APTU Uniform Rules (Appendix F to COTIF 1999)

Uniform Technical Prescriptions (UTP) applicable to all vehicles and other railway material (General provisions) –

ASSESSMENT PROCEDURES (MODULES) - (UTP GEN-D)

These regulations have been developed in accordance with the provisions of APTU, in 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 since 1 December 2010.

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

Text in square brackets [ ] will not be included when the document is submitted to the Committee of Technical Experts for adoption as regulations.

Note: The 11th WG TECH (June 2010) decided that the Secretariat should base this document on the new modules drafted by the European Railway Agency, which modules have been referenced in UTP WAG and in UTP NOI. The new EU modules became EU law by Commission Decision 2010/713/EU.

WG TECH also decided that module SE and SG should not be included in this version.

As far possible, amendments according to the remarks included in the EU documents 08/57-DV37, dated 24.08.2010, 08.09.2010 and ERA document from March 2011 (presented at 13th WG TECH) and the outcome of discussions with DG MOVE and ERA on 04.-05.04.2011 have been incorporated in this revised version dated **05.05.2011**.

UTP GEN-D is intended to be submitted to the Committee of Technical Experts for adoption in September 2011.

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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:

0.1 EQUIVALENCE

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

The assessments of conformity with the applicable UTPs/TSIs and the provisions concerning the Quality Management Systems (in EU regulations both tasks of a Notified Body (NoBo)) specified in the Modules included in Chapter 2 and 3 are fully equivalent.

In accordance with ATMF Article 6a, Aassessments, reports, declarations, and certificates and other evidencing documents established according to the rules of this UTP shallare therefore to be considered as equivalent to those made according to the corresponding EU regulations (see footnote [1]) and vice versa. See list of equivalent certificates and other evidencing documents in Annex 3. Thus, these certificates and documents shall be mutually recognised in all OTIF Contracting States. and EU Member States.

0.2 ENTRY INTO FORCE

Unless sufficient objections are received in accordance with § 4 of Article 35 of COTIF 1999, this UTP shall enter into force in accordance with § 4 of the same Article, i.e. on the first day of the sixth month following that in which the Member States have been notified by the Secretary General. The date of entry into force will be published on the Organisation's website.

By that date, the Contracting States shall have brought into force the national laws, regulations and administrative provisions necessary to implement it. If a Contracting State has not, or has only partly complied with this provision, it may be that other Contracting States might not recognise technical admissions for vehicles in international traffic issued by that Contracting State during the period until this provision has been fully complied with.

These national laws, regulations and admin-

[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.

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

istrative provisions shall contain a reference to this UTP or be accompanied by such reference on the occasion of their official publication. The Contracting State shall determine how such reference is to be made.

A Contracting State shall inform the Secretary General of these national laws, regulations and procedures, including the texts, if he so requires.

1. GENERAL PROVISIONS

1.1 SCOPE AND CONTENT OF THIS UTP

This UTP shall be applied when assessments of the conformity with provisions of the ~~other~~ UTPs applicable[3] to structural subsystems and of applicable national technical requirements (rules) notified according to Article 12 of APTU are carried out.

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

INTEROPERABILITY CONSTITUENTS

(in APTU and ATMF called “elements of construction”)

Chapter 2:

The assessment of the ICs conformity with applicable requirements of UTPs or 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).

SUBSYSTEMS

The assessment of a subsystem’s conformity with the applicable regulations falls into two parts:

Chapter 3 (part 1):

The assessment of conformity with the provisions included in applicable UTPs, but excluding open points and specific cases as they require application of technical rules not included in the relevant UTP(s); 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):

(See the provisions of the Articles 15 and

[3] This also includes UTP Noise as that UTP applies to (conventional) rolling stock.

OTIF UTP

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

The assessment of

- conformity with the applicable national technical requirements notified according to APTU Article 12; and
- the safe integration in the rail system into which the subsystem shall be integrated.

A flow diagram of the assessment procedures (modules) to be carried out for subsystems is shown in Annex 4. The diagram is intended as a guide only.

1.2 DEFINITIONS AND TERMINOLOGY

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

Furthermore,

a) ~~when the term UTP is used in this UTP, it includes~~RID means the "Regulation concerning the International Carriage of Dangerous Goods by Rail" (RID – Appendix C to the Convention).

b) a "Validated Standard" [4] 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; ~~cf. APTU Article 5~~

c) an "assessing entity" means an entity authorised by a Contracting State to carry out assessments of conformity with the technical requirements applicable to railway material set out in the COTIF regulations. It can be:
   - the competent authority for the technical admission of railway material of a Contracting State. The applicant is free to choose the Contracting State for his application unless otherwise indicated,
   - a "Suitable Body" which a competent authority of a Contracting State according to ATMF Article 5 § 2 has transferred competence to carry out assessments and which "Suitable Body" has been published on the Organisation's website with indication of its area of responsibility,
   - an "EU Notified Body" under

17 of 2008/57/EC).

[4] 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]
Directive 2008/57/EC, which in accordance with section 1.3.2 of this UTP is considered as a "Suitable Body". A list of all authorised assessing entities (authorities, Suitable Bodies and EU Notified Bodies) will be published on the Organisation's website.		
d) "Interoperability Constituent" (IC) is an "Elements 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 made public in accordance with Article 12 of APTU.		
f) "Technical admission" and "Technical Certificate", see ATMF Article 2 point cc) and dd).		
g) "Applicant" for assessment: *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 can only be one of those indicated in ATMF Article 10 § 2 which are:~~technical admission of a subsystem can according to ATMF Article 10 § 2 be:~~ 1. the manufacturer, 2. a rail transport undertaking, 3. the keeper of the vehicle, 4. the owner of the vehicle, 5. the infrastructure manager. ~~This applies also to application for assessments of a subsystem. If not being the manufacturer himself, the applicant shall provide fulfilment of his obligations through his contract with the manufacturer.~~ *Interoperability constituent:* As assessments of ICs are voluntary, ~~T~~there is no specification in ATMF of 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		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
authorised representative as indicated in the modules.		
h) ”authorised representative” means any natural or legal person established within		2010/713/EC Art 3, 12.
a Contracting State	the Union	
who has received a written mandate from a manufacturer or a contracting entity to act on their behalf in relation to specified tasks. A signed copy of the mandate shall be forwarded to the assesing entity/competent authority on request.		
i) “contracting entity” ~~means any entity, whether public or private, which orders the design and/or construction or the renewal or upgrading of a subsystem.~~ see definition in ATMF Article 2 point da).	see Directive 2008/57/EC Article 2 (r). ~~This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for carrying out a project.~~	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) “safe integration of a subsystem in its environment” means that the following needs to be demonstrated in order to meet the “essential requirements”: (set out in UTP GEN-A)		2011/217/EU, 5.3.2
– for the technical admission of an individual subsystem, the safe integration between this subsystem and all other subsystems in which it is integrated,	– for the placing in service	
– for the technical admission of a vehicle, the safe integration between the vehicle’s relevant subsystems (only in the case of the first technical admission) and the safe integration between the vehicle and the network concerned.	– for the placing in service authorisation)	
When demonstrating safe integration	by applying the CSM on RA,	
the applicant will have:		
– to refer to either the UTPs’ requirements or the (notified) national requirements/rules, which can be considered as “use of codes of practices”, or	TSIs by application of the first risk acceptance principle	
– if the subject is not covered by the UTPs or notified national requirements/rules, to perform an explicit risk estimation or a similarity study to identify the missing requirements.	TSIs and (third and second risk acceptance principles of the CSM on RA) which should be made public, so that what the 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		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
UTPs and notified	TSIs. By analogy, this also applies to national rules; UTPs and notified national rules shall remain mandatory.	
l) "risk analysis" means systematic use of all available information to identify hazards and to estimate the risk; i.e. the rate of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm.		2009/352/EC

1.3 PROVISIONS RELATING TO ASSESSING ENTITIES

1.3.1 In order to be authorised to carry out assessments in the sense of this UTP, an assessing entity must

- meet the requirements of UTP GEN-E [5] "Assessing entities - Qualifications and independence", and ATMF Article 5 §§ 2-7; and
- ~~if not being the competent authority itself, have been assigned assessment power by the competent authority of a Contracting State which has the entity under under its jurisdiction, and~~
- ~~have been notified to the Secretary General by the Contracting State with indication of its area of responsibility (professional competence), and~~
- be included in the list of assessing entities published on the website of the Organisation ~~(see 1.3.2)~~.

~~When these four conditions are fulfilled, the authorised assessing entity shall be considered as a "Suitable Body" in the sense of ATMF Article 5 § 2.~~

~~The national authority competent for technical admission of subsystems (railway vehicles) in a Contracting State shall – unless national regulations does not allow the admitting authority to perform assessments – be considered as authorised to carry out assessments provided it fulfils the requirement of the first and third indent above.~~ If the competent authority itself does not have, or has only limited, professional competence and/or capacity to carry out assessments itself, this shall ~~also~~ be notified to the Secretary General.

1.3.2 A "Notified Body" (NoBo) notified to EU in accordance with the EU ~~regulations~~Directive 2008/57/EC thus meeting the provisions of that Directive, in particular the critera set up in Annex VIII, and insofar the body is registered in the public so-called EU Nando

[5] (formerly named APTU Annex 1-E). The EN 45000 series of standards and accreditation are important instruments to help in establishing conformity with the requirements of UTP GEN-E.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
database[6] shall be considered as a "Suitable Body" with assessment competance and be included in the list mentioned above in ~~provided it fulfils the requirements of~~ the second indent of first paragraph ~~(the four indents)~~ above.		
~~1.3.2 The Secretary General shall on the website of the Organisation publish and update a list of notified authorised assessing entities (including authorities and NoBos) with indication of their area of responsibility (professional competence).~~		~~2008/57/EC, Art. 28 (1)~~
1.3.3 An assessing entity may only carry out assessment task(s) within its authorised area of responsibility (professional competence) as published on the Organisation's website. The competence of an authorised assessing entity shall be subject to surveillance, which is carried out at regular intervals and follows the practice established by the accreditation organisation in the Contracting State which has assigned the assessment power to the assessment entity.		
1.3.4 By agreement with the party that commissioned one or more specific assessment task to it, an assessing entity may subcontract[7] some of its assessment tasks, but not its overall responsibility, to another listed authorised assessing entity, e.g. in the case where the entity's area of responsibility does not cover the complete assessment task; the subcontractor may not subcontract to other entities. ~~The national authority responsible for technical admission may NOT delegate or subcontract the issue of Design Type Certificates and Certificates of Operation.~~		
1.3.5 In accordance with ATMF Article 6 § 4 and Article 6a ~~A~~assessments (including tests) already carried out with a documented positive result shall not be repeated, except if this is justified being necessary for the assessment of conformity with notified national technical requirements. ~~(cf. ATMF Article 6 § 4 and Article 6a).~~ The equivalence table set up according to ATMF Article 13 shall be observed in all cases where assessments are carried out.		
1.3.6 ~~Technical admissions, including the~~ In accordance with ATMF Article 10 § 5 as-		

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

[7] The national authority responsible for technical admission may NOT delegate or subcontract the issue of Design Type Certificates and Certificates of Operation.

OTIF UTP		*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	sessments~~,~~ may not be carried out for profit~~.~~ ~~(cf. ATMF Article 5 § 5~~). An assessing entity may refuse to release reports, certificates and other documentation it produces until the fee agreed has been paid or security for payment has been arranged.		
1.3.7	A Contracting State shall withdraw approval from a an assessing entity which no longer meets the criteria referred to in ATMF Artice 5 § 2 and/or UTP GEN-D. It shall forthwith inform the Committee of Technical Experts and the other Contracting States thereof.	A Member State a body Annex VIII. Commission Member States	2008/57/EC, Art. 28 (3)
1.3.8	If a Contracting State (competent national authority) has evidence or reasoned arguments that an assessing entity does not comply with the criteria of ATMF Article 5 § 2 or UTP GEN-D, the infringement procedure in ATMF Article 5 § 7 shall be initiated. In this case, all Contracting State shall be informed without delay.	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 the latter Member State of any changes that are necessary for the notified body to retain the status conferred upon it.	2008/57/EC, Art. 28 (4)
1.3.9	If an assessing entity closes down, it shall transfer all documentation in its possession relating to assessments that have been carried out to the competent authority which has transferred competence to it; notified bodies shall transfer all documentation to the competent authority of the State that has notified it.		
1.3.10	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). All notified authorised assessing entities listed on the website of the Organisation may participate in the group; competent national authorities from Contracting States not represented in the group as assessment entities may participate as observers. The group may decide to invite experts and representatives from EU Notified Bodies. The coordination group shall refer to the Committee of Technical Experts as a permanent working group. The Secretary General forming the secretariat of the group	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)

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

shall inform the Committee of Technical Experts of problems detected by in the UTP(s), recommendations made and other work carried out by the group. The Secretary General shall initiate the correction procedures included in APTU Article 8a and, when appropriate, propose the measures needed to remedy the problems.

1.4 NON-COMPLIANCE WITH ESSENTIAL REQUIREMENTS

1.4.1 INTEROPERABILITY CONSTITUENTS

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:

1.4.1.1 A manufacturer shall cease to use/issue a Declaration of conformity if the conformity of the interoperability constituent in question with the UTP in force is no longer ensured, whether as a result of changes to the constituent, to the production process or to the applicable regulations. A similar obligation exists with regard to a ~~Certificate~~Declaration of suitability for use.

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) where application of such regulations is relied upon;	European specifications / specifications	
(c) inadequacy of UTP or Validated Standards.	European specifications.	

[8] of 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]
1.4.1.3. The Secretary General	The Commission	
shall consult the parties concerned as quickly as possible. Where, following that consultation, the		
Secretary General	Commission	
establishes that the measure is justified		
he	it	
shall immediately inform the		
Contracting State	Member State	
that has taken the initiative, as well as the other		
Contracting States	Member States	
thereof.		
Where, after that consultation, the		
Secretary General	Commission	
establishes that the measure is unjustified,		
he	it	
shall immediately inform the		
Contracting State	Member State	
that has taken the initiative and the manufacturer		
	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	Article 12 (of EU Directive 2008/57/EC)	
shall apply.		
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 manufacture does not take place in a Contracting State, according to the first paragraph of point 1, 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 and shall prohibit its use.		
The Secretary General	The Commission	
shall ensure that the		
Contracting States and the European Commission	Member States	
are kept informed of the course and results of that procedure.		
1.4.2 SUBSYSTEMS		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Concerning 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 ~~as well as the documentation annexed to them~~ shall be printed in one of the official working languages of the Organisation (~~cf.~~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 belonging 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** ~~and~~ 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 IDENTIFICATION OF DOCUMENTS

Applications, Certificates, Declarations and changes to them shall in all cases bear a unique reference (for identification), information of the issuer, and shall be dated and signed by a person authorised to do so. Annexed items shall clearly indicate which application, certificate or declaration they belong to, e.g. by indicating the reference of the main document.		
~~Design Type Certificates and Certificates of Operation issued by a competent national authority shall bear an EIN harmonised document number as set out in Annex 3.~~		

1.7 USE OF THE MODULES

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Modules CA1, CA2 or CH may for certain interoperability constituents specified in the UTP be used only in the case of products placed on the market, and therefore developed, before the entry into force of a UTP for a subsystem (e.g. UTP WAG) where these modules have been indicated in chapter 6 of the UTP. In that case, these modules may only be used, provided that the manufacturer demonstrates to the assessing entity that design review and type examination were performed for previous applications under comparable conditions, and are in conformity with the requirements of the UTP for the subsystem. 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.	(Similar text is included in the preliminary draft 1.0 of the revised TSI WAG, section 6.1.2 note *)	
~~*For a single specimen of a subsystem:*~~ ~~A single specimen (vehicle) not produced in conformity with an approved type may be assessed using module SB~~ [9] ~~and assessment of the applicable national technical requirements (rules) according to chapter 4.~~		

[9] Module SB includes the testing of a specimen (prototype) and thereby ensures that the specimen is in compliance with the UTP(s).

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 in 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 assessment and declaration of Interoperability Constituents used on their territory to be mandatory, in which case this 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
- test reports.

[10] see definition in section 1.2 b).

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

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. Declaration of conformity | EC declaration of conformity

4.1 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 | EC 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.

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.

~~6. Monitoring~~

~~The competent authority of the Contracting State where the production of the constituent takes place and/or the assessing entity are allowed to inspect the manufacturers internal production control and from testing samples of the constituents produced.~~

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,

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

[11] see 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 | 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
Declaration of conformity | EC declaration of conformity

[12] see section 1.2 b).

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

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.

~~8. Monitoring~~

~~If the checks specified in point 4 are carried out by an in-house body, the assessing entity and the competent authority of the State where the production of the constituents takes place are not precluded from inspections of the internal production control or from testing samples of the constituents produced.~~

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,

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

[13] A "Validated Standard" has in COTIF regulations 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]

– 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 | 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
Declaration of conformity | EC declaration of conformity
shall identify the interoperability constituent for which it has been drawn up.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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.		
~~8. Monitoring~~ ~~If the checks specified in point 4 are carried out by an in-house body, the assessing entity and the competent authority of the State where the production of the constituents takes place are not precluded from inspecting the internal production control or from testing samples of the constituents produced.~~		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
MODULE CB. TYPE EXAMINATIONS	EC-TYPE EXAMINATION	
1. ~~This module~~Type examination is the part of a conformity assessment procedure in which an assessing entity 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) that apply to it.	EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an interoperability constituent and verifies and attests that the technical design of the interoperability constituent meets the requirements of the technical specification for interoperability (TSI) that apply to it.	
2. The Type examination may be carried out in either of the following manners:	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 of his choice.	EC-type examination with a 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 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:		
o a general description of the interoperability constituent,		
o conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,		
o 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,		
o conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,		
o 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,		
o results of design calculations made, examinations carried out, etc., and		
o 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 whether, where the solutions in the relevant		

[14] see section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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
the competent authority | ~~and shall, periodically or upon request, make available to~~ its notifying authorities

	OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
		~~the list of certificates and/or any additions thereto~~	
	the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
	Each assessing entity shall ensure that the other assessing entities will be informed concerning 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 information shall include the names and adresses of the manufacturer and assessing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.		
	~~The competent authority in question shall keep an updated list of the Type-examination certificates and their status. The list shall include the same data as required for the information.~~		
	~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~		
	The Secretary General, the Contracting States and the other assessing entities ~~Through the competent authority that has registered (listed) the Type examination certificate, the competent authorities of the other Contracting States, the other assessing entities and the Secretary General may,~~ may upon request, obtain a copy of the	The Commission, the Member States and the other notified bodies ~~may~~	
	Type examination certificate and/or additions thereto.	EC-Type examination certificate.	
	Upon request, the Secretary General and the Contracting States~~they~~ may also similarly obtain a copy of the technical documentation and the results of the examinations carried out by the	the Commission and the Member States may	
	assessing entity.	notified body.	
	The assessing entity shall keep a copy of the	The notified body	
	Type examination certificate, its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.	EC-Type examination certificate.	
9.	The manufacturer shall keep a copy of the		
	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	EC-Type examination certificate,	
	UTP	TSI	

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

~~5.~~ ~~Monitoring~~

~~The competent authority of the State where the production of the constituent takes place is not precluded from inspecting the internal production control or from testing samples of the constituents produced.~~

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
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. 1.

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 ~~competent authority~~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* [2] *ref.*

– 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 audits purposes, allow the assessing entity | notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

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

4.3 The 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.

4.4 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 verify that the quality management system is functioning correctly. The assessing entity | notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Declaration of conformity | EC declaration of conformity

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

5.2 The Declaration of conformity | EC declaration of conformity 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 mar-

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
ket 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 ~~(this doesn't follow on)~~ referred to in points 3.5, 4.3 and 4.4.	notified body ~~(nor does this)~~

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

~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of "quality management system approvals"~~

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 concerning 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.

The information shall include the names and adresses of the manufacturer and assessing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.

~~The competent authority in question shall keep an updated list of the Certificates of verification and their status. The list shall include the same data as required for the~~

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU* [2] *ref.*
~~information.~~ ~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~ The assessing entity shall keep a copy of the "quality management system approval" its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the "quality management system approval".		

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 or 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 Prescription (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:

- o a general description of the interoperability constituent,
- o conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- o 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,
- o conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- o 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,
the technical documentation shall specify the parts which have been applied,

[16] see section 1.2 c)

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

- o results of design calculations made, examinations carried out, etc., and
- o 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
assessing entity | notified body
shall not assess again the entire quality manual and all the procedures already as-

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

sessed 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
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.

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

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.

4.4 In addition, the
assessing entity | notified body
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.

5. Declaration of conformity

5.1 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.

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 | 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 national authorities:

– the technical documentation referred to in point 3.1,
– the documentation concerning the quality management system referred to in point 3.1,
– the change referred to in point 3.5, as approved, and

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, 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

~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of "quality management system approvals"~~ 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.

The information shall include the names and adresses of the manufacturer and assessing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.

~~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.~~

~~The competent authority in question shall keep an updated list of the "quality management system approvals" and their status. The list shall include the same data as required for the information.~~

~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~

Why not EU ?

The assessing entity shall keep a copy of the "quality management system approval", its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the "quality management system approval".

On request, the Secretary General, the Contracting States and other assessing entities may obtain a copy of the "quality management system approval" and corresponding technical documentation and the results of the examinations carried out by the assessing entity.

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

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

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 techniques, processes and systematic actions that will be used,

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

– 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.

It shall notify the manufacturer of its decision. The notification shall contain the conclu-

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

sions 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

~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of “quality management system approvals”~~

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 concerning 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.

The information shall include the names and adresses of the manufacturer and assessing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.

~~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.~~

~~The competent authority in question shall keep an updated list of the “quality management system approvals” and their status. The list shall include the same data as required for the information.~~

~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~

The assessing entity shall keep a copy of the “quality management system approval” its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the “quality management system approval”.

Why not in EU?

Upon request, the Secretary General, the Contracting States and the other assessing entities may obtain a copy of the “quality management system approval” and corresponding technical documentation and the results of the examinations carried out by the assessing entity.

4. Design examination

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

notified body

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

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:

- o a general description of the interoperability constituent,
- o conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- o 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,
- o conditions of integration of the interoperability constituent in its system environment (sub-assembly, assembly, subsystem) and the necessary interface conditions,
- o a list of the
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,
- o results of design calculations made, examinations carried out, etc., and
- o 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.

[17] see section 1.2 b)

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

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.

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 | ~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of certificates and/or any additions thereto~~
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each assessing entity shall ensure that the other assessing entities will be informed concerning 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 information shall include the names and adresses of the manufacturer and assess- | ~~and/or any additions thereto which it has refused, withdrawn, suspended or other-~~

	OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	ing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.	~~wise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.~~	
	~~The competent authority in question shall keep an updated list of the Design examination certificates and their status. The list shall include the same data as required for the information.~~ ~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States. The list shall include the name of the manufacturer and the assessing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and the reference number of the issuing document; the EIN harmonised document numbering system set out in Annex 3 shall be used.~~		
	~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~		
	The Secretary General, the competent authorities of the other Contracting States and the other assessing entities may, on request, obtain a copy of the Design examination certificate. and/or additions thereto.	The Commission, the Member States and the other notified bodies EC design examination certificate.	
	Upon request, the Secretary General and the other Contracting States may obtain a copy of the technical documentation and the results of the examinations carried out by the assessing entity.	Commission and the Member States notified body.	
	The assessing entity shall keep a copy of the Design examination certificate. its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.	The notified body EC design examination certificate.	
4.6	The manufacturer shall keep a copy of the 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 and, where the UTP does not define this period, for 10 years after the last interoperability constituent has been manufactured.	EC design examination certificate, TSI TSI	

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

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 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 Direc-

a) meet the requirements set out in Annex

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
1 to this UTP, and	tive 2008/57/EC.	
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 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 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 | notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

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

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:
  - o by operating the interoperability constituent in service,
  - o by monitoring the in-service behaviour, and
  - o 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.

The technical documentation shall cover the design, manufacturing, maintenance and

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

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,
the assessing entity | the notified body
shall issue

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
a Certificate of suitability for use to the manufacturer.	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	TSI, the notified body an EC certificate of suitability for use

and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The manufacturer shall inform the assessing entity | notified body
that holds the technical documentation relating to the Certificate of suitability for use | EC certificate of suitability for use
of all modifications to the approved type that may affect the suitability for use of the interoperability constituent or the conditions for 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. | 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 | Each notified body shall inform its notifying authorities concerning the EC 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 | ~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of certificates and/or any additions thereto~~
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

~~The competent authority in question shall keep an updated list of the Certificates of suitability for use and their status.~~

The list shall include the name of the manufacturer and the assessing entity, the identification (type and name) of the interoperability constituent, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and the reference number of the issuing document.~~; the EIN harmonised document numbering system set out in Annex 3 shall be used.~~

9. Each assessing entity shall ensure that the other assessing entities will be informed concerning the Certificates of suitability for | Each notified body shall inform the other notified bodies concerning the EC Certificates of suitability for use

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	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.	
~~9.~~	~~The Secretary General shall be informed of new entries and any other change to the list of the Certificates of suitability for use and make the information available to the competent authorities of the other Contracting States.~~	~~Each notified body shall inform the other notified bodies concerning the EC 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.~~
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~~other~~ Contracting States may obtain a copy of the technical documentation and the results of the examinations carried out by the assessing entity.	Commission and the Member States notified body.
	The assessing entity shall keep a copy of the Certificate of suitability for use, its annexes and additions, until the expiry of the validity of the certificate.	The notified body EC Certificate of suitability for use
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 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 suitability for use shall identify the interoperability constituent for which it has been drawn up.	EC declaration of suitability for use TSI TSI EC declaration of suitability for use
	A copy of the Declaration of suitability for use shall be made available to the relevant authorities upon request.	EC declaration of suitability for use
11.2	The 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	EC declaration of suitability for use shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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 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 ~~11.3~~ ~~(Reserved)~~declarations have been drawn up: – Declaration of suitability for use referred to in point 11.1, and – Declaration of conformity.	~~The interoperability constituent may be placed on the market only after the following~~ EC declarations have been drawn up: – EC declaration of suitability for use referred to in point 11.1, and – EC declaration of conformity.	

12. Authorised representative

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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
3. MODULES FOR THE PROCEDURES FOR ASSESSMENT OF 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 COTIF regulations such as RID 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.	
When the term "UTP" is used below in this module, it includes those other applicable COTIF regulations, if any.		
2. Type examination shall be carried out by: – assessment of the adequacy of the technical design of the subsystem through examination of the technical documentation and supporting evidence referred to in point 3 (design type), and – examination of a specimen, representative of the production envisaged, of the complete subsystem (production type). A type may cover several versions of the subsystem provided that the differences between the versions do not affect the provisions of the relevant UTP(s).	EC-type examination TSI(s).	
3. The applicant shall lodge an application for Type examination with an assessing entity of his choice. The application shall include: – the name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well, – a written declaration that the same application has not been lodged with any other assessing entity, – the technical documentation.[18] The technical documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant UTP(s). The technical documentation shall specify the requirements of the relevant UTP(s) and cover, as far as relevant for the assessment, the design, manufacture and operation of the subsystem. The technical documenta-	EC-type examination with a notified body notified body, TSI(s). TSI(s) EC-type examination procedure,	

[18] the technical documentation includes descriptions and explanations necessary for the understanding of the functioning and possible risks/failures of safety related software used in the subsystem,

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

tion shall contain, at least the following elements:

- o a general description of the subsystem, its overall design and structure,
- o 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,
- o 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,
  - o copy of EC declaration(s) of intermediate statements of verification (hereinafter referred to as ISV) issued for the subsystem according to point 2 of Annex VI to Directive 2008/57/EC, if any,
- o ~~conceptual design and manufacturing drawings (when available) and schemes of the subsystem, components, sub-assemblies, circuits, etc.,~~ *[as in the IC modules]*
- o ~~descriptions and explanations necessary for the understanding of the functioning and possible risks/failures of safety related software used in the subsystem,~~ *[has been changed to footnote 18, but ERA wants both indents deleted]*
- o a draft of the Technical File as required by ATMF Article 10 § 6 with a content according to the requirements set out in UTP GEN-C [19],
- o if relevant, descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- o conditions of integration of the subsystem in its system environment and the necessary interface conditions,
- o 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,
- o results of design calculations made, examinations carried out, etc.,
- o test programme and reports,

[19] formerly named APTU Annex 1-C

[20] see section 1.2 b)

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

- o evidence of conformity with other applicable COTIF regulations | regulations deriving from the Treaty (including certificates, if any),
- o supporting documentation regarding the manufacture and the assembly of the subsystem,
- o a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation,
- o conditions for use of the subsystem (restrictions of running time or distance, wear limits etc.),
- o conditions for maintenance and technical documentation on maintenance of the subsystem,
- o 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,
- o all other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- o 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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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 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	notified body	
thereof.		
The applicant shall also provide the assessing entity	notified body	
with a precise reference to the UTP(s)	TSI(s)	
(or their parts) for which the derogation is requested.		
~~The assessing entity shall analyse whether the derogation complies with the essential requirements and follow the procedure(s) 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 procedure(s).~~ The applicant shall communicate to the assessing entity the outcome of the derogation procedure.		
6. The assessing entity	The notified body	
shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes.		
The evaluation report shall as an annex include the assessing entity's compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [21] "Technical File".		
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		

[21] formerly named APTU Annex 1-C

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3), the assessing entity	notifying authorities, the notified body	
shall release the content of that report, in full or in part, only with the agreement of the applicant.		
7. Where the type meets the requirements of the relevant		
UTP(s)	TSI(s)	
that apply to the subsystem concerned, the assessing entity	notified body	
shall issue a UTP Type-examination certificate	an EC-type examination certificate	
to the applicant.		
The certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.		
The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems with the examined type to be evaluated.		
Where the type does not satisfy the requirements of the relevant		
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 shall instead of a certificate issue an examination report clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body shall issue an intermediate statement of verification (ISV) in compliance with Article 18(4) of Directive 2008/57/ EC. 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	Each notified body shall inform its notifying authorities concerning the EC-type examination certificates	

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 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	~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of certificates and/or any additions thereto~~ the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.	
Each assessing entity shall ensure that the other assessing entities will be informed of the UTP 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.	Each notified body shall inform the other notified bodies concerning the EC-type examination certificates	
~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~ The information shall include the names and adresses of the applicant and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.	~~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 competent authority in question shall keep an updated list of the Type-examination certificates and their status. The list shall include the same data as required for the information.~~		
~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~		
The Secretary General, the Contracting States and the other assessing entities Through the competent authority that has registered (listed) the UTP Type-examination certificate, the competent authorities of the other Contracting States, the other assessing entities and the Secretary General ~~may,~~ may upon request, obtain a copy of the UTP Type-examination certificate and/or additions thereto.	The Commission, the Member States and the other notified bodies ~~may~~ EC-Type examination certificate.	
Upon request, the Secretary General and the Contracting States~~they~~ may also ~~similarly~~ obtain a copy of the technical documentation and the results of the examinations carried out by the	the Commission and the Member States may	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
assessing entity.	notified body.	
The assessing entity shall keep a copy of the UTP Type-examination certificate, its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.	The notified body EC-Type examination certificate.	

10. The applicant shall keep a copy of the UTP 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.

	EC-type examination certificate,	

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)~~procedure for admission to operation of a subsystem~~ 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 that the subsystem concerned is in conformity with the type described in the UTP Type-examination Certificate and thereby satisfies the requirements of the relevant UTP(s) and other applicable COTIF regulations such as RID that apply to it.	EC verification is the part of a EC verification procedure whereby the applicant fulfils the obligations laid down in points 2 and 8, and ensures and declares on his sole responsibility that the subsystem concerned is in conformity with the type described in the EC type examination certificate and thereby satisfies the requirements of the relevant TSI(s) as well as any other regulations deriving from the Treaty that apply to it.	
When the term "UTP" is used below in this module, it includes those other applicable COTIF regulations, if any.		
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 or the manufacturer *[as the applicant might be a RU, ERA agrees]* shall lodge an application for assessment of his quality management system with an assessing entity 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, – a written declaration that the same application has not been lodged with any other assessing entity, – 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, – the technical documentation of the approved type and a copy of the UTP Type-examination certificate and its annexes.	3.1 The applicant shall lodge an application for assessment of his quality management system 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 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 EC-type examination certificate.	
3.2 The quality management system shall ensure that the subsystem is in conformity with the type described in the UTP Type-examination certificate	3.2 The quality management system shall ensure that the subsystem is in conformity with the type described in the EC-type examination certificate	

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

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 quality management system in place is intended to be applied to the production of subsystems conforming to another specific UTP Type-examination certificate, only the parameters different from those already positively assessed and the applicability of the quality management system in total to this (new) type need be verified.

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 or the manufacturer | applicant
operates a certified quality management system certified by an accredited certification body, 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

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	assessing entity	notified body
	will make a detailed assessment of quality management system specific documents and records of the subsystem~~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 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 auditing team shall review the technical documentation referred to in point 3.1, second paragraph,	
	sixth indent,	seventh indent,
	to verify the ability of the relevant entities concerned to identify the requirements of the	
	UTP(s)	TSI(s)
	and to carry out the necessary examinations with a view to ensuring compliance of the subsystem with those requirements.	
	The decision shall be notified to the applicant 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	notified body
	shall issue a “quality management system approval” to the	
	applicant who shall forward a copy to the manufacturer.	applicant.
3.4	The applicant and the manufacturer	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 manufacturer shall keep the applicant informed and	
	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, and the applicant shall forward it to 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	Each notified body shall inform its notifying authorities of

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 "quality management system approvals" issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	and shall, periodically or upon request, make available to its notifying authorities the list of "quality management system approvals"	
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 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	
The information shall include the names and adresses of the applicant, manufacturer and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.	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.	
The competent authority in question shall keep an updated list of the "quality management system approvals" and their status. The list shall include the same data as required for the information.		
The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.		
The assessing entity shall keep a copy of the "quality management system approval", its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the "quality management system approval".		Why not in EU?
On request, the Secretary General and the Contracting States may obtain a copy of the "quality management system approval" and the corresponding technical documentation and the results of the quality management system assessments carried out by the assessing entity.		
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 author-		

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

ised 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.),

– 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 evi-

[22] see section 1.2 b)

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
dence 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 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 assessing entity considers the UTP Type-examination certificate no longer remains valid or is not appropriate and that a new UTP Type-examination certificate is necessary, the assessing entity shall refuse to assess the quality management system of the applicant and shall justify its refusal.	notified body EC type examination Certificate EC type examination Certificate notified body	
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, the applicant shall inform the assessing entity thereof.	Article 9 of Directive 2008/57/EC, 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)	
The assessing entity shall analyse whether the derogation complies with the essential requirements and follow the procedure(s) 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 procedure(s).	The applicant shall communicate to the notified body the outcome of the derogation procedure.	
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	

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

— 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 | 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.

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

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

The applicant shall forward these reports to the manufacturer.

7.5 The assessing entity | The notified body
responsible for the assessment of conformity of the manufactured subsystems with the approved type | 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:

— 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).

7.6 The assessing entity shall draw up an evaluation report that records the activities undertaken in accordance with section 7 and their outcome. 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.

8. **UTP Certificate of verification** | EC certificate of verification and EC 8.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	declaration of verification	
8.1 Where the subsystem meets the requirements of the relevant TSI(s), the assesing entity shall issue	notified body	
a UTP Certificate of verification.	an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.	
The certificate shall in an annex include 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	EC certificate	
UTP(s) or their parts to which conformity has not been examined during the assessments carried out.	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 instead of a certificate issue an examination report clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body shall issue an intermediate statement of verification (ISV) in compliance with Article 18(4) of Directive 2008/57/EC.	
8.2 **Note:** A UTP Declaration of verification is **not** mandatory in COTIF. However, it may be drawn up on a voluntary basis or as mandatory 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.		
~~8.2~~ 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 for the subsystem shall also indicate the references to the	EC declaration	
UTP(s) or their parts to which conformity has not been examined during the	TSI(s)	

[23] formerly named APTU Annex 1-C

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
verification procedure.	EC verification	
(ISV is not foreseen in COTIF)	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	
~~The EC declaration~~ and the accompanying documents shall be written in accordance with ~~Annex V to Directive 2008/57/EC.~~ 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 EC type examination certificate and its additions.~~		
~~A copy of the EC declaration of verification and EC ISV declarations, if any, shall be made available to the relevant authorities upon request.~~		
— the UTP Type examination certificate and its additions.	— the EC type examination certificate and its additions.	
A copy of the UTP Declaration of verification shall be made available to the relevant authorities upon request.	A copy of the EC declaration of verification and EC ISV declarations, if any,	
(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,		
— 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 issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	Each notified body shall inform its notifying authorities concerning the EC Certificates of verification ~~type examination certificates~~ ~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of certificates and/or any additions thereto~~	
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the	Each notified body shall inform the other	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
other assessing entities will be informed of the UTP Certificates of verification	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.		
The information shall include the names and adresses of the applicant, manufacturer and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.	~~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 EC certificates of verification which it has issued.~~	
~~The competent authority in question shall keep an updated list of the Certificates of verification and their status. The list shall include the same data as required for the information.~~		
~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~		
11. Authorised representative		
The applicant's obligations set out in points 3.1, 3.5, 6, 8.2		
	~~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 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)~~procedure for admission to operation of a subsystem~~ whereby the applicant fulfils the obligations laid down in point 2 in order that assessments can be carried out to verify that the subsystem concerned, which has been subject to the provisions of point 4, is in conformity with the type described in the UTP ~~Design~~ Type-examination ~~C~~certificate and thereby satisfies the requirements of the relevant UTP(s) and other applicable COTIF regulations such as RID that apply to it.	EC verification a EC verification procedure and 5, and ensures and declares on his sole responsibility EC type examination certificate and TSI(s) as well as any other regulations deriving from the Treaty	
When the term "UTP" is used below in this module, it includes those other applicable COTIF regulations, if any.		
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 and with the requirements of the relevant UTP(s) that apply to it.	EC-type examination certificate TSI(s)	
3. 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, – 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 and its annexes, as issued after completion of the procedure defined in module SB.	EC type examination certificate	
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 – a separate file with the set of data required by the relevant UTP(s) for each relevant register	as described in point 4 of Annex VI to Directive 2008/57/EC, TSI(s)	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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 the Validated Standards [24] 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 relevant 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,		
— 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)	TSI(s)	
that shall be taken into account during production, maintenance or operation of the subsystem,		
— other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,		
— conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,		
— evidence of conformity with other 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	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		

[24] see section 1.2 b)

	OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	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)	
	(or their parts) for which the derogation is requested.		
	The assessing entity shall analyse whether the derogation complies with the essential requirements and follow the procedure(s)	The applicant shall communicate to the notified body the outcome of the derogation procedure.	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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 procedure(s).		
4.5. **UTP Certificate of verification**	EC certificate of verification and EC declaration of verification	
The assesing entity shall issue a UTP Certificate of verification if the sub-system meets the requirements of the relevant, and in respect of the examinations and tests carried out.	notified body an EC certificate of verification in	
The certificate shall in an annex include the assessing entity's compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [25] "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 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 instead of a certificate issue an examination report clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body shall issue an intermediate statement of verification (ISV) in compliance with Article 18(4) of Directive 2008/57/EC.	
The applicant shall keep the UTP Certificate of verification and the documentation referred to in point 3. available for inspection by the national authorities throughout the service lifetime of the subsystem.	EC certificate of verification	
5. **UTP Declaration of verification** **Note:** A UTP Declaration of verification is **not** mandatory in COTIF. However, it may be drawn up on a voluntary basis or as mandatory 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.	EC declaration of verification	

[25] formerly named APTU Annex 1-C

OTIF UTP		*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	A Contracting State which is also a member of the European Union shall apply European law concerning EC declarations of verification.		
~~5.~~	~~**Note**: COTIF does not include requirements that the applicant shall draw up a declaration of verification for a subsystem.~~	~~EC declaration of verification~~	
5.1	The applicant shall, if applicable, draw up a written UTP 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	shall draw up a written EC declaration of verification	
5.1	~~(Reserved)~~The UTP Declaration of verification	EC declaration~~The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service lifetime of the subsystem.~~ ~~Where the subsystem referred to in point 3 is subject to a derogation, upgrade, renewal or specific case(s), the EC declaration for the subsystem shall also indicate the references to the TSI(s) or their parts to which conformity has not been examined during the EC verification procedure.~~	
	for the subsystem shall also indicate the references to the UTP(s) or their parts to which conformity has not been examined during the assessment procedure.	TSI(s) EC verification procedure.	
	(ISV is not foreseen in COTIF)	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 V to Directive 2008/57/EC.~~ Annex 2 to this UTP.	The EC declaration Annex V to Directive 2008/57/EC.	
	A copy of the UTP Declaration of verification shall be made available to the relevant authorities upon request.	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	~~(Reserved)~~ (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	Each notified body shall inform its notify-	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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 issued or withdrawn, and shall, periodically or upon request, make available to the competent authority the list of certificates refused, suspended or otherwise restricted.	ing authorities concerning the EC declarations of verification ~~type examination certificates~~ and shall, periodically or upon request, make available to its notifying authorities ~~the list of certificates~~	
Each assessing entity shall ensure that the other assessing entities will be informed of the UTP Certificates of verification which it has refused, suspended, withdrawn, or otherwise restricted, and, upon request, of UTP Certificates of verification which it has issued.	Each notified body shall inform the other notified bodies concerning of EC-certificates of verification EC certificates of verification	
The information shall include the names and adresses of the applicant, manufacturer and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.	~~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 EC certificates of verification which it has issued.~~	
~~The competent authority in question shall keep an updated list of the Certificates of verification and their status. The list shall include the same data as required for the information.~~		
~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~		

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)~~procedure for admission of a design type and admission to operation of a subsystem~~	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 COTIF regulations such as RID	TSI(s) as well as any other regulations deriving from the Treaty	
that apply to it.		
When the term "UTP" is used below in this module, it includes those other applicable COTIF regulations, if any.		
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 quality management system with		
an assessing entity	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 requirements of the relevant		
UTP(s)	TSI(s)	
that apply to it.		
All the elements, requirements and provisions adopted by the applicant shall be docu-		

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

mented 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 [26] 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 quality management system in place is intended to be applied to the production of subsystems conforming to another specific UTP Type-examination certificate (or UTP Design examination certificate), only the parameters different from those already positively assessed and the applicability of the quality management system in total to this (new) type need be verified.

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

- wheter 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

[26] see section 1.2 b)

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

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.

When the applicant operates a certified quality management system certified by an accredited certification body, for the design, manufacturing and final testing of the relevant subsystem, the
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.

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 | ~~and shall, periodically or upon request, make available to~~ its notifying authorities

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	~~the list of "quality management system approvals"~~	
	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 concerning the "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
The information shall include the names and adresses of the applicant, manufacturer and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document.	~~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.~~	
~~The competent authority in question shall keep an updated list of the "quality management system approvals" and their status. The list shall include the same data as required for the information.~~		
~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States.~~		
Upon request, the Secretary General, the Contracting States and the other assessing entities may obtain a copy of the technical documentation and the results of the quality management system assessments carried out by the assessing entity.		
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,	

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

– the technical documentation.[27] 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:

- o a general description of the subsystem, its overall design and structure,
- o 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 2008/547/EC,
- o 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,
- o ~~conceptual design and manufacturing drawings and schemes of the subsystem, components, sub-assemblies, circuits, etc.,~~*[as in the IC modules]*
- o ~~descriptions and explanations necessary for the understanding of the functioning and possible risks/failures of safety related software used in the subsystem,~~*[changed to footnote 27, but ERA wants tse two indents deleted]*
- o a draft of the Technical File as required by ATMF Article 10 § 6 with a content according to the requirements set out in UTP GEN-C [28],
- o if relevant, descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem,
- o conditions of integration of the subsystem in its system environment and the necessary interface conditions,
- o a list of the
  Validated Standards [29] 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

[27] the technical documentation includes descriptions and explanations necessary for the understanding of the functioning and possible risks/failures of safety related software used in the subsystem,

[28] formerly named APTU Annex 1-C

[29] see section 1.2 b)

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

Validated Standards, | harmonised standards,
the technical documentation shall specify the parts which have been applied,

- o results of design calculations made, examinations carried out, etc.,
- o test programme and reports,
- o evidence of conformity with other applicable COTIF regulations, | regulations deriving from the Treaty (including certificates, if any),
- o documentation regarding the manufacture and the assembly of the subsystem,
- o a list of manufacturers involved in the subsystem's design, manufacturing, assembly and installation,
- o conditions for use of the subsystem (restrictions of running time or distance, wear limits etc.),
- o conditions for maintenance and technical documentation on maintenance of the subsystem,
- o 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,
- o all other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,
- o 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 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) (or their parts) for which the derogation is requested.

The assessing entity shall analyse whether the derogation complies with the essential requirements and shall inform the applicant thereof.

The applicant shall follow the derogation procedure(s) set out by the Committee of

OTIF UTP		*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	Technical Experts according to Article 7a of ATMF.		
	The applicant shall communicate to the notified body		
	assessing entity	notified body	
	the outcome of the derogation procedure.		
4.4	The assessing entity	The notified body	
	shall examine the application, and where the design meets the requirements of the relevant		
	UTP(s),	TSI(s),	
	it shall issue		
	a UTP Design examination certificate	an "EC design examination certificate" to the applicant.	
	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 in an annex include the assessing entity's compilation of the Technical File in accordance with the requirements set out in UTP GEN-C [30] "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	the EC design 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 shall instead of a certificate issue an examination report clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body shall issue an intermediate statement of verification (ISV) in compliance with Article 18(4) of Directive 2008/57/ EC.	
	The examination report shall be given to the applicant.	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	notified body	
	that has issued the		
	UTP 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 relevant		
	UTP(s)	TSI(s)	
	or the conditions for validity of the certificate until the expiry of the validity of the certificate.		

[30] formerly named APTU Annex 1-C

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
Such modifications shall require additional approval — from the assessing entity that issued the	notified body	
UTP Design examination certificate	EC design examination certificate	
— in the form of an addition to the original UTP 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	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	~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of certificates and/or any additions thereto~~	
the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
Each assessing entity shall ensure that the other assessing entities will be informed concerning the UTP Design examination certificates	Each notified body shall inform the other notified bodies concerning of EC Design examination certificates	
and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.		
The information shall include the names and adresses of the applicant, manufacturer and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, restriction, etc.) and the date and reference number of the issuing document.	~~Each notified body shall inform the other notified bodies concerning of EC Design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.~~	
~~The competent authority in question shall keep an updated list of the Design examination certificates and their status. The list shall include the same data as required for the information.~~		
~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the competent authorities of the other Contracting States and other listed assessing entities.~~		
The Secretary General, the Contracting States and the other assessing entities may, on request, obtain a copy of the	The Commission, the Member States and the other notified bodies	
UTP Design examination certificate	EC design examination certificates	
and/or additions thereto. On request, the Secretary General and the Contracting	the Commission and the Member States	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
States may obtain a copy of the technical documentation and of the results of the examinations carried out by the assessing entity.	notified body.	
The assessing entity shall keep a copy of the UTP Design examination certificate its annexes and additions, as well as the technical file including the documentation submitted by the applicant until the expiry of the validity of the certificate.	The notified body EC design examination certificates	
4.7 The applicant shall keep a copy of the UTP 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.	EC design examination certificate,	
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 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.	notified body	
5.3 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 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 referred to in point 4.4. When the applicant operates a certified quality management system, the assessing entity shall take this into account during the periodic audits.	The notified body EC design examination notified body	
5.4 In addition, the assessing entity may pay unexpected visits to the applicant and the sites mentioned in point 5.2. During such visits the assessing entity 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.	notified body notified body	
5.5 The assessing entity responsible for the verification of the conformity	The notified body EC verification	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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: — 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).	
5.6 The assessing entity shall draw up an evaluation report that records the activities undertaken in accordance with section 5 and their outcome. 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.		
6. **UTP Certificate of verification** ~~**Note**: COTIF does not include requirements that the applicant shall draw up a declaration of verification for a subsystem.~~	**EC certificate of verification and EC declaration of verification**	6.
6.1 Where the subsystem meets the requirements of the relevant TSI(s), the assesing entity	notified body	
shall issue a UTP Certificate of verification. The certificate shall in an annex include 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 shall be given to the applicant.	an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.	
Where the subsystem referred to in point 4.1 is subject to derogation, upgrade, renewal or specific case, the 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 shall instead of	TSI(s), the notified body shall issue an	

[31] formerly named APTU Annex 1-C

OTIF UTP		*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	a certificate issue an examination report clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	intermediate statement of verification (ISV) in compliance with Article 18(4) of Directive 2008/57/EC.	
6.2	**UTP Declaration of verification** **Note:** A UTP Declaration of verification is **not** mandatory in COTIF. However, it may be drawn up on a voluntary basis or as mandatory 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.	EC declaration of verification	
~~6.2~~	The applicant shall keep the UTP Certificate of verification, and if issued, the 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 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	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.		
	(ISV is not foreseen in COTIF)	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 V to Directive 2008/57/EC.~~	
	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" referred to in point 3.3 and audit reports indicated in point 5.3, if any, ~~– the EC Design examination certificate referred to in point 4.4 and its additions.~~ ~~A copy of the EC declaration of verification and EC ISV declarations, if any, shall be made available to the relevant authorities upon request.~~		
	– 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	A copy of the EC declaration of verification and EC ISV declarations, if any,	
	shall be made available to the relevant authorities upon request.		

OTIF UTP		*Corresponding text in EU regulations* [1]	*EU ref.* [2]
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.	6.3
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, — 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 issued or withdrawn, and shall, periodically or upon request, make available to the competent authority	Each notified body shall inform its notifying authorities concerning the EC Certificates of verification ~~type examination certificates~~ ~~and shall, periodically or upon request, make available to~~ its notifying authorities ~~the list of certificates and/or any additions thereto~~	
	the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.		
	Each assessing entity shall ensure that the other assessing entities will be informed concerning the UTP Certificates of verification which it has refused, suspended, withdrawn, or otherwise restricted, and, upon request, of UTP Certificates of verification which it has issued.	Each notified body shall inform the other notified bodies concerning of EC-certificates of verification EC certificates of verification	
	The information shall include the names and adresses of the applicant, manufacturer and assessing entity, the identification (type and name) of the subsystem, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and reference number of the issuing document. ~~The competent authority in question shall keep an updated list of the Certificates of verification and their status. The list shall include the same data as required for the information.~~ ~~The Secretary General shall be informed of new entries and any other change to the list and make the information available to the~~	~~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 EC certificates of verification which it has issued.~~	

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
~~competent authorities of the other Contracting States and other registered assessing entities.~~		

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 AND ITS SAFE INTEGRATION INTO ITS ENVIRONMENT

1. The task of ensuring that the assessments according to this 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 request the vehicle (or vehicle type) to be admitted.

   Alternatively, a Contracting State may designate one or more permanent "designated bodies" to carry out the assessments of subsystems' conformity with the applicable notified national technical requirements; the Contracting State may decide to let the assessment of the subsystems safe integration in their environment be the task of a "designated body".

   A "designated body" must meet the provisions in chapter 1, section 1.3 and shall therefore be deemed assessing entity to carry out the assessments required by this chapter 4. In this case, the competent national authority shall forward the application received to the designated body/bodies.

   All competent national authorities, designated bodies 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.

   If a Contracting State has chosen to appoint a "designated body", this Contracting State is responsible for setting up and publishing the necessary procedure rules if they derogate from the provisions below. The Contracting State shall notify the "designated body" and any derogating procedure to the Secretary General.

   Member States shall draw up, for each subsystem, a list of the (national) technical rules in use for implementing the essential requirements and notify this list to the Commission — 2008/57/EC, Article 17

   …. On that occasion, Member States shall also designate the bodies responsible for carrying out, in the case of these technical regulations, the verification procedure referred to in Article 18.
   The Commission shall communicate this information to the Agency, which shall publish it.

2. This procedure is the one whereby it, under the responsibility of the national authority

   ….Member States shall take all appropriate steps to ensure that these subsystems — 2008/57/EC, Article

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU* [2] *ref.*
competent for technical admission of railway material or the "designated body" of a Contracting State, and based on an examination, is verified and attested that the technical design and manufactured subsystem meet the requirements of the relevant notified national technical requirements (cf. APTU Art. 12) that apply to it. Furthermore, this procedure includes a verification of the safe integration of the subsystem in its environment (see definition in point 1.2 k)). Verifications which demonstrate (also partly) the safe integration shall be taken into consideration and not be repeated. This procedure can only be applied when the assessment procedures of the module or combination of modules as specified in the applicable UTP(s) have been carried out with a positive result and evidenced through the certificates and reports prescribed in the modules used. The provisions of chapter 1 apply also to this procedure.	may be placed in service 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: – the technical compatibility of these subsystems with the system into which they are being integrated, – the safe integration of these subsystems in accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC.	15
3. **Application**		
3.1 The applicant entitled to apply according to chapter 1.2 point g) may lodge an application for a technical admission with the national authority competent for technical admission of subsystems in a Contracting State of his choice. The applicant might be different from the applicant which applied for assessments included in chapter 3. In order that the assessments and tests can be coordinated, thus saving time and reducing costs, the applicant may lodge this application for technical admission at the same time as application for assessment according to chapter 3 is lodged. [32]		
3.2 The application shall at least include: – 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 different from the applicant, – the assessing entities chosen for the assessments carried out according to the assessment modules referred to in chapter 3,		

[32] A parallel application is useful if one or more of the assessing entities in modules SB, SD, SF or SH1 is the same as the one in this procedure.

[33] See definition in section 1.2 e)

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

– a list of the modules used and the corresponding certificates, including annexed documentation, received,
– if a "Quality Management System" is applied, the "Quality management system approval" referred to in module SD or SH1,
– 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,
– additional technical documentation which shall make it possible to assess the subsystem's conformity with the notified national technical requirements [33] of the Contracting State where the application is lodged,

and, if not included in the documentation referred to in the fourth indent above

– the documentation provided through the modules of chapter 3 used.

If the assessing entity needs more documentation, (e.g. risk analysis and/or vehicle tests) in order to assess the subsystems conformity with applicable notified national technical requirements and its safe integration in its environment, the entity may in accordance with ATMF Article 6 § 4 request such documentation from the applicant; the request shall include a justification.

3.3 The authority that has received the application shall in the case of the subsystem being subject to ATMF Article 6 § 4 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 competent national authority or the "designated body" shall, either itself or by using one or more assessing entities of its choice – for example, if acceptable, one that has carried out the assessment of conformity with the UTP(s) – verify that the subsystem complies with the applicable notified national technical requirements of the Contracting State and that it is safely integrated in its environment.

4.2 If the authority or the "designated body" itself do not carry out the assessments, it may in

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

agreement with the applicant delegate this assessment task, or part of it, to another assessing entity.

4.3 The assessments of the subsystem's conformity with the applicable notified national technical requirements and of its safe integration in its environment shall be carried out by ***mutatis mutandis*** applying 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 in its environment".

~~– checking the existence and validity of the certificates (including annexed documents such as the Technical File) resulted from the assessment procedures included in chapter 3;~~

~~– assessing the adequacy of the technical design of the subsystem through examination of the technical documentation;~~

~~– examination and tests, if so justified, of the specimen (production type) referred to in module SB, representative of the production envisaged;~~

~~– examination of applied quality managements systems capability to ensure compliance also for national requirements;~~

~~analysis of any changes to the technical design or the quality managements systems.~~

~~4.2 The applicant shall, if necessary through contracts, ensure that the assessing entity is allowed access to the design, manufacture, inspection, testing and storage sites, and that it is provided with all necessary information.~~

~~Thus, the assessing entity may participate in the surveillance of quality management systems used as prescribed in the modules in chapter 3.~~

4.4 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 set up according to ATMF Article 13 shall be observed in all cases where assessments are carried out.

5. **Assessment report**

5.1 The assessing entity shall draw up an assessment report containing the findings

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
and conclusion of the assessments carried out. The assessment report shall be given to the applicant and to the national authority competent for technical admission of railway vehicles in the case when the authority is not the assessing entity itself. The assessment report 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 serie 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).		
5.2 If the subsystem does <u>not</u> satisfy the applicable notified national technical requirements, the assessing entity shall in its assessment report indicate this with a detailed reasoning, including which requirements have not been met and/or why a safe integration cannot be achieved.		
~~5. If the subsystem is subject to derogation from the applicable notified national technical requirements, this shall be indicated in the assesment report with information about which requirements are concerned by the derogation.~~		
~~6. The applicant shall inform the national authority competent for technical admission of railway vehicles of all modifications to the subsystem that may affect its conformity with the relevant national technical requirements and/or its safe integration in its environment. Such modifications shall require additional admission in the form of additional assessments.~~		
~~7. The applicant shall keep a copy of the assessment report set up according to point 4.5 and of the Technical Certificates, their annexes and additions together with all the technical documentation at the disposal of the national authorities, including investigation bodies, throughout the service life of the subsystem.~~		
6. The applicant's authorised representative may lodge the application referred to in point 3 and meet other obligations related to the applicant provided it is specified in the		

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

mandate.

[The text in chapter 4 has been limited to cover the assessment procedure, and the former text related to Technical Certificates has been deleted].

~~5.~~ ~~**Technical Certificates (Design Type Certificate and Certificate of Operation)**~~

~~5.1~~ ~~Where the subsystem according to the certificates and reports of the modules applied from chapter 3 meet the requirements of the UTP(s) and the assessments of this module proves that the subsystem can be safely integrated in its environment and that all other requirements, including those applicable national technical requirements of the Contracting State where the application has been lodged that apply to the subsystem concerned have been fulfilled, the competent national authority of that (first) Contracting State shall admit the subsystem.~~

~~5.2~~ ~~If the subsystem is a design type, the (first) admitting authority shall ensure that it is registered in the "Register of approved types" and issue a Design Type Certificate to the applicant. The assessed prototype shall be admitted through a Certificate of Operation, if the applicant so requests.~~

~~A design type of may cover several versions of the subsystem provided that the differences between the versions do not affect the applicable notified national technical requirements.~~

~~5.3~~ ~~Before the (first) admitting authority may issue the Certificate of Operation for a subsystem, it shall ensure that each subsystem produced is registered in the "National Vehicle Register" (NVR) including data of its keeper and Entity in Charge of Maintenance (ECM).~~

~~A Certificate of Operation may 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).~~

~~5.4~~ ~~If the admitted subsystem is subject to ATMF Article 6 § 3, it shall be indicated in the Certificate that it is admitted in **all** OTIF Contracting States.~~

~~5.5~~ ~~If the subsystem is subject to ATMF Article 6 § 4, the competent national authorities of~~

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
those other Contracting States which are also requested to admit the subsystem for their territory, shall submit the assessment report to the competent national authority of the (first admitting) Contracting State.		
If the conclusion of the assessment report is that the applicable notified national technical requirements of this other Contracting State have been complied with and that the subsystem can be safely integrated in its environment, the competent national authority of this other Contracting State shall admit the subsystem for its territory and in writing authorise the competent national authority of the "first" admitting Contracting State to include this additional admission of the subsystem in the Register of authorised types and note it in the Design Type Certificate and in the Certificates of Operation.		
These other Contracting States shall not issue separate Certificates.		
5.6 If the subsystem does not satisfy the applicable notified national technical requirements, the assessing entity shall in its assessment report indicate this with a detailed reasoning, including which requirements have not been met and/or why a safe integration cannot be achieved. The competent national authority shall in this case refuse to issue a Technical Certificate and shall inform the applicant accordingly with its justification.		
5.7 The certificates shall be drawn up following the uniform formats adopted by the Committee of Technical Experts according to ATMF Article 12.		
The certificates may have annexes attached, but they shall bear the same reference as the certificate.		
5.8 If the subsystem is subject to derogation from the applicable UTP(s) and/or applicable notified national technical requirements or if it is subject to specific case(s), this shall be indicated in the certificate with information about which provisions are concerned by the derogation and which specific case(s) is/are applied.		
6. The applicant shall inform the competent national authority that has issued the Certificate of all modifications to the approved subsystem that may affect its conformity with the requirements of the relevant national technical requirements, the safe integration or the conditions for the validity		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
~~of the certificate. Such modifications shall require additional admission in the form of an addition to the original Design Type Certificate.~~		
~~7.~~ ~~**Information**~~		
~~7.1~~ ~~The competent authority in the Contracting State where the application has first been lodged shall keep an updated register/list of the Technical Certificates (Design Type Certificates and Certificate of Operation) and any additions thereto which it has issued, refused, suspended, withdrawn or otherwise restricted.~~		
~~The register/list shall, as a minimum, for each certificate include the name of the applicant, the manufacturer, the assessing entity(ies), the identification (type and name) of the subsystem, the unique identification numbers of the subsystem(s) concerned, the validity, the type of document (issue/change, refusal, withdrawal, suspension, etc.) and the date and the reference number of the issuing document; the EIN harmonised document numbering system set out in Annex 3 shall be used for the reference.~~		
~~The Secretary General shall be informed of new entries and any other change to the register/list of the Technical Certificates and make the information public on the website of the Organisation.~~		
~~7.2~~ ~~The competent authorities of other Contracting States than those admitting and the Secretary General may from the (first) admitting authority require a copy of the Technical Certificate and/or additions thereto.~~		
~~Upon request, they may also obtain a copy of the technical documentation and the assessment report related to a subsystem.~~		
~~8.~~ ~~Documentation to be archived~~		
~~8.1~~ ~~The competent authority in the Contracting State where the application has first been lodged shall for each subsystem keep a copy of the assessment reports, of the admissions from other Contracting State(s) and of the Certificates, their annexes and additions, until the expiry of their validity.~~		
~~8.2~~ ~~The applicant shall keep a copy of the assessment report set up according to point 4.5 and of the Technical Certificates, their annexes and additions together with all the technical documentation at the disposal of the national authorities, including investiga-~~		

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.* [2]
	~~tion bodies, throughout the service life of the subsystem.~~	
~~9.~~	~~The applicant's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 4.2, 6 and 8.2 of this procedure provided it is specified in his mandate.~~	

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* [34]	*EU ref.* [35]
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 ~~[for use of the constituent?]~~ and must	
contain the following:		
	– the Directive references,	
– name and address of the manufacturer or its authorised representative esteblished within a Contracting State	~~or its authorised representative established within~~ the Community ~~(give trade name and full address; in the case of the authorised representative, also give the trade name of the manufacturer);~~	
(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 bodies involved in the procedure followed in respect of conformity or suitability for use	notified body or	
– date of examination certificate [36] 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.	
– indication of European Directives, other than the Interoperability Directive, which have been applied.		

34 Annex IV of Directive ~~2001/16/EC~~2008/57/EC

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

36 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 "DESIGN TYPE CERTIFICATE" AND OF THE "CERTIFICATE OF OPERATION" (FOR A SUBSYSTEM)

OTIF UTP	*Corresponding text in EU regulations* [37]	*EU ref.* [38]
DESIGN TYPE CERTIFICATE		
The Design Type Certificate shall	The EC type examination certificate shall contain:	
a)indicate the applicant by name and full address and the reference (number) of the application lodged;	a)name and address of the applicant,	
b)indicate the assessing entity/entities chosen by the applicant;	b)the conclusions of the examination(s),	
c)specify the designer and intended manufacturer(s) of the serial production of the railway vehicles based on this type of construction (including the manufacturer of the prototype assessed and tested);	c)the conditions (if any) for its validity and	
d)include the necessary data for identification of the approved type;	d)the necessary data for identification of the approved type.	
e)include a brief description of the subsystem;		
f)have the Technical File, including the Maintenance File and instructions for use, attached;		
g)if appropriate, specify the special operating limitations and conditions for the type of construction of a railway vehicle and for railway vehicles which correspond to this type of construction;		
h)include reference(s) to the evaluation report(s) produced during the assessment(s);		
i)if appropriate, specify all related Declarations (of Conformity and Suitability for use of interoperability constituents) issued;		
j)if appropriate, specify the certificate's conditions and period of validity;		
k)		
l)specify the issuing competent authority, date of issue and contain the signature of a person empowered to enter into commitments on behalf of that authority;		
m)if the construction is subject to ATMF Article 6 § 3, indicate that Certificates of Operation based on this Design Type Certificate shall permit operation in all Contracting States;		
n)if the construction is subject to ATMF Article 6 § 4, indicate those Contracting States for which Certificates of Operation based on this Design Type Certificate may permit operation.		

37 EU Assessment module document……

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

OTIF UTP	*Corresponding text in EU regulations* [37]	*EU ref.* [38]
CERTIFICATE OF OPERATION The Certificate of Operation shall contain the same information as the Design Type Certificate, see points a) – k) above. In addition it shall contain: o)the identification code(s) of the vehicle(s) covered by the certificate; p)information on the keeper of the railway vehicle(s) covered by the certificate on the day of its issue; q)information on the Entity in Charge of Maintenance (ECM) of the railway vehicle(s) covered by the certificate on the day of its issue; r)information that the Certificate of Operation permits operation in all Contracting States in the case where the vehicle(s) is/are subject to ATMF Article 6 § 3; s)information on those Contracting States for which the Certificate of Operation permits operation in the case where the vehicle(s) is/are subject to ATMF Article 6 § 4. If the Certificate of Operation covers a group of individual vehicles of the same type, the information required, which may vary, shall be specified for each of the vehicles of the group and the Technical File attached shall contain a list with identifiable documentation concerning the tests carried out on each vehicle.	Note: A specification of the content of the EC authorisation of placing into service has not been found in EU regulations.	

ANNEX 3

STRUCTURE AND CONTENT OF THE "EIN" NUMBERING SYSTEM

Code for the harmonised numbering system, called European Identification Number (EIN), for Safety Certificates and other documents

Example:

I	T	5	1	2	0	0	6	0	0	0	5
Country code (2 letters)		Type of document (2 digits)		Issue year (4 digits)				Counter (4 digits)			
Field 1		Field 2		Field 3				Field 4			

FIELD 1 - Country code (2 letters)

Table 1.

COUNTRY	CODE	
Albania	AL	41
Algeria	DZ	92
Armenia	*AM*	*58*
Austria	AT	81
Azerbaijan	*AZ*	*57*
Belarus	*BY*	*21*
Belgium	BE	88
Bosnia Herzegovina#	BA	(50)
""		(44)
Bulgaria	BG	52
Croatia	HR	78
Cyprus	CY	-
Czech Republic	CZ	54
Denmark	DK	86
Egypt	*EG*	*90*
Estonia	EE	26
Finland	FI	10
France	FR	87
Georgia	*GE*	*28*
Germany	DE	80
Greece	EL*	73
Hungary	HU	55

COUNTRY	CODE	
Iceland	*IS*	-
Iran	IR	96
Iraq	IQ	99
Ireland	IE	60
Israel	*IL*	*95*
Italy	IT	83
Japan	*JP*	*42*
Kazakhstan	*KZ*	*27*
Kyrgyzstan	*KG*	*59*
Latvia	LV	25
Lebanon	LB	98
Liechtenstein	LI	-
Lithuania	LT	24
Luxembourg	LU	82
FYR Macedonia	MK	65
Malta	*MT*	-
Moldova	*MD*	*23*
Monaco	MC	-
Mongolia	*MN*	*31*
Montenegro	ME	62
Morocco	MA	93
Netherlands	NL	84

COUNTRY	CODE	
North Korea	*KP*	*30*
Norway	NO	76
Poland	PL	51
Portugal	PT	94
Romania	RO	53
Russia	RU	20
Serbia	RS	72
Slovak Republic	SK	56
Slovenia	SI	79
South Korea	*KR*	*61*
Spain	ES	71
Sweden	SE	74
Switzerland	CH	85
Syria	SY	97
Tajikistan	TJ	66
Tunisia	TN	91
Turkey	TR	75
Turkmenistan	*TM*	*67*
Ukraine	UA	22
United Kingdom	UK*	70
Uzbekistan	*UZ*	*29*
Vietnam	*VN*	*32*

* Not according to ISO 3166 (2 letter code), but is the European Community abbreviation
# Bosnia-Herzegovina is a federal state and uses 2 railway codes
A country indicated in italics is not a member of OTIF

FIELD 2 – Type of document (2 digit number)

~~Two digits allow the type of document to be identified:~~

- ~~the first digit identifies the general classification of the document;~~
- ~~the second digit specifies the subtype of document.~~

~~If other codes are needed, this numbering system can be extended. The following is the proposed list of known, possible combinations of two digit numbers extended by the proposal for authorisation for placing in service of vehicles and the OTIF technical certificates:~~

~~Fields in blue are for EU Members States~~

~~Number combination for field 2~~	~~Document Type~~	~~Subtype of document~~
~~[0 1]~~	~~Licences~~	~~Licences for RUs~~
~~[0 x]~~	~~Licences~~	~~Others~~
~~[1 1]~~	~~Safety Certificate~~	~~Part A~~
~~[1 2]~~	~~Safety Certificate~~	~~Part B~~
~~[1 x]~~	~~Safety Certificate~~	~~Others~~
~~[2 1]~~	~~Safety Authorisation~~	~~Part A~~
~~[2 2]~~	~~Safety Authorisation~~	~~Part B~~
~~[2 x]~~	~~Safety Authorisation~~	~~Others~~
~~[3 x]~~	~~Reserved~~	~~e.g. maintenance for rolling stock, for infrastructure or others~~
~~[4 x]~~	~~reserved for assessing bodies~~	~~e.g. different kinds of assessing bodies (e.g. Notified Bodies)~~
~~[5 1] and [5 5]*~~	~~Authorisation for placing in service or Design Type Certificate or Certificate of Operation~~	~~Tractive rolling stock~~
~~[5 2] and [5 6]*~~	~~Authorisation for placing in service or Design Type Certificate or Certificate of Operation~~	~~Hauled passenger vehicles~~
~~[5 3] and [5 7]*~~	~~Authorisation for placing in service or Design Type Certificate or Certificate of Operation~~	~~Wagons~~
~~[5 4] and [5 8]*~~	~~Authorisation for placing in service or Design Type Certificate or Certificate of Operation~~	~~Special vehicles~~
~~[6 x] … [9 x]~~	~~Reserved (4 document types)~~	~~Reserved (10 subtypes each)~~

~~FIELD 3 – Issue year (4 digit number)~~

~~This field indicates the year (in the specified format yyyy, i.e. 4 digits) in which the authorisation/admission was issued.~~

~~FIELD 4 – Counter~~

~~The counter is a progressive number to be increased by one unit each time a document is issued, regardless of whether it is a new, renewed or updated/amended authorisation. Even in the case when a certificate is revoked or an authorisation is suspended, the number to which it refers cannot be used again.~~

~~Every year the counter shall restart from zero.~~

~~(*) If the 4 digits foreseen for field 4 'Counter' are fully used within a year, the first two digits of field 2 will move respectively from:~~

~~[5 1] to [5 5] for tractive rolling stock,~~

~~[5 2] to [5 6] for hauled passenger vehicles,~~

~~[5 3] to [5 7] for wagons,~~

~~[5 4] to [5 8] for special vehicles.~~

ANNEX 2

CONTENT OF THE "DECLARATION OF VERIFICATION" OF SUBSYSTEMS

OTIF UTP	*Corresponding text in EU regulations* [39]	*EU ref.* [40]
The 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 Declaration of verification,	'EC' declaration,	
identity of the signatory.		
– indication of European Directives, other than the Interoperability Directive, which have been applied.		

[39] Annex V of Directive 2008/57/EC

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

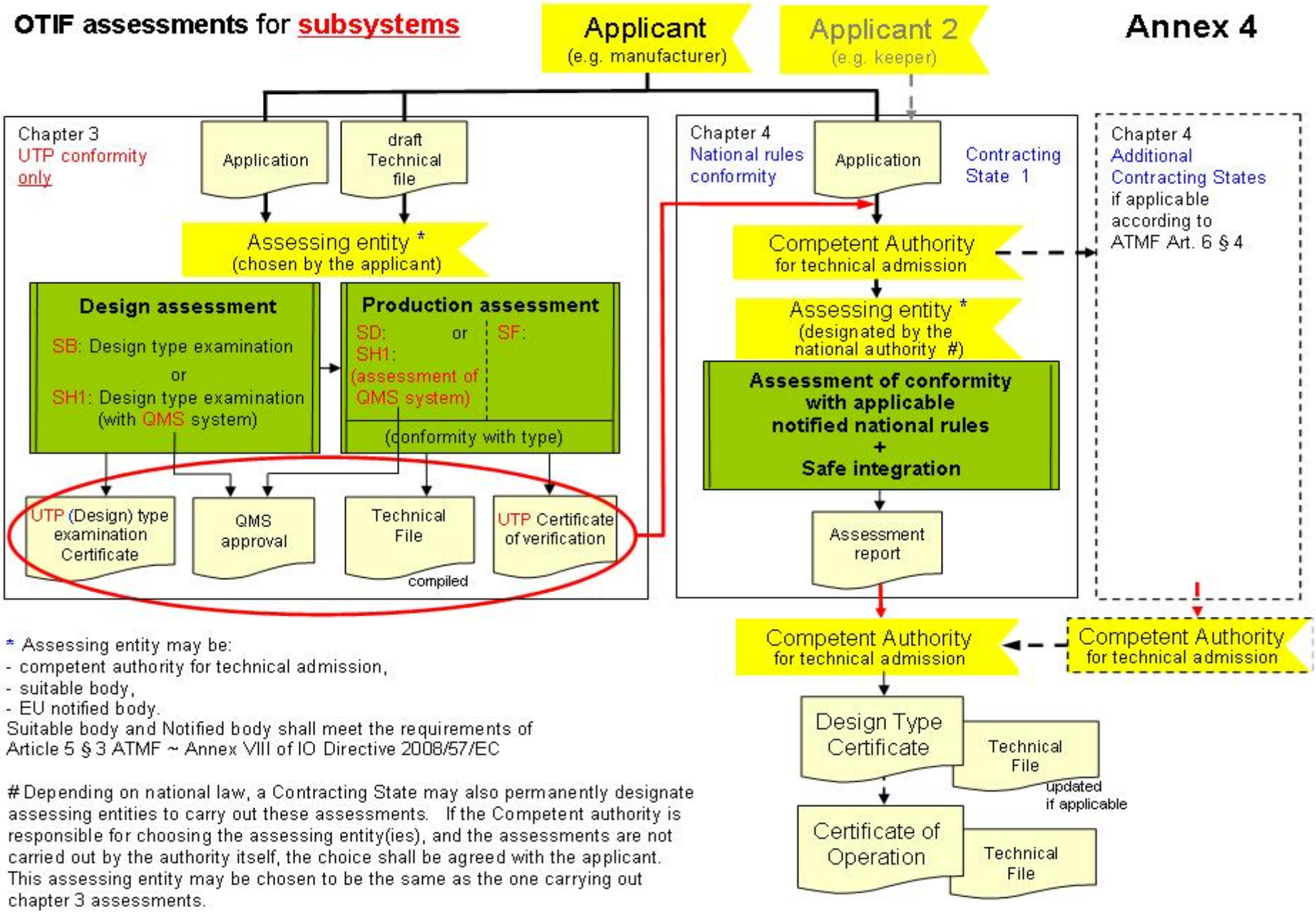
ANNEX 3

EQUIVALENCE BETWEEN OTIF AND EU CERTIFICATES AND OTHER EVIDENCING DOCUMENTS

The table below show the documents produced through the assessment Modules of chapter 2 and 3, although having different titles according to the regulations under which they are produced, have the same purpose, content and value.

These documents shall be considered equivalent and mutually recognised by all admitting authorities, assessing entities (including NoBos) of OTIF Contracting States and other EU Member States - in accordance with the principles laid down in ATMF Article 6a.

OTIF document		*Corresponding EU document*
Module(s)	**Name of document**	**Name of document**
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~~, SB~~	Type examination certificate	EC-Type examination certificate
CD, CH, CH1, SD, SH1	"quality management system approval"	"quality management system approval"
CH1~~, SH1~~	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
SB,	(no parallel)	EC declaration of intermediate statements of verification (ISV)
SB	evaluation report	evaluation report
SB, SD, SF, SH1	Technical File	Technical File
SB	UTP Type-examination certificate	EC Type-examination certificate
SB	examination report (if no UTP Type-examination certificate can be issued)	(no parallel)
SH1	UTP Design examination certificate	EC design examination certificate
SD, SH1	Evaluation report	(no parallel)
SD, SF, SH1	UTP Certificate of verification	EC certificate of verification
SD, SF, SH1	(no parallel)	intermediate statements of verification (ISV)
SD, SF, SH1	~~(no parallel)~~UTP Declaration of verification	EC declaration of verification



* 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.