



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

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**Groupe de travail TECH**  
**Arbeitsgruppe TECH**  
**Working Group TECH**

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## **51<sup>ST</sup> SESSION**

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Requirements for conformity assessment bodies seeking notification

Review of a technical document issued by the European Union Agency for Railways

At its 15<sup>th</sup> session (Bern, 13-14 June 2023), the Committee of Technical Experts (CTE) discussed the relevance to OTIF of an ERA technical document with requirements for conformity assessment bodies.

Excerpt from [the minutes of CTE](#):

*[...] Germany suggested reviewing the recently revised ERA assessment scheme at a future WG TECH meeting. The aim of the exercise would be to identify the relevant rules that could be transposed into COTIF. This step would establish equivalence of the assessment procedures between EU and non-EU assessing entities.*

*The Secretariat informed the meeting that the OTIF Secretariat had followed the revision of the ERA assessment scheme. The revision involved coordination between ERA, several sector associations and the EU Member States. It reminded the meeting that the accreditation scheme, recognised and applied by the members of the European Accreditation organisation (EA), encompassed conformity assessing entities from both EU and non-EU Member States. The Secretariat supported Germany's proposal, as it would raise awareness among accreditation bodies, competent authorities and ministries. It was of the view that a detailed analysis of the accreditation scheme was not necessary.*

*[...]*

*The Chair summarised the discussion, took note of the proposal from Germany concerning the ERA assessment scheme, and noted that there were no further comments. [...]*

The ERA document referred to is the technical document entitled “Requirements for conformity assessment bodies seeking notification” (further referred to as the ERA requirements). It is available on ERA’s website under [https://www.era.europa.eu/domains/conformity-assessment\\_en](https://www.era.europa.eu/domains/conformity-assessment_en) and under this direct [link to the document](#).

It is worth noting that the ERA requirements are based on standard EN ISO/IEC 17065:2012 “Conformity assessment – requirements for bodies certifying products, processes and services”. The requirements can only be read and understood together with this standard, which can be purchased from the standardisation bodies.

At its 15<sup>th</sup> session, the CTE adopted a revised UTP concerning the qualifications and independence of assessing entities (UTP GEN-E). This UTP will enter into force on 1 January 2024. It lays down, among other things, that *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*.

UTP GEN-E exhaustively covers the 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. The provisions in UTP GEN-E are complementary to those laid down in Article 5 of the ATMF UR

Notes from the OTIF Secretariat concerning the ERA requirements:

- The requirements provide interpretation for the application of EN ISO-IEC 17065:2012 in the scope of the EU Interoperability Directive (EU) 2016/797 and subsidiary EU rules based on this Directive.
- Some of the requirements may be interesting for or relevant to OTIF Member States when recognising or accrediting<sup>1</sup> assessing entities in the meaning of Article 5 of the ATMF UR and when applying UTP GEN-E.
- Some of the requirements may not be relevant to non-EU OTIF Member States, as they relate specifically to the application of the EU Directive, or relate to the assessment of products or to providing services that are not in the scope of COTIF.

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<sup>1</sup> By the national accreditation body