

ADVICE

ERA/ADV/2014-15

OF THE EUROPEAN RAILWAY AGENCY

FOR

EUROPEAN COMMISSION

REGARDING

*The establishment of an harmonised
accreditation scheme for NoBos*

Disclaimer:

The present document is a non-legally binding advice of the European Railway Agency. It does not represent the view of other EU institutions and bodies, and is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

1. General context

The 28th March 2014 the European Commission has requested the Agency to provide an advice, in collaboration with European co-operation for Accreditation (EA), on an harmonised accreditation scheme for notified bodies under the interoperability directive 2008/57/EC (letter num. ARES (2014) 977679).

The objective of this scheme is to increase the mutual trust amongst the NSAs and relevant stakeholders in the work performed by notified bodies and subsequently in the EC certification processes. This increased trust could reduce burdens in the authorisation process.

2. Legal background

In consideration of Article 21b(2b) of the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency¹, the European Commission has the possibility to request an opinion from the Agency “*providing technical advice in matters requiring specific know-how*”.

3. The Advice

The following ERA Reports constitute the Advice:

1. Analysis of current situation;
2. Harmonised requirements;
3. Light impact assessment, and
4. Ad Hoc Task Force activities.

ERA has drafted the above reports in consultation with the members of the Ad Hoc Task Force representing the following entities:

- › EA: European co-operation for accreditation;
- › NB-Rail: The association of the European notified bodies under the IOD;
- › ANSF: the Italian national safety authority for railways;
- › EBA: the German national safety authority for railways;
- › EPSF: the French national safety authority for railways;
- › EIM: The European association of the railway infrastructure managers;
- › CER: The European association of railways;
- › UNIFE: the association of the European railway industry;
- › OTIF: the Intergovernmental organisation for international carriage by rail.

The Agency proposes DG MOVE to:

1. endorse an harmonized accreditation scheme based on this ERA advice, in particular on the Report “Requirements”;
2. select one of the options examined by the Report “Light impact assessment”;
3. send the endorsed harmonized accreditation scheme to European co-operation for accreditation (EA) for approval.

¹ OJ L 164, 30.04.2004, p. 1, as last amended by Regulation (EC) No 1335/2008 (OJ L 354, 31.12.2008, p. 51)

4.4. Report “Ad Hoc Task Force activities”

This report summaries the activities performed in the Ad Hoc Task Force. It includes also comments and positions raised by the members which have not been taken into account in the final version of the harmonized accreditation scheme.

ERA code for this document: ERA/ADV/2014-15/REP-004 V 1.0

5. Post project consideration

After the finalization of the project, UNIFE and EBA sent to ERA a complaint regarding the limitation to Type A inspection bodies in case of outsourced inspection activities (see point 6.2.2.1 of the Report “Harmonised requirements” ERA/ADV/2014-15/REP-002 V 6.1).

UNIFE and EBA asked to allow also Type B and Type C inspection bodies to carry out outsourced inspection activities.

The ERA proposed harmonised accreditation scheme is based on EA 2/17:2014 “EA Document on Accreditation for Notification Purposes” which allows only for Type A inspection bodies for Notified Bodies inspection activities. Therefore, based on the current legislation and the EC mandate to ERA on this matter, ERA agrees with the EA position.

However, ERA is prepared to further examine this topic in the framework of a future revision of the harmonised accreditation scheme.

6. Outlook

During the development of the project, ERA identified the following ancillary tasks further supporting and complementing the identified objective of the project:

- › dissemination of the harmonised accreditation scheme towards (e.g.) National accreditation bodies, Member State’s notifying authority, notified bodies, industries;
- › creation and development of a centralised database for technical experts for supporting the national accreditation bodies,
- › improvement of the consistency between accreditation/recognition of notified bodies and other assessment bodies, in particular CSM-RA Assessment bodies (AsBos),
- › regular maintenance and updating of the harmonised accreditation scheme, including post project consideration.

Valenciennes, 3.3.2016



Josef DOPPELBAUER

Executive Director

4. Summary of the content of the reports

4.1. Report “Analysis of current situation”

This report describes the analysis performed from March 2014 to February 2015 regarding the available documentation.

It describes also the bilateral meetings initiated by the Agency to gather information on assessment methods used by national accreditation bodies.

The main outcomes of those bilateral meetings are included in this report; it contains also aspects which are out of the scope of the accreditation scheme project, which might be interesting for any further development.

ERA code for this document: ERA/ADV/2014-15/REP-001 V 2.0

4.2. Report “Harmonised requirements”

This report details the harmonised accreditation scheme for conformity assessment bodies (CABs) seeking accreditation as basis for notification by Member States to European Commission within the scope of the Interoperability Directive 2008/57/EC.

The ERA proposed harmonised accreditation scheme uses as baseline standard the EN ISO/IEC 17065:2012 “Conformity assessment — Requirements for bodies certifying products, processes and services”.

Therefore the harmonised accreditation scheme requires full compliance with EN ISO/IEC 17065:2012 plus amplified requirements defined by ERA and the Ad Hoc Task Force.

ERA code for this document: ERA/ADV/2014-15/REP-002 V 6.1

4.3. Report “Light impact assessment “

This report identifies three possible options to implement the harmonised accreditation scheme:

- › **Option 1**
 - *Accreditation: advised accreditation scheme **voluntary**.*
 - *Recognition: as currently practiced.*
- › **Option 2**
 - *Accreditation: advised accreditation scheme **mandatory***
 - *Recognition: as currently practiced.*
- › **Option 3**
 - *Accreditation: advised accreditation scheme **mandatory***
 - *Recognition: requirements of the advised accreditation scheme **mandatory**.*

The analysis has shown that option 3 has the biggest potential to achieve the objective of the increased mutual trust in the work performed by the notified bodies.

ERA code for this document: ERA/ADV/2014-15/REP-003 V 1.0