



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

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

TECH-23005-CTE15-6.1

20.02.2023

Original: EN

15TH SESSION

Proposal for the adoption of a full revision of UTP GEN-E concerning the qualifications and independence of assessing entities

1. INTRODUCTION AND LEGAL BASIS

At its 14th session, the Committee of Technical Experts (CTE) decided, inter alia, that an analysis of the applicable criteria to be met by assessing entities and, if relevant, proposals for new provisions or for modifications to the existing provisions of UTP GEN-E should be prepared.

This document contains in:

- Annex 1: an analysis of the applicable criteria for assessing entities, which compares the provisions of UTP GEN-E with the latest provisions of the European Union (EU).
- Annex 2: a proposal for a full revision of UTP GEN-E.

In accordance with Article 6 § 1 of the APTU Uniform Rules (Appendix F to COTIF), “*The Committee of Technical Experts shall decide whether to adopt a UTP or a provision amending it in accordance with the procedure laid down in Articles 16, 20 and 33 § 6 of the Convention. [...]*”

Article 5 § 3 letter c) of the ATMF Uniform Rules (Appendix G to COTIF) requires that “*The assessing entity shall meet the requirements as set out in the relevant UTP.*”

The proposal has been developed on the basis of COTIF, as last amended on 1 March 2019.

2. CONTEXT AND SUBSTANCE OF THE PROPOSAL

The aim of this proposal for the complete revision of UTP GEN-E is to formulate more simply and clearly the rules concerning the qualifications and independence of assessing entities and to align UTP GEN-E with the provisions applicable in the European Union, where relevant.

Compared with the version in force, the proposed full revision of UTP GEN-E will:

- Structure the provisions more clearly;
- Clarify its scope, in particular in relation to EU law;
- Align the provisions with the latest provisions applicable in the EU.

The proposed text is set out in Annex 2 to this document.

3. PREPARATORY WORK

The proposal in Annex 2 was drafted in accordance with the analysis in Annex 1. Annex 1 lists the latest EU provisions on the subject, compares them with the existing COTIF provisions of UTP GEN-E and the ATMF UR and analyses whether provisions similar to those of the EU should be laid down in COTIF.

The first version of the analysis in Annex 1 was reviewed at the 47th session of WG TECH (Bern, 7 September 2022). At its 48th session (Paris, 16-17 November 2022), WG TECH reviewed an updated version of the analysis. The updated version was modified on the basis of the discussion at the 47th session.

A draft proposal for a full revision of UTP GEN-E, based on the analysis in Annex 1, was reviewed at the 48th session of WG TECH, after which minor modifications were made to Article 9.

4. JUSTIFICATION FOR THE AMENDMENTS

Since the entry into force of UTP GEN-E, several developments have taken place.

Firstly, the European Union's Directive 2008/57/EC on the interoperability of the rail system within the Community, on which the current version of UTP GEN-E is based, has been replaced by Directive (EU) 2016/797 of 11 May 2016 on the interoperability of the rail system within the European Union. This new Directive has more detailed provisions concerning the qualification and independence of conformity assessment bodies than the previous Directive.

Secondly, in 2017, the European Union Agency for Railways published 'requirements for conformity assessment bodies seeking notification'. This document is currently subject to revision.

Thirdly, UTP GEN-E has not been reviewed in over 10 years.

These reasons justified an analysis of whether UTP GEN-E requires modification.

PROPOSALS FOR DECISION

- The Committee of Technical Experts takes note of Annex 1 to document TECH-23005-CTE15-6.1 of 20 February 2023 concerning the comparison between the provisions concerning the qualification and independence of assessing entities as laid down in UTP GEN-E and the latest European Union (EU) provisions on the subject.
- In accordance with Article 20 § 1 e) and Article 35 of COTIF, Article 6 § 1 of the APTU UR and Article 5 § 3 letter c) of the ATMF UR, the Committee of Technical Experts adopts a revised UTP GEN-E concerning the qualifications and independence of assessing entities, as set out in Annex 2 to document TECH-23005-CTE15-6.1 of 20 February 2023[, as modified at the session]. The revised UTP GEN-E replaces UTP GEN-E of 1 December 2011; the previous version shall therefore be repealed from the moment of entry into force of the new version.
- The Committee of Technical Experts instructs the Secretary General to publish the new version of UTP GEN-E on the Organisation's website, although the repealed version should also remain available online for future reference.



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TECH-23005-CTE15-6.1 Annex 1

20.02.2023

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Comparison between the provisions concerning the qualification and independence of assessing entities as laid down in the UTP GEN-E and the latest EU provisions on the subject

The aim of this comparison was to assist WG TECH in analysing whether UTP GEN-E needed to be revised. In the right-hand column of the table, the current EU provisions of Articles 27-45 of Directive (EU) 2016/797 are reproduced. The left-hand column contains observations on whether it is necessary to include provisions in COTIF similar to those of the EU. The comments consider whether the (principles of the) EU provisions would also be relevant or necessary in terms of the scope of the APTU and ATMF UR.

A preliminary version of this table was issued for WG TECH 47 (Bern, 7 September 2022) in a document with reference TECH-22034, dated 9 August 2022. The table was modified after the session and the document was renamed TECH-22042 Annex 1, dated 18 October 2022 and was reviewed by WG TECH 48 (Paris, 15-16 November 2022). After WG TECH 48, the table was finalised for the purpose of the 15th session of the Committee of Technical Experts and the document renamed as Annex 1 of TECH-23005-CTE15-6.1.

Quoted texts are shown in *italics*.

Bold text is used for titles and in some cases to place emphasis on key parts of the text.

Comments concerning the relevance of taking over the EU provisions in COTIF	CHAPTER VI of Directive (EU) 2016/797 concerning conformity assessment bodies
	<i>Article 27</i>
	<i>Notifying authorities</i>
<p>Article 5 of the ATMF UR lays down the requirements for Contracting States concerning their competent authorities, assessing entities and other entities and the requirement to notify the Secretary General of these bodies.</p>	<p><i>1. Member States shall appoint notifying authorities that shall be responsible for setting up and carrying out the necessary procedures for the assessment, notification and monitoring of conformity assessment bodies, including compliance with Article 34.</i></p>
<p>The attribution of responsibilities can vary between states that apply EU law and states that apply the ATMF UR.</p>	<p><i>2. Member States shall ensure that those authorities notify the Commission and other Member States' bodies authorised to carry out third-party conformity assessment tasks as provided for in Articles 10(2) and 15(1). They shall also ensure that they inform the Commission and the other Member States of the designated bodies referred to in Article 15(8).</i></p>
<p>Unlike EU law, the ATMF UR do not require the strict separation between the responsibilities of the state, the responsibilities of notifying authorities and the responsibilities of assessing entities. Strict separation of these entities should not therefore be imposed at a lower level (i.e. in the UTP GEN-E).</p>	<p><i>3. Member States may decide that the assessment and monitoring referred to in paragraph 1 are to be carried out by a national accreditation body within the meaning of, and in accordance with, Regulation (EC) No 765/2008.</i></p>
<p>Within the scope and purpose of COTIF, Article 5 of the ATMF UR seem adequately to cover the subjects of Article 27 of EU Directive 2016/797.</p>	<p><i>4. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal person and shall comply with the requirements laid down in Article 28. It shall put in place arrangements to cover liabilities arising out of its activities.</i></p>
	<p><i>5. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.</i></p>

	<i>Article 28</i>
	Requirements relating to notifying authorities
<p>Article 5 § 5 of the ATMF UR requires that</p> <p><i>Each Contracting State shall ensure, by notification, that the Secretary General is informed of the competent authority, the assessing entities and, if applicable the accreditation body, or the competent national body referred to in Article 2 wa (1) [i.e. a competent national body other than the accreditation body], indicating each body's area of responsibility. [...]</i></p> <p>The tasks which, in the EU, fall within the remit of the notifying authority are therefore the tasks of Contracting States under the scope of the ATMF UR.</p> <p>Within the scope and purpose of COTIF, Article 5 of the ATMF UR seem adequately to cover the subjects of Article 28 of EU Directive 2016/797.</p>	<p><i>A notifying authority shall:</i></p> <p><i>(a) be established in such a way as to avoid any conflict of interest with conformity assessment bodies;</i></p> <p><i>(b) be organised and operated in such a way as to safeguard the objectivity and impartiality of its activities;</i></p> <p><i>(c) be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment;</i></p> <p><i>(d) not offer or provide any activities that are performed by conformity assessment bodies or consultancy services on a commercial or competitive basis;</i></p> <p><i>(e) safeguard the confidentiality of the information it obtains;</i></p> <p><i>(f) have at its disposal a sufficient number of competent personnel for the proper performance of its tasks.</i></p>
	<i>Article 29</i>
	Obligation of notifying authorities to provide information
<p>COTIF does not require Contracting States to inform the Secretary General of procedures for the assessment, notification and monitoring of conformity assessment bodies.</p> <p>The ATMF UR require:</p> <ul style="list-style-type: none"> – specific qualifications and independence of assessing entities in accordance with Article 5 §§ 2 and 3 and UTP GEN-E; – the supervision of assessing entities in Article 5 § 6. <p>The current COTIF provisions seem adequately to cover the subject.</p>	<p><i>Member States shall inform the Commission of their procedures for the assessment, notification and monitoring of conformity assessment bodies, and of any changes to those procedures.</i></p> <p><i>The Commission shall make that information publicly available.</i></p>
	<i>Article 30</i>
	Conformity assessment bodies
<p>This is merely a reference to requirements.</p>	<p><i>1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 7 of this Article and in Articles 31 and 32.</i></p>
<p>It would seem sufficient that Contracting States notify their assessing entities and that these entities comply with the requirements laid down in COTIF. Their</p>	<p><i>2. A conformity assessment body shall be established under national law and shall have legal personality.</i></p>

<p>legal personality under national law does not seem critical for the purposes of COTIF.</p>	
<p>Requirements concerning resources and procedures are covered by points 2(3) and 2(4) of UTP GEN-E of 2011.</p> <p><i>(3) The assessing entity must employ staff and possess the means required to perform adequately the technical and administrative tasks linked with the checks; it shall also have access to the equipment needed for exceptional checks.</i></p> <p><i>(4) The staff responsible for the checks must currently possess:</i></p> <ul style="list-style-type: none"> -proper technical and vocational training, -a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks, -the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted. <p>Elements that are not explicitly covered by the OTIF texts:</p> <ul style="list-style-type: none"> – The EU texts explicitly mention the possibility that tasks are not carried out by the assessment body itself. – Requirement for transparency of procedures. – Policies to keep conformity assessment tasks separated from other tasks. 	<p><i>3. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by the relevant TSI and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.</i></p> <p><i>At all times and for each conformity assessment procedure and each kind or category of product in relation to which it has been notified, a conformity assessment body shall have at its disposal:</i></p> <p><i>(a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;</i></p> <p><i>(b) the relevant descriptions of procedures in accordance with which conformity assessment is to be carried out, ensuring the transparency and the ability to apply those procedures. It shall have in place appropriate policies and procedures that distinguish between the tasks it carries out as a notified conformity assessment body and other activities;</i></p> <p><i>(c) the proper procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.</i></p> <p><i>It shall have the means necessary to perform in an appropriate manner the technical and administrative tasks connected with the conformity assessment activities and shall have access to all necessary equipment or facilities.</i></p>
<p>It may be useful to add these elements to the COTIF provisions.</p> <p>The provisions are covered in draft revised UTP GEN-E Articles 4 and 8.</p>	
<p>Point 2(6) of UTP GEN-E of 2011 requires the following:</p> <p><i>(6) The assessing entity must take out civil liability insurance unless that liability is covered by the State under national law or unless the checks are carried out directly by that Contracting State.</i></p> <p>The current COTIF provisions seem adequately to cover the subject.</p> <p>The provisions are covered in draft revised UTP GEN-E point 4.3.</p>	<p><i>4. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or unless the Member State itself is directly responsible for the conformity assessment.</i></p>
<p>Point 2(7) of UTP GEN-E of 2011 requires the following:</p> <p><i>(7) The staff of the assessing entity are bound by professional secrecy with regard to everything they learn in the performance of their duties (with the exception of the competent administrative authorities and accident investigation bodies in the State where they perform those activities as well as accident investigation bodies responsible for the investigation of accidents caused by the failure of the interoperability constituents or subsystems checked)</i></p>	<p><i>5. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under the relevant TSI or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.</i></p>

in pursuance of the COTIF Uniform Rules or any legal requirement and/or regulations of the Contracting State or regional organisation that has acceded to COTIF according to Article 38 of COTIF.

The current COTIF provisions seem adequately to cover the subject.

The provisions are covered in draft revised UTP GEN-E point 6.1.

This provision mainly refers de facto to the standardisation activities of CEN/CENELEC/ETSI and to the coordination activities of NB-Rail.

With regard to standardisation, several, but not all, standardisation bodies of the non-EU Contracting States are members of CEN/CENELEC/ETSI.

The non-EU assessing entities are invited to the subgroup rolling stock of NB-Rail, but not to other NB-Rail (sub)groups.

It might be useful to add a provision to COTIF concerning the awareness of and participation in standardisation and coordination activities. This could only be a mandatory provision if the cooperation forums are defined in law and if admission to them is guaranteed for all.

The provisions are covered in draft revised UTP GEN-E point 6.2 letter d) and Article 9.

Currently, there are no ERTMS requirements in COTIF. For the moment, this EU provision should not be taken over in COTIF.

6. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified conformity assessment bodies' coordination group established under the relevant Union law, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

7. Conformity assessment bodies that are notified for trackside and/or on-board control-command and signalling subsystems shall participate in, or shall ensure that their assessment personnel are informed of, the activities of the ERTMS group referred to in Article 29 of Regulation (EU) 2016/796. They shall follow the guidelines produced as a result of the work of that group. In the event that they consider it inappropriate or impossible to apply them, the conformity assessment bodies concerned shall submit their observations for discussion to the ERTMS group for the continuous improvement of the guidelines.

Article 31

Impartiality of conformity assessment bodies

Article 5 § 2 of the ATMF UR requires the following:

The competent authorities may or, according to the provisions in force in their State, shall transfer to assessing entities the competence to carry out assessments as a whole or partly, including the issuing of the corresponding certificates of verification. The transfer of competence to

- a) a rail transport undertaking,*
- b) an infrastructure manager,*
- c) a keeper,*

1. A conformity assessment body shall be a third-party body independent of the organisation or of the manufacturer of the product it assesses.

d) an entity in charge of maintenance (ECM) in accordance with Article 15,

e) a designer or manufacturer of railway material participating directly or indirectly in the manufacture of railway material,

including subsidiaries of the foregoing entities shall be prohibited.

Furthermore, Article 5 § 3 of the ATMF UR requires that:

In order to be recognised or accredited as an assessing entity mentioned in § 2 the following conditions must be fulfilled:

- a) The assessing entity must be independent in its organisation, legal structure and decision making from any railway undertaking, infrastructure manager, applicant and procurement entity;*
- b) In particular, the assessing entity and the staff responsible for the assessments shall be functionally independent of the bodies in charge of investigations in the event of accidents;*
- c) The assessing entity shall meet the requirements as set out in the relevant UTP*

The current COTIF provisions appear adequately to cover the subject.

COTIF does not currently contain such a provision. There is no obvious practical need for a similar provision in COTIF.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body.

Point 2(5) of UTP GEN-E of 2011 requires that:

(5) The independence of the staff responsible for inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.

The EU text requires that the assessment body as an organisation, the top-level management and the assessment personnel remain impartial.

The COTIF text requires the independence of staff responsible for inspections.

Independence and impartiality are slightly different concepts.

Impartiality implies not being biased, treating all parties equally and making assessments fairly without being influenced by own interests.

Independence implies the freedom to take decisions without external influence.

The verb ‘to guarantee’ is used in both EU and COTIF texts and implies a pledge, promise or assurance by a party. Although the implicit meaning in both texts is clear, it raises the question of who is

2. The impartiality of the conformity assessment bodies, of their top-level management and of the assessment personnel shall be guaranteed.

to guarantee; the notifying authority, the assessing entity, the staff, etc.?

It might be useful to add some text to the COTIF provisions to explain that the assessing entities must act impartially.

The provisions are covered in draft revised UTP GEN-E point 5.1.

This provision effectively prohibits designers, manufacturers, suppliers, installers, purchasers, owners, users or maintainers of products from also being a conformity assessment body of those products.

The provisions of Article 5 § 2 of the ATMF UR appear adequately to cover the subject.

3. *A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks **shall not be** the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer **of the products which they assess**, or the authorised representative of any of those parties.*

This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

Compared to the previous point, this point prohibits the involvement of assessment bodies in certain activities.

Point 2(1) of UTP GEN-E of 2011 requires that:

*The assessing entity, its Director and the staff responsible for carrying out the checking operations **may not become involved** either directly or as authorised representatives in the design, manufacture, construction, marketing or maintenance of the interoperability constituents or subsystems or in their use.*

This does not exclude the possibility of an exchange of technical information between the manufacturer and that assessing entity.

Both COTIF and EU texts are ambiguous with regard to their scope.

The EU text “*of those products*”, is not quite clear. This could refer to a group or type of products in general, such as rolling stock. It could also refer to particular products, such as a particular type of rolling stock.

The latter interpretation would be much more restrictive than the former.

Similar ambiguity exists in the COTIF text “*of the interoperability constituents or subsystems.*”

It would seem useful to clarify these matters in the COTIF text.

The provisions are covered in draft revised UTP GEN-E points 5.2 and 5.3.

4. *A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks **shall not be directly involved** in the design, manufacture or construction, marketing, installation, use or maintenance **of those products**, or represent the parties engaged in those activities.*

They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This prohibition shall apply, in particular, to consultancy services.

COTIF does not currently contain such a provision. See also comments on Article 30(3).

The provisions on outsourcing are covered in draft revised UTP GEN-E Article 8.

5. *Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.*

Point 2(4) of UTP GEN-E of 2011 requires that:

(4) The staff responsible for the checks must currently possess:

- *proper technical and vocational training,*
- *a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks,*
- *the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.*

Point 2(5) of UTP GEN-E of 2011 requires that:

(5) The independence of the staff responsible for inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.

The EU text is more broadly defined, particularly as it refers to both the assessment bodies and their staff and explains that both should be free from all pressure which could influence judgments.

The OTIF texts refer to staff (not assessing entities) and to remuneration (not to any type of pressure). It might be useful to refer to “any type of pressure” and to mention remuneration as an example.

The provisions are covered in draft revised UTP GEN-E points 4.2 a) and Article 5.

6. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

Article 32

Personnel of conformity assessment bodies

Point 2(4) of UTP GEN-E of 2011 requires that:

(4) The staff responsible for the checks must currently possess:

- *proper technical and vocational training,*
- *a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks,*
- *the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.*

Point c of the EU text is not reflected in the COTIF text. It is important that staff carrying out assessments adequately understand the legal framework they are working under, and not only the requirements relating to the checks.

The provisions are covered in draft revised UTP GEN-E point 6.2.

1. The personnel responsible for carrying out conformity assessment activities shall have the following skills:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;*
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;*
- (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Union law;*
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.*

Point 2(5) of UTP GEN-E of 2011 requires that:

(5) The independence of the staff responsible for inspections must be guaranteed. No official must be

2. The remuneration of the top-level management and assessment personnel of a conformity assessment

<p><i>remunerated either on the basis of the number of inspections performed or of the results of those inspections.</i></p> <p>The EU provision extends the requirement to top-level management; the OTIF text does not. It might be useful to modify the OTIF text accordingly.</p> <p>The provisions are covered in draft revised UTP GEN-E point 5.3.</p>	<p><i>body shall not depend on the number of assessments carried out or on the results of those assessments.</i></p>
	<p><i>Article 33</i></p>
	<p><i>Presumption of conformity of a conformity assessment body</i></p>
<p>In practice, the EU provision means that if an assessment body is accredited on the basis of ISO 17065, it is presumed to comply with the provisions of Articles 30 to 32. COTIF does not currently contain such a provision. A similar provision could therefore be added to UTP GEN-E, so that compliance of an assessing entity with ISO 17065 presumes conformity with certain requirements of UTP GEN-E.</p> <p>The provisions are covered in draft revised UTP GEN-E point 0.4.</p>	<p><i>Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Articles 30 to 32, in so far as the applicable harmonised standards cover those requirements.</i></p>
	<p><i>Article 34</i></p>
	<p><i>Subsidiaries of, and subcontracting by, notified bodies</i></p>
<p>COTIF does not currently contain any provisions that regulate the subcontracting of tasks or subsidiaries.</p> <p>The question is whether OTIF should regulate this, or leave it to national interpretation and implementation.</p> <p>Not all Contracting States permit subcontracting or outsourcing. However, if subcontracting or outsourcing is permitted, the responsibilities and qualifications should be clear. This should be reflected in UTP GEN-E.</p> <p>The provisions are covered in draft revised UTP GEN-E Article 8.</p>	<p><i>1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Articles 30 to 32 and shall inform the notifying authority accordingly.</i></p> <p><i>2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.</i></p> <p><i>3. Activities of notified bodies may be subcontracted or carried out by a subsidiary only with the agreement of the client.</i></p> <p><i>4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the relevant TSI.</i></p>
	<p><i>Article 35</i></p>
	<p><i>Accredited in-house bodies</i></p>
<p>In practical terms, the EU text permits manufacturers that are also applicants for authorisation of their product to rely (partly) on accredited in-house assessment bodies instead of third party NoBo</p>	<p><i>1. Applicants may use an accredited in-house body to carry out conformity assessment activities for the purpose of implementing the procedures set out in modules A1, A2, C1 or C2 laid down in Annex II to</i></p>

assessment. This is only permitted for particular assessment modules, which are linked to particular products (e.g. products that are of low risk or minor complexity).

Of the listed modules, only CA1 and CA2 currently exist in COTIF (UTP GEN-D). Both modules concern internal production control and declarations by the manufacturer of the product.

For rolling stock, CA1 or CA2 may only be used for products that have been developed previously (and are thus service proven). Furthermore, the manufacturer has to demonstrate to the assessing entity that design review and type examination were performed for previous applications under comparable conditions.

There is no obvious need to modify the COTIF provisions on this matter.

Decision No 768/2008/EC and modules CA1 and CA2 laid down in Annex I to Decision 2010/713/EU. That body shall constitute a separate and distinct part of the applicant concerned and shall not participate in the design, production, supply, installation, use or maintenance of the products it assesses.

2. An accredited in-house body shall meet the following requirements:

(a) it shall be accredited in accordance with Regulation (EC) No 765/2008;

(b) the body and its personnel shall, within the undertaking of which they form a part, be organisationally identifiable and have reporting methods which ensure their impartiality, and shall demonstrate it to the competent national accreditation body;

(c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess, nor shall they engage in any activity that might conflict with their independence of judgement or integrity in relation to their assessment activities;

(d) the body shall supply its services exclusively to the undertaking of which it forms a part.

3. An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article 36

In COTIF, there are no specific requirements concerning the application to be designated as an assessing entity.

It does not seem obvious that this should be regulated in COTIF.

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Articles 30 to 32.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Articles 30 to 32.

	<i>Article 37</i>
	<i>Notification procedure</i>
There does not seem to be any practical need to modify or clarify the procedure for Member States to notify the Secretary General.	<i>1. Notifying authorities shall only notify conformity assessment bodies which comply with the requirements laid down in Articles 30 to 32.</i>
However, it might be worth specifying the information to be included in the notification, in particular the UTPs, modules and products the assessing entity is notified for and whether there is an accreditation certificate.	<i>2. Notifying authorities shall notify the bodies referred to in paragraph 1 to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.</i>
The provisions are covered in draft revised UTP GEN-E Article 10.	<i>3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the product or products concerned, and the relevant accreditation certificate or other attestation of competence provided for in paragraph 4.</i>
	<i>4. Where a notification is not based on an accreditation certificate as referred to in Article 36(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored periodically and will continue to satisfy the requirements laid down in Articles 30 to 32.</i>
	<i>5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.</i>
	<i>6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.</i>
	<i>Article 38</i>
	<i>Identification numbers and lists of notified bodies</i>
There is no obvious need to regulate identification numbers for assessing entities in COTIF.	<i>1. The Commission shall assign an identification number to a notified body.</i>
	<i>A notified body shall be assigned a single identification number even where it is notified under several legal acts of the Union.</i>
	<i>2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.</i>
	<i>The Commission shall ensure that that list is kept up to date.</i>

	<i>Article 39</i>
<p>Article 5 §§ 6 and 7 of the ATMF UR lay down the following:</p> <p>§ 6 <i>A Contracting State shall ensure the consistent supervision of the assessing entities indicated in § 2 and shall withdraw the competence from an assessing entity which no longer meets the criteria referred to in § 3, in which case it shall immediately inform the Secretary General thereof.</i></p> <p>§ 7 <i>Should a Contracting State consider that an assessing entity or competent authority of another Contracting State, does not meet the criteria of § 3, the matter shall be transferred to the Committee of Technical Experts which, within four months, shall inform the Contracting State in question of any changes that are necessary for the assessing entity or authority to retain the status conferred upon it. In relation to this, the Committee of Technical Experts may decide to instruct the Contracting State to suspend or withdraw technical certificates made on the basis of work done by the assessing entity or by the authority in question.</i></p> <p>It may be worth adding a provision to COTIF to ensure that the files of assessing entities that cease their activities are either processed by another assessing entity or kept available for the responsible authorities at their request.</p> <p>The provisions are covered in draft revised UTP GEN-E points 10.2 and 10.3.</p>	<p>Changes to notifications</p> <p>1. <i>Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Articles 30 to 32, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.</i></p> <p>2. <i>In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.</i></p>
	<i>Article 40</i>
<p>Article 5 § 7 of the ATMF UR lays down the following:</p> <p>§ 7 <i>Should a Contracting State consider that an assessing entity or competent authority of another Contracting State, does not meet the criteria of § 3, the matter shall be transferred to the Committee of Technical Experts which, within four months, shall inform the Contracting State in question of any changes that are necessary for the assessing entity or authority to retain the status conferred upon it. In relation to this, the Committee of Technical Experts may decide to instruct the Contracting State to suspend or withdraw technical certificates made on the basis of work done by the assessing entity or by the authority in question.</i></p> <p>There is no obvious need to modify the COTIF provisions on this matter.</p>	<p>Challenges to the competence of notified bodies</p> <p>1. <i>The Commission shall investigate all cases where it has any doubt, or where a doubt is brought to its attention, regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.</i></p> <p>2. <i>The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.</i></p> <p>3. <i>The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.</i></p> <p>4. <i>Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including withdrawal of notification if necessary.</i></p>

	<i>Article 41</i>
	<i>Operational obligations of notified bodies</i>
<p>It might be worth including similar provisions related to the conduct of assessing entities in UTP GEN-E.</p> <p>The provisions are covered in draft revised UTP GEN-E points 4.1, 7.2, 7.3 and 7.4.</p>	<p><i>1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant TSI.</i></p> <p><i>2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies, when performing their activities, shall take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.</i></p> <p><i>In so doing, they shall nevertheless operate with the aim of assessing the compliance of the product with this Directive.</i></p> <p><i>3. Where a notified body finds that requirements laid down in the relevant TSI or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.</i></p> <p><i>4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies with the relevant TSI or corresponding harmonised standards or technical specifications, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.</i></p> <p><i>5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.</i></p>
	<i>Article 42</i>
<p>If the competent authority in the meaning of Article 5 of the ATMF UR is also an assessing entity, it could not be requested to inform itself of the elements mentioned in point 1 of the EU text.</p>	<i>Obligation of notified bodies to provide information</i>

	<p><i>1. Notified bodies shall inform the notifying authority of the following:</i></p> <p><i>(a) any refusal, restriction, suspension or withdrawal of a certificate;</i></p> <p><i>(b) any circumstances affecting the scope of, and conditions for, notification;</i></p> <p><i>(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;</i></p> <p><i>(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.</i></p> <p><i>The competent national safety authorities shall also be informed of any refusal, restriction, suspension or withdrawal of a certificate under point (a).</i></p>
<p>It would be helpful to understand the practical implementation of this provision at EU level, i.e. do all notified bodies individually inform all other notified bodies of relevant information, or is there a platform to facilitate exchanges?</p>	<p><i>2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.</i></p>
<p>There is no central registration of certificates at OTIF level. If a central registration were to be created, the legal provision should probably not be contained in UTP GEN-E but rather in the ATMF UR and UTP GEN-D (assessment procedures).</p> <p>Non-EU assessing entities should not be requested to provide information to the Agency.</p>	<p><i>3. Notified bodies shall provide the Agency with 'EC' certificates of verification of subsystems, 'EC' certificates of conformity of interoperability constituents and 'EC' certificates of suitability of use of interoperability constituents.</i></p>
	<p><i>Article 43</i></p>
	<p><i>Exchanges of best practice</i></p>
<p>It may be worth including provisions concerning the exchange of best practices in COTIF if Contracting States identify a need to do so. Currently, no OTIF budget is allocated to facilitate such exchanges.</p>	<p><i>The Commission shall provide for the organisation of exchanges of best practices between the Member States' national authorities responsible for notification policy.</i></p>
	<p><i>Article 44</i></p>
	<p><i>Coordination of notified bodies</i></p>
<p>The non-EU assessing entities are invited to the subgroup rolling stock of NB-Rail, but not to other NB-Rail (sub)groups.</p> <p>Currently, no OTIF budget is allocated to facilitate coordination and cooperation between assessing entities.</p>	<p><i>The Commission shall ensure appropriate coordination and cooperation between bodies notified under this Directive through the establishment of a sectoral group of notified bodies. The Agency shall support the activities of notified bodies in accordance with Article 24 of Regulation (EU) 2016/796.</i></p>
<p>It might be worth including a similar provision in COTIF.</p> <p>The provisions are covered in draft revised UTP GEN-E point 9.1.</p>	<p><i>Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.</i></p>

	<i>Article 45</i>
	<i>Designated bodies</i>
COTIF does not distinguish between assessing entities' competences to assess UTPs and national technical requirements.	<p><i>1. The requirements relating to conformity assessment bodies set out in Articles 30 to 34 shall also apply to bodies designated under Article 15(8), except:</i></p> <p><i>(a) in the case of skills required by its personnel under point (c) of Article 32(1), where the designated body shall have appropriate knowledge and understanding of national law;</i></p> <p><i>(b) in the case of documents to be kept at the disposal of the notifying authority under Article 34(4), where the designated body shall include documents relating to work carried out by subsidiaries or subcontractors under the relevant national rules.</i></p> <p><i>2. The operational obligations laid down in Article 41 shall also apply to bodies designated under Article 15(8), except that those obligations refer to national rules instead of TSIs.</i></p> <p><i>3. The information obligation laid down in Article 42(1) shall also apply to designated bodies, which shall inform Member States accordingly.</i></p>



Organisation intergouvernementale pour les transports internationaux ferroviaires

Zwischenstaatliche Organisation für den internationalen Eisenbahnverkehr

Intergovernmental Organisation for International Carriage by Rail

TECH-23005-CTE15-6.1 Annex 2


Uniform Technical Prescription

General provisions

Qualifications and
independence of
assessing entities

UTP GEN-E

Applicable from [Click here to enter a date.](#)

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APTU Uniform Rules (Appendix F to COTIF 1999)

Uniform Technical Prescription

General provisions

Qualifications and independence of assessing entities

(UTP GEN-E)

This UTP has been developed in accordance with COTIF in the version of 1 March 2019 and in particular with Articles 3, 4, 6, 7a and 8 of the APTU Uniform Rules (Appendix F to COTIF) and Article 5 of the ATMF Uniform Rules (Appendix G to COTIF).

For definitions, see also Article 2 of the APTU Uniform Rules and Article 2 of the ATMF Uniform Rules.


0. EQUIVALENCE

- 0.1 The provisions in this UTP are based on the European Union provisions in Articles 27 to 45 of Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union, further referred to as the EU provisions.
- 0.2 The provisions in this UTP are adapted to the scope of application and aims of the APTU and ATMF UR.
- 0.3 Assessing entities that comply with the EU provisions are deemed also to comply with the provisions of this UTP and the provisions of Article 5 of the ATMF UR.
- 0.4 Assessing entities accredited or recognised on the basis of their compliance with ISO 17065 shall be presumed to comply with the provisions laid down in points 4, 5 and 6 of this UTP.

1. SCOPE

- 1.1 This UTP lays down the requirements concerning qualification and independence criteria as referred to in Article 5 § 3 letter c) of the ATMF UR to be met by assessing entities that perform assessments for technical admissions in the scope of the ATMF UR¹.
- 1.2 The provisions in this UTP are complementary to those laid down in Article 5 of the ATMF UR.

¹ The criteria to be met by assessment bodies involved in risk assessments according to the common safety method are laid down in UTP GEN-G. The criteria to be met by ECM certification bodies are laid down in Annex A to the ATMF UR.

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2. DEFINITIONS

The definitions of the APTU and ATMF UR shall apply. In addition, the following definitions shall apply:


- a) “Assessing entity” means an entity that is designated, recognised or accredited in a Contracting State and that is notified to the Secretary General by or on behalf of that Contracting State as being competent to carry out assessments and to issue corresponding certificates in the meaning of Article 5 of the ATMF UR.
- b) “NTR” means national technical requirement in the meaning of Article 12 of the APTU UR.

3. CORRELATION WITH OTHER INTERNATIONAL AGREEMENTS

- 3.1 All assessing entities performing assessments in the scope of the APTU and ATMF UR shall be designated, accredited or recognised either in accordance with Article 5 of the ATMF UR and this UTP, or in accordance with the EU provisions.
- 3.2 For the purpose and scope of the APTU and ATMF UR, all Contracting States shall accept assessment results and certificates produced or issued by assessing entities designated, accredited or recognised either in accordance with Article 5 of the ATMF UR and this UTP, or in accordance with the EU provisions.

4. GENERAL REQUIREMENTS

- 4.1 The assessing entity shall be capable of carrying out all the assessment tasks assigned to it by the relevant UTP and NTR and in relation to which it has been notified.
- 4.2 The assessing entity shall have at its disposal:
 - a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the assessment activities;
 - b) procedures in accordance with which the assessment is to be carried out, ensuring the transparency of the assessment and the ability to apply those procedures;
 - c) policies and procedures that ensure separation between the activities as an assessing entity in the scope of this UTP and other activities;
 - d) the proper procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;
 - e) the means necessary to perform in an appropriate manner the technical and administrative tasks connected with the assessments;
 - f) all necessary equipment and facilities.
- 4.3 The assessing entity must take out civil liability insurance unless that liability is covered by the State under national law, or unless the assessments are carried out directly by that Contracting State.

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5. IMPARTIALITY AND INDEPENDENCE


- 5.1 Assessing entities, including their management and staff, shall act impartially, unbiasedly and shall make assessments fair, without being influenced by their own interests.
- 5.2 The independence of the persons carrying out assessment activities must be ensured.
The remuneration of management and staff shall not depend on the number of assessments carried out or on the results of those assessments.
- 5.3 The assessing entities, including their management and staff, may not become involved, either directly or indirectly, in the design, manufacture or construction, marketing, installation, use or maintenance of the products they assess.
This does not exclude the possibility of an exchange of technical information between the manufacturer and an assessing entity.
- 5.4 Persons carrying out assessment activities shall not engage in any other activity that may conflict with their independence of judgement or integrity in relation to assessment activities.

6. MANAGEMENT AND STAFF

- 6.1 The management and staff of an assessing entity shall observe professional secrecy with regard to all information obtained in carrying out their tasks, except in relation to the competent authority of the Contracting State in which its activities are carried out. Proprietary rights shall, however, be protected.
- 6.2 The staff responsible for carrying out assessment activities shall have the following skills:
- sound technical and vocational training covering all the assessment activities that are carried out by the assessing entity;
 - satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - appropriate knowledge and understanding of the essential requirements, the applicable harmonised standards and the relevant provisions of COTIF;
 - up to date knowledge of relevant standardisation activities and other relevant developments;
 - the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

7. OPERATIONAL OBLIGATIONS OF ASSESSING ENTITIES

- 7.1 Assessing entities shall carry out assessments in accordance with the assessment procedures provided for in the relevant UTP or NTR and shall monitor the continued conformity of the products they have assessed when this is required by law.
- 7.2 Assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Assessing entities, when performing their activities, shall take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

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In so doing, they shall nevertheless operate with the aim of assessing the compliance of the product with the applicable rules.

- 7.3 Where an assessing entity finds that requirements laid down in the relevant UTP, NTR, or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.
- 7.4 Where, in the course of monitoring conformity following the issuing of a certificate, an assessing entity finds that a product no longer complies with the relevant UTP, NTR, or corresponding harmonised standards or technical specifications, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary. Where corrective measures are not taken or do not have the required effect, the assessing entity shall restrict, suspend or withdraw any certificates, as appropriate.
- 7.5 Assessing entities shall keep files and archives of the assessments that they carry out, including the results of tests and checks, and shall make them available upon request to the competent authority or accident investigation body of the Contracting State in which they are established.

8. **OUTSOURCING AND SUBCONTRACTING**


- 8.1 Assessing entities may only outsource or subcontract activities if this is permitted in the Contracting State concerned.
- 8.2 Any rule in this UTP that applies to the assessing entities, their management and staff, shall apply, *mutatis mutandis*, to any subsidiary, subcontractor, or any other natural or legal person that performs activities on behalf of the assessing entity.
- 8.3 Assessing entities shall take full responsibility for the results of outsourced activities.

9. **COORDINATION OF ACTIVITIES**

- 9.1 Contracting States shall require assessing entities to participate in the activities of coordination groups to which they are invited.
- 9.2 Assessing entities should apply *mutatis mutandis* the administrative decisions and documents produced by the groups referred to in point 9.1.

10. **NOTIFICATION BY CONTRACTING STATES**

- 10.1 When notifying the Secretary General of an assessing entity in accordance with Article 5 of the ATMF UR, the Contracting State shall describe the scope, including the UTPs, NTRs and the products, for which the entity is notified.
- 10.2 Where a Contracting State has ascertained or has been informed that an assessing entity no longer meets the requirements laid down in this UTP, or that it is failing to fulfil its obligations, the Contracting State shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

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It shall immediately inform the Secretary General, who in turn shall modify the information on OTIF's website accordingly.

- 10.3 In the event of restriction, suspension or withdrawal of notification, or where the assessing entity has ceased its activity, the notifying Contracting State shall take appropriate steps to ensure that the files and archives of that entity are either processed by another assessing entity or kept available for the responsible authorities.
- 10.4 The Secretary General shall publish a list on OTIF's website of the assessing entities notified to him and shall keep it updated.