)	
that apply to it.		
It shall include:		
▯ the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,		
▯ a written declaration that the same application has not been lodged with any other competent national authority,	notified body,	
▯ the technical documentation.[29] The technical documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant UTP(s).	TSI(s).	
The technical documentation shall specify the requirements of the relevant UTP(s)	TSI(s)	
and cover, as far as relevant for the assessment, the design and operation of the subsystem. The technical documentation shall, wherever applicable, contain, at least the following elements:		
○ a general description of the subsystem, its overall design and structure,		
○ documents necessary for the compilation of the technical file according to the provisions of UTP GEN-C "Technical File"	as described in point 4 of Annex VI to Directive 2008/547/EC,	
○ a separate file with the set of data required by the UTP(s)	TSI(s)	
for each relevant register set up by the Committee of Technical Experts according to ATMF Article 13,	provided for in Articles 34 and 35 of Directive 2008/57/EC,	
○ if relevant, descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,		
○ conditions of integration of the subsystem in its system environment and the necessary interface conditions,		
○ a list of the		

[29] The technical documentation includes descriptions and explanations necessary for understanding the functioning and possible risks/failures in safety-related software used in the subsystem, if appropriate,

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Validated Standards [30] and/or other relevant technical specifications which have been	harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*,	

applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the

UTP(s)	TSI(s)
where those	
Validated Standards	harmonised standards

have not been applied. In the event of partly applied

Validated Standards,	harmonised standards,

the technical documentation shall specify the parts which have been applied,

- results of design calculations made, examinations carried out, etc.,
- test programme and reports,
- evidence of conformity with other applicable COTIF regulations, | regulations deriving from the Treaty (including certificates, if any),
- documentation regarding the manufacture and the assembly of the subsystem,
- a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation,
- conditions for use of the subsystem (restrictions of running time or distance, wear limits etc.),
- conditions for maintenance and technical documentation on maintenance of the subsystem,
- any technical requirement specified in the relevant

UTP(s)	TSI(s)

  that shall be taken into account during production, maintenance or operation of the subsystem,
- all other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- any further information, if required by the relevant

UTP(s),	TSI(s),

- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant

Validated Standards	harmonised standards

  and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests (including those in operational conditions) carried out by the appropriate testing body of the applicant, or by another testing body on his behalf and under his responsibility.

4.3 When the subsystem referred to in point 4.1 is subject to derogation(s) procedure according to

Article 7a of ATMF and the regulations/ guidelines adopted by the Committee of Technical Experts in pursuance of that Article,	Article 9 of Directive 2008/57/EC,

the applicant shall inform the

[30] See section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
assessing entity thereof.	notified body	
The applicant shall also provide the assessing entity with a precise reference to the UTP(s) (or their parts) for which the derogation is requested.	notified body TSI(s)	
When the assessing entity is the competent authority, it shall analyse whether the derogation complies with the essential requirements and follow the procedure set out by the Committee of Technical Experts according to Article 7a of ATMF. The applicant shall be informed of the result of the analysis and the outcome of the derogation procedure.		
If the assessing entity is not the competent authority, the applicant shall communicate to the assessing entity the outcome of the derogation procedure.	The applicant notified body	
4.4 The assessing entity shall examine the application, and where the design meets the requirements of the relevant UTP(s), it shall issue a UTP Design examination certificate to the applicant.	The notified body TSI(s), an “EC design examination certificate” to the applicant.	
The certificate shall give the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.		
The certificate may have one or more annexes attached.		
The UTP Design examination certificate shall include in an annex the assessing entity’s compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [31] “Technical File”.		
The certificate and its annexes shall contain all relevant information to allow the conformity of the subsystem with the examined design to be evaluated.		
Where the subsystem referred to in point 4.1 is subject to derogation, upgrade, renewal or specific case, the the UTP Design examination certificate shall also indicate the precise reference to the UTP(s) or their parts to which conformity has not been examined during the assessments carried out.	the EC design examination certificate TSI(s) EC verification procedure.	
If only certain parts of the subsystem are covered and they meet the requirements of the relevant UTP(s), the assessing entity	TSI(s), the notified body	

[31] Formerly named APTU Annex 1-C

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
shall issue an intermediate statement of verification (ISV) clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	in compliance with Article 18(4) of Directive 2008/57/ EC.	
Based on the ISV, the applicant may draw up a written UTP declaration of intermediate statement of verification (ISV).	The applicant shall draw up a written EC declaration of intermediate subsystem conformity according to section 2 of Annex VI to Directive 2008/57/EC.	
4.5 The applicant shall keep the assessing entity that has issued the UTP Design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the relevant UTP(s) or the conditions for validity of the certificate until the expiry of the validity of the certificate.	notified body EC design examination certificate TSI(s)	
Such modifications shall require additional approval — from the assessing entity that issued the UTP Design examination certificate — in the form of an addition to the original UTP Design examination certificate.	notified body EC design examination certificate EC design examination certificate.	
Only those examinations and tests that are relevant and necessary to the changes shall be performed.		
4.6 Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any UTP Design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the competent authority the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.	Each notified body shall inform its notifying authorities concerning the EC Design examination certificates its notifying authorities	
Each assessing entity shall ensure that the other assessing entities are informed of the UTP Design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.	Each notified body shall inform the other notified bodies concerning of EC Design examination certificates	
The Secretary General, the Contracting States and the other assessing entities may, upon request, obtain a copy of the UTP Design examination certificate and/or additions thereto. Upon request, the Secretary General and the Contracting States may obtain a copy of the technical documentation and of the results of the examinations carried out by the assessing entity.	The Commission, the Member States and the other notified bodies EC design examination certificates the Commission and the Member States notified body.	
The assessing entity	The notified body	

OTIF UTP | *Corresponding text in EU regulations* [1] *EU ref.* [2]

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

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

5. **Surveillance under the responsibility of the**
assessing entity | **notified body**

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

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

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

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

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

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

5.4 In addition, the
assessing entity | notified body
may pay unexpected visits to the applicant
and the sites mentioned in point 5.2. |

During such visits the
assessing entity | notified body
may, if necessary, carry out subsystem tests, or have them carried out, in order to check the proper functioning of the quality management system.
It shall provide the applicant with a visit report and, if tests have been carried out, with a test report.

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
☐ to be ensured that correct management of interfaces between the different quality management systems relating to subsystem integration has been performed,		
☐ to collect, in liaison with the applicant, the necessary elements for the assessment to guarantee the consistency and the overall supervision of the different quality management systems.		
This coordination includes the right of the assessing entity	notified body	
☐ to receive all documentation (approval and surveillance), issued by the other assessing entity(ies),	notified body(ies),	
☐ to witness the surveillance audits as in point 5.2, and		
☐ to initiate additional audits as in point 5.3 under its responsibility and together with the other assessing entity(ies).	notified body(ies).	
6. **UTP Certificate of verification**	**EC certificate of verification and EC declaration of verification**	
6.1 Where the subsystem meets the requirements of the relevant TSI(s), the assessing entity shall issue a UTP Certificate of verification.	notified body an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.	
The certificate shall include in an annex the assessing entity's compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [32] "Technical File". The certificate shall be given to the applicant.		
Where the subsystem referred to in point 4.1 is subject to derogation, upgrade, renewal or specific case, the UTP Certificate of verification shall also indicate the precise reference to the UTP(s) or their parts to which conformity has not been examined during the assessments carried out.	EC certificate TSI(s) EC verification procedure.	
If only certain parts or certain stages of the subsystem are covered and they meet the requirements of the relevant UTP(s), the assessing entity shall issue an intermediate statement of verification (ISV) clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body in compliance with Article 18(4) of Directive 2008/57/ EC.	
Based on the ISV, the applicant may draw up a written UTP declaration of intermediate statement of verification (ISV) in accordance with Annex 2.	The applicant shall draw up a written EC ISV declaration of intermediate subsystem conformity according to section 2 of Annex VI to Directive 2008/57/EC.	
6.2 **UTP declaration of verification**	EC 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		

[32] Formerly named APTU Annex 1-C

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
this case the provisions in this UTP relating to the UTP declaration of verification shall apply. A Contracting State which is also a member of the European Union shall apply European law concerning EC declarations of verification.		
The applicant shall keep the UTP Certificate of verification and, if issued, the Declaration of verification at the disposal of the national authorities throughout the service lifetime of the subsystem.	draw up a written EC declaration of verification for the subsystem and keep it	
Where the subsystem referred to in point 4.1 is subject to a derogation, upgrade, renewal or specific case(s), the UTP Certificate of verification and, if issued, the UTP Declaration of verification for the subsystem shall also indicate the references to the UTP(s) or their parts to which conformity has not been examined during the verification procedure.	EC declaration TSI(s) EC verification	
[covered by last sentence in 6.1]	In case of ISV procedure the applicant shall draw up a written EC ISV declaration.	
If a UTP declaration of verification is drawn up, it and the accompanying documents shall be written in accordance with Annex 2 to this UTP.	The EC declaration Annex V to Directive 2008/57/EC.	
The certificates to be referred to are: - the "quality management system approval" referred to in point 3.3 and audit reports indicated in point 5.3, if any, - the UTP Design examination certificate referred to in point 4.4 and its additions.	- the EC Design examination certificate	
A copy of the UTP declaration of verification and UTP declaration(s) of intermediate statement of verification (ISV), if any, shall be made available to the relevant authorities upon request.	A copy of the EC declaration of verification and EC ISV declarations, if any,	
6.3 (Reserved) (see point 4.4)	The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity. The technical file must be drawn up in accordance with Article 18(3) and point 4 of Annex VI to Directive 2008/57/EC.	

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

- the documentation concerning the quality management system referred to in point 3.1,
- the change(s) referred to in point 3.5, as approved,

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
the decisions and reports of the assessing entity referred to in points 3.5, 5.3 and 5.4	notified body	
the technical file referred to in point 4.4.	6.3	
8. Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any UTP Certificates of verification	Each notified body shall inform its notifying authorities concerning the EC Certificates of verification	
issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	its notifying authorities	
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities are informed of the UTP Certificates of verification	Each notified body shall inform the other notified bodies concerning of EC-certificates of verification	
which it has refused, suspended, withdrawn, or otherwise restricted, and, upon request, of		
UTP Certificates of verification	EC certificates of verification	
which it has issued.		
9. Authorised representative		
The applicant's authorised representative may lodge the application referred to in points 4.1 and 4.2, and fulfil the obligations set out in points 3.1, 3.5, 4.3, 4.5, 4.7, 6.2 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
4. PROCEDURE FOR ASSESSMENT OF A SUBSYSTEM'S CONFORMITY WITH NOTIFIED NATIONAL TECHNICAL REQUIREMENTS/RULES	**VERIFICATION PROCEDURE IN THE CASE OF NATIONAL RULES**	2011/18/EC, Annex VI, 3
1. Where no applicable rules for assessing conformity with the notified national technical requirements/rules are in force in a Contracting State at the time of the entry into force of this UTP, the following procedure shall apply in that State: This procedure is the one whereby, based on an assessment of the subsystem, it is verified and certified that the technical design and manufactured subsystem meet the requirements of the relevant national technical requirements notified according to Article 12 of APTU that apply to it, if any.	The verification procedure in the case of national rules is the procedure whereby the body designated pursuant to Article 17(3) (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 17(3).	3.1
2. The task of ensuring that the assessments according to chapter 4 are carried out is the responsibility of the authority competent for COTIF technical admission of vehicles in the Contracting State(s) on which territory the applicant requests the vehicle (or vehicle type) to be admitted. The authority may delegate the assessment task or part of it to another assessing entity.		
3. Application		
3.1 The applicant entitled to apply according to chapter 1.2 point g) may lodge an application for an assessment of the applicable national technical requirements with the national authority competent for technical admission of subsystems in a Contracting State of his choice. The applicant may be one other than the applicant which applied for assessments included in chapter 3.		
3.2 The application shall include: - information on derogations from the applicable notified national technical requirements, if any, - a list of Contracting States other than the one where the application is lodged, in which the subsystem is requested to be admitted to operate, if any, - the technical documentation which shall make it possible to assess the subsys-		

OTIF UTP | *Corresponding text in EU regulations* [1] | *EU ref.* [2]

tem's conformity with the notified national technical requirements [33] of the Contracting State where the application is lodged,

and, if required by the assessing entity,

- the documentation provided through the modules of chapter 3 which have been applied.

3.3 If the assessing entity needs more documentation, (e.g. additional vehicle tests) in order to assess the subsystem's conformity with applicable notified national technical requirements and its safe integration into its environment, the entity may, in accordance with ATMF Article 6 § 4, request such documentation from the applicant; the request shall include justification.

3.4 If the subsystem is subject to ATMF Article 6 § 4, the authority that has received the application shall ensure that (a copy of) the application is forwarded to the competent authorities of those other Contracting States for which the subsystem is requested to be admitted to operate.

4. Assessments

4.1 The assessments of the subsystem's conformity with the applicable notified national technical requirements and of its safe integration into its environment shall be carried out by applying ***mutatis mutandis*** an appropriate combination of modules from chapter 3, whereby the term "UTP" in these modules shall be replaced by the term "applicable notified national technical requirements and the subsystem's safe integration into its environment".

4.2 In accordance with ATMF Article 6a, assessments and tests carried out with a positive result and documented, thus proving conformity with the UTPs and other requirements (including national requirements), shall not be repeated. The equivalence table prepared in accordance with APTU Article 13 shall be observed in all cases where assessments are carried out.

4.3 All competent national authorities and assessing entities involved in the assessment procedures (including the modules in chapter 3) shall, in accordance with ATMF Article 10 § 4, cooperate in order to minimise the assessment time and costs.

[33] See definition in section 1.2 e)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

5. Certificate of verification of a subsystem in the case of applicable national rules 3.2

The assessing entity responsible for

assessing the notified national technical requirements (rules) shall, provided that the subsystem complies with the applicable notified national requirements,

the verification procedure in the case of national rules shall

draw up a Certificate of verification of a subsystem in the case of applicable national rules

intended for the applicant.

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the assessing entity

through the assessment,

in the verification process,

including those related to parts subject to derogation from a

UTP,

TSI,

upgrade or renewal.

In the case of national rules related to the subsystems composing a vehicle, the assessing entity shall divide the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

The Certificate of verification of a subsystem in the case of applicable national rules may cover several versions of the subsystem provided that the differences between the versions do not affect the applicable notified national technical requirements. It may also cover a series of identical subsystems produced in one batch, provided the vehicle(s) to which the information in the annexes attached to the certificate relates is/are clearly identifiable (e.g. with their 12 digit unique identification numbers).

6. Technical File 3.3

The technical file accompanying the certificate of verification in the case of national rules must be included in the technical file

which shall be annexed to the subsystem's technical certificates and be drawn up in accordance with UTP GEN-C.; it

referred to in point 2.4 (of 2011/18/EC, Annex VI) and

shall contain the technical data relevant for the assessment of the conformity of the subsystem with the national rules.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
7. Declaration of verification of a subsystem in the case of applicable national rules		
A "Declaration of verification of a subsystem in the case of applicable national rules" 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 in this UTP relating to a UTP Declaration of verification shall apply. If issued by the applicant, it shall contain the same information as specified in Annex 2 to this UTP. A Contracting State which is also a member of the European Union shall apply European law concerning EC declarations of verification.	Where reference is made in Annex VI to the declaration of verification of subsystems in the case of national rules, the provisions of Section 1 shall apply *mutatis mutandis* to that declaration.	2011/18/EC, Annex V, 2.
8. Authorised representative		
The applicant's authorised representative may lodge the application referred to in point 3 and meet other obligations on his behalf and under his responsibility, provided that they are specified in the mandate.		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]

5. PROCEDURE FOR ASSESSMENT OF A SUBSYSTEM'S SAFE INTEGRATION INTO ITS ENVIRONMENT

2010/57/EC, Article 15

1. Before issuing a technical admission, the competent national authority shall have ascertained that the level of safety in the rail system will not be reduced by the placing into service of the structural subsystem in question.

Note: See Recommendation 2011/217/EU.

2. Therefore, Contracting States shall take all appropriate steps to ensure that subsystems may be technically admitted only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them when integrated into the rail system. In particular, they shall check:

…., Member States be placed in service

- the technical compatibility of these subsystems with the system into which they are being integrated,
- the safe integration of these subsystems into their environment.

in accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC.

3. Technical compatibility shall in principle be provided through compliance with the provisions of the applicable UTPs.

Where there is no relevant UTP covering the essential requirement of technical compatibility (e.g. the interface with legacy signalling/train protection systems, non-UTP conform infrastructure, energy, and CCS subsystems) the notified national rules apply.

4. The requirement for "safe integration" is also part of the essential requirements and should be covered by the applicable UTP(s) and/or notified national rules.

5. If neither the UTPs nor the applicable notified national rules provide an adequate basis [34] for full assessment of compliance with the essential requirements in accordance with section 5.2 above, the applicant shall perform an explicit risk assessment and evaluation in accordance with UTP GEN-G "Risk evaluation and assessment".

The applicant's documentation shall be assessed by an independent assessment body as prescribed in UTP GEN-G.

See article 2(2) of EU Regulation EC N° 352/2009.

[34] In the case of a dispute, the national authority competent for technical admissions of railway vehicles shall decide.

ANNEX 1

CONTENT OF THE "DECLARATION OF CONFORMITY" AND OF THE "DECLARATION OF SUITABILITY FOR USE" OF INTEROPERABILITY CONSTITUENTS

OTIF UTP	*Corresponding text in EU regulations* [35]	*EU ref.* [36]
The Declaration of conformity and/or suitability for use	The EC-declaration of conformity and/or suitability for use	
and the accompanying documents must be dated and signed.		
The declaration must		
be written in the same language as the instructions for use of the constituent and must	be written in the same language as the instructions and must	
contain the following:		
	the Directive references,	
name and address of the manufacturer or its authorised representative established within		
a Contracting State	the Community	
(give trade name and full address; in the case of the authorised representative, also give the trade name of the manufacturer);		
description of the interoperability constituent (make, type, etc.);		
description of the procedure followed in order to declare conformity or suitability for use;		
	(Article 13)	
all the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use;		
name and address of the		
assessing entity and other	notified body or	
bodies involved in the procedure followed in respect of conformity or suitability for use		
date of examination certificate [37] together with, where appropriate, the duration and conditions of validity of that certificate;		
where appropriate, reference to the		
UTPs, Validated Standards and other standards applied;	European specifications;	
identification of the signatory empowered to enter into commitments on behalf of the manufacturer		
	or of the manufacturer's authorised representative established within the Community.	
where applicable, indication of the European Directives, other than the Interoperability Directive, which have been applied.		

35 Annex IV of Directive 2008/57/EC

36 If no EU reference is indicated, it means that the chapter/section number is the same as in the OTIF text.

37 Such as Certificate of conformity, Type examination certificate, "Quality management system approval", Design examination certificate, Certificate of suitability for use

ANNEX 2

CONTENT OF THE "DECLARATION OF VERIFICATION" OF SUBSYSTEMS

OTIF UTP	*Corresponding text in EU regulations* [38]	*EU ref.* [39]
The UTP declaration of verification and the accompanying documents must be dated and signed.	The 'EC' declaration of verification	
That declaration must be written in the same language as the technical file and must contain the following:		
	the Directive references,	
name and address of the applicant or the manufacturer, or its authorised representative established within a Contracting State (give trade name and full address; in the case of the authorised representative, also give the trade name of the contracting entity or the manufacturer),	Contracting entity the Community	
a brief description of the subsystem,		
name and address of the assessing entity which carried out the verifications referred to in the Modules in chapter 3,	notified body which conducted the 'EC' verification referred to in Article 18,	
the references of the documents contained in the technical file,		
all the relevant temporary or definitive provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,		
if temporary: duration of validity of the UTP declaration of verification,	'EC' declaration,	
identity of the signatory.		
where applicable, indication of the European Directives, other than the Interoperability Directive, which have been applied.		

38 Annex V of Directive 2008/57/EC

39 If no EU reference is indicated, it means that the chapter/section number is the same as in the OTIF text.

ANNEX 3

CONVERSION TABLE FOR OTIF AND EU CERTIFICATES AND OTHER EVIDENCING DOCUMENTS

The conversion table below shows the documents produced through the assessment modules of chapters 2 and 3. They have different titles, depending on the regulations under which they are produced, but have the same purpose and content.

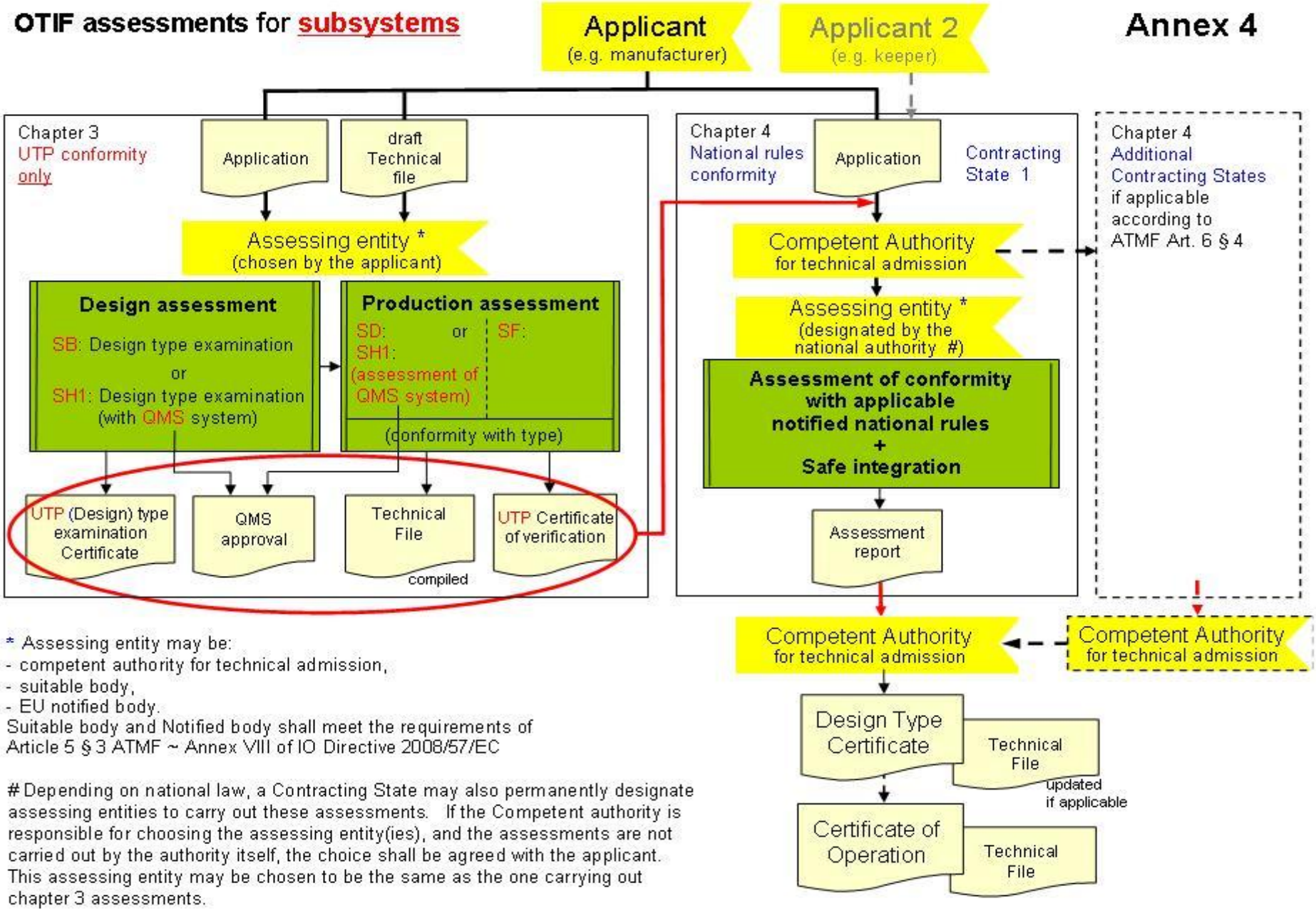
OTIF document		*Corresponding EU document*
Module(s)	**Name of document**	**Name of document**
chapter 2		
CA, CA1, CA2, CC, CD, CF, CH, CH1	Declaration of conformity	EC declaration of conformity
CA1, CA2, CF	Certificate of conformity	EC Certificate of conformity
CB	Evaluation report	Evaluation report
CB	Type examination certificate	EC-Type examination certificate
CD, CH, CH1, SD, SH1	“quality management system approval”	“quality management system approval”
CH1	Design examination certificate	EC design examination certificate
CV	Certificate of suitability for use	EC certificate of suitability for use
CV	Declaration of suitability for use	EC declaration of suitability for use
chapter 3		
SB	UTP declaration of intermediate statement of verification (ISV)	EC declaration of intermediate statement of verification (ISV)
SB, SD, SF, SH1	Technical File	Technical File
SB	UTP Type-examination certificate	EC Type-examination certificate
SH1	UTP Design examination certificate	EC design examination certificate
SD, SF, SH1	UTP Certificate of verification	EC certificate of verification
SD, SF, SH1	intermediate statements of verification (ISV)	intermediate statements of verification (ISV)
SD, SF, SH1	UTP declaration of verification	EC declaration of verification
chapter 4	Certificate of verification of a subsystem in the case of applicable national rules	EC Certificate of verification in the case of national rules
chapter 4	Declaration of verification of a subsystem in the case of applicable national rules	EC declaration of verification in the case of national rules

GUIDELINES

The following two annexes are not part of the UTP regulations, but guidelines to help understand the complexity of the assessment procedures (Annex 4) and in particular the assessment of “the safe integration of a subsystem into its environment” (Annex 5).

OTIF assessments for subsystems

Annex 4



* Assessing entity may be:
- competent authority for technical admission,
- suitable body,
- EU notified body.

Suitable body and Notified body shall meet the requirements of Article 5 § 3 ATMF ~ Annex VIII of IO Directive 2008/57/EC

Depending on national law, a Contracting State may also permanently designate assessing entities to carry out these assessments. If the Competent authority is responsible for choosing the assessing entity(ies), and the assessments are not carried out by the authority itself, the choice shall be agreed with the applicant. This assessing entity may be chosen to be the same as the one carrying out chapter 3 assessments.

ANNEX 5

OTIF UTP | *Corresponding text in EU regulations* *EU ref.*

GUIDELINE FOR THE ASSESSMENT OF

THE SAFE INTEGRATION OF A SUBSYSTEM INTO ITS ENVIRONMENT

The following needs to be demonstrated in order to meet the "essential requirements" [40]: 2011 / 217 / EU, 5.3.2

- for the technical admission | for the placing in service
  of an individual subsystem, the safe integration between this subsystem and all other subsystems in which it is integrated,
- for the technical admission | for the placing in service
  of a vehicle, the safe integration between the vehicle's relevant subsystems (only in the case of the first
  technical admission) | authorisation)
  and the safe integration between the vehicle and the network concerned.

When demonstrating safe integration by applying the Common Safety Method on Risk analysis (CSM on RA), the applicant will have:

- to refer to either the
  UTPs' | TSIs'
  requirements or the (notified) national requirements/rules,
  which can be considered as | by application of the first risk acceptance principle
  "use of codes of practices", or
- if the subject is not covered by the
  UTPs or notified | TSIs and
  national requirements/rules, to perform an explicit risk estimation
  and evaluation |
  or a similarity study to identify the missing requirements.
  (third and second risk acceptance principles of the CSM on RA) which should be made public, so that what the
  authority competent for COTIF technical admission in the Contracting State | NSA
  accepts is made transparent. As stated in the CSM on RA, the application of the CSM on RA for safe integration must not lead to requirements that are contradictory to those laid down in the
  UTPs and notified | TSIs. By analogy, this also applies to
  national rules; thus UTPs/TSIs and notified national rules shall remain mandatory.

[40] The "essential requirements" are specified in UTP GEN-A