

Moving Europe towards a sustainable and
safe railway system without frontiers.

DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN UNION AGENCY FOR RAILWAYS
adopting the Technical Document 000MRA1044 ver. 2.0 providing requirements
for conformity assessment bodies seeking notification and
making further provisions for audits and inspections
ERA-ED-DEC-2110-2022

THE EXECUTIVE DIRECTOR OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

Having regard to Regulation (EU) 2016/796 of the European Parliament and the Council of 11 May 2016 on the European Union Agency for Railways (hereinafter referred to as “the Agency”) and repealing Regulation (EC) No. 881/2004¹ (hereinafter referred to as “the Agency Regulation”), and in particular Articles 34(2), (3) and (6) and 54(5) thereof;

Whereas

- (1) In accordance with Article 34 of the Agency Regulation, the Agency shall support the Commission, for the purposes of Article 41 of Directive (EU) 2016/797 of the European Parliament and of the Council on the interoperability of the rail system within the European Union² (hereinafter referred to as the “Interoperability Directive”), in monitoring the notified conformity assessment bodies through the provision of assistance to accreditation bodies and to the relevant national authorities, and through audits and inspections;
- (2) Decision n°156 of the Management Board adopting the provisions on auditing notified conformity assessment bodies in the framework of Article 34(3) of Regulation (EU) 2016/796 provides at recital 5(a) that the set of detailed requirements for notified conformity assessment bodies are described in the Agency Technical Document “*Requirements for conformity assessment bodies seeking notification*” – ref. 000MRA1044 (ver. 1.1);
- (3) For the purposes of this present decision, conformity assessment bodies are those seeking accreditation or recognition for the purpose of notification under the Interoperability Directive;
- (4) The Agency Technical Document “*Requirements for conformity assessment bodies seeking notification*” – ref. 000MRA1044 ver. 1.1 was drawn up in June 2017 and is followed by conformity assessment bodies seeking accreditation or recognition for the purpose of notification under the Interoperability Directive;
- (5) Technical Document “*Requirements for conformity assessment bodies seeking notification*” – ref. 000MRA1044 ver. 2.0 provides updated requirements and should be annexed to and adopted by this present decision;

¹ OJ L 138, 26.5.2016, p. 1-43.

² OJ L 138, 26.5.2016, p. 44-101.

- (6) The Agency would recommend to the appropriate body³ that accredited and recognised notified conformity assessment bodies apply the Annex to this Decision by 31 December 2024, and would recommend for conformity assessment bodies seeking accreditation or recognition to apply the Annex to this Decision from 2023 onwards;
- (7) It would be necessary for the Agency to audit and inspect the capacity of the notified conformity assessment bodies to meet the requirements in the Annex to this Decision.

HAS DECIDED

Article 1

To adopt the requirements for monitoring accredited and recognised notified conformity assessment bodies, in the Annex to this Decision, in the framework of Article 34(2), (3) and (6) of the Agency Regulation, as set out in the Technical Document “*Requirements for conformity assessment bodies seeking notification*” – ref. 000MRA1044 ver. 2.0.

Article 2

1. To recommend to the Member States and the European coordination for Accreditation the requirement for the mandatory application of the Annex to this Decision for:
 - a) accredited and recognised notified conformity assessment bodies, by 31 December 2024;
 - b) conformity assessment bodies seeking accreditation or recognition, from 1 January 2023 onwards.
2. The Agency, in principle, does not object to conformity assessment bodies applying the Annex to this Decision in the absence of the requirement for its mandatory application in paragraph 1.

Article 3

Between 1 January 2023 and 31 December 2024, the Agency shall audit and inspect the capacity of accredited and recognised notified conformity assessment bodies **that have already implemented** the requirements in the Annex to this Decision, against the requirements therein.

Article 4

From 1 January 2025, the Agency shall audit and inspect the capacity of **all** accredited and recognised notified conformity assessment bodies to meet the requirements in the Annex to this Decision.

Article 5

This Decision shall enter into force on 1 January 2023. It shall be published, together with its Annex, on the Agency’s website.

³ *The Member States and the European coordination for Accreditation.*

Done at Valenciennes, on 13/12/2022.


Josef DOPPELBAUER
Executive Director

Annex: Technical Document *“Requirements for conformity assessment bodies seeking notification”* – ref. 000MRA1044 ver. 2.0.