

Date: 01.10.2012

### APTU Uniform Rules (Appendix F to COTIF 1999) Uniform Technical Prescriptions (UTP) General Provisions –

## ASSESSMENT PROCEDURES (MODULES)

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

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

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



### GENERAL PROVISIONS ASSESSMENT PROCEDURES (MODULES)

Status: IN FORCE

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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

With reference to Article 8 § 8 of Appendix F (APTU) to the Convention, the following regulations shall apply:

Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### 0. EQUIVALENCE

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

See conversion table in Annex 3.

### 1. GENERAL PROVISIONS

### 1.1 SCOPE AND CONTENT OF THIS UTP

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

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

### INTEROPERABILITY CONSTITUENTS

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

### Chapter 2:

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

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

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> If no EU reference is indicated, it means that the chapter/section number is the same as in the OTIF text.

<sup>&</sup>lt;sup>3</sup> Chapter 4 needs no declaration of equivalence as the chapter concerns assessment of a Contracting State's national requirements/rules.

<sup>&</sup>lt;sup>4</sup> This also includes UTP Noise as those UTP apply to (conventional) rolling stock.

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### **GENERAL PROVISIONS ASSESSMENT PROCEDURES (MODULES)**

Ref.: A 94-01D/3.2011

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OTIF UTP		Corresponding text in EU regulations <sup>1</sup>	EU ref. <sup>2</sup>
	SUBSYSTEMS		2011/18/EC Annex VI,
	<ul> <li>The subsystem, or certain parts of the subsystem at each of the following stages:</li> <li>overall design,</li> <li>production: construction, including, in particular final testing.</li> </ul>	articular, civil-engineering activities, manu-	2.2.3
	The assessment of a subsystem's confor- mity with the applicable regulations falls into three parts:		
	Chapter 3 (part 1): The assessment of conformity with the provisions included in applicable UTPs; for this task the applicant may choose any authorised "assessing entity" (see defini- tion).	(See the provisions of Article 18 of 2008/57/EC).	
	Chapter 4 (part 2):	(See the provisions of the Articles 15 and 17 of 2008/57/EC).	
	The assessment of conformity with the applicable national technical requirements notified in accordance with APTU Article 12, including, where appropriate, open points and specific cases, as they require the application of technical rules not included in the relevant UTP(s).	17 01 2008/37/EC).	
	Chapter 5 (part 3):		
	The assessment of the safe integration of a subsystem into its environment.		
	Guidelines		
	(Not part of the legal provisions).		
	<b>Annex 4:</b> A flow diagram of the assessment procedures (modules) to be carried out for a subsystem.		
	<b>Annex 5:</b> Assessment of the safe integration of a subsystem into its environment.		
1.2	DEFINITIONS AND TERMINOLOGY		
	The definitions included in Article 2 of ATMF and APTU are valid for this UTP.		
	Furthermore,		
	<ul> <li>a) RID means the "Regulation concerning the International Carriage of Dangerous Goods by Rail" (RID – Appendix C to the Convention).</li> </ul>		

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OTIF UTP				Correspondina te	ext in EU regulations	s <sup>1</sup> E	U ref. <sup>2</sup>
	b)	which with / of Te	alidated Standard <sup>* 5</sup> is a standard has been validated in accordance APTU Article 5 by the Committee echnical Experts and published as on the OTIF website;			_	
	c)	"asse GEN-	essing entity" see definition in UTP E.				
	d)	"Elem nition opera	operability Constituent" (IC) is an nent of construction" (see the defi- in ATMF Article 2 g)). The Inter- ability Constituents are listed in oter 5 of) the UTPs.	(same defini Article 2 (f))	tion of IC in	2008/57/EC	
	e)	Secre	onal technical requirements" is those requirements of which the etary General has been informed which have been made public in dance with Article 12 of APTU.				
	f)		nnical admission" and "Technical icate", see ATMF Article 2 cc) and				
	g)	"Appli	icant" for assessment:	(see Article 18	8(1) of Directive	2008/57/EC).	
		techn sessn regula sessn be on	<i>ystem:</i> In ATMF the procedures for ical admission include the as- nents of conformity with applicable ations. Thus, the applicant for as- nent(s) of a subsystem may only be of those indicated in ATMF Arti- 0 § 2, which are:				
		1. the	e manufacturer,				
		2. a i	rail transport undertaking,				
		3. the	e keeper of the vehicle,				
		4. the	e owner of the vehicle,				
		5. the	e infrastructure manager.				
		ments not s sessn stitue cant the in autho in the	operability constituent: As assess- s of ICs are voluntary, ATMF does pecify who may apply for an as- nent of an interoperability con- nt. In the IC modules the appli- may only be the manufacturer of nteroperability constituent or his prised representative as indicated modules.				
	h)		orised representative" means any na htracting State	atural or legal p the Union	person establish		10/713/ C Art 3, 12.

<sup>&</sup>lt;sup>5</sup> 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.

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OTIF UTP				written mandate fro relation to specified	m a manufactu	ext in EU regulations urer or a contrac		EU ref. <sup>2</sup>
	i)		racting entity" definition in AT	MF Article 2 point	see Direc	tive 2008/57/EC	CArticle 2 (r).	2008/57/EC Art 2 (r)
	j)	has a		ed or manufactured				2008/57/EC Art 3, 11.
	k)	(ISV) asses tion c for ce	" means a state ssing entity whi of compliance w ertain stages of a	nent of verification ment issued by the ch covers verifica- ith the UTP(s) <u>only</u> an assessment pro- s of the subsystem.	diate stat certain st cedure or tem. In su	ed body may is ement verificati ages of the ver certain parts o uch a case, the p nex VI shall appl	ions to cover rification pro- of the subsys- procedure set	2008/57/EC Art 18, 4
1.3			IONS RELA G ENTITIES	TING TO AS-				
1.3.1	upo ing Bos ing	date a entitio s) on t	list of notified es (including a he Organisation area of respons	shall publish and authorised assess- uthorities and No- 's website, indicat- sibility (professional	Official Journalist of bodies	ssion shall pu al of the Europe , their identifica responsibility, a ed.	ean Union the tion numbers	2008/57/EC, Art. 28 (1)
1.3.2	by EU pro crit the call ere ten	a Cor Directovisions eria se body led Na ed as a oce to c	ntracting State i tive 2008/57/EC s of that Directive t out in Annex is registered in t ando database <sup>6</sup> a "Suitable Bod	) notified to the EU in accordance with C, thus meeting the ve, in particular the VIII, and insofar as the EU's public, so- d, shall be consid- y" with the compe- ments and shall be oned above.				
1.3.3	sha an whi AT It s Coi and Coi	all with assess ich no MF Art hall for mmitte d the o	ticle 5 § 2 and/o rthwith inform th ee of Technical E	e criteria referred to r this UTP GEN-D. e				2008/57/EC, Art. 28 (3)
1.3.4	lf a aut me cor § 2	a Cont hority) nts th nply <sup>7</sup> 2 or w	has evidence at an assessin with the criteria ith this UTP G	competent national or reasoned argu- ng entity does not of ATMF Article 5 EN-D, the infringe- F Article 5 § 7 shall	sion conside another Mem criteria refer Commission	r that a body ber State does red to in Ann shall consult	v notified by not meet the nex VIII, the the parties	2008/57/EC, Art. 28 (4)

http://ec.europa.eu/enterprise/newapproach/nando
 This includes if an assessing entity carries out asses

<sup>&</sup>lt;sup>7</sup> This includes if an assessing entity carries out assessments which do not fall within its published area of responsibility (professional competence).

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OTIF UTP	be initiated. In this case, all Contracting States shall be informed without delay.	Corresponding text in EU regulations <sup>1</sup> the latter Member State of any changes that are necessary for the notified body to retain the status conferred upon it.	EU ref. <sup>2</sup>
1.3.5	The Committee of Technical Experts shall set up an assessing entity coordination group which shall discuss any matter relat- ing to the application of the procedures for assessing conformity or suitability for the use of interoperability constituents (chapter 2) and the procedures for assessing con- formity of subsystems with the applicable UTP(s) (chapter 3).	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 verifi-	2008/57/EC, Art. 28 (5)
		The Commission and the observers shall inform the committee referred to in Article 29 of the work carried out in the frame- work of the Coordination Group. The Commission, when appropriate, will propose the measures needed to remedy the problems. Where necessary, coordina- tion of the notified bodies shall be imple- mented in accordance with Article 30(4).	

### 1.4 NON-COMPLIANCE WITH ESSENTIAL REQUIREMENTS

### 1.4.1 INTEROPERABILITY CONSTITUENTS

1.4.1.1	According to Article 3 § 3 of ATMF, the subsequent ATMF Articles apply "mutatis mutandis" to "Elements of construction", i.e. Interoperability Constituents. Therefore, ATMF Article 10a concerning suspensions and withdrawals shall apply in an adapted form as below:		
1.4.1.2	Where a Contracting State finds that an interoperability constituent cover Declaration of conformity or a Declaration of suitability for use is unlikely, when used as intended, to meet necessary steps to restrict its field of applicat	EC declaration of conformity or suitability the essential requirements, it shall take all	2008/57/EC Art 14 <sup>8</sup> ↓↓
	<ul> <li>The Contracting State shall inform the Secretary General without delay of the measures taken and give the reasons failure to conform is due to:</li> <li>(a) failure to meet the essential requirements</li> <li>(b) incorrect application of UTP, Validated Standards or other CO-TIF regulations (e.g. RID)</li> </ul>	the Commission for its decision, stating in particular whether s;	

<sup>&</sup>lt;sup>8</sup> EU Interoperability Directive 2008/57/EC, published in the EU Official Journal L191 on 18.07.2008.

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OTIF UTP	regula is reli (c) inade	e application of s ations ed upon; equacy of or Validated Star		specificat	ext in EU regulations ions specifications.	5 <sup>1</sup>	EU ref. <sup>2</sup>
1.4.1.3.	shall constation, the Secretary establishe he shall imm Contracti	e / General es that the meas nediately inform t ng State aken the initiativ	-	Commission  it  Member State	Where, following	g that consul-	
	Secretary establishe he shall imm Contracti that has t	es that the meas nediately inform t ng State aken the initiativ	ure is unjustified, he e and the manufact	or his autho lished within t	rised represen he Community t	hereof.	
	UTP or V	alidated Standar dure set out in ticle 8a		European spe			
1.4.1.4	Declaration declaration fails to cont the Cont takes play shall take shall infor Secretary ing State	on of conformity on of conformity) omply with the re racting State w ce appropriate me rm the / General and the s thereof. The	constituent bearing (including the EC gulations applicable here manufacture asures against who he other Contract- Secretary General pean Commission.	EC declaratio to it, the competen omsoever has o Commission a thereof.	t Member State drawn up the de	claration and	
	Contracti informed immediat restrict th	ng State, the 0 by the Secret ely take all ne ne field of applio y constituent in	not take place in a Contracting States ary General shall ecessary steps to cation of the inter- question or shall	Member Stat steps to restr the market of ent in questi withdrawn fro	e shall take al ict or prohibit th the interoperat on, or to ensu	ne placing on bility constitu- ure that it is n accordance	2008/57/EC Ar 13 (5) b)
	shall ens		d the European	The Commiss			

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

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

### 1.4.2 SUBSYSTEMS

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

### 1.5 LANGUAGE

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

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

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

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

**Declarations of verifications** (if issued) for a subsystem shall be written in the same  $\frac{2008/57}{EC, Annex V}$  language as the technical file

### 1.6 USE OF THE MODULES

1.6.1 The assessment modules included in chapters 2 and 3 shall be combined according to the specification in the applicable UTP. Modules CA1, CA2 or CH may be used only in the case of products placed on the see footnote 9 market, and therefore developed, before the entry into force of the UTP in question, this TSI. provided that the manufacturer demonstrates to the assessing entity NoBo that design review and type examination were performed for previous applications under comparable conditions, and are in conformity with the requirements of the UTP in question; this TSI; this demonstration shall be documented, and is considered as providing the same level of proof as module CB or design examination according to module CH1.

 $<sup>^{9}</sup>$  Preliminary draft 1.0 of the revised TSI WAG, section 6.1.2 note  $^{\ast}$ 

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OTIF UTP

Corresponding text in EU regulations <sup>1</sup>

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 <u>not</u> mandatory in COTIF. Such assessments may be carried out on a voluntary basis, in which case the provisions in this UTP shall apply.

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

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

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### 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

is in accordance with the

UTP

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

TSI

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, subassemblies, 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" <sup>10</sup> and/or other harmonised standards and/or other relevant technical specifications which relevant technical specifications the have been 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 ÛTP 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

<sup>&</sup>lt;sup>10</sup> See definition in section 1.2 b).

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OTIF UTP	□ test r	eports.		Corresponding te	ext in EU regulations	3 <sup>1</sup>	EU ref. <sup>2</sup>
3.	Manufact	uring					
	and its m cal docur UTP	onitoring ensure	ake all measures ne e compliance of the ed to in point 2 and v	interoperability	constituents wi		
4.	Declarati	on of conformity		EC declaratio	n of conformity		
4.1	Declaration for the in-	on of conformity teroperability co posal of the nati	raw up a written nstituent and keep i ional authorities for	t together with			
	been mai Declarati	nufactured. The on of conformity	iod, for 10 years af	EC declaratio	n of conformity		
		on of conformity	o the relevant autho		n of conformity uest.		
4.2	shall a) meet 1 to th b) in ca consti and if of EU than tions e.g. e that	his UTP, and ases where the tuent is intended the constituent directives cover those covered (including the environmental p the interopera the requiremen	ts set out in Annex he interoperability d for the EU market is also the subject ering other aspects by COTIF regula- applicable UTPs) ollution, also state ibility constituents ts of those EU di-	shall meet t 13(3) and po tive 2008/57/I			
5.	Authorise	ed representative	Э				

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.

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### 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

m 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, subassemblies, 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,

"Validated Standards" <sup>11</sup> and/or other relevant technical specifications which	
applied in full or in part, and description	ns of the solutions adopted to meet the re-
quirements of the	
ÚTP	TSI
where those	
Validated Standards	harmonised standards
have not been applied. In the event of pa	
	harmonised standards,
the technical documentation shall specify	
	relevant technical specifications which have been applied in full or in part, and description quirements of the UTP where those Validated Standards have not been applied. In the event of pa Validated Standards,

<sup>&</sup>lt;sup>11</sup> See section 1.2 b).

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3.	Manufact	uring				
	and its m	onitoring ensure nentation referre	ike all measures ne compliance of the d to in point 2 and	interoperability	constituents wi	
4.	Product c	checks				
	aspects of	of the interopera	uct manufactured, bility constituent sh ed in the technical	nall be carried	out in order to	verify confor-
	in-house accredita where ma or under an asses	body accredite	of	accredited in-	house body	
5.		e of conformity		EC Certificate	e of conformity	
0.	The asse cate of co	essing entity sha onformity	all issue a Certifi- tions and tests carr	The notified Certificate of	body shall is	sue an EC
	Certificate		eep the v the national autho		e of conformity priod defined in t	he relevant
	UTP does not		od, for 10 years at	TSI fter the last inf	teroperability co	nstituent has
6.	Declaratio	on of conformity		EC declaratio	n of conformity	
6.1	Declaration for the interview.	posal of the natio	aw up a written nstituent and keep onal authorities for	it together with		
	been mar Declaratio	nufactured. The on of conformity	od, for 10 years at ability constituent f	EC declaratio	n of conformity	
		on of conformity	o the relevant autho	-	n of conformity uest.	
6.2	The					

<sup>&</sup>lt;sup>12</sup> See section 1.2 b).

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OTIF UTP	shall a) meet 1 to th b) in ca consti and if of EU than tions e.g. e that	is UTP, and ases where the tuent is intended the constituent directives cover those covered (including the environmental per the interopera the requirement	s set out in Annex ne interoperability d for the EU market is also the subject ring other aspects by COTIF regula- applicable UTPs) ollution, also state bility constituents ts of those EU di-	EC declaratio shall meet f 13(3) and po tive 2008/57/I	ext in EU regulations n of conformity the requiremen bint 3 of Annex EC.	ts of Article

### 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.

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### 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

n 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
	4	

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, subassemblies, 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" <sup>13</sup> and/or other harmonised standards and/or other relerelevant technical specifications which vant technical specifications the referhave been ences 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 harmonised standards, Validated Standards,

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

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OTIF UTP	result		ntation shall specify ulations made, exar	the parts which	•	
3.	Manufact	uring				
	and its m	onitoring ensure nentation referre	ake all measures ne compliance of the ed to in point 2 and v	interoperability	constituents wit	
4.	Product c	hecks				
4.1	in-house accredita where the by the res an assess	body accredite tion organisation e manufacture ta sponsibility of sing entity y the manufactu	facturer, either an d by the national on in the State ikes place or irer, shall carry out	a notified bod	у	carried out at
4.2	take all		resent his products ssary in order tha produced.			
4.3	neous lot ents in a out to ens tion and t UTP(s)	s. A random sar sample shall be sure the product he requirements	uents shall be avail mple shall be drawr e individually exam conformity with the s of the ermine whether the	n from each lot ined and appro type described	t. All interoperab opriate tests sha d in the technica	oility constitu- all be carried
5.		e of conformity			e of conformity	
	The asse cate of co	essing entity sha onformity	all issue a Certifi- tions and tests carri	The notified Certificate of	body shall is	sue an EC
	Certificate available UTP and when UTP does not	e the define this peri		TSI	eriod defined in t	
6		nufactured.		EC dealeration	n of conformity.	
6.		on of conformity		LC declaratio	n of conformity	
6.1	Declaration for the intra at the dis UTP and, whe UTP	posal of the nation	nstituent and keep i onal authorities for	t together with the period defin  TSI  TSI	ned in the releva	nt
		define this peri nufactured. The	od, for 10 years af	ter the last int	eroperability co	nstituent has

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OTIF UTP		on of conformity	rability constituent f	EC declaratio	ext in EU regulations n of conformity been drawn up.	
		on of conformity	o the relevant autho		n of conformity uest.	
6.2	shall a) meet 1 to th b) in ca consti and if of EU than t tions e.g. e that	is UTP, and uses where the tuent is intended the constituent directives cover hose covered (including the nvironmental per the interoperation the requirement	s set out in Annex ne interoperability d for the EU market is also the subject ring other aspects by COTIF regula- applicable UTPs) ollution, also state bility constituents ts of those EU di-	shall meet t 13(3) and po tive 2008/57/B	n of conformity the requiremen bint 3 of Annex 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.

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OTIF UTP					Corresponding t	ext in EU regulations	EU ref. <sup>2</sup>
MODU	LE	CB.	ΤΥΡΕ ΕΧΑ	MINATIONS	EC-TYPE E	EXAMINATIO	N
1.	is t an exa tha the	he par asses amines t the t	sing entity the technical d	esign of an interope of the interoperab	a notified boc erability consti ility constituer	ly tuent and verifie	uirements of
	tha	t apply	y to it.		(10)		
2.			e examination arried out in eith	er of the following n	EC-type exar	nination	
				ecimen, representa tuent (production ty		roduction envis	aged, of the
		ent th ferred envis	nrough examinat d to in point 3, pl aged, of one or	lequacy of the tech ion of the technical lus examination of s more critical parts of and design type),	documentatior	n and supporting presentative of th	evidence re- ne production
		ent th	nrough examinat	lequacy of the tech ion of the technical ithout examination o	documentatior	n and supporting	
3.	typ		nination with an	dge an application f assessing entity		nination with a n	otified body
	Th	e appli	cation shall inclu	ıde:			
		autho	prised representa	ss of the manufactu ative, his name and	address as we	ell,	
			ten declaration t ssing entity,	hat the same applic	ation has not notified b	-	n any other
			ss the interopera	ntation. The technic ability constituent's of			
		UTP.			TSI.		
		as fa opera tain, r	r as relevant for ation of the inter- wherever applica	entation shall spec r the assessment, t operability constitue able, at least the foll	he design, ma ent. The techni owing elemen	anufacture, mair ical documentati ts:	tenance and
			•	tion of the interoper	•		componente
		S	ub-assemblies, o				
		ir	ngs and scheme	explanations neces s and of the operati eroperability constit	ion (including		
		n		gration of the intero bly, assembly, subs			
			list of the				

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OTIF UTP	r	/alidated Standards <sup>14</sup> and/or other elevant technical specifications /hich have been	harmo other tions the been	at in EU regulations nised standa relevant technic he references of published in al of the Europe	rds and/or cal specifica- of which have the <i>Official</i>
	rr L W V h V th C	pplied in full or in part, and descrip equirements of the JTP where those ave not been applied. In the event of alidated Standards, ne technical documentation shall spe esults of design calculations made, e	otions of the so TSI harmo of partly applied harmo ecify the parts w	lutions adopted nised standards nised standards vhich have beer	I to meet the S s, n applied,
	the s asses may	est reports. pecimens representative of the prod ssing entity request further specimens if needed supporting evidence for the adequa	notified bo for carrying ou	dy t the test progra	
	supp when Valid and/c denc priate	orting evidence shall mention any do e the relevant ated Standards or technical specifications have not e shall include, where necessary, the a laboratory of the manufacturer, or under his responsibility.	bournents that h harmonise t been applied he results of tes	ave been used d standards in full. The su sts carried out b	, in particular pporting evi- by the appro-
4.		essing entity shall:	The notified bo	ody shall:	
4.1	examine	nteroperability constituent: the technical documentation and su chnical design of the interoperabilit			
	For the s	pecimen(s):			
4.2	of the UTP and the t in accord Validated and/or te	t the specimen(s) have been manuf echnical documentation, and identif ance with the applicable provisions Standards echnical specifications, as well as pplying the relevant provisions of the	TSI fy the elements of the relevant harmonised sta the elements	which have be andards	en designed
4.3	whether I UTP	t appropriate examinations and te requirements of the en applied correctly;	ests, or have t  TSI	hem carried o	ut, to check
4.4	whether, Validated	t appropriate examinations and te where the manufacturer has choser I Standards chnical specifications, these have be	to apply the so harmonised sta	olutions in the re andards	
4.5	carry out	t appropriate examinations and te	ests, or have t	hem carried o	ut, to check

<sup>&</sup>lt;sup>14</sup> See section 1.2 b)

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OTIF UTP	Validated and/or te	Standards chnical specifica	ons in the relevant ations have not be presponding require	harmonised s en applied, th		
4.6	agree wit carried ou		urer on a location	where the ex	aminations and	tests will be
5.	shall drav	ssing entity w up an evaluati : 4 and their outo	on report that reco	The notified b rds the activition		accordance
	authority assessme the asses	that has author ents (cf. sectior ssing entity ase the content	bligations vis-à vis t ised it to perform 1.2 c) and 1.3), of that report, in fu	the notifying a		
6.	UTP that apply assessing nation ce to the ma turer, the	y to the interoper g entity shall iss rtificate nufacturer. The conclusions of	e requirements of th rability constituent c sue a Type exami- certificate shall con the examination, th ication of the appro-	TSI oncerned, the notified body examination of tain the name e conditions (	certificate and address of t	the manufac-
	The certif	icate may have	one or more annexe	es attached.		
			nexes shall contain nstituents with the e			w the confor-
	UTP, the shall refus A Type ex	assessing entity se to issue xamination certif	satisfy the requirem , icate cant accordingly, giv	TSI, the notifi an EC-Type e	examination certi	
7.	The manu assessing that holds Type exa of all mod erability o UTP	ufacturer shall in g entity the technical de mination certifica difications to the constituent with t	form the ocumentation relatir ate approved type that he requirements of	notified body ng to the EC-Type exai at may affect t the TSI	mination certifica he conformity of	ate f the interop-
	approval		addition to the orig	inal	mination certifica	
	Only thos be perform		and tests that are r	elevant and ne	ecessary to the c	hanges shall
8.	competer competer which has ments (ct Type-exa and/or an	nt authority, it nt authority in the s authorised it t f. sections 1.2 of mination certifica	eto which it has iss	ing authoritie examination o	es concerning certificates	the EC-type

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OTIF UTP			nd/or any additions	its notifying a			EU ref. <sup>2</sup>
	Each assessing entity shall ensure that the other assessing entities are informed of the 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 refused.						
	States an may upor Type exa	cretary General d the other asse n request, obtain mination certifica ditions thereto.	essing entities a copy of the	The Commission, the Member States and the other notified bodies EC-Type examination certificate.			
	States ma	etary General an ay also similarly copy of the techr	nd the Contracting	may			
	shall keep Type exa its annex		ate, s, including the doc dity of the certificate	umentation sul	mination certifica		
9.	Type exa its annex the nation UTP and when UTP does not	mination certifica es and additions nal authorities fo e the	s together with the r the period defined	technical docu in the relevan  TSI  TSI	t	e disposal of	
10.			orised representativ	ve may lodge t	the application i	referred to in	

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.

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OTIF UTP				Corresponding t	ext in EU regulations	<b>;</b> <sup>1</sup>	EU ref. <sup>2</sup>
MODUL		CONFORMIT CONTROL	Υ ΤΟ ΤΥΡΕ ΒΑ	SED ON IN	TERNAL PRO	DUCTION	
1.	assessme points 2 a bility cons Type exa and satis	ent procedure v and 3, and ensu stituents concerr mination certifica fy the requireme Fechnical Prescr	nts of the	acturer fulfils n his sole resp y with the type  EC-Type exa	the obligations consibility that th	laid down in e interopera- e ate.	
2							
2.	and its n proved ty Type exa	ufacturer shall ta nonitoring ensur pe described in mination certifica the requirements	ate	e interoperabi		with the ap-	
3.		on of conformity		EC declaratio	on of conformity		
3.1	The man Declaration for the int at the dis UTP and, whe UTP does not been man Declaration	ufacturer shall dr on of conformity teroperability cor posal of the nation re the define this perinufactured. The on of conformity	nstituent and keep i onal authorities for od, for 10 years af	EC declaratic t together with the period defi TSI TSI ter the last in	on of conformity the technical do ned in the releva teroperability co on of conformity	ant nstituent has	
		on of conformity	o the relevant autho		on of conformity juest.		
4.2	shall a) meet 1 to th b) in ca consti and if of EU than tions e.g. e that	is UTP, and ases where the tuent is intended the constituent directives covered (including the environmental por the interoperal the requirement	s set out in Annex ne interoperability for the EU market is also the subject ring other aspects by COTIF regula- applicable UTPs) pllution, also state bility constituents is of those EU di-	shall meet 13(3) and p tive 2008/57/			
		•••	red to is: a certificate and its	□ the EC- and its ac	type examinatic dditions.	on certificate	

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EU ref.<sup>2</sup>

### 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.

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### 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 1. 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. 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 the notified body an assessing entity of his choice, for the interoperability constituents concerned. The application shall include: The name and address of the manufacturer, and, if the application is lodged by the authorised representative, his name and address as well, a written declaration that the same application has not been lodged with any other assessing entity, notified body, all relevant information for the interoperability constituent category envisaged, the documentation concerning the quality management system, the technical documentation of the approved type and a copy of the EC-Type examination certificate. 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 manufac-
  - the examinations and tools that this be carried out before, during and anot manual ture, and the frequency with which they will be carried out,
     the quality records, such as inspection reports and test data, calibration data, quali-
  - □ the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and

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OTIF UTP			ring the achievements the quality manage	ent of the requ	ext in EU regulations iired product qu			
3.3	shall ass	ssing entity ess the quality ents referred to i	management sys n point 3.2.	The notified b tem to determ		satisfies the		
	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 <sup>15</sup> 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 entityassessing entitynotified body notified bodyshall take this into account in the assessment. In this case, the assessing entitynotified body notified bodywill make a detailed assessment of quality management system specific documents and records of the interoperability constituent only. The assessing entitynotified body notified bodyshall not assess again the entire quality manual and all the procedures already as- 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 with experience of evaluation in the relevant interoperability con- stituent field and product technology concerned, and knowledge of the requirements of the							
	team sha graph, fift UTP and to ca	Il review the te h indent, to verif rry out the nece	assessment visit to chnical documenta y the manufacturer ssary examinations t with those require	ation referred t 's ability to ider  TSI s with a view to	to in point 3.1, so in the requirer	second para- nents of the		
	The decision conclusion of the quarter referred to assessing	sion shall be no ns of the audit a ality manageme o in point 3.2 are g entity	nd the reasoned as nd the reasoned as nt system provided	facturer. The ssessment dec satisfying evi	ision. Where the dence that the	e assessment		
3.4			ndertake to fulfil the oved and to maint					
3.5	assessing that has a the quality	approved the qu y management s	eep the ality management system having impa nagement system o	ct on the interc				
	agement	luate any propo	sed changes and ntinue to satisfy th is necessary.					

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OTIF UTP					ext in EU regulations		
			cturer of its decision and the reasoned as			n the conclu-	
4.	Surveillar assessing		sponsibility of the	notified body			
4.1			ce is to make sure t proved quality mana			ls the obliga-	
4.2	<ul> <li>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:</li> <li>the quality management system documentation,</li> <li>the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.</li> </ul>						
4.3	The assessing shall carr	g entity y out periodic au		notified body hat the manufa			
	The frequ	ency of the perio	odic audits shall be	at least once e	every two years.		
	assessing	g entity	perates a certified c	notified body	ment system, th	e	
4.4	assessing may, if ne in order to assessing	g entity unexpected visit g entity ecessary, carry o o verify that the o g entity vide the manufac	out interoperability of quality management	notified body constituent tes t system is fun notified body	ts, or have them ctioning correctly	y. The	
5.	Declaratio	on of conformity		EC declaratio	n of conformity		
5.1	Declaration for the inter- for the per- UTP and, when UTP	riod defined in th	nstituent and keep ne relevant	it at the dispos  TSI  TSI			
	been mar Declaration shall iden A copy of Declaration	nufactured. The on of conformity tify the interope the on of conformity	ability constituent for	EC declaratio or which it has EC declaratio	n of conformity been drawn up. n of conformity		
5.2	shall a) meet 1 to tl	his UTP, and	ts set out in Annex ne interoperability	shall meet t 13(3) and po tive 2008/57/I	n of conformity the requirement bint 3 of Annex EC.		

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OTIF UTP	ket a subje aspec regula UTPs state	nd if the const ct of EU directive cts than those of ations (includin ) e.g. environment that the interopret the require	ed for the EU mar- tituent is also the ves covering other covered by COTIF g the applicable ental pollution, also perability constitu- ments of those EU	Corresponding to	ext in EU regulations	s <sup>1</sup> EU ref. <sup>2</sup>
	the "c indica	ited in point 4.3, ype examination	nent system approv		ype examinatio	
6.	UTP and, when UTP does not erability of	re the define this perio	or the period defined od, for a period end been manufactured	TSI  TSI ling at least 10	) years after the	
	<ul><li>the ch</li><li>the de</li><li>asses</li></ul>				ody	
7.	competer competer which has ments (cf "quality m upon requ the comp	nt authority, it at authority in the s authorised it t . sections 1.2 c) nanagement sys uest, make availa etent authority f "quality manage	tem approvals" issuable to	ing authorities ued or withdra	s of wn, and shall, p uthorities	periodically or
	other ass "quality m otherwise	essing entities a anagement sys	all ensure that the re informed of the tem approvals" whic I, upon request, of	notified bodie ch it has refus	s of ed, withdrawn, s	suspended or
8.		d representative	ations set out in poi	nts 31 25 5	and 6 may be f	ulfilled by his

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.

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### MODULE CF. CONFORMITY TO TYPE BASED ON PRODUCT VERIFICA-TION

1.	6, and ensures and declares on his sole re-	cation is the part of a conformity assessment the obligations laid down in points 2, 5.1 and esponsibility that the interoperability constitu- to the provisions of point 3, are in conformity		
	Type examination certificate and satisfy the requirements of the	EC-Type examination certificate.		
	Uniform Technical Prescriptions (UTP)	technical specification for interoperability (TSI)		
	that apply to them.			
2.	Manufacturing			
	and its monitoring ensure conformity of the proved type described in the	ecessary so that the manufacturing process ne interoperability constituents with the ap-		
	Type examination certificate and with the requirements of the	EC-type examination certificate		
	UTP	TSI		
	that apply to them.			
3.		A notified body appropriate examinations and tests in order ability constituents with the approved type		
	Type examination certificate	EC-Type examination certificate.		
	and with the requirements of the UTP.	TSI.		
	The examinations and tests to check the c	onformity of the interoperability constituents		
	with the requirements of the UTP	TSI		
	shall be carried out, at the choice of the ma	nufacturer either by examination and testing ified in point 4 or by examination and testing		
4.	Verification of conformity by examination a ent.	nd testing of every interoperability constitu-		
4.1	All interoperability constituents shall be indi out in the relevant	vidually examined and appropriate tests set		
	UTP, Validated Standard(s) and/or technical specifications, or equivalen conformity with the approved type described Type examination certificate	TSI, harmonised standard(s) t tests, shall be carried out in order to verify i in the 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) and/or technical specifications, the appropr	TSI, harmonised standard(s) iate tests to be carried out shall be decided		
	between the manufacturer and the assessing entity concerned.	notified body		
4.2	The assessing entity shall issue	The notified body		

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OTIF UTP	in respec	ate of conformity t of the examinat ufacturer shall ke	tions and tests carri	an EC certific	ext in EU regulations ate of conformity		EU ref. <sup>2</sup>
	Certificate available UTP and, when UTP does not	e of conformity for inspection by re the	the national author	TSI	riod defined in th		
5.	Statistical	verification of c	onformity				
5.1	and its m	onitoring ensure	the all measures ne the homogeneity of ts for verification in	of each lot pro	duced, and shal	Il present his	
5.2	A random UTP.	sample shall be	e taken from each lo	ot according to TSI.	the requirement	s of the	
	ate tests UTP, Vali and/or te ensure th UTP and to de the releva	set out in the rele dated Standard( chnical specific eir conformity wi	s) ations, or equivale th the requirements r the lot is accepted	TSI, harmonis nt tests, shall of the TSI or rejected.	sed standard(s) be carried out	t in order to	
	and/or tee	chnical specifica the manufacture g entity	tion(s), the appropri r and the			ll be decided	
5.3	proved, e		nteroperability cons interoperability cor sts.				
	The assessing shall issu			notified body			
	a Certifica	ate of conformity	tions and tests carri		ate of conformity	/	
	Certificate at the dis UTP and, when		onal authorities for t	UTP		int	
		define this peri- nufactured.	od, for 10 years af	TSI ter the last int	eroperability co	nstituent has	
5.4	assessing in the Co tion of the shall take the event assessing	ntracting State constituent take appropriate me of the frequent i g entity	asures to prevent the rejection of lots the	nat the lot is be	ing placed on th		
			al verification and ta		e measures.		

	OTIF		GENERAL PROVISIONS ASSESSMENT PROCEDURES (MODULES)			UTP GEN-D Page 31 of 90	
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OTIF UTP				Corresponding t	ext in EU regulations	EU ref. <sup>2</sup>	
6.		on 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.						
		on of conformity	o the relevant autho		on of conformity quest.		
6.2	shall a) meet 1 to tl b) in ca const ket a subje aspec regula UTPs state ents r direct The certif the T additi	his UTP, and ases where the ituent is intended and if the const ct of EU directive cts than those of ations (includin b) e.g. environment that the intero meet the require ives. icate to be refer ype examination	ts set out in Annex ne interoperability ed for the EU mar- tituent is also the ves covering other covered by COTIF g the applicable ental pollution, also perability constitu- ments of those EU red to is: n certificate and its ormity	ar- ne er IF ole so u- EU			
7.		d 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.

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

### MODULE CH. CONFORMITY BASED ON FULL QUALITY MANAGEMENT SYSTEM

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

Uniform Technical Prescriptions (UTP)

Technical Specifications for Interoperability (TSI)

that apply to them.

2. Manufacturing

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

- 3. Quality management system
- 3.1 The manufacturer shall lodge an application for assessment of his quality management system with

an assessing entity the notified body of his choice, for the interoperability constituents concerned.

of his choice, for the interoperability constituents conc

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,
- 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,

0	a list of the Validated Standards <sup>16</sup> and/or othe relevant technical specifications which have been		harmonised standards and/or other relevant technical specifica- tions the references of which have been published in the Official Journal of the European Union,
	applied in full or in part, and descri	iptions o	f 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	
	Validated Standards,		harmonised standards,

<sup>&</sup>lt;sup>16</sup> See section 1.2 c)

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OTIF UTP	o re o te □ the do □ a writ	esults of design est reports. ocumentation co	Corresponding to umentation shall specify the parts calculations made, examinations of oncerning the quality management that the same application has not notified b	carried out, etc., system, and been lodged wit	n applied, and	
3.2	The quality management system shall ensure compliance of the interoperability con- stituents 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, proce- dures and instructions. The quality management system documentation shall permit a					

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,

consistent interpretation of the quality programmes, plans, manuals and records.

- 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 Inotified body Inotified body shall take this into account in the assessment. In this case, the assessing entity Inotified body Inotifi

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OTIF UTP		assess again t		notified body anual and all			
	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 con- stituent field and product technology concerned, and knowledge of the requirements of the UTP. TSI.						
	team sha verify the UTP and to ca	Il review the tec manufacturer's arry out the nece	shall include an assessment visit to the manufacturer's premises. The auditing review the technical documentation referred to in point 3.1, second indent, to nanufacturer's ability to identify the requirements of the [TSI] ry out the necessary examinations with a view to ensuring compliance of the pility 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] [notified body] shall issue a "quality management system approval" to the applicant.						
3.4		he manufacturer shall undertake to fulfil the obligations arising out of the quality man- gement system as approved and to maintain it so that it remains adequate and effi- ient.					
3.5	assessing that has the qualit	approved the query management s		t on the interd			
	shall eva agement		osed changes and continue to satisfy the		er the modified		
	It shall notify the manufacturer of its decision. The notification shall contain the conclu- sions of the examination and the reasoned assessment decision.					n the conclu-	
4.	Surveillar assessing		sponsibility of the	notified body			
4.1			ce is to make sure the proved quality mana			ls the obliga-	
4.2	assessing access to	g entity o the design, m	or periodic audit purp   nanufacture, inspect ary information, in pa	notified body ion, testing a		es, and shall	
	<ul> <li>the quality management system documentation,</li> <li>the quality records as provided for by the design part of the quality management system documentation,</li> </ul>					managamant	
			s provided for by th Its of analyses, calcu			management	
	agem	nent system, suc	s provided for by th th as inspection repo personnel concerned	orts and test			
4.3	The asse	ssing entity	ľ	The notified b	ody		

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	OTIF	GENERAL F ASSESSME	UTP GEN-D Page 35 of 90					
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OTIF UTP	Corresponding text in EU regulations <sup>1</sup> EU ref. <sup>2</sup> 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							
4.4	shall take In additio assessing may pay carry out	assessing entity Inotified body shall take this into account during the periodic audits. In addition, the assessing entity Inotified 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 manufac-						
_	turer with	urer with a visit report and, if tests have been carried out, with a test report.						
5.1	The man Declaration for the int at the dis UTP and, whe UTP does not been man Declaration	posal of the nation re the define this perinufactured. The on of conformity	nstituent and keep i onal authorities for od, for 10 years af	t together with the period defi  TSI  TSI ter the last in  EC Declaratio	ned in the releva teroperability co on of conformity	int		
	shall identify the interoperability constituent for which it has been drawn up.A copy of theDeclaration of conformityEC Declaration of conformityshall be made available to the relevant authorities upon request.							
5.2	shall a) meet 1 to ti b) in ca const ket a subje aspea regula UTPs state	his UTP, and ases where the ituent is intended and if the const oct of EU direction cts than those of ations (includin b) e.g. environment that the intero meet the require	mity ts set out in Annex ne interoperability ed for the EU mar- tituent is also the ves covering other covered by COTIF g the applicable ental pollution, also perability constitu- ments of those EU	shall meet	aration of conform the requirement pint 3 of Annex EC.	ts of Article		
	the q	icate to be refer uality managem ated in point 4.3,	ent system approv	al indicated ir	n point 3.3 and	audit reports		
6.	UTP and, whe UTP does not erability o thorities:	re the define this perio constituent has	or the period defined od, for a period end been manufactured ntation referred to in	TSI  TSI ling at least 10 l, keep at the	) years after the			



Corresponding text in EU regulations<sup>1</sup>

EU ref.<sup>2</sup>

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

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

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

8. Authorised representative

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



Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

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

that apply to them.

2. Manufacturing

UTP

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

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.

TSI

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

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

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OTIF UTP	the e	xaminations and	s and systematic act tests that will be car cy with which they wi	ions that will t rried out befor	re, during and at	
	ficatio	on reports on the	uch as inspection rep personnel concerne ing the achievement	ed, etc., and		·
			ration of the quality n			outor quanty
3.3	shall ass	ssing entity ess the quality ents referred to i	management syste	The notified b om to determ		satisfies the
	quality m national s Validated	anagement syst		h the corresp	onding specific agement standar	ations of the
	accredite erability of assessing shall take assessing will make records of assessing shall not sessed b	d certification be constituent, the g entity this into accour g entity a detailed asse f the interoperate g entity assess again t y the quality mar	nt in the assessment. ssment of quality ma bility constituent only he entire quality ma nagement system cer	and manufacture notified body In this case, notified body anagement system The notified body anual and all rtification body	uring of the rele the stem specific do the procedures y.	cuments and already as-
	at least o	one member exp	in quality managem perienced as an ass technology concerno	essor in the	relevant interop	erability con-
	The audit	shall include an	assessment visit to		urer's premises.	
		sion shall be noti horised represei	fied to the manufactunt field to the manufacture.	urer		
	decision. evidence assessing	Where the asse that the requirer g entity	tain the conclusions essment of the quality ments referred to in p agement system app	y managemer point 3.2 are n notified body	nt system provic net, the	
3.4			ndertake to fulfil the oved and to maintai			
3.5	assessing that has the qualit	approved the qu y management s		t on the interc		
	agement	luate any propo	osed changes and d			

	OTIF	GENERAL PROVISIONS ASSESSMENT PROCEDUR	ES (MODL	JLES)	UTP GEN-D Page 39 of 90		
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TIF UTP		-	Corresponding te	ext in EU regulations	EU ref.		
		ptify the manufacturer of its decision the examination and the reasoned as			n the conclu-		
3.6.	competer competer which ha ments (cf "quality n upon req the comp	f "quality management system app	ng authorities ed or withdra ts notifying a	s of wn, and shall, p uthorities	eriodically or		
	other ass "quality n otherwise	essing entity shall ensure that the essing entities are informed of the nanagement system approvals" which e restricted, and, upon request, of as issued.	notified bodie n it has refus	s of ed, withdrawn, s	suspended or		
<b>.</b>	Design e	xamination					
1.1	assessin	ufacturer shall lodge an application fo g entity   o in point 3.1.	r examinatior notified body	n of the design w	<i>v</i> ith the		
1.2	nance ar with the r UTP						
	that apply It shall in						
		ame and address of the manufacture	r				
	a writ	en declaration that the same application sing entity,			any other		
	asses of the		onformity with				
	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 con- tain, wherever applicable, at least the following elements:						
		general description of the interopera	•				
		onceptual design and manufacturing ub-assemblies, circuits, etc.,	g drawings a	nd schemes of	components,		
		escriptions and explanations necess ngs and schemes and of the operatio					

- 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

tenance of the interoperability constituent,

	OTIF	GENERAL PROVISIONS ASSESSMENT PROCEDU			
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OTIF UTP	re	alidated Standards <sup>17</sup> and/or other elevant technical specifications hich have been	harmo other tions been	ext in EU regulations onised standa relevant technic the references o published in	ards and/or cal specifica- of which have the <i>Official</i>
	re U W V h V	pplied in full or in part, and descri equirements of the ITP where those falidated Standards ave not been applied. In the event falidated Standards, me technical documentation shall sp	ptions of the set TSI harmon of partly applied harmon ecify the parts	onised standard d onised standard which have beer	t to meet the s s, n applied,
		esults of design calculations made,	examinations of	carried out, etc.,	and
	<ul> <li>the s evide relevation</li> <li>Validation</li> <li>and/c dence</li> <li>priate</li> </ul>	est reports. upporting evidence for the adequa nce shall mention any documents t ant ated Standards or technical specifications have no e shall include, where necessary, t e laboratory of the manufacturer, or under his responsibility.	hat have been harmonised s t been applied he results of te	used, in particul tandards d in full. The su ests carried out b	lar where the pporting evi- by the appro-
4.3	shall example UTP that apply a Design to the maturer, the data nece	ssing entity mine the application, and where the v to the interoperability constituent i examination certificate anufacturer. The certificate shall gi conclusions of the examination, the essary for identification of the appre- ict's functioning. The certificate may	TSI t shall issue an EC design ive the name a ne conditions ( oved design an	the requirement examination ce and address of t if any) for its va id if relevant, a c	rtificate the manufac- lidity and the description of
		ficate and its annexes shall contain teroperability constituents with the e			
	UTP, the shall refu	e design does not satisfy the requir assessing entity use to issue a design examinatior gly, giving detailed reasons for its re	TSI, the notifi certificate an		the applicant
4.4	assessing that has i Design ex informed the requir UTP	ssued the xamination certificate of any modification to the approve rements of the	d design that m  TSI	-	nformity with
					of the certifi-
	— in the	xamination certificate form of an addition to the original xamination certificate.		amination certification amination certification	

<sup>&</sup>lt;sup>17</sup> see section 1.2 b)

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OTIF UTP			Corresponding to	ext in EU regulations	5 <sup>1</sup> EU ref. <sup>2</sup>		
	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 Each notified body shall inform its notifycompetent authority, it shall inform the ing authorities concerning the EC design competent authority in the Contracting State examination certificates which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any Design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the competent authority its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted. Each assessing entity shall ensure that the Each notified body shall inform the other other assessing entities are informed of the notified bodies concerning the EC design Design examination certificates examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued. The Secretary General, the competent The Commission, the Member States and authorities of the other Contracting States the other notified bodies and the other assessing entities may, upon request, obtain a copy of the Design examination certificate. EC design examination certificate. and/or additions thereto. Upon request, the Secretary General and the other Contract- Commission and the Member States ing States may obtain a copy of the technical documentation and the results of the examinations carried out by the assessing entity. notified body. The notified body The assessing entity shall keep a copy of the EC design examination certificate. Design examination certificate, its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate. 4.6 The manufacturer shall keep a copy of the Design examination certificate, EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant UTP TSI and, where the UTP TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured. 5. Surveillance under the responsibility of the notified body assessing entity 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 Intermanufacture, inspection, testing and storage sites and shall provide it with

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OTIF UTP	all necessary information, in particular:							
	the c syste	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 man-						

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

5.4

assessing entity Inotified 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.

- 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.
- EC declaration of conformity 6. 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 meet the requirements of Article shall a) meet the requirements set out in Annex 13(3) and point 3 of Annex IV to Direc-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

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			g	

7.

state that the interoperability constituents meet the requirements of those EU directives.

Corresponding text in EU regulations<sup>1</sup>

EU ref.<sup>2</sup>

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

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 end	ing at least 10 years aft

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

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

notified body

8. Authorised representative

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



Ref.: A 94-01D/3.2011

Original: EN Date: 01.10.2012

Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

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

# MODULE CV. TYPE VALIDATION BY IN-SERVICE EXPERIENCE (SUIT-ABILITY 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, re	presentative 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 of his choice.

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,
- $\Box$  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 inservice 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.

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

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

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

The technical documentation shall contain the following elements:

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

If the UTP

## TSI

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

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

The assessing entity shall:

The notified body shall:

- 5.1 examine the technical documentation and the programme for validation by in-service experience;
- 5.2 verify that the type is representative and has been manufactured in conformity with the technical documentation;
- 5.3 verify that the programme for validation by in-service experience is well adapted to assess the required performance and in-service behaviour of the interoperability constituents;
- 5.4 agree with the applicant and the company(ies) undertaking the operation of the interoperability constituent referred to in point 2 the programme and the location where the inspections will be carried out and if necessary, the test(s) and the body performing the test(s);
- 5.5 monitor and inspect the progress of in-service running, operation and maintenance of the interoperability constituent;
- 5.6 assess the report, to be issued by the company(ies) undertaking the operation the interoperability constituent referred to in point 2, and all other documentation and information, collected during the procedure (test reports, maintenance experience etc.);
- 5.7 evaluate whether the in-service behaviour results meet the requirements of the UTP. TSI.
- Where the type meets the requirements of the UTP |TSI that apply to the interoperability constituent concerned,

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OTIF UTP	shall issu a Certifica	ssing entity e ate of suitability nufacturer.	for use	the notified bo	ext in EU regulations ody ate of suitability		EU ref. <sup>2</sup>
	of the val	idation, the cond	ain the name and ac ditions (if any) for its pe. The certificate n	s validity and th	ne necessary dat	ta for identifi-	
	Certificate and a cop	e of suitability fo by kept by the	s of the technical do r use	EC certificate	of suitability for		
	assessing			notified body.			
	UTP, the	e type does not assessing entity se to issue	meet the requireme	nts of the TSI, the notifi	ed body		
_	and shall		cant accordingly, gi		ate of suitability easons for its ref		
7.	assessing that holds Certificate of all mo interopera modificat	s the technical de e of suitability fo difications to the ability constituer	ocumentation relation r use e approved type th nt or the condition e additional approva	EC certificate at may affect s for the valic al in the form o	lity of the certif	or use of the ficate. Such he original	
	Only thos be perfor		and tests that are r	elevant and ne	ecessary to the c	hanges shall	
8.	competer competer which ha ments (cf Certificate and/or ar upon requ the comp	nt authority, it nt authority in the s authorised it it sections 1.2 c) e of suitability fo ny additions ther uest, make avail etent authority f certificates an	r use eto which it has iss able to	EC certificate ued or withdra	of suitability for wn, and shall, p uthorities	use eriodically or	
9.	other ass Certificate and/or ar	essing entities a es of suitability f ny additions the , and, upon requ	hall ensure that the are informed of the or use reto which it has re uest, concerning the	notified bodie cates of suita efused, withdra	es concerning th bility for use wn, suspended	e EC Certifi- or otherwise	
10.	authoritie and the o may, upo Certificate		n a copy of the	the other noti			
	Upon req Secretary States		I the Contracting	Commission a	and the Member	States	

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OTIF UTP	may obta carried of assessing	ut by the	e technical docume			
	shall kee Certificat	essing entity p a copy of the e of suitability fo es and additions	r use, s, until the expiry of t		e of suitability for	ruse
11.		on of suitability f			on of suitability fo	or use
11.1	Declaration for the in	on of suitability f	nstituent and keep		on of suitability fo sal of the nation	
	UTP and, whe			TSI		
	UTP			TSI		
	been mai Declarati	nufactured. The on of suitability f	iod, for 10 years af for use rability constituent fo	EC declaration	on of suitability fo	or use
		on of suitability f	or use o the relevant autho		on of suitability fo juest.	or use
11.2	shall a) meet 1 to t b) in c const ket a subje aspeet regula UTPs state	his UTP, and ases where the ituent is intende and if the cons act of EU directi cts than those ations (includir s) e.g. environment that the intero meet the require	for use ts set out in Annex he interoperability ed for the EU mar- tituent is also the ves covering other covered by COTIF ng the applicable ental pollution, also operability constitu- ements of those EU	shall meet	on of suitability fo the requiremen bint 3 of Annex EC.	ts of Article
		ficate to be refer certificate of suita		the EC ce	ertificate of suita	bility for use.
11.3		operability const ons have been d	ituent may be place rawn up:		et only after the ons have been di	
	Decla		lity for use referred	EC decla	aration of suital o in point 11.1, a	pility for use
		aration of conform	mity.		ration of conform	
12.	Authorise	ed representative	e			
	authorise		pations set out in p e, on his behalf and			

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[			HE PROCE- SSMENT OF CONFOR-	Modules			EU ref. <sup>2</sup>
r F	ΜΙΤΥ Μ		TECHNICAL	EC TYPE E		N	
1.		mination is the		EC-type exam	nination is the p		
	an assess examines design of UTP(s) ar	the subsystem r nd other applicat	esign of a subsyster neets the requireme ble regulations <sup>18</sup>	ents of the rele	and attests that vant ell as any othe		
	that apply	v to it.					
2.	Type exa shall be c	mination arried out by:		EC-type exam	nination		
	exam		dequacy of the te chnical documentat and				
			ecimen, representa (production type).	ative of the p	roduction envisa	aged, of the	
			al versions of the not affect the provis			e differences	
3.		mination with an	an application for assessing entity	EC-type exan	nination with a ne	otified body	
	The appli	cation shall inclu	de:				
			ss of the applican tive, his name and			dged by the	
		en declaration th ssing entity,	at the same application	ation has not b notified be		any other	
	the te to ass UTP( The te UTP(	echnical docume sess the subsyste s). echnical docume	ntation. <sup>19</sup> The tech em's conformity wit entation shall specify elevant for the	nical documer h the requirem TSI(s).	ntation shall make ents of the relev	ant	

<sup>&</sup>lt;sup>18</sup> The assessing entity will request evidence of conformity with all "other applicable regulations" from the applicant. The applicant must provide such evidence of conformity as is relevant and the assessing entity will include this evidence without further assessments in its compilation of the Technical File.

UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

<sup>&</sup>lt;sup>19</sup> The technical documentation includes descriptions and explanations necessary for understanding the functioning and possible risks/failures in safety-related software used in the subsystem, if appropriate.

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OTIF UTP	the o		ure and operation o east the following el	EC-type exan f the subsyste	ext in EU regulations nination procedu m. The technica	re,
		•	tion of the subsyste		•	ure,
	; (	according to the GEN-B "Technica		as de VI to	hnical file escribed in point Directive 2008/5	
	1	UTP(s) for each relevant set up by the Col cal Experts accor	h the set of data red register mmittee of Techni- ding to ATMF Arti-	TSI(s	) ded for in Article ective 2008/57/E	
	0	cle 13, copy of UTP declarations intermediate state	of ements of verificatio	n (ISV) issued issue ing to	eclarations of for the subsyste d for the subsyste point 2 of Anne 008/57/EC,	stem accord-
		f any, f relevant, descrii	otions and explanat			anding of the
			intenance of the sul			
		conditions of intenets of intenets of intenets of the second second second second second second second second s	gration of the subs	system in its s	system environn	nent and the
	, I	a list of the Validated Standa relevant technic which have been	rds <sup>20</sup> and/or other cal specifications	other tions been	onised standa relevant technic the references c published in pal of the Europe	cal specifica- of which have the <i>Official</i>
	I	applied in full or requirements of th UTP(s)	in part, and descrip ne		olutions adopted	
	,	where those				
		Validated Standar	plied. In the event o	f partly applied harm	onised standards	5,
			calculations made, e			1 F /
		test programme a			,,	
	0	evidence of confo	rmity with other			
		applicable COTIF			ations deriving fro ding certificates, i	
		supporting docun subsystem,	nentation regarding	the manufact	ure and the ass	embly of the
		a list of manufact sembly and instal	turers involved in th lation,	ne subsystem'	s design, manuf	acturing, as-
		conditions for us wear limits etc.),	e of the subsystem	n (restrictions	of running time	or distance,
		conditions for ma subsystem,	intenance and tech	nical documen	tation on mainte	nance of the
	0	any technical requ	uirement specified in	n the relevant		

<sup>&</sup>lt;sup>20</sup> See section 1.2 b)

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	OTIF					UTP GEN- Page 50 o	
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OTIF UTP	0	the subsystem, all other approp	n into account duri riate technical evic have been succes	TSI(s ng production, dences, which	maintenance or demonstrate t	operation of	EU ref. <sup>2</sup>
	o □ the	UTP(s),	ent bodies, nation, if required by sentative of the prod	TSI(s	ed. The		
	may a sı sub: test UTF the sup whe Vali and den pria	<ul> <li>request further s</li> <li>pecimen or speci</li> <li>system in a pre-as</li> <li>or examination m</li> <li>P(s),</li> <li>supporting evide</li> <li>porting evidence s</li> <li>ere the relevant</li> <li>dated Standards</li> <li>/or technical species</li> <li>ce shall include, w</li> </ul>	pecimens if needed mens of a sub-ass ssembled condition tethods and specifie nce for the adequa shall mention any do cifications have not where necessary, the the applicant, or by	for carrying ou sembly or assistant be provided in the relevation TSI(s), acy of the tector ocuments that harmonistic been applied he results of te	ut the test progra embly or a spe ded, if so require nt chnical design s have been used ed standards I in full. The su sts carried out b	cimen of the ed for specific solution. This , in particular pporting evi- py the appro-	
4.	The ass	essing body shall		The notified b	ody shall		
	For the	design type:					
4.1		al design of the su	ocumentation and s bsystem is adequat				
4.2	UTP(s), examine	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					
		production type:					
4.3	of the re UTP(s) and wit designe UTP(s), and/or	verify that the specimen(s) have been manufactured in conformity with the requirements of the relevant UTP(s)  TSI(s) and with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant UTP(s), Validated Standards  TSI(s), harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;					
4.4	whether Validate	, where the applic ed Standards	kaminations and te cant has chosen to a tions, these have be	apply the soluti harmonised s	ons in the releva tandards		
4.5	whether Validate and/or	, where the solution of Standards technical specification	kaminations and te ons in the relevant ations have not be prresponding require	harmonised s en applied, th	tandards ne solutions add		

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OTIF UTP	UTP(s);			Corresponding te TSI(s);	ext in EU regulations	<sup>1</sup> EU ref. <sup>2</sup>
4.6	agree wit out.	h the applicant	on a location where	e the examinat	ions and tests w	vill be carried
5.	ing to Article 7 guideline Technica Article,	a of ATMF an s adopted by I Experts in p cant shall inform	erred to in point 3 is d the regulations/ the Committee of oursuance of that the	Article 9 of Di	0 () (	
	assessing with a pre UTP(s)	ecise reference t		notified body TSI(s) uested.		
	authority, derogatio requirement out by th	it shall anal n complies w ents and follow	ty is the competent lyse whether the rith the essential the procedure set Technical Experts ATMF.			
	of the a		ormed of the result e outcome of the			
	authority, the applic assessing	cant shall commo	not the competent unicate to the ation procedure.	notified body		
6.	shall drav	ssing entity w up an evaluati t 4 and their outo	ion report that reco comes.	The notified b rds the activitie		accordance
	applicant authority	and, on request	all be given to the t, to the competent ng State which has entity.			
	competer which ha ments (c assessing	nt authority in the s authorised it f f. sections 1.2 g entity ase the content	oligations vis-à-vis t e Contracting State to perform assess- c) and 1.3), the of that report, in fu	notifying auth		
7.	UTP(s)	/ to the subsyste g entity	e requirements of th em concerned, the	e relevant  TSI(s)  notified body		
		pe-examination	certificate	an EC-type ex	xamination certif	icate

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Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

	The certificate shall contain the name and a the examination, the conditions (if any) for its cation of the approved type. The certificate m	s validity and the necessary data for identifi-								
	The certificate and its annexes shall contain mity of manufactured subsystems with the ex									
	shall refuse to issue a UTP Type-examination certificate	TSI(s), the notified body 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									
	shall also indicate the precise reference to th UTP(s) or their parts to which conformity has not bee	TSI(s) en examined during								
	the assessments carried out. If only certain parts of the subsystem are cov	EC verification procedure.								
	relevant UTP(s), the assessing entity shall issue an intermediate statement of verif clearly stating which parts of the subsystem meet the requirements of the relevant UTP(s).	TSI(s), the notified body ication (ISV) in compliance with Article 18(4) of Direc-								
	Based on the ISV, the applicant may draw up a written UTP declaration of intermediate statement of verification (ISV).									
8.	of all modifications to the approved type that with the requirements of the relevant	EC-type examination certificate may affect the conformity of the subsystem TSI(s) . Such modifications shall require additional								
9.	Unless the assessing entity is itself the competent authority, it shall inform the competent authority in the Contracting State which has authorised it to perform assessments (cf. sections 1.2 c) and 1.3) of any UTP Type-examination certificates and/or any additions thereto which it has iss upon request, make available to	Each notified body shall inform its notify- ing authorities concerning the EC-type examination certificates ued or withdrawn, and shall, periodically or its notifying authorities								
	Each assessing entity shall ensure that the other assessing entities are informed of the UTP Type-examination certificates	Each notified body shall inform the other notified bodies concerning the EC-type examination certificates								

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OTIF UTP	Corresponding text in EU regulations <sup>1</sup> EU ref. <sup>2</sup> 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.							
	States an may upon UTP Type	Secretary General, the Contracting es and the other assessing entities upon request, obtain a copy of the Type-examination certificate or additions thereto.						
	States ma	etary General and the Contracting the Commission and the Member States ay also may popy of the technical documentation and the results of the examinations carried						
	The assessing entity shall keep a copy of the UTP Type-examination certificate, its annexes and additions, including the documentation submitted by the man until the expiry of the validity of the certificate.							
10.	UTP Type its annexe	es and additions		technical docu				

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.

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OTIF UTP				Corresponding to	ext in EU regulations	s <sup>1</sup> EU ref. <sup>2</sup>			
			MANAGE- PRODUCTION	ITY MANAG	ATION BASED EMENT SYSTI ON PROCESS				
1.	This assessmentEC verificationbased on quality management system of the procedure for assessment of a subsys- tem's conformity with the requirements of the applicable UTP(s)EC verification a EC verification process is the part of a EC verification procedurewhereby the applicant fulfils the obligations laid down in points 2EC verification a EC verification process is the part of a EC verification proceedure								
	5, 7 and be carrie that the s UTP Ty thereby	9, in order that d out to verify	t assessments can erned is in conformit Certificate and	aid down in points 2 and 8, and ensures and declares on his sole responsibility ity with the type described in the EC type examination certificate and					
	UTP(s) a	nd other applica	ble regulations <sup>21</sup>	TSI(s) as we deriving from	ell as any othe the Treaty	r regulations			
	that apply	y to it.							
2.	Manufact	turing							
	shall be	covered by app	bsystem inspection proved quality mana prveillance as specifi	igement syste					
3.	Quality m	nanagement syst	tem						
3.1	the quality m to be use	ge an application anagement syste ad with an assess	em	his with the notifi	ed body				
	The appl	ication shall inclu	ude:						
	□ the n	ame and addres	ss of the manufactu ative, his name and			odged by the			
		tten declaration t ssing entity,	that the same applic	ation has not l notified b	•	n any other			
		reakdown struct involved entity,	ture of the project m	nanagement a	nd the name ar	d address of			
			on for the subsystem	-					
	□ the d	ocumentation cc	oncerning the quality	copy of E diate sub	system, EC declaration(s osystem conforr the subsystem, i	nity (ISV) is-			
		echnical docume Type-examinatio	ntation of the appro-		a copy of the examination cert	ificato			

UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

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OTIF UTP	and i	ts annexes.		Corresponding to	ext in EU regulations	EU ref. <sup>2</sup>		
3.2	The quality management system shall ensure that the subsystem is in conformity with the type described in the							
	UTP Type-examination certificate EC-type examination certificate and comply with the requirements of the relevant UTP(s) TSI(s) that apply to it.							
	All the elements, requirements and provisions adopted by the applicant shall be docu- mented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality management system documentation shall permit a consis- tent interpretation of the quality programmes, plans, manuals and records.							
	It shall, ir	n particular, cont	ain an adequate de	scription of:				
			and the organisat vith regard to subsys		, responsibilities	and powers		
			anufacturing, qualit is and systematic ac			ment system		
			I tests that will be ca cy with which they v			fter manufac-		
	the q	uality records, s	uch as inspection re e personnel concern	eports and test		n data, quali-		
			ing the achievemer the quality manage		ed subsystem q	uality and the		
3.3	shall ass	essing entity sess the quality ents referred to i	management syst	The notified b tem to determ		satisfies the		
	quality m national s Validated	anagement sys		ith the corresp	oonding specific agement standa	ations of the		
	If the con UTP(s)	npliance of the s	ubsystem with the r	equirements o TSI(s)	f the relevant			
	is based assessing		e quality managem		e			
	whet		and interfaces bet	ween the qual	ity management	systems are		
	of the		onsibilities and pow ubsystem are clear project.					
			fic for the subsyste e applicant to the su		taking into cons	sideration the		
	When			L				
	is used		ement system certifi		edited certificatio	n body,		
	assessin	g entity e this into accour	d final testing of the nt in the assessmen	notified body				

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

	OTIF	GENERAL PROVISIONSUTP GEN-DASSESSMENT PROCEDURES (MODULES)Page 56 of 90							
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OTIF UTP	assessing shall not	assess again t	only. The he entire quality n nagement system c	notified body nanual and all					
	at least o	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).							
	one or me to the pre technical sixth inde to verify t UTP(s) and to ca	documentation i ent, he ability of the	elevant entities con referred to in point 3 relevant entities cor essary examinations	3.1, second par seventh inder cerned to iden TSI(s)	uditing team sha ragraph, ht, htify the requirem	nents of the			
			fied to the vard a copy to the	applicant.					
	The notifi decision.	cation shall con	tain the conclusions	s of the audit a	nd the reasoned	assessment			
	that the reassessing	equirements refe g entity	f the quality manag erred to in point 3.2 agement system ap	are met, the notified body		ing evidence			
3.4	shall und		nufacturer e obligations arisin it so that it remains	•	ality manageme	nt system as			
3.5	informed the applic assessing that has a the qualit and final	and cant shall keep th g entity approved the qu y management	ality management s system having imp ing and operation,	  notified body system informe act on the sub	system design,	manufacture,			
	shall eva agement		osed changes and ntinue to satisfy th is necessary.		er the modified				
	and the a tion to th	e manufacturer	t of its decision, prward the notifica- if the quality man- ated by the manu-						
		ication shall co ent decision.	ntain the conclusio	ons of the exa	amination and t	he reasoned			
4.	competer competer	nt authority, it nt authority in the	entity is itself the shall inform the e Contracting State to perform assess-	ing authorities		rm its notify-			

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	от	IF		PROVISIONS INT PROCEDUI	RES		JLES)	UTP GEN Page 57 d	
Status: IN	FOR	CE		Ref.: A 94-01D/3.2	011		Original: EN	Date: 01.10.	2012
OTIF UTP	"qua upon the c	ility n requ ompo ist o	uest, make avail etent authority f "quality mana	stem approvals" iss able to	ued or its no	r withdra	uthorities	periodically or	
	other "qual other	⁺asso ity m wise	essing entities a anagement sys	all ensure that the ire informed of tem approvals" whi I, upon request, o	notifi ch it h	ed bodie as refus	s of ed, withdrawn, s	suspended or	
5.	Verifi UTP(		on of conformi	ty with applicable	EC v	erificatio	n		
5.1	verifi	catio (s) w	n of conformit ith an assessing	an application for y with applicable entity		C verific ed body	ation of the sub	system with a	
	The a	appli	cation shall inclu	ıde:					
				ess of the applican ative, his name and				odged by the	
	<ul> <li>the technical documentation regarding the approved type, including the UTP Type-examination certificate, as issued after completion of the procedure defined in module SB,</li> </ul>								
	and i	f not	included in this	documentation:					
	a	gen	eral description	of the subsystem, it	ts ove	rall desig	n and structure		
	a	iccor		sary for the compila rovisions of UTP e"	a	is descril	nnical file bed in point 4 o 2008/57/EC,	of Annex VI to	
	a	i sep	arate file with th	e set of data require	ed by t	the relev	ant		
		JTP			т	SI			
	S	et u		ster nittee of Technical ATMF Article 13,			for in Articles 3 2008/57/EC,	34 and 35 of	
	a	list	of						
	r	eleva	ated Standards ant technical sp been	<sup>22</sup> and/or other becifications which	ro ro li	elevant eference	ed standards technical spec s of which hav the <i>Official Jo</i> o <i>Union</i> ,	ifications the /e been pub-	
	q L W	juirer JTP vhere	ments of the those	art, and descriptior	т	SI		meet the re-	
	h p V	ave artly /alida	applied ated Standards,	ed. In the event of	h p V	ave not artly app /alidated	Standards,		
				ntation shall specify	•			•	
			tions for use of , etc.),	the subsystem (res	STRICTIO	ons of ru	nning time or d	istance, wear	

<sup>&</sup>lt;sup>22</sup> See section 1.2 b)

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6.

Article,

thereof.

assessing entity

assessing entity

the applicant shall inform the

The applicant shall also provide the

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Ref.: A 94-01D/3.2011

Original: EN Date: 01.10.2012

Corresponding text in EU regulations <sup>1</sup>

EU ref.<sup>2</sup>

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

evidence of conformity with other	
applicable COTIF regulations,	regulations deriving from the Treaty
	(including certificates, if any),

- any further information, if required by the relevant UTP(s). TSI(s).
- The notified body The assessing entity 5.2 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 considers the	notified body	
UTP Type-examination certificate no longer remains valid or is not appropriate	EC type examination Certificate and that a new	
UTP Type-examination certificate	EC type examination Certificate	
is necessary, the assessing entity shall refuse to assess the quality managem- its refusal.	notified body nent system of the applicant and shall justify	
When the subsystem referred to in point 3 is ing to		
Article 7a of ATMF and the regulations/ guidelines adopted by the Committee of Technical Experts in pursuance of that		

notified body

notified body

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OTIF UTP	UTP(s)	ecise reference to parts) for which th	o the he derogation is rec	TSI(s)	ext in EU regulations	EU ref. <sup>2</sup>
	authority, derogatio requirement out by th	it shall anal n complies w ents and follow	y is the competent yse whether the ith the essential the procedure set Technical Experts ATMF.			
	of the a		ormed of the result o outcome of the			
	authority, the applic assessing	cant shall commu		notified body		
7.	Surveillar assessing		sponsibility of the	notified body		
7.1			ce is to make sure d quality managem		ant duly fulfils th	e obligations
7.2	assessing access to all necess	g entity the manufactur sary information,	-	notified body g and storage	sites and shall p	rovide it with
	the q	uality records, su	ent system docume uch as inspection re personnel concern	eports and test	ata, calibration	n data, quali-
7.3	shall carr		udits to make sure t em and shall provid		ant maintains an	
	The frequ	ency of the perio	odic audits shall be	at least once e	every two years.	
	assessing	g entity	ites a certified quali nt during the periodi	notified body	t system, the	
7.4	assessing may, if ne that the q assessing	g entity unexpected visit g entity ecessary, carry c uality managem g entity vide the applicar	s to the applicant. out subsystem tests ent system is functi nt with a visit report	oning correctly notified body	carried out, in o . The	
7.5	responsite assessme tured sub of the su	systems with the	y of the manufac- e approved type carrying out the s nder point 3, shall o	urveillance of	n all the quality	

	OTIF	GENERAL F ASSESSME	UTP GEN-D Page 60 of 90					
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OTIF UTP	other	g entity		Corresponding te	ext in EU regulations	; 1	EU ref. <sup>2</sup>	
	responsit to be mana	ble for that task, ensured that congement systems	in order: orrect management s relating to subsyst	ent of interfaces between the different quality vstem integration has been performed,				
	to gu		vith the applicant, th nsistency and the o s.					
	assessing	g entity eive all docume	s the right of the ntation (approval an			other		
		ssing entity(ies), ness the surveill	ance audits as in po	notified be oint 7.3, and	ody(ies),			
		tiate additional a	audits as in point 7.		sponsibility and	together with		
	asses	ssing entity(ies).		notified b				
8.	UTP Cert	tificate of verific	cation	EC certificat declaration of	e of verification	on and EC		
8.1 Where the subsystem meets the requirements of the relevant assessing entity Inotified body shall issue a UTP Certificate of verification.					nt TSI(s), the cate of verification	on in compli-		
	The certif assessing nical File ments se File".	ficate shall inclu g entity's compil e in accordance t out in UTP GI	de in an annex the lation of the Tech- with the require- EN-C <sup>23</sup> "Technical given to the appli-		pint 3 of Annex			
	or specific UTP Cert shall also UTP(s) or their pa	c case, the ificate of verifica indicate the pre	cise reference to the	EC certificate e TSI(s)	uring	ade, renewal		
	requireme UTP(s), the shall issue clearly state meet the UTP(s). Based or	ents of the releva he assessing en e an intermediat ating which parts e requirements n the ISV, the a	tity e statement of verifi s of the subsystem of the relevant pplicant may draw	TSI(s), the no cation (ISV) in compliance tive 2008/57/ The applicant	ntified body e with Article 18 EC. t shall draw up	3(4) of Direc- a written EC		
	statemen dance wit	t of verificatior h Annex 2.	tion of intermediate n (ISV) in accor-	conformity ac	on of intermediat cording to section e 2008/57/EC.			
8.2			erification may be or mandatory basis					

<sup>&</sup>lt;sup>23</sup> Formerly named APTU Annex 1-C

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OTIF UTP	State who according this case	ere the applicati to this module the provisions i	in the Contracting on for assessment has been made. In n this UTP relating of verification shall	Corresponding to	ext in EU regulations	, 1	EU ref. <sup>2</sup>			
	of the E	uropean Union / concerning E	h is also a member shall apply Euro- C Declarations of							
	keep the if issued,									
	or specific UTP Cert the UTP I for the su UTP(s)	c case(s), the ificate of verifica Declaration of ve bsystem shall al arts to which cor	ation and, if issued, prification lso indicate the refe							
	•	v last sentence of 8.1	]		SV procedure t p a written EC					
	up, it and the a		ocuments shall be w	The EC declaration written in accordance with Annex V to Directive 2008/57/EC.						
	the q	icates to be refe uality managem ated in point 7.3,	nent system approv	al indicated ir	n point 3.3 and	audit reports				
	the l	•	nination certificate	the EC and its ac	type examinatic Iditions.	on certificate				
	and UTI statemen	declaration(s t of verification (	ation of verification ) of intermediate ISV), if any, o the relevant autho	and EC ISV d	leclarations, if ar					
		be annexed to	red to in point 8.1 the UTP Declara-	compiling the accompany the tion and the ate subsyste file must be of	body shall be re technical file ne EC declaration EC declaration m conformity. T drawn up in acc and point 4 of 8/57/EC.	that has to on of verifica- of intermedi- The technical ordance with	8.3			
9.	the natior	nal authorities:	ghout the service lif ferred to in point 3.1		rstem, keep at th	e disposal of				

□ the change(s) referred to in point 3.5, as approved,

	OTIF	GENERAL F	UTP GEN-D Page 62 of 90					
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OTIF UTP			Corresponding	g text in EU regulation	s <sup>1</sup>	EU ref. <sup>2</sup>		
the decisions and reports of the notified body referred to in points 3.5, 7.3 and 7.4, and								
	the T	echnical File ref	erred to in					

point 8.1 (and 8.3).

point 8.3.

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 in the restricted.

Each assessing entity shall ensure that the other assessing entities are informed of the UTP Certificates of verification which it has refused, suspended, withdrawn, or otherwise restricted, and, upon request, of UTP Certificates of verification EC certificates of verification which it has issued.

11. Authorised representative

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

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OTIF UTP				Corresponding te	ext in EU regulations	; 1	EU ref. <sup>2</sup>	
		VERIFICAT VERIFICATI		EC VERIFICATION BASED ON PROD- UCT VERIFICATION				
1.	the proce tem's con the applic whereby t in order out to veri that the s conformity UTP Ty thereby satisfies th	product verificat dure for assess nformity with the able UTP(s) the applicant fulf that assessment ify ubsystem conce y with the type d ype-examination the requirements and other applicat	e requirements of ils the obligations la ts can be carried rned, which has be escribed in the certificate and	and 5, and e sole responsi en subject to t EC type exam	ion procedure nt 2 ensures and dec bility he provisions of nination certificat ell as any othe	point 4, is in te and		
2.	Manufact							
	The manu tured subs UTP Type	ufacturing proces system with the e-examination ce he requirements	approved type desc ertificate s of the relevant	ring shall ensure conformity of the manufac- scribed in the EC-type examination certificate				
3.	verificatio	e an application n of conformit ith an assessing	y with applicable	the EC verific notified body		system with a		
	<ul> <li>the name autho</li> <li>name turer(s)</li> <li>the te UTP and its</li> <li>It shall als tion:</li> <li>a gen the do accord</li> </ul>	rised representa and address s), if not the app chnical documer Type-examinatio s annexes, as is so include the fo eral description ocuments necess	ss of the applicant tive, his name and a of the manufac- licant himself, ntation regarding the n certificate sued after completio llowing if it is not al of the subsystem, it sary for the compila irements set out in	address as we e approved typ EC type e on of the proce ready included s overall desig tion of the tech as descril	II, be, including the examination certi edure defined in d in the technical n and structure,	ficate module SB. I documenta-		

<sup>&</sup>lt;sup>24</sup> The assessing entity will request evidence of conformity with all "other applicable regulations" from the applicant. The applicant must provide such evidence of conformity as is relevant and the assessing entity will include this evidence without further assessments in its compilation of the Technical File.

UTP (e.g. UTP WAG) may contain provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

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OTIF UTP		a sep	<i>Correspondir</i> arate file with the set of data required by the rel	g text in EU regulation. evant	s <sup>1</sup> EU ref. <sup>2</sup>			
		UTP(s	S) TSI(S)	evant				
		set u		ed for in Articles 3 ve 2008/57/EC,	34 and 35 of			
			ated Standards <sup>25</sup> and/or other harmon ont technical specifications which been referer lished					
			d in full or in part, and descriptions of the so nents of the relevant   TSI	ptions of the solutions adopted to meet the re-				
		Valida have i Valida	not been applied. In the event of partly applied	nised standards nised standards, hich have been ap	plied,			
		condit limits,	tions for use of the subsystem (restrictions of etc.),	running time or d	istance, wear			
			iptions and explanations necessary for the und enance of the subsystem,	erstanding of the o	operation and			
			tions for maintenance and technical documenta subsystem,	tion regarding the	maintenance			
		UTP(s	hall be taken into account during production, r	naintenance or op	eration of the			
			appropriate technical evidences, which demon have been successfully performed, under con odies,					
			tions of integration of the subsystem in its systen to the subsystems,	em environment a	nd the neces-			
				ions deriving fror ing certificates, if a				
		result	s of design calculations made, examinations ca	rried out, etc.,				
		test re						
		a list o	nentation regarding the manufacture and the as of manufacturers involved in the subsystem's d istallation, and	-	•			
		any fu	rrther information, if required by the relevant s) and Validated Standards. TSI(s).					
4.		rificatio P(s)	on of conformity with applicable EC verifica	tion				
4.1	cho	osen by	ssing entity The notifie the applicant shall first examine the application e-examination certificate.					
	lf tl	he						

<sup>&</sup>lt;sup>25</sup> See section 1.2 b)

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Status: IN	FORCE		Ref.: A 94-01D/3.2	2011	Original: EN	Date: 01.10.20	)12
OTIF UTP	no longer UTP Type is necess assessing	the e-examination ce remains valid or e-examination ce ary, the pentity se to assess the	r is not appropriate a artificate	Corresponding text in EU regulations 1       EU ref. 2         notified body       EC type examination Certificate         e and that a new       EC type examination Certificate         IEC type examination Certificate       Inotified body         motified body       Inotified body			
	The assessing entity shall carry out appropriate examinations and subsystem with the approved type described UTP Type-examination certificate and with the requirements of the relevant UTP(s).						
4.2	vant UTP(s), V and/or teo conformity UTP Type	alidated Standa	tions, or equivalent ved type described ertificate	TSI(s), harmo tests, shall be in the	nised standard(	s) rder to verify	
	Validated	entity	e carried out shall b	harmonised s e decided betw notified body		nt and the	
4.3	shall agree agree tha UTP(s), tests or va	tests or validation under full operating condit direct supervision and attendance of the			uired in the relev	/ant	
	The assessing entity shall have entrance for testing and verified			notified body. The notified body fication purposes to production workshops, and where appropriate, prefabrication and ts as provided for in the relevant TSI(s). TSI(s).			
4.4	ing to Article 7a guidelines Technical Article,	a of ATMF and a adopted by t Experts in p ant shall inform	rred to in point 3 is d the regulations/ the Committee of pursuance of that the	Article 9 of Di			
	assessing	cant shall also p entity cise reference to		notified body			

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OTIF UTP	(or their p	arts) for which th	he derogation is req		ext in EU regulations	EU ref. <sup>2</sup>	
	authority, gation co ments an the Comming to Arti The appli of the a	it shall analyse mplies with the d follow the pro- nittee of Technic cle 7a of ATMF. cant shall be info	y is the competent whether the dero- essential require- ocedure set out by cal Experts accord- ormed of the result e outcome of the	o- ∋- yy d-			
	If the assessing entity is not the competent authority, the applicant shall communicate to the assessing entity the outcome of the derogation procedure.				The applicant		
4.5.		ificate of verific	-	EC certificat declaration of	e of verificatio	on and EC	
	system i relevant l	e ertificate of veri meets the req JTPs, and	fication if the sub- uirements of the	notified body		n in	
	in respect of the examinations and tests car The certificate shall include in an annex the assessing entity's compilation of the Tech nical File in accordance with the require ments set out in UTP GEN-C <sup>26</sup> "Technica File".		de in an annex the lation of the Tech- with the require-	ne h- e-			
	The certin	ficate shall be g	given to the appli-				
	specific ca UTP Cert shall also UTP(s) or their pa	ase, the ificate of verifica indicate the pre	cise reference to the	EC certificate e  TSI(s)	Iring	e, renewal or	
	requireme UTP(s), t shall issu clearly st	ents of the releva he assessing en e an intermediat ating which parts		TSI(s), the no ication (ISV) in compliance	tified body e with Article 18		
	up a writt statemen	en UTP declarat	pplicant may draw tion of intermediate n (ISV) in accor-	ISV declaration conformity ac		te subsystem	
	The appli	cant shall keep t	he				

<sup>26</sup> Formerly named APTU Annex 1-C

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OTIF UTP	document	rtificate of verification and the ation referred to in point 3. for inspection by the national authon.	EC certificate			
5.	UTP decl	aration of verification	EC declaratio	n of verification		
	drawn up as if it is State whe according this case	leclaration of verification may be on a voluntary or mandatory basis required by law in the Contracting ere the application for assessment to this module has been made. In the provisions in this UTP relating TP declaration of verification shall				
	of the E	cting State which is also a member uropean Union shall apply Euro- / concerning EC declarations of n.				
5.1	declaratio for the su	cant pplicable, draw up a written UTP n of verification bsystem and keep it at the disposa etime of the subsystem.	verification			
		e subsystem referred to in point 3 is c case(s), the	s subject to a d	derogation, upgr	ade, renewal	
	for the sul UTP(s) or their pa	aration of verification bsystem shall also indicate the refer arts to which conformity has not bee ant procedure.	TSI(s)			
	[covered by	4.5]		SV procedure t a written EC		
	up, it and the a	declaration of verification is drawn ccompanying documents shall be w o this UTP.	ritten in accord		/EC.	
	A copy of and UTF statement	the UTP declaration of verification declaration(s) of intermediate of verification (ISV), if any, nade available to the relevant author	A copy of the and EC ISV d	EC declaration eclarations, if ar	of verification	
5.2	(see point 4	.5)		ody shall be re		
		nical File referred to in point 4.5 be annexed to the UTP Declara- ification.	accompany th tion and the ate subsyster file must be o	e technical file ne EC declaration EC declaration m conformity. T drawn up in acc and point 4 of B/57/EC.	on of verifica- of intermedi- The technical ordance with	
6.	competen	ne assessing entity is itself the t authority, it shall inform the t authority in the Contracting State	ing authorities	s concerning the		

o	DTIF	GENERAL PROVISIONS ASSESSMENT PROCEDURES (MODULES)				UTP GEN-D Page 68 of	
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me UT iss the the Ea Oth UT Wh of	ents (cf. TP Certif sued or v e compe e list of c ach asse her asse TP Certif nich it ha	sections 1.2 c ficates of verifica withdrawn, and s etent authority certificates refus essing entity sha essing entities a ficates of verifica	shall, periodically or ed, suspended or o all ensure that the re informed of the ation pended, withdrawn,	upon request its notifying au therwise restri Each notified notified boc certificates of or otherwise r	uthorities cted. body shall info lies concernin verification	e to orm the other ig of EC-	EU ref. <sup>2</sup>

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.

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OTIF UTP				Corresponding te	ext in EU regulations	; 1	EU ref. <sup>2</sup>			
ON F	ULL QUA	VERIFICAT ALITY MANA SIGN EXAMI	GEMENT SYS-							
1.	This assessment based on full quality management system of the part of the procedure for assessment of a subsystem's conformity with the require- ments of the applicable UTP(s)EC verification procedure1.whereby the applicable UTP(s) whereby the applicant fulfils the obligations laid down in points 2 5 and 7, in order that assessments can be 									
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.									
		uacy of the tecl ce with point 4.	hnical design of the	e subsystem s	shall have been	examined in				
3.	Quality m	nanagement sys	stem							
3.1	the quality ma to be use	e an application anagement syste d with an assess		his with the notifi	ed body					
	The applie	cation shall inclu	de:							
	autho	rised representa	s of the manufactu tive, his name and	address as we	II,					
		eakdown struct	ure of the project n	nanagement a	nd the name an	d address of				
			n for the subsystem	•						
	□ the do	ocumentation co	ncerning the quality		system, EC declaration(s psystem conforn he subsystem, if	) of interme- nity (ISV) is- any				
		ten declaration the sing entity.	hat the same applic	ation has not b notified body.		any other				
3.2	The quali	ty management	system shall ensu	ire compliance	e of the subsys	tem with the				
must pro assessmo UTP (e.g	vide such evi ents in its com . UTP WAG) r	dence of conformity pilation of the Techr nay contain provisior	of conformity with all "oth as is relevant and the hical File. Is which have references	assessing entity v to requirements of	will include this evide	ence without furt	her			

or provisions which have references to requirements of RID; however, the assessment of conformity with RID is the task of the national authority (in the first admitting Contracting State) competent for RID, its delegate or an inspection body approved by it, see RID 2011, 1.8.6.2-1.8.6.8. The competent authority for RID may delegate power to an assessing entity performing assessment of conformity with the UTP in accordance with this UTP GEN-D, provided that entity has the necessary qualifications in RID.

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Corresponding text in EU regulations<sup>1</sup>

EU ref.<sup>2</sup>

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

TSI(s)

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

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

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and subsystem quality,
- the technical design specifications, including standards, that will be applied and, where the relevant
  - Validated Standards<sup>28</sup> and/or other relevant technical specifications harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the requirements of the relevant

UTP(s)

TSI(s)

that apply to the subsystem will be met,

- □ the design control and design verification techniques, processes and systematic actions that will be used when designing the subsystem pertaining to the product category covered,
- □ the corresponding manufacturing, quality control and quality management system techniques, processes and systematic actions that will be used,
- □ the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- □ the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality management system.

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

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

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

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

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

<sup>&</sup>lt;sup>28</sup> See section 1.2 b)

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OTIF UTP	When			Corresponding te	ext in EU regulations	EU ref. <sup>2</sup>
	the applicant operates         a certified quality management system certified by an accredited certification body,         is used                 for the manufacturing and final testing of the relevant subsystem, the         assessing entity         notified body         shall take this into account in the assessment. In this case, the         assessing entity         notified body         will make a detailed assessment of quality management system specific documents and         records of the subsystem only. The         assessing entity         notified body         shall not assess again the entire quality manual and all the procedures already assessed by the quality management system certification body.					
	at least o	ne member with	in quality managen experience of eva rned, and knowledg	luation in the	relevant subsyst	tem field and
	one or mo	shall include ore assessment mises of the rele	visits evant entities conce	an assessme rned.	nt visit	
	The appli	cant		or his authoris	sed representati	ve
	or his authorised representative shall be notified of the decision.					
	decision. evidence assessing	Where the asse that the requiren g entity	ain the conclusions ssment of the qual nents referred to in agement system ap	ity managemei point 3.2 are n notified body	nt system provic net, the	
3.4			take to fulfil the ob and to maintain it s			
3.5	assessing that has a the qualit and final	approved the quarter y management s	ality management s system having impa ng and operation,	act on the sub	system design,	manufacture,
	shall eval ment syst		ed changes and de to satisfy the requ ary.		the modified qua	
			it of its decision. The reasoned assessr		shall contain the	e conclusions
	to the ma	anufacturer if th	ard the notification e quality manage- d by the manufac-			
3.6	competer competer which has ments (cf	at authority, it at authority in the s authorised it t . sections 1.2 c)	entity is itself the shall inform the e Contracting State o perform assess- and 1.3) of any tem approvals" issu	ing authorities	s of	

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OTIF UTP	UTP       Corresponding text in EU regulations 1       EU ref. 2         upon request, make available to the competent authority       its notifying authorities       EU ref. 2         the list of "quality management system approvals" refused, suspended or otherwise restricted.       Each assessing entity shall ensure that the other assessing entities are informed of the "quality management system approvals" which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of "quality management system approvals" which it has issued.							
4.	Verification of conformity with applicable EC verification UTP(s)							
4.1	The applicant shall lodge an application for verification of the subsystems' conformity the EC verification of the subsystem with the applicable UTP(s) (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		nd operation of t the	ke it possible to und he subsystem, and					
	It shall in							
	autho	orised representa	ess of the applicant ative, his name and a hat the same applica uthority,	address as we	ll, been lodged with			
	the te	echnical docume sess the subsyst	entation. <sup>29</sup> The tech tem's conformity with					
	UTP( and o subsy	(s) cover, as far as	entation shall specify relevant for the ass nnical documentatio ments:	TSI(s) sessment, the	design and ope	eration of the		
	∘ d a	locuments neces	tion of the subsyster ssary for the compila provisions of UTP al File"	tion of the tech as de	•	t 4 of Annex		
	L fo s c c	JTP(s) or each relevant et up by the Co al Experts accor le 13,	mmittee of Techni- rding to ATMF Arti-	TSI(s provid of Dir	ded for in Article ective 2008/57/E	EC,		
	0	peration and ma	ptions and explanati intenance of the sub gration of the subs	system,		-		
	n	ecessary interfa						
<sup>29</sup> The tech			criptions and explanations	nocoscon for uno	lorotanding the functi	aning and passible		

risks/failures in safety-related software used in the subsystem, if appropriate,

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	0	TIF		PROVISIONS INT PROCEDUR	RES (MOE	OULES)	UTP GEN-D Page 73 of 90
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OTIF UTP		r	'alidated Standa elevant technic vhich have been		har oth tior bee	g text in EU regulation monised standa er relevant techni is the references en published in urnal of the Europe	ards and/or ical specifica- of which have the <i>Official</i>
		rd L V h V	equirements of th JTP(s) vhere those validated Standar ave not been ap validated Standar ne technical docu	rds plied. In the event o rds, umentation shall spe	tions of the TS har f partly appli har ccify the part	solutions adopted (s) monised standard ed monised standard s which have bee	d to meet the Is Is,
			-	calculations made, e	examinations	carried out, etc.,	
			est programme a	•			
			vidence of confo pplicable COTIF			ulations deriving aty (including c ⁄),	
		o d	ocumentation re	garding the manufac	cture and the	e assembly of the	subsystem,
			list of manufact	turers involved in th lation,	ne subsyster	n's design, manu	facturing, as-
			onditions for use ear limits etc.),	e of the subsystem	(restriction	s of running time	e or distance,
			onditions for ma ubsystem,	intenance and tech	nical docum	entation on mainte	enance of the
		o a	ny technical requ	uirement specified ir	the relevan	t	
		L	JTP(s)		TS	(s)	
			nat shall be take ne subsystem,	n into account durir	ng productio	n, maintenance of	r operation of
		С		riate technical evid have been succes nt bodies,			•
			ny further inform y the relevant	mation, if required			
		ι	JTP(s),		TS	(s),	
		evide relev	ence shall mentio	nce for the adequad on any documents th	hat have bee	en used, in particu	
		and/o denc tiona	e shall include, v l conditions) carr	cifications have not where necessary, th ied out by the appr on his behalf and un	been appli e results of opriate testi	tests (including th ng body of the ap	ose in opera-
4.3	cor Arti guio Teo	ding to cle 7 deline chnica	o a of ATMF an s adopted by	erred to in point 4.1 d the regulations/ the Committee of pursuance of that	Article 9 of		
	Arti the	-	cant shall inform	the	I		

<sup>&</sup>lt;sup>30</sup> See section 1.2 b)

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OTIF UTP	assessing thereof.	g entity		Corresponding te notified body	ext in EU regulations	EU ref. <sup>2</sup>
	The applicant shall also provide assessing entity with a precise reference to the UTP(s) (or their parts) for which the der		o the	notified body TSI(s) uested.		
	When the assessing entity is the competer authority, it shall analyse whether the der gation complies with the essential requir ments and follow the procedure set out the Committee of Technical Experts accor- ing to Article 7a of ATMF. The applicant shall be informed of the res of the analysis and the outcome of the derogation procedure.					
	authority, shall com assessing	the applicant municate to the	not the competent	The applicant	t	
4.4	.4 The assessing entity			The notified body the design meets the requirements of the TSI(s), an "EC design examination certificate" to the applicant.		
	to the app	olicant.				
	examinati		the name and addrons (if any) for its va In.			
	The certif	icate may have o	one or more annexe	s attached.		
	shall incl entity's co accordance	ude in an anr ompilation of the	nination certificate nex the assessing e Technical File in irements set out in I File".			
			nexes shall contain h the examined des			w the confor-
	or specific the UTP I shall also UTP(s) or their pa	c case, the Design examinat indicate the pre	cise reference to the	the EC design e TSI(s)	n examination ce	
	relevant	rtain parts of the he assessing en	subsystem are cov tity	I ered and they TSI(s), the no		ements of the

<sup>&</sup>lt;sup>31</sup> Formerly named APTU Annex 1-C

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OTIF UTP	clearly st	ating which parts	e statement of verif s of the subsystem of the relevant	ication (ISV) in complianc		
	up a writt		pplicant may draw ion of intermediate SV).	declaration conformity a	t shall draw up of intermediate according to s Directive 2008/57	e subsystem ection 2 of
4.5	assessing that has i UTP Desi informed the requir UTP(s)	ssued the ign examination of of any modificati rements of the rel	certificate on to the approved levant	design that m	-	nformity with
	assessing that issue UTP Des — in the	g entity	on to the original	notified body EC design examination certificate EC design examination certificate.		
	Only thos be perform		and tests that are re	elevant and ne	ecessary to the c	changes shall
4.6	competer competer which ha ments (cr UTP Desi and/or an	nt authority, it nt authority in the s authorised it to f. sections 1.2 c ign examination o by additions there	eto which it has iss	ing authoritie examination	s concerning th certificates	e EC Design
	the comp			its notifying a thereto refus		or otherwise
	other ass UTP Desi and/or ar	essing entities a ign examination on additions there	all ensure that the are informed of the certificates eto which it has re uest, of the certific	notified bodie examination fused, withdra	es concerning o certificates wn, suspended	f EC Design or otherwise
	States an may, upo UTP Desi and/or ad the Secre States	d the other asses n request, obtain ign examination o Iditions thereto. I etary General an	a copy of the certificate Upon request, id the Contracting	the other noti EC design ex the Commiss	fied bodies camination certifi ion and the Men	cates nber States
	may obta carried ou assessing	ut by the	echnical document	notified body		examinations
	The asse	ssing entity		The notified b	body	

	OTIF	GENERAL P ASSESSMEN	ROVISIONS NT PROCEDUI		ILES)	UTP GEN- Page 76 o	
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OTIF UTP	UTP Desi its annex		ertificate , as well as the until the expiry of	EC design ex		icates	EU ref.
4.7	UTP Desi its annexe			technical docu			
5.	Surveilla assessing		sponsibility of th	e  notified body	ý		
5.1			e is to make sure quality manageme		ant duly fulfils th	ne obligations	
5.2	assessing access to provide it	gentity the design, ma with all necessary	odic audit purpose anufacture, inspec y information, in pa	notified body ction, testing a articular:	and storage sit	es and shall	
	the qu	uality records as	nt system documen provided for by t s of analyses, calc	he design part		management	
	ment	system, such as	provided for by the inspection reports el concerned, etc.				
5.3	shall carry		lits to make sure t n and shall provide		int maintains an		
	one audit ture, asse design ex	during the time period	dic audits shall be period of performin on) for the subsyst	ng the relevant	activities (desi ubject of the		
	assessing	entity	es a certified qualit	notified body	t system, the		
5.4				notified body			
	assessing may, if ne the proper	cessary, carry ou r functioning of th ovide the applicar	t subsystem tests, e quality manager nt with a visit repo	nent system.			
5.5	responsib verification of the su	n of the conformit bsystem, if not c concerned as unc	y carrying out the s der point 3, shall o		n all the quality		

	OTIF				UTP GEN-D Page 77 of 90		
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OTIF UTP	man to co guar	agement systems ollect, in liaison wi	relating to subsyste th the applicant, the	Corresponding text in EU regulations <sup>1</sup> EU ref. <sup>2</sup> nt of interfaces between the different quality stem integration has been performed, he necessary elements for the assessment to erall supervision of the different quality man-			
	<ul> <li>This coordination includes the right of the assessing entity</li> <li>to receive all documentation (approval assessing entity(ies),</li> <li>to witness the surveillance audits as in</li> <li>to initiate additional audits as in point the other assessing entity(ies).</li> <li>UTP Certificate of verification</li> </ul>			notified body(ies),			
6.	UTP Ce	rtificate of verific	cation		te of verificat	ion and EC	
6.1	assessir shall iss a UTP C The cer assessir cal File set out i	ng entity ue Certificate of verific tificate shall inclue ng entity's compila in accordance wit n UTP GEN-C <sup>32</sup>	ets the requirements cation. de in an annex the ation of the Techni- h the requirements 'Technical File". given to the appli-	notified body an EC certifie	cate of verification		
	or speci UTP Ce shall als UTP(s) or their p the asset If only co requiren UTP(s), shall iss clearly s meet t UTP(s). Based o up a wris stateme	fic case, the rtificate of verifica o indicate the pre- parts to which con essments carried of ertain parts or ce nents of the releva the assessing en ue an intermediat stating which parts he requirements on the ISV, the a tten UTP declarat	cise reference to the formity has not bee but. rtain stages of the ant	EC certificate TSI(s) n examined du EC verificatio subsystem are TSI(s), the no cation (ISV) in compliance tive 2008/57/ The applicant ISV declaratio conformity ac	uring n procedure. e covered and th otified body e with Article 18 EC.	ney meet the s(4) of Direc- a written EC se subsystem	
6.2		claration of verifi	ication	1	on of verification		
	drawn u if it is State w	p on a voluntary o required by law nere the applicati	erification may be or mandatory basis in the Contracting on for assessment has been made. In				

<sup>&</sup>lt;sup>32</sup> Formerly named APTU Annex 1-C

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OTIF UTP			n this UTP relating of verification shall	Corresponding t	ext in EU regulations	EU ref. <sup>2</sup>
	of the Eur	ropean Union sh	n is also a member all apply European arations of verifica-			
	The applicant shall keep the UTP Certificate of verification and, if issued, the Declaration of verification at the disposal of the national authorities throughout the service lifetime of the subsys- tem.					
	newal or s UTP Cert the UTP I for the su UTP(s)	specific case(s), ificate of verifica Declaration of ve bsystem shall al arts to which con n	ation and, if issued,	EC declaration ences to the TSI(s)	on uring the	upgrade, re-
	•	last sentence in 6.1	]		SV procedure t p a written EC	
	up, it and the a		erification is drawn cuments shall be w	ritten in accord		/FC
	The certif	icates to be refe	ient system approva			
		•	nination certificate and its additions.	the EC D	esign examinatio	on certificate
	and UTF statement	D declaration(s t of verification (	ation of verification ) of intermediate ISV), if any, o the relevant author	tion and EC I	SV declarations,	
6.3	(Reserved (see point 4	d)		The notified compiling th accompany t tion and the ate subsyste file must be	body shall be re e technical file he EC declaration EC declaration m conformity. T drawn up in acc and point 4 of	that has to on of verifica- of intermedi- The technical ordance with
7.	the nation	hal authorities: locumentation	ghout the service lif concerning the qua	e of the subsy	stem, keep at th	-

□ the change(s) referred to in point 3.5, as approved,

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OTIF UTP				Corresponding te	ext in EU regulations	EU ref. <sup>2</sup>	
	asses referr	ecisions and rep sing entity ed to in points 3 chnical file refer	.5, 5.3 and 5.4	notified b	ody		
8.	competen competen which has ments (cf UTP Cert issued or the compo	at authority, it authority in the s authorised it to s sections 1.2 of ficates of verific withdrawn, and etent authority f certificates an	shall, periodically or	ing authoritie cates of verifi upon request its notifying a	s concerning th cation , make available uthorities	e EC Certifi-	
	other ass UTP Cert which it h of	essing entities a ificates of verific as refused, susp ificates of verific	pended, withdrawn,	notified boo certificates of or otherwise r	dies concernin verification	g of EC-	
9.	Authorise	d representative					

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

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OTIF UTI	P		I	Corresponding te	ext in EU regulations	EU ref. <sup>2</sup>	
	CONFO	OF A SU RMITY WIT	JBSYSTEM'S TH NOTIFIED INICAL RE-		ON PROCEDU ATIONAL RULE	RE IN THE 2011/18/ C, Ann S VI, 3	
1.	conformity requirements ing State	y with the notifie ents/rules are in at the time of the the following pro	les for assessing d national technical force in a Contract- e entry into force of ocedure shall apply	national rules the body de 17(3) (the de certifies that the national	s is the proced signated pursua esignated body) the subsystem of rules notified in	ant to Article checks and complies with	
	on an as verified a design ar the requi technical	sessment of th and certified t nd manufactured rements of the	he whereby, based e subsystem, it is hat the technical d subsystem meet relevant national otified according to oply to it, if any.	with Article 1	7(3).		
2.	according responsib COTIF teo Contractir applicant	to chapter 4 an ility of the author chnical admission g State(s) on	t the assessments e carried out is the ority competent for on of vehicles in the which territory the vehicle (or vehicle				
			te the assessment rassessing entity.				
3.	Applicati	on					
3.1	chapter 1 tion for a national national	.2 point g) may an assessment technical requi authority compe n of subsystems	apply according to lodge an applica- of the applicable rements with the etent for technical s in a Contracting				
	applicant		ne other than the for assessments				
3.2	inform applic quirer	able notified na ments, if any,	ogations from the tional technical re-				
	the or in wh be ad	ne where the ap ich the subsyste mitted to operate	•				
			ntation which shall assess the subsys-				



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*Corresponding text in EU regulations*<sup>1</sup> tem's conformity with the notified national technical requirements <sup>33</sup> of the Contracting State where the application is lodged,

and, if required by the assessing entity,

- the documentation provided through the modules of chapter 3 which have been applied.
- 3.3 If the assessing entity needs more documentation, (e.g. additional vehicle tests) in order to assess the subsystem's conformity with applicable notified national technical requirements and its safe integration into its environment, the entity may, in accordance with ATMF Article 6 § 4, request such documentation from the applicant; the request shall include justification.
- 3.4 If the subsystem is subject to ATMF Article 6 § 4, the authority that has received the application shall ensure that (a copy of) the application is forwarded to the competent authorities of those other Contracting States for which the subsystem is requested to be admitted to operate.

#### 4. Assessments

- 4.1 The assessments of the subsystem's conformity with the applicable notified national technical requirements and of its safe integration into its environment shall be carried out by applying **mutatis mutandis** an appropriate combination of modules from chapter 3, whereby the term "UTP" in these modules shall be replaced by the term "applicable notified national technical requirements and the subsystem's safe integration into its environment".
- 4.2 In accordance with ATMF Article 6a, assessments and tests carried out with a positive result and documented, thus proving conformity with the UTPs and other requirements (including national requirements), shall not be repeated. The equivalence table prepared in accordance with APTU Article 13 shall be observed in all cases where assessments are carried out.
- 4.3 All competent national authorities and assessing entities involved in the assessment procedures (including the modules in chapter 3) shall, in accordance with ATMF Article 10 § 4, cooperate in order to minimise the assessment time and costs.

EU ref.<sup>2</sup>

<sup>&</sup>lt;sup>33</sup> See definition in section 1.2 e)

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EU ref.<sup>2</sup>

#### 5. Certificate of verification of a subsystem in the case of applicable national rules <sup>3.2</sup>

The assessing entity responsible for

assessing the notified national technical requirements (rules) shall, provided that the subsystem complies with the applicable notified national requirements, draw up a Certificate of verification of a subsystem in the case of applicable national rules

intended for the applicant.

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the assessing entity through the assessment, including those related to parts subject to derogation from a UTP, ITSI,

upgrade or renewal.

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

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

#### 6. Technical File

3.3

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

which shall be annexed to the subsystem's referred to in point 2.4 (of 2011/18/EC, technical certificates and be drawn up in accordance with UTP GEN-C.; it

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

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#### OTIF UTP

Corresponding text in EU regulations<sup>1</sup>

EU ref.<sup>2</sup>

#### 7. Declaration of verification of a subsystem in the case of applicable national rules

A "Declaration of verification of a subsystem in the case of applicable national rules" may be drawn up on a voluntary or mandatory basis if it is required by law in the Contracting State where the application for assessment according to this module has been made. In this case the provisions in this UTP relating to a UTP Declaration of verification shall apply.

If issued by the applicant, it shall contain the same information as specified in Annex 2 to this UTP.

A Contracting State which is also a member of the European Union shall apply European law concerning EC declarations of verification.

#### 8. Authorised representative

The applicant's authorised representative may lodge the application referred to in point 3 and meet other obligations on his behalf and under his responsibility, provided that they are specified in the mandate.

Where reference is made in Annex VI to <sup>2011/18/</sup><sub>EC, Annex V</sub>, the declaration of verification of subsys-<sup>2</sup>. tems in the case of national rules, the provisions of Section 1 shall apply *mutatis mutandis* to that declaration.

	OTIF	GENERAL PRO		RES (MODU	ILES)	UTP GEN- Page 84 o	
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OTIF UTP				Corresponding te	ext in EU regulations	; <sup>1</sup>	EU ref. <sup>2</sup>
		DURE FOR AS			UBSYSTEN	I'S SAFE	2010/57/E C, Article 15
1.	competen ascertaine system w	suing a technical it national authori ed that the level of s rill not be reduced ce of the structura	ity shall have safety in the rail by the placing	Note: See Re	commendation 2	2011/217/EU.	
2.	shall take be technic only if the tial requir they shall		s to ensure that nstructed and ins them when inte	be placed in s stalled in such egrated into th	ay service a way as to me ne rail system.	In particular,	
	being	chnical compatibility integrated,	-	stems with the	e system into w	hich they are	
		afe integration of the neir environment.	se subsystems		lance with Artic rective 2004/49/		
3.	provided	compatibility shall through compliance ne applicable UTPs.	with the provi-				
	essential bility (e.g ling/train conform	ere is no relevant U requirement of tec . the interface with protection syste infrastructure, ene ns) the notified	hnical compati- legacy signal- ms, non-UTP rgy, and CCS				
4.	part of should be	rement for "safe inte the essential req e covered by the ap tified national rules.	uirements and				
5.	fied nation <sup>34</sup> for full essential section 5 form an e tion in ac evaluation	the UTPs nor the nal rules provide an assessment of com- requirements in a .2 above, the appli- xplicit risk assessme- cordance with UTF n and assessment".	adequate basis pliance with the ccordance with icant shall per- ent and evalua- C GEN-G "Risk		(2) of EU Regu	lation EC N°	
	assessed	licant's documenta by an independe rescribed in UTP GI	ent assessment				

<sup>&</sup>lt;sup>34</sup> In the case of a dispute, the national authority competent for technical admissions of railway vehicles shall decide.

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### ANNEX 1

# CONTENT OF THE "DECLARATION OF CONFORMITY" AND OF THE "DECLARATION OF SUITABILITY FOR USE" OF INTEROPERABIL-ITY CONSTITUENTS

OTIF U	JTP		Corresponding text in EU regulations <sup>35</sup>	EU ref. <sup>3</sup>				
	ity	e Declaration of conformity and/or suitabil- for use d the accompanying documents must be dat	- The EC-declaration of conformity and/or suitability for use uted and signed.					
	be stru	e declaration must written in the same language as the in- uctions for use of the constituent and must ntain the following:	be written in the same language as the instructions and must					
		, and the second s	the Directive references,					
		name and address of the manufacturer within	or its authorised representative established					
		a Contracting State	the Community case of the authorised representative, also					
		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	notified body or respect of conformity or suitability for use					
		date of examination certificate <sup>37</sup> togethe conditions of validity of that certificate;	r with, where appropriate, the duration and					
		where appropriate, reference to the UTPs, Validated Standards and other standards applied;	European specifications;					
		identification of the signatory empowered manufacturer	to enter into commitments on behalf of the					
			or of the manufacturer's authorised rep- resentative established within the Community.					
		where applicable, indication of the Euro- pean Directives, other than the Interop- erability Directive, which have been ap- plied.						

Annex IV of Directive 2008/57/EC

<sup>&</sup>lt;sup>36</sup> If no EU reference is indicated, it means that the chapter/section number is the same as in the OTIF text.

<sup>&</sup>lt;sup>37</sup> Such as Certificate of conformity, Type examination certificate, "Quality management system approval", Design examination certificate, Certificate of suitability for use

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EU ref. 39

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## **ANNEX 2**

# CONTENT OF THE "DECLARATION OF VERIFICATION" OF SUBSYSTEMS

OTIF UTP

TPCorresponding text in EU regulations 38The UTP declaration of verificationThe 'EC' declaration of verificationand the accompanying documents must be dated and signed.

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
   Contracting entity
   or the manufacturer, or its authorised representative established within
   a Contracting State
   the Community
   (give trade name and full address; in the case of the authorised representative, also give the trade name of the contracting entity or the manufacturer),
   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,
   name and address of the assessing entity which carried out the verification referred to in Article 18,
- $\hfill\square$  the references of the documents contained in the technical file,
- all the relevant temporary or definitive provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,
- if temporary: duration of validity of the UTP declaration of verification,
- 'EC' declaration,

- □ identity of the signatory.
- where applicable, indication of the European Directives, other than the Interoperability Directive, which have been applied.

Annex V of Directive 2008/57/EC

<sup>&</sup>lt;sup>39</sup> If no EU reference is indicated, it means that the chapter/section number is the same as in the OTIF text.

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# ANNEX 3

# CONVERSION TABLE FOR OTIF AND EU CERTIFICATES AND OTHER EVIDENCING DOCUMENTS

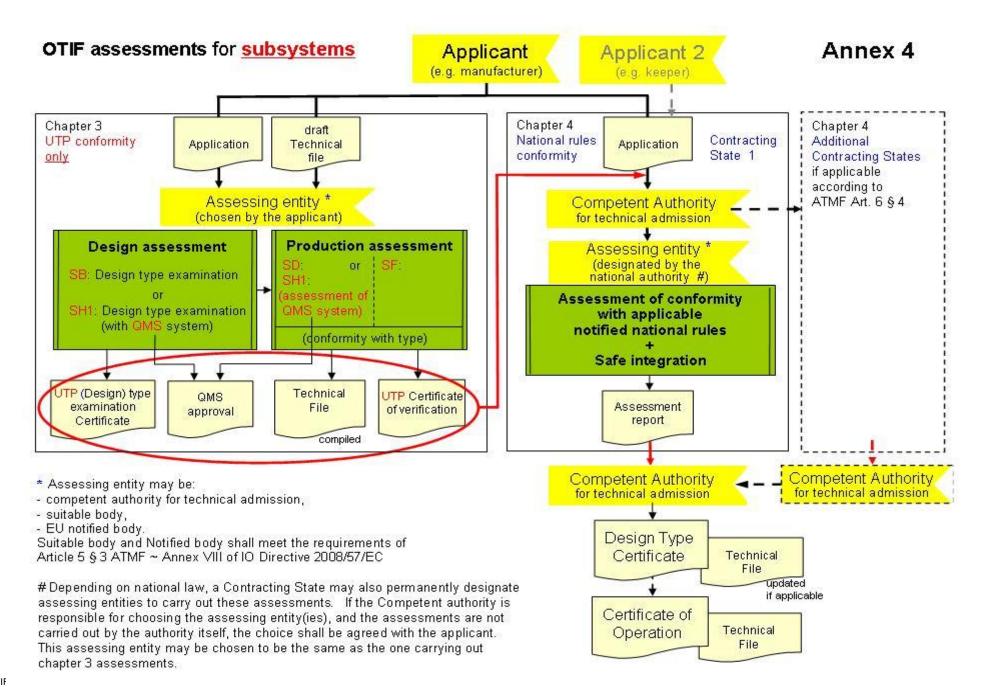
The conversion table below shows the documents produced through the assessment modules of chapters 2 and 3. They have different titles, depending on the regulations under which they are produced, but have the same purpose and content.

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

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# **GUIDELINES**

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





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### **ANNEX 5**

OTIF UTP

Corresponding text in EU regulations

EU ref.

#### **GUIDELINE FOR THE ASSESSMENT OF**

### THE SAFE INTEGRATION OF A SUBSYSTEM INTO ITS ENVIRONMENT

The following needs to be demonstrated in order to meet the "essential requirements" <sup>40</sup>: <sup>2011/217/</sup><sub>EU, 5.3.2</sub>

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

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

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

 $<sup>^{\</sup>rm 40}$  The "essential requirements" are specified in UTP GEN-A

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