

56 Making the railway system
work better for society.

DECISION n°156

of the Management Board of the European Union Agency for Railways adopting the provisions on auditing notified conformity assessment bodies in the framework of Article 34 § 3 of Regulation (EU) 2016/796

THE MANAGEMENT BOARD 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 Article 34 § 3 thereof;

Having regard to Decision n° 147 of the Management Board of the European Union Agency for Railways amending the Policy for Visits to Member States²;

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 Union³ (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) To fulfill the obligations laid down in Article 34 of the Agency Regulation, the Agency has developed a monitoring system for notified conformity assessment bodies, which is composed by: (i) a set of detailed requirements for notified conformity assessment bodies, (ii) provisions for performing audits, (iii) provisions for performing inspections, (iv) provisions for annual reporting and (v) the provisions for establishment of a forum for exchange of best practices on assessing conformity assessment bodies seeking notification;
- (3) Provisions for audits are described in this Management Board Decision; in accordance with Article 34 § 3 of the Agency Regulation, the Agency Management Board shall adopt the provisions for performing the audits;
- (4) The set of detailed requirements for notified conformity assessment bodies, the provisions for performing inspections, the provisions for annual reporting and the provisions for a forum for exchange of best practices, although not requiring the adoption by the Agency Management Board, are fundamental elements of the system for monitoring notified conformity assessment bodies;

¹ OJ L 138, 26.5.2016, p. 1-43.

² Adopted by written procedure of the Management Board, WP 03-2016.

³ OJ L 138, 26.5.2016, p. 44-101.

They will be described in the Agency's internal quality management system, the Integrated Management System (IMS);

(5) In this context:

- a. 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;
- b. Audits concern recognised (i.e. not accredited) notified conformity assessment bodies. The Agency audits the capacity of those bodies to meet the requirements set out in Article 30 of the Interoperability Directive. The Agency Technical Document "Requirements for conformity assessment bodies seeking notification" – ref. 000MRA1044 details the requirements checked by audits; Audits are always pre-announced;
- c. Inspections concern notified conformity assessment bodies which are either accredited or recognised (i.e. not accredited). The Agency verifies specific areas of their activities and operations, and in particular reviews documents, certificates and records relating to their tasks as referred to in Article 41 of the Interoperability Directive. The Agency Technical Document "Requirements for conformity assessment bodies seeking notification" – ref. 000MRA1044 details the requirements checked by inspections. The inspections can be pre-announced or unannounced;
- d. The requirements checked by inspections are a subset of the requirements checked by audits. The requirements checked by inspections will be defined in the provisions for performing inspections within the quality management system of the Agency. The annual reporting is the activity in which the Agency gathers and presents the main outputs derived from the application of the monitoring system during the reference period;
- e. The forum for exchange of best practices is a network in which takes place a multilateral exchange of views, comments, feedback and other information amongst the involved parties aiming at improving the definition of the requirements described in the Agency Technical Document "Requirements for conformity assessment bodies seeking notification" – ref. 000MRA1044.

HAS DECIDED AS FOLLOWS:

Article 1

The provisions on auditing notified conformity assessment bodies in the framework of Article 34 § 3 of the Agency Regulation, as set out in Annex to this Decision, are adopted.

Article 2

The present Decision shall enter into force on the day following that of its adoption. It will be published on the Agency website.

Done at Lille, on 27-06-2017
For the Management Board

The Chairperson
Mats ANDERSSON

Annex: Provisions on auditing notified conformity assessment bodies in the framework of Article 34 § 3 of the Agency Regulation