



Organisation intergouvernementale pour les transports internationaux ferroviaires

Zwischenstaatliche Organisation für den internationalen Eisenbahnverkehr

Intergovernmental Organisation for International Carriage by Rail


# **Uniform Technical Prescription**

General provisions

Qualifications and independence of assessing entities

**UTP GEN-E**

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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 UR<sup>1</sup>.
- 1.2 The provisions in this UTP are complementary to those laid down in Article 5 of the ATMF UR.

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<sup>1</sup> 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:
- a) sound technical and vocational training covering all the assessment activities that are carried out by the assessing entity;
  - 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, the applicable harmonised standards and the relevant provisions of COTIF;
  - d) up to date knowledge of relevant standardisation activities and other relevant developments;
  - e) 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.