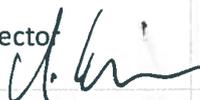


Report

Sectorial scheme for accreditation of notified bodies under Directive 2008/57/EC

ANALYSIS OF CURRENT SITUATION

ERA/ADV/2014-15/REP-001 V 2.0

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FOREWORD

This document is the merge of two previous documents called “Preliminary Analysis of current situation” and “Final Analysis of current situation”.

This document has been requested by the Ad Hoc Task Force member during the kick off meeting, held in Lille (F) the 11th February 2015

The content of this document is the same as the previous documents, plus some editorial improvements.

EXECUTIVE SUMMARY

This report describes the development of the analysis performed from March 2014 to February 2015 within the project on accreditation scheme for notified bodies under the interoperability Directive.

The project, initiated following a request from DG MOVE, aims at drafting an accreditation scheme for the conformity assessment bodies for the purpose of notification under the railway interoperability directive [1].

The relevant documentation available in NANDO database has been analysed after selecting some notified bodies representing the complete range of the EU NoBos (e.g. accredited, recognised etc.).

The search for documentation available was possible only for bodies notified under the recognition process, and not for bodies recognised under the accreditation path; therefore for those latter NoBos it was not possible to obtain specific information about the processes carried out to grant the accreditation.

In this context the documentation has been requested directly to the NAB which performed the assessment. Obtaining the documents in this way was not possible for privacy reasons.

Therefore, ERA focused on the process to obtain the accreditation by the NAB more than the analysis of the documentation produced for particular NoBos in the framework of the accreditation.

For this purpose ERA has decided to request bilateral meetings with the NABs in order to gather information on assessment methods used.

The main outcomes of those bilateral meetings are included in this report. The report also includes outputs of the bilateral meeting which are out of the scope of the accreditation scheme project, which might, however, be interesting for any further development.

ERA has identified different findings after internal analysis taking into account the discussions during the bilateral meetings held with NABs and with other entities.

The final ERA Accreditation Scheme will be based on those findings.

The following table shows the bilateral meeting held.

Table 1: Meetings held

| <i>Member State</i> | <i>NAB/other</i> | <i>Name</i> | <i>Date of the meeting</i> |
|---------------------|------------------|-------------|----------------------------|
| Europe | other | EA | 21/08/2014 |
| Belgium | NAB | BELAC | 29/10/2014 |
| France | NAB | COFRAC | 10/12/2014 |
| Germany | other | EBA | 23/10/2014 |
| Italy | other | ANSF | 27/11/2014 |
| The Netherlands | NAB | RVA | 28/10/2014 |

| <i>Member State</i> | <i>NAB/other</i> | <i>Name</i> | <i>Date of the meeting</i> |
|---------------------|------------------|-------------|----------------------------|
| Sweden | NAB | SWEDAC | 19/11/2014 |
| United Kingdom | NAB | UKAS | 17/09/2014 |

The structure and the content of the Accreditation Scheme will be defined after analysing the gathered best practice from the most mature NABs and recognition entities in European Union.

The text will be discussed with the members of the Ad Hoc Task force during the four planned meetings during 2015.

1. REFERENCES, DEFINITIONS AND ABBREVIATIONS

1.1 Reference Documents

Table 2: Reference Documents

| <i>[Ref.]</i> | <i>Title</i> | <i>Reference</i> |
|---------------|--|-----------------------|
| [1] | Agency Regulation | Reg. 881/2004 |
| [2] | Interoperability of the rail system | Dir. 2008/57/EC |
| [3] | Requirements for accreditation and market surveillance relating to the marketing of products | Reg. 765/2008/EC |
| [4] | Common framework for the marketing of products | Dec. 768/2008/EC |
| [5] | Regulation on CSM-RA repealing Regulation (EC) No 352/2009 | Reg. (EU) No 402/2013 |
| [6] | EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes | EA-2/17 M : 2009 |

1.2 Standard Terms and Abbreviations

The general terms and abbreviations used in the present document can be found in a standard dictionary. Furthermore, a glossary of railway terms that focuses primarily on safety and interoperability terminology, but also on other areas that the Agency can use in its day-to-day activities as well as in its Workgroups for the development of future publications, is available on the Agency website (<http://www.era.europa.eu/Document-Register/Pages/Glossary-of-railway-terms.aspx>).

Specific terms and abbreviations are defined in the sections below.

1.3 Specific Terms and Abbreviations

Table 3: Terms

| <i>Term</i> | <i>Definition</i> |
|-----------------------------|--|
| Agency | The European Railway Agency (ERA) such as established by the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European railway agency, as last amended by Regulation (EC) No 1335/2008. [1] |
| Conformity assessment body | Shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection (ref. art 2(13) of [3]) |
| National accreditation body | Shall mean the sole body in a Member State that performs accreditation with authority derived from the State (ref. art 2(11) of [3]) |
| Notifying entities | Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article [ref. art R14 of [4]]. |
| Technical expert | Person taking part to the assessment team with a strong competence in the field of the assessment. |

| <i>Term</i> | <i>Definition</i> |
|-----------------------------------|--|
| Technical assessor | Person taking part to the assessment team with a lower competence in the field of assessment in comparison with the technical expert, but with an higher competence on the process of accreditation and of assessment. |
| Designated bodies | Bodies as described in art 17(3) of IOD |
| Notified National technical rules | Rules notified by Member States to the EC in the cases described in art 17(3) of IOD |

Table 4: Abbreviations

| <i>Abbreviation</i> | <i>Meaning</i> |
|---------------------|--|
| BELAC | Belgian National Accreditation Body |
| CAB | Conformity Assessment Body |
| COFRAC | French National Accreditation Body |
| EA | European Co-operation for Accreditation |
| EC | European Commission |
| ERA | Agency, the European Railway Agency |
| EU | European Union |
| IOD | Interoperability Directive (Directive 2008/57/EC) |
| IU | ERA Interoperability Unit |
| NAB | National Accreditation Body |
| NANDO | New Approach Notified and Designated Organisations - http://ec.europa.eu/growth/tools-databases/nando/ |
| NoBo | Notified Body |
| NSA | National Safety Authority |
| RVA | Dutch National Accreditation Body |
| SWEDAC | Swedish National Accreditation Body |
| UK | United Kingdom |
| UKAS | United Kingdom National Accreditation Body |
| NNTR | Notified national technical rules |

2 INTRODUCTION

Up to MAY 2014, according to NANDO database, in Europe there are 58 NoBos under the IOD [1].

The Member States have the possibility to choose between two paths to assess and ensure conformity with the applicable requirements of the conformity assessment bodies to be notified under Directive 2008/57/EC: accreditation and recognition.

In both cases, the Member States must take into account the minimum criteria set in Annex VIII to Directive 2008/57/EC.

In the first option, the competence of the body to be notified is assessed by the National Accreditation Body (NAB). In the second option, the Member States appoint a body, usually a dedicated sector within the Ministry of Transport or Ministry of Industry. There are also example in which the NSA is appointed to check the competence of the body to be notified¹.

3 BACKGROUND

The 28th March 2014, DG MOVE sent a note to ERA Executive Director² in which ERA is requested to provide a formal advice, in collaboration with European co-operation for Accreditation (EA), on an accreditation scheme for notified bodies under IOD 2008/57/EC.

“At several RISC meetings, the NB-Rail chairman criticised a lack of participation of some notified (conformity assessment) bodies (NoBos) the NB-Rail meetings and activities. This was supported by the report of the representative of Belgium to the Committee, who attends the NBRail plenary meeting, as Committee observer. This led, in the audience, to a concern about the common approach among the NoBos, on the verification of conformity with the requirements set out in the Commission Decisions and Regulations on technical specifications for interoperability.

A lack of quality in the work of NoBos will inevitably lead to a lack of confidence by the MS in the EC verification process and ultimately undermine the achievement of the goals of the Interoperability Directive.

*The Commission services intend to strengthen their cooperation with the European Co-operation for Accreditation (EA) exploring pertinence and possibilities of establishing an accreditation scheme for railways' NoBos”.*³

3.1 ERA internal background

ERA has in its WP2014 the activity 4(5.2) “Advice [the EC] in drafting of an EA Policy for the Accreditation”.

This activity is the base for the terms of reference ERA-REC-113-NBACS-ToR presented at the ERA management meeting and positively voted. In the same Management meeting, the HoUs agreed on the relative resources to allocate to this project.

To draft the advice, ERA needs additional contribution, both inside and outside ERA staff; to this intention an “ad hoc task force” has been envisaged.

¹ NOTE: This report does not provide the description of:
role of notified bodies under the IOD;
concept of accreditation, recognition and notification.

This information is broadly described and can be consulted in the documents (standards, EU regulations, etc.) referred to in this document. Thus, this knowledge is considered already acquired by the reader of this document.

² Ref. ARES (2014) 977679

³ The text in italics is an extract as quotation from the DG MOVE letter.

3.2 Supporting documents

The following documents provide mandatory elements to be respected and integrated. Their knowledge is recommended to better understand the deliverables of this project:

- › Interoperability directive [2] – especially the chapter on NoBo and related annex VIII "MINIMUM CRITERIA WHICH MUST BE TAKEN INTO ACCOUNT BY THE MEMBER STATES WHEN NOTIFYING BODIES";
- › Regulation 765/2008/EC [3];
- › Decision 768/2008/EC [4].

To be notified, any conformity assessment body shall comply with the requirements of the legislation (Annex VIII of the IOD), and shall have the necessary technical competences.

Those technical competences are taken from the following harmonised standards:

- › EN ISO/IEC 17020, setting general criteria for the operation of various types of bodies performing inspection
- › EN ISO/IEC 17021, setting the principles and requirements for the competence, consistency and impartiality of the audit and certification of management systems of all types
- › EN ISO/IEC 17024, setting general requirements for bodies operating certification of persons
- › EN ISO/IEC 17025, setting the general requirements for the competence of testing and calibration laboratories
- › EN ISO/IEC 17065, setting the requirements for bodies certifying products, processes and services.

Those harmonised standards are general and should be complemented with amplified criteria.

4 PURPOSE OF THE PROJECT

The purpose of the project is to deliver an Agency advice to the EC on an accreditation scheme for Notified Bodies under the interoperability Directive. This advice should be drafted in collaboration with the EA.

The final aim of this advice is to suggest an integration to the EU legal framework in order to improve the harmonisation of the assessment of the notified bodies in EU. In particular, it should:

- › provide a uniform framework for the accreditation of notified bodies (and therefore increase the confidence of the Member States in certificates delivered by the different notified bodies in any Member State);
- › harmonize the technical competence of the EU rail notified bodies (and therefore mitigate the risks of having different approaches to conformity assessment and verification procedures of the requirements set out in the TSIs).

The accreditation scheme shall in particular cover the competences described hereunder necessary for the NoBos to properly perform their duties.

- › Technical competence: knowledge of railway technical domain in reference to the specific TSI(s) and modules for conformity assessment, suitability for use or EC verification the entity seeking for accreditation shall have;
- › Organisational and operational competence: knowledge of all the aspects related to methods of organisations and conducting assessments including audits and inspections as well as the proper means required to perform the tasks.

5 METHODOLOGY

The methodology proposed to develop the project is based on a holistic approach. Afterwards, and as the project progress, the different steps are refined and move towards those activities that can add more value to the expected outcomes.

The phases considered at this moment are the following:

- › Analyse current situation of NoBos through the information contained in NANDO;
- › Classify NoBos according to the path chosen for notification (namely recognition or accreditation);
- › Classify Accredited NoBos according to the international standards used by the NAB for the assessment;
- › Classify Non-Accredited NoBos according to the international standards used by the entities appointed by the Member States for the assessment;
- › Identify Non-Accredited NoBos assessed against Annex VIII to IOD;
- › Define different categories for the NoBos based on the path chosen and the reference documents used for the assessment;
- › For each category, select some NoBos to understand the application of the assessment methods. The following criteria has been taken into account:
 - Within each category, select NoBos from different Member states, if possible;
 - To select the NoBo of one particular Member State, the maturity of the MS in applying the EU legislation could be taken into account. If this criterion cannot be applied, the NoBos would be selected randomly.
- › Request to the EC services dealing with NANDO the supporting documentation for the above identified Notified Bodies;
- › Analyse the documentation received. In view of the analysis, select the organizations to propose bilateral meetings. One organization by Member State corresponding to the NoBos selected above;
- › Carry out the bilateral meetings and gather existing EU best practice in assessing the competence of the bodies seeking accreditation for the purpose of notification.

6 ANALYSIS PERFORMED

6.1 Selection of EU representative Notified Bodies cases

According to the information collected in May 2014 from the NANDO database published on Internet, there were 58 notified bodies in Europe: 40 notified bodies have been assessed by the NAB and 18 notified bodies have been assessed by other entities appointed by the Member States.

It is clear that the entities assessed by NABs have been later notified following the path of accreditation where the other has been notified under the path of recognition.

6.1.1 Assessment for accreditation

The competence of the bodies seeking notification have been assessed by the NABs and entities appointed by the MS according to several different documents.

In case of entities assessed by the NABs, the requirements have been assessed against the international harmonised standards of the 17000 series.

The following table resumes the international harmonized standards used for the assessment of the conformity assessment bodies.

Table 5: International Standards used for the Assessment of CABs

| <i>EN ISO/IEC std</i> | <i>Number of time used</i> |
|-----------------------|----------------------------|
| 17020 | 28 |
| 17021 | 23 |
| 17024 | 2 |
| 17025 | 6 |
| 17065 | 35 |
| 45001 ⁴ | 5 |

Most of the notified bodies have been assessed against more than one international harmonized standard. It should be highlighted that one NoBo can accumulate several accreditations against different international standards, but not all of them are useful for the purpose of notification for the interoperability directive. In fact, the NoBo can perform several activities for which other accreditation are needed; in this case, in the notification document all of their accreditation are noted, however for the scope and purpose of the IOD only one applies.

The table below shows the notified bodies assessed against two or more international harmonized standard.

Table 6: NoBos assessed against two or more international standard

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|--|---------------------|
| NB 0038 | Lloyd's Register Verification Limited | United Kingdom |
| NB 0942 | AGENCE DE CERTIFICATION FERROVIAIRE (CERTIFER) | France |
| NB 1020 | TECHNICKY A ZKUSEBNI USTAV STAVEBNI PRAHA s.p. | Czech Republic |
| NB 1125 | RAILWAY APPROVALS LTD | United Kingdom |
| NB 1127 | DELTA RAIL NOTIFIED BODY LIMITED | United Kingdom |
| NB 1133 | INTERFLEET CERTIFICATION LIMITED | United Kingdom |
| NB 2191 | Plurel | Netherlands |
| NB 1143 | ATKINS NOTIFIED BODY | United Kingdom |
| NB 1358 | VYSKUMNY USTAV DOPRAVNY, A.S. | Slovakia |
| NB 1467 | Instytut Kolejnictwa | Poland |
| NB 1468 | TRANSPORTOWY DOZOR TECHNICZNY | Poland |
| NB 1675 | HALCROW RAIL APPROVALS LIMITED | United Kingdom |
| NB 1714 | Vyzkumny Ustav Zeleznicni, a.s. | Czech Republic |
| NB 1807 | VANAHEIM AB | Sweden |

⁴ The 45001 has been replaced by the 17025.

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|--|---------------------|
| NB 2030 | Network Rail Infrastructure Ltd | United Kingdom |
| NB 2192 | MMRA Ltd | United Kingdom |
| NB 2237 | Sconrail UK Ltd | United Kingdom |
| NB 2250 | Arsenal Railway Certification GmbH | Austria |
| NB 2329 | ERC GmbH | Austria |

The above mentioned Notified Bodies are accredited:

- **13 NoBos against two standards, and**
- **5 NoBos against three standards.**

Notified bodies assessed against only one international harmonized standard are distributed as shown in the following tables.

Table 7: NoBos assessed only against the EN ISO/IEC 17020

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|---|---------------------|
| NB 0062 | BUREAU VERITAS | France |
| NB 0640 | DEKRA Industrial AB | Sweden |
| NB 0941 | RAILCERT B.V. | Netherlands |
| NB 1010 | LUXCONTROL NEDERLAND BV | Netherlands |
| NB 1602 | Bahn Consult TEN Bewertungsges.m.b.H. | Austria |
| NB 1869 | HHC/DRS Inspecties BV | Netherlands |
| NB 2212 | Schieneninfrastruktur-Dienstleistungsgesellschaft mbH | Austria |
| NB 2269 | Organismul Notificat Feroviar Roman - AFER (Romanian Railway Notified Body) | Romania |
| NB 2444 | Network Rail Certification Body limited | United Kingdom |
| NB 1144 | SGS CORREL RAIL LTD | United Kingdom |
| NB 1157 | Altran UK Ltd. | United Kingdom |
| NB 1412 | JSC Inspecta Latvia | Latvia |

12 Notified Bodies have been accredited against the EN ISO/IEC 17020 only standard.

Table 8: NoBos assessed only against the EN ISO/IEC 17025

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|---|---------------------|
| NB 1736 | MOVARES POLSKA Sp. z o.o. LABORATORIUM BADAWCZE URZADZEN I SYSTEMOW STEROWANIA TRANSPORTU SZYNOWEGO | Poland |

1 Notified Body has been accredited against the EN ISO/IEC 17025

Table 9: NoBos assessed only against the EN ISO/IEC 17065

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|--|---------------------|
| NB 0986 | <u>ASOCIACIÓN DE ACCIÓN FERROVIARIA (CETREN)</u> | Spain |
| NB 1615 | <u>BELGORAIL S.A.</u> | Belgium |
| NB 1696 | <u>LLC BALTIC TESTING CENTRE - BALTIC CERTIFICATION ORGAN RAILWAY TECHNICAL FACILITIES</u> | Latvia |
| NB 2365 | <u>Certyfikacja Infrastruktury Transportu Sp. z o. o</u> | Poland |
| NB 2411 | <u>TÜV Nord Luxembourg s.à.r.l.</u> | Luxembourg |
| NB 2443 | <u>TÜV SÜD Danmark</u> | Denmark |

6 Notified Bodies have been accredited against the EN ISO/IEC 17065

Table 10: NoBos assessed only against the EN ISO/IEC 45001

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|--|---------------------|
| NB 0676 | <u>LLOYD'S REGISTER NEDERLAND B.V.</u> | Netherlands |
| NB 1940 | <u>INSTYTUT POJAZDOW SZYNOWYCH TABOR</u> | Poland |

2 Notified Bodies has been accredited against the EN ISO/IEC 45001

The following list summaries the situation in Europe at MAY 2014 concerning the use of European standards for accreditation of Notified Bodies under the IOD:

- 18 Notified Bodies have been accredited against two or more international standards:
 - o 13 NoBos against two standards, and
 - o 5 NoBos against three standards;
- 12 Notified Bodies have been accredited against only the EN ISO/IEC 17020 standard;
- 1 Notified Body has been accredited against only the EN ISO/IEC 17025;
- 6 Notified Bodies have been accredited against only the EN ISO/IEC 17065;
- 2 Notified Bodies has been accredited against only the EN ISO/IEC 45001.

6.1.2 Assessment for recognition

In the case of recognition, the competence of the bodies seeking notification has been assessed by several entities appointed by the MSs, different from the NAB. To perform this check, the information contained in NANDO has been taken into account.

In some cases, this competence has been assessed according to the ISO international standards, in other cases the demonstration of their competence has been based upon the minimum requirements described in Annex VIII to IOD.

The following table show the notified bodies assessed against the minimum requirements described in Annex VIII to IOD.

Notified bodies assessed against the minimum requirements described in Annex VIII to IOD

Table 11: NoBos assessed against the minimum requirements described in Annex VIII to IOD

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|--|---------------------|
| NB 1304 | SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ | Slovenia |
| NB 1404 | ZAG - ZAVOD ZA GRADBENISTVO SLOVENIJE | Slovenia |
| NB 2106 | Q TECHNIA D.O.O. | Slovenia |
| NB 2129 | BUREAU VERITAS, d.o.o. | Slovenia |
| NB 2508 | DIS Consulting d.o.o. | Slovenia |
| NB 2536 | Paritet d.o.o. | Slovenia |

The following table describes the notified bodies assessed against international harmonised standards.

Table 12: NoBos assessed against international standards

| <i>Ref NANDO</i> | <i>Name</i> | <i>Member State</i> |
|------------------|---|---------------------|
| NB 0474 | RINA Services S.P.A. | Italy |
| NB 0475 | IIS CERT Srl | Italy |
| NB 0893 | EISENBAHN-CERT (EBC) Benannte Stelle Interoperabilität beim Eisenbahn-Bundesamt | Germany |
| NB 1278 | SINTEF | Norway |
| NB 1370 | BUREAU VERITAS ITALIA S.P.A. | Italy |
| NB 1960 | ITALCERTIFER S.P.A. | Italy |
| NB 2058 | Scandpower AS | Norway |
| NB 2071 | KTI Közlekedéstudományi Intézet Nonprofit Kft. | Hungary |
| NB 2101 | Associação Portuguesa para a Normalização e Certificação Ferroviária | Portugal |
| NB 2387 | TINSA Ltd. | Bulgaria |
| NB 2424 | ISARail S.p.a. | Italy |
| NB 2493 | CERTUNIV VASÚTI TANÚSÍTÓ ÉS MŰSZAKI SZAKÉRTŐ Kft | Hungary |

6.2 Consideration on the assessments of the notified bodies

Based on the above information, ERA identified 4 group of notification:

1. Accredited assessment bodies (accreditation by NAB)
 - 1.1. Against more than one ISO standard;
 - 1.2. Against one single ISO standard.
2. Non-accredited assessment bodies (recognition by MSs)
 - 2.1. Against one or more ISO standards;
 - 2.2. Against IOD minimum criteria (Annex VIII)

On the above considerations ERA based its sampling representing the whole European Union IOD notified bodies population.

ERA considered the 4 groups above described. Depending on the number of NoBos belonging to each group, the number of the chosen NoBo for analysis of documentation varies. There is a majority of NoBos in the category 1.1.

ERA identified 13 representative notified bodies, not belonging to the same MS:

Category 1.1 - Accredited notified bodies assessed against more than one ISO standard: 5 samples

1. NB 1615 BELGORAIL S.A.

2. NB 1696 LLC BALTIC TESTING CENTRE - BALTIC CERTIFICATION ORGAN RAILWAY TECHNICAL FACILITIES
3. NB 1736 MOVARES POLSKA Sp. z o.o. LABORATORIUM BADAWCZE URZADZEN I SYSTEMOW STEROWANIA TRANSPORTU SZYNOWEGO
4. NB 1157 Altran UK Ltd.
5. NB 1010 LUXCONTROL NEDERLAND BV

Category 1.2 - Accredited notified bodies assessed against one ISO standard: 2 samples

6. NB 1807 VANAHEIM AB
7. NB 0942 AGENCE DE CERTIFICATION FERROVIAIRE (CERTIFER)

Category 2.1 - Recognised notified bodies assessed against one or more ISO standards: 4 samples

8. NB 1960 ITALCERTIFER S.P.A.
9. NB 0893 EISENBAHN-CERT (EBC) Benannte Stelle Interoperabilität beim Eisenbahn-Bundesamt
10. NB 2101 Associação Portuguesa para a Normalização e Certificação Ferroviária
11. NB 2071 KTI Közlekedéstudományi Intézet Nonprofit Kft.

Category 2.1 - Recognised notified bodies assessed against IOD minimum criteria: 2 samples

12. NB 2508 DIS Consulting d.o.o.
13. NB 2129 BUREAU VERITAS, d.o.o.

6.3 Documentation received

ERA asked the EC services dealing with NANDO database to receive the supporting documentation for the above identified notified bodies.

6.3.1 Notified bodies for which ERA received the complete documentation

The following list shows the set of documentation provided to ERA by NANDO services. The documentation is the same as the documentation uploaded when the bodies have been notified by the MS.

- › NB 1960 ITALCERTIFER S.P.A. – previous list num. 8
- › NB 0893 EISENBAHN-CERT (EBC) – previous list num. 9
- › NB 2101 APNCF – previous list num. 10
- › NB 2071 KTI – previous list num. 11
- › NB 2508 DIS Consulting d.o.o. – previous list num. 12
- › NB 2129 BUREAU VERITAS, d.o.o. – previous list num. 13

As it could be seen clearly from the above description, ERA received the documentation only for the recognised notified bodies (category 2.1 and 2.2).

6.3.2 Documentation of accredited notified bodies

For the bodies notified under an accreditation procedure, the NANDO system does not request to upload additional supporting documents than the accreditation certificate. For this reason:

- › it was impossible to obtain the specific documents we asked for;
- › ERA asked these documents directly to the NAB which have performed the assessment.

Obtaining the documents in this way was not possible for privacy reasons and they, the NABS, suggested us to request directly to the notified bodies those documents.

In this framework the available documentation showed that more valuable inputs could be gathered from the assessment methods rather than in the results and in the documentation, therefore we decided to move towards bilateral meetings with NABS in order to identify their best practise in assessing the bodies seeking for accreditation for notification.

6.4 Bilateral meetings

6.4.1 Organisation of the bilateral meetings

As above described, after having analysed the documentation regarding the notification of a representative group of conformity assessment bodies, it was proposed to conduct bilateral meetings with the different organizations of the Member States appointed to carry out the assessments: the notifying authorities, authorities appointed to make the assessment and the National Accreditation Bodies.

The following table describes the meetings organised.

Table 13: Bilateral meetings proposed

| <i>Member State</i> | <i>NAB/other</i> | <i>Name</i> |
|---------------------|------------------|-------------|
| Europe | other | EA |
| Belgium | NAB | BELAC |
| France | NAB | COFRAC |
| Germany | other | EBA |
| Italy | other | ANSF |
| The Netherlands | NAB | RVA |
| Sweden | NAB | SWEDAC |
| Poland | NAB | PCA |
| United Kingdom | NAB | UKAS |

The purpose of the bilateral meetings is to take into account the already existing European best practice in assessing the competence of the bodies seeking notification in the framework of the IOD.

6.4.2 Proposed agenda of the bilateral meetings

ERA tried to have similar agendas through all the planned meetings.

The template agenda is as following:

- › Description of ERA project on accreditation scheme for notified bodies under the interoperability directive 2008/57/EC;
- › Requirements that ERA would like to define for the accreditation scheme; Discussion about on which EN standards the scheme should be based
- › NAB practice: what (and how) are the railway-related requirements now assessed.

7 MEETINGS HELD

Following the meetings planning described in the first deliverable, the following table describes the meetings held, including the dates in which the meetings took place.

The three meetings held with entities “other” than the NAB, were held with the National Safety Authority in Germany and Italy, and with the European Cooperation for Accreditation (EA).

Table 14: Bilateral meetings held

| <i>Member State</i> | <i>NAB/other</i> | <i>Name</i> | <i>Date of the meeting</i> |
|---------------------|------------------|-------------|----------------------------|
| Europe | other | EA | 21/08/2014 |
| Belgium | NAB | BELAC | 29/10/2014 |
| France | NAB | COFRAC | 10/12/2014 |
| Germany | other | EBA | 23/10/2014 |
| Italy | other | ANSF | 27/11/2014 |
| The Netherlands | NAB | RVA | 28/10/2014 |
| Sweden | NAB | SWEDAC | 19/11/2014 |
| United Kingdom | NAB | UKAS | 17/09/2014 |

ERA drafted the mission reports containing the findings of these meetings. For brevity and privacy sake, the meeting reports are not part of this document. The ERA mission report can be requested to ERA.

8 MAIN TOPICS DISCUSSED

It is worth to highlight the main topics issued by the bilateral meetings.

- › In the planned accreditation scheme, ERA should not provide any requirements concerning the certification of the product (Interoperability Constituent or Subsystem) because it is already described in the TSI and in decision on railway modules;
- › The core part of ERA project will be defining the requirements applicable to the NoBos which specifying criteria on organization, mode of operation, staff, equipment, reporting, etc.;
- › The requirements applicable to the organizations that perform assessments of NoBos should not be in the scope of the ERA accreditation scheme. It is already well covered by Regulation 765/2008 and the EA activities (e.g. ISO 17011);
- › The accreditation scheme shall be based on one or more harmonized international standards and not on the EA-2/17. The first step for ERA is to decide which standard(s) should be the base for the accreditation scheme. Likely the decision would be between EN 17020, EN 17021 or EN 17065. It seems to us at the moment of drafting this report that the EN 17065 is the best suitable for the purpose of the ERA project;
- › Pay attention to the difference between “certification of the QMS of the manufacturer” and “approval of the QMS of the manufacturer”. In fact, the final aim of the work performed by the NoBos is to ensure that the products manufactured (either Interoperability Constituent or Subsystem) are in accordance to the technical file already approved after the CB or SB module application. To this respect, there is no need to “certify” the QMS of the manufacturer (in the sense of the EN 17021), but to issue an “approval” of the QMS.

The minutes of the meeting are available by ERA under request.

9 USEFUL FINDINGS FOR THE ACCREDITATION SCHEME

The findings described in this chapter have been developed after an ERA internal analysis taking into account the discussions had during the above mentioned bilateral meetings.

The Accreditation Scheme, as envisaged, is a document of lev 4 under the EA 1-06 (lev 4 of the sectoral scheme⁵) and under the Reg 765/2008 art 2, point 10.

At the same time, the provisions described in the EA 2-17:2009 apply.⁶

The EN ISO/IEC 17065 is considered by all the meetings as the best suitable international standard upon which the Accreditation Scheme for the NoBos under the Interoperability Directive should be based.

The Accreditation Scheme will affect also the NAB assessment team and the overall process of accreditation; for this purpose the reference to the EN ISO/IEC 17011 is taken into account.

In case of already existing national Accreditation Scheme, a transitional period should be considered to allow Member States to adequate to the European Accreditation Scheme. A transitional period of 18 months is considered adequate.

The main findings for the Accreditation Scheme have been grouped into the following points. A detailed description of each is provided in the following points of this document. Each of them will be included in the Accreditation Scheme text.

1. Scope of the accreditation
2. Consultancy activities

⁵ http://www.european-accreditation.org/publication/ea-1-06-a-ab_rev07

⁶ The EA 2-17 has a new version since December 2014 (<http://www.european-accreditation.org/publication/ea-2-17-rev02-december-2014>). This new version has not been analysed for the drafting of this document; however the Accreditation Scheme will take it into account.

3. Independency of the NoBos
4. Establishment of the mechanism to safeguard the impartiality
5. Personnel competence assessment
6. Process for the quality management system approval
7. Overall process of accreditation
8. Information exchange
9. Reporting
10. NAB assessment team
11. Language skills
12. Complaint procedure
13. Users feedback procedure

9.1 Scope of the accreditation

According to the feedback obtained during the bilateral meetings, this is – most likely - the most important part. The scope of the accreditation should be as clearer as possible and should not provide possible misinterpretations. The final use of the NoBos services should be reassured by the clear definition of the scope of the accreditation. The main idea is to limit what has been accredited in order to make it more readable by the final user. In this context, the scope of the accreditation contains also the “technical annex” attached to it.

To clarify the scope of accreditation, we should say in advance that the main purpose of the notified bodies (and therefore of the accreditation) is to assess the conformity or suitability for use of the interoperability constituents and/or to appraise the ‘EC’ procedure for verification of the subsystems. At the end of the assessment process, the NoBo issues “EC certificates”.

After reflection, the conclusion is that there are 5 families of products to be certified as following:

- Infrastructure;
- Energy
- CCS –on board;
- CCS – trackside;
- Rolling stock.

Each family has two kind of products assessed according to different procedures: interoperability constituents and subsystems.

Therefore the scope of accreditation shall be one (or more) of the following items;

1. Infrastructure interoperability constituents;
2. Infrastructure subsystem;
3. Energy interoperability constituents
4. Energy subsystem;
5. CCS –on board interoperability constituents;
6. CCS –on board subsystem;
7. CCS – trackside interoperability constituents;

8. CCS – trackside subsystem;
9. Rolling stock interoperability constituents.
10. Rolling stock subsystem.

There is no other possible scope of accreditation.

Each scope of accreditation contains in itself all the applicable modules for its purpose. Each scope of accreditation is underpinned by one or more TSI applicable.⁷

The scope of the accreditation cannot be amended by the NoBo itself; however a certain flexibility should be taken into account for the amendments to the TSI. In fact, by definition, the TSIs' amendments provide minor modifications to the TSIs (e.g. editorial corrections, typos, references...); therefore the TSIs amendments are not affecting the role of NoBos. The same approach is also already taken into account by the NANDO system.

9.2 Consultancy activities

The discussion held on this topic had two sides: from one perspective, the independency of the NoBos in front of their clients, on the other hand, the problem of keeping the NoBos' competencies updated.

ERA intends to include in the Accreditation Scheme the possibility of the NoBos to act as consultancy company for their clients. This consultancy activity should be on "projects" that later will not be assessed by the same NoBo.

The limitation should be on product base between the NoBo and the client and not on all the products of that family.

The same approach should be applied to any company (legal entities) linked to the NoBo (see later "Independency").

ERA suggest to investigate further the economic feasibility of this solution⁸.

9.3 Independency

To allow a correct assessment of the independency of the CAB seeking accreditation, ERA supports the idea of providing guidance on how the organizational structure of the company has to be shown in terms of relationships within the company and with other external companies. Guidance will be provided as well for how this information should be kept up to date.

The term relationships should be understood also in front of holding and subsidiaries companies, and all the related bodies. Any modification in the structure of the CAB should be addressed to the NAB.

It is important to stress the importance of this independency and its violation should lead to the withdrawn of the accreditation.

It should be highlighted that the relationships of the NoBo with other companies should not be treated as a negative or positive aspect: the only fact that will be included in the Accreditation Scheme is about the transparency of the relations and the possibility to provide an external judgement on those relation and on the influence on the independency of the NoBo.

⁷ For the sake of clarity, there is no bilateral link between the accreditation scope and the TSI.

⁸ Recently (June 2014) ILAC published the "ILAC P15:06/2014 – Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies" (<http://ilac.org/news/ilac-p15062014-published>).

This guide is provides an interpretation of the independency of the inspection bodies under ISO/IEC 17020 Standard. This interpretation states that entities acting as NoBo cannot act as consultancy company on any other possible project similar to the NoBos' accreditation scope.

The ISO/IEC 17020 is a standard published in 2012, and then EC provide to this standard the value of "harmonised" standard. This ILAC interpretation is later (2014) therefore not necessarily agreed by the EC. However, ERA considers that, being the Accreditation Scheme based on the ISO/IEC 17065, this interpretation cannot be applied.

Moreover, ERA, on behalf of EC as scheme owner, provides its own interpretation of the concepts of independency on consultancy activities.

9.4 Establishment of the mechanism to safeguard the impartiality

The EN ISO/IEC 17065 obliges the NoBo to have an appropriate mechanism to safeguard the impartiality.

This “mechanism” can be organised and managed in different possibilities, eventually it can be also organised for several NoBos or even at the Member State level.

The Accreditation Scheme would not provide strict indication on how this mechanism should be organised, however the mechanism should be put in place. Special attention should be paid to the multi-national companies, active in several MS. The mechanism should be always clearly visible, traceable and identifiable.

9.5 Personnel competence assessment

The Accreditation Scheme should include a detailed list of competence to be discussed at technical interviews stage.

The competence will be divided into two main categories: general and technical.

The term general will include all the competence that will be common to any NoBo independently of its specific scope of accreditation. The competence will cover (for example) the IOD, the role of the NoBo in the framework of the IOD, the modules and the concept of authorisation for placing in service structural subsystems.

The technical competence will cover instead the specific railway peculiarities needed to perform the activity of NoBo. Those technical competences will be directly linked to the scope of the accreditation.

9.6 Process for the quality management system approval

There are some modules that need the approval of the manufacturer quality management system by the NoBo.

The Accreditation Scheme will provide specific details on how this QMS approval should be performed and should be organised. The EN ISO/IEC 17065 mentions the EN ISO/IEC 17021 as the reference standard for the QMS approval. In this case, the main finding from the bilateral meetings addresses to the element of the chapter 9 of the EN ISO/IEC 17021 standard. The Accreditation Scheme will provide clarification on how to use this chapter.

9.7 Timing for accreditation

The Accreditation Scheme will provide also timing reference for the first and second period of accreditation.

It will be left to the NAB how to manage and organise the surveillance, taking into consideration the size of the NoBo and of the NAB itself.

Concerning the timing of the accreditation, ERA has received the advice to not include in the timing the calendar period in which the surveillance should be provided, leaving this choice to the NAB (in agreement with the NoBo).

9.8 Information exchange

The Accreditation Scheme should contain a direct link between the NABs which apply the scheme and the scheme owner (the EC, or ERA). This direct link should facilitate the collection of the information about the accredited NoBo and their maintenance of competence.

This “information exchange” tool would also create an “early warning system”. Any problem found in a Member State could be immediately shared with the community.

9.9 Reporting

The Accreditation Scheme should provide as much as possible guidance to harmonise the way the information is displayed.

NB-Rail templates could be taken into account in certain cases.

9.10 NAB Assessment team

During the bilateral meetings, one common problem perceived is the lack of technical experts to perform the assessment to the entities seeking accreditation for the purpose of notification. Most of the NABs hire experts from the NSA of their Member State or from the infrastructure manager or the incumbent railway undertaking.

It could be perceived as a positive value if the Accreditation Scheme could provide some information concerning the overall competence of the technical expert to be hired.

It has been very well perceived the possibility to hire staff from ERA and from the NSAs. Some previous impartiality and conflict management solutions should be put in place in case of ERA or NSA staff dealing with the same NoBo for other activities.

Similar problem has been discussed for the technical assessor, even if this professional figure is considered easier to find on the market.

The final advice from the bilateral meeting is to concentrate on the technical experts.

In this context a possible further role for ERA has been introduced as described later.

9.11 Language skills

During the bilateral meetings, the topic of the English language (with an adequate level of competence) has been discussed.

It seems appropriate that NoBos should be skilled in English language with a B2 level.⁹

9.12 Complaint procedure

The scheme should contain mandatory provision for the NoBo to put in place a specific procedure to trace and follow up complaints raised by the NoBo customers.

The information dealt with this procedure should be transparent, not public, to NAB and to the scheme owner (EC or ERA).

9.13 Feedback from users

The scheme should contain the possibility to inform the scheme owner (EC or ERA) about improvements for the scheme itself.

⁹ The European Union has developed a scale for the linguistic competence. Further information are available here http://www.coe.int/t/dq4/linguistic/Cadre1_en.asp

10 FINDINGS FOR FURTHER ACTIVITIES

The findings described in this chapter have been developed after an ERA internal analysis taking into account the discussions had during the above mentioned bilateral meetings.

This chapter describes the elements discussed during the bilateral meeting which are (or could be) related to the Accreditation Scheme, even if not directly connected with the mandate received by ERA. Those elements are here described for traceability and for eventually further developments. They are listed hereunder and detailed in the following points.

1. Extension of mandate scope to include the recognition path
2. Extension of mandate scope to include the designated bodies
3. ERA role in peer review of recognition
4. ERA management of list of experts
5. Alignment between CSM-RA and NoBo

10.1 Extension of mandate scope to include the recognition path

In several meetings it has been argued that to harmonise the playing field in Europe, the analysis of the recognition path for the Notified Bodies together with the accreditation path should be taken into account.

For the time being this path has not been considered because it is out the scope of the mandate received from the EC.

A possible further activity could be to perform the same analysis performed for the accredited NoBo for the recognised NoBo, and then to develop a common scheme that could harmonise the two paths, no matter which one each Member State has chosen.

10.2 Extension of mandate scope to include the designated bodies

In several meetings it has been identified the topic of the designated bodies as a possible additional item to include in the analysis. Most of the general requirements for the notified bodies can be transposed to designated bodies; however the specific competences can vary in Member States, especially linked to the particular situation concerning the NNTR. The availability and reliability of the NNTR plays a major role in this topic.

10.3 ERA role in peer review of recognition

In several meetings, discussing about a possible scope extension for the recognition path, it has been also proposed the possibility to ERA to act as body organising/facilitating the peer analysis of the recognition path.

This approach could be similar to what is now described as an ERA task in the context of the CSM-RA.

10.4 ERA management of list of experts

As previously described, the availability of technical experts and technical advisor is considered a major problem for the purpose of notification.

It has been discussed the possibility to create a sort of EU database of technical experts in which the NABs and entities performing assessments for notification purpose could search for a particular competence. The development and maintenance of this database could be mandated to ERA.

10.5 Alignment between CSM-RA and NoBo

In several meetings, has been raised the topic of the alignment between the accreditation scope for the NoBo and the accreditation scope for the assessor in the framework of CSM-RA. In fact the technical competence

should be the same and those two documents need to be harmonised. To be more precise, there should be harmonisation between the Accreditation Scheme for NoBo and the Annex II of 402/2013 on:

- › point 1.b “relevant competence”; and
- › point B, scope of the accreditation.

11 CONCLUSIONS

After the meetings and all the analysis the scope and the content of the Accreditation Scheme has been defined gathering the best practice from the most mature NABs and recognition entities.

The next step of this project will be the draft text of the Accreditation Scheme which will include at least all the points mentioned above.

The text will be discussed with the members of the Ad Hoc Task force during the four planned meeting from February to December 2015.