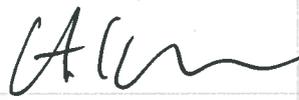


Report

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

AD HOC TASK FORCE ACTIVITIES

ERA/ADV/2014-15/REP-004 V 1.0

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EXECUTIVE SUMMARY

ERA has managed the Ad Hoc Task Force (AHTF) for the development of the project on a sectorial scheme for accreditation of notified bodies under Interoperability Directive 2008/57/EC from February 2015 to December 2015.

The AHTF had the aim of providing advices to ERA in drafting the accreditation scheme through 4 plenary meetings and several bilateral meetings; consensus was not targeted.

A consensus on the accreditation scheme, especially concerning the chosen baseline standard EN ISO/IEC 17065:2012, has not been achieved during the course of the activity of the task force. During the meeting there were two specific objections as summarised here below:

- UNIFE criticises the exclusion of the eligibility of in-house conformity assessment bodies to notified bodies activities, and
- Some CER members believe that the harmonised scheme should not be applicable for infrastructure related activities.

A part the two above comments, the rest of the AHTF members were supporting the ERA proposal for an harmonised accreditation scheme.

During the development of the accreditation scheme, ERA received several ideas, suggestions and contributions not strictly related to the scope of the project.

In order to keep trace of these thoughts ERA invited the AHTF members to produce a position paper on this topic; those position paper are included as annexes to this report.

1 SCOPE

This report describes the activities of the Ad Hoc Task Force (AHTF) created for the development of the project on a sectorial scheme for accreditation of notified bodies under Directive 2008/57/EC.

This report is part of the ERA advice 2014-015 addressed to European Commission regarding the establishment of an harmonised accreditation scheme for NoBos.

2 INTRODUCTION

On the 28th March 2014, DG MOVE sent a note to ERA Executive Director in which ERA was 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.

To draft the advice, ERA needed additional contribution from external experts. For this purpose ERA envisaged to establish an Ad Hoc Task Force.

According to the internal rules for working groups providing inputs for ERA activities, a task force is any group other than working parties and working parties subgroups that requires the involvement of external participants for carrying out tasks to support the Agency in its work. Members of a task force can be any necessary expert.

The selection of the members of the task force was made according to the following categories:

- › Representation of the accreditation sector, as experts in the topic and users of the future scheme;
- › Association of notified bodies, users of the future scheme and competent to bring the best practice in the CAB sector for railways to the discussion;
- › Clients of the notified bodies, experts in identifying needs to be included in the accreditation scheme, such as: representatives from the industry, infrastructure managers and railway undertakings;
- › National Safety Authorities (NSA), key element in the authorisation process and users of the outputs produced by the notified bodies;
- › International transport organisations, with a focus on the links between the EU rail area and third countries.

3 OBJECTIVE OF THE AD HOC TASK FORCE

The objective of the Ad Hoc task force was to provide to ERA feedback from the point of view of the organisations involved in the activities of the accredited NoBos.

Feedback from the ad hoc task force has been taken into account by ERA when drafting the final advice to EC and in revising all the supporting reports to the advice.

The tasks assigned to the “Ad hoc task force” were:

- › Participate actively at the “Ad hoc task force” meetings;
- › Provide advice and comments related to the deliverables;
- › Disseminate the findings of the project to their related organisations.

Given the consultancy role of the task force, consensus, although welcomed, was not needed.

4 MEMBERS OF THE AD HOC TASK FORCE

The following external organisations were invited to be part of the “Ad hoc task force”:

- › 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 above listed organisations nominated the following experts to participate in the meetings:

Table 1: AHTF nominated members

#	Name	Family Name	Company	Organisation	Role
1			Luxcontrol	NB-Rail	
2			Cetren	NB-Rail	
3			Belgorail	NB-Rail	Deputy
4			Luxcontrol	NB-Rail	Deputy
5			Enac	EA	
6			Latak	EA	
7			Danak	EA	Deputy
8			Swedak	EA	Deputy
9			EBA	NSA-DE	
10			ANSF	NSA-IT	
11			ANSF	NSA-IT	Deputy
12			EPSF	NSA-FR	
13			EPSF	NSA-FR	
14			EPSF	NSA-FR	Deputy
15			OTIF	OTIF	
16			OTIF	OTIF	
17			Bombardier	UNIFE	
18			UNIFE	UNIFE	
19			Siemens	UNIFE	Deputy
20			Network Rail	EIM	
21			EIM	EIM	

Table 1: AHTF nominated members

#	Name	Family Name	Company	Organisation	Role
22				EIM	
23			ATOC/RSSB	CER	Main Speaker
24			ÖBB	CER	Rotative
25			DB	CER	Rotative
26			SNCF	CER	Rotative
27			SBB	CER	Rotative
28			FSI	CER	Rotative

5 MEETINGS HELD

According to the project plan, four meetings have been held in the following dates in ERA Lille premises:

Table 2: Ad hoc task force meetings

Name	Date
Ad hoc meeting num.1: kick-off	11 th FEB 2015
Ad hoc meeting num.2: progress	29 th MAY 2015
Ad hoc meeting num. 3: intermediate	22 nd SEP 2015
Ad hoc meeting num.4: final	3 rd DEC 2015

In addition, and as requested by some members of the ad hoc task force, additional bilateral meetings were held to tackle specific issues.

The outcomes of the bilateral meetings have been presented in the meetings of the ad hoc task force and included in the accreditation scheme text as needed.

Table 3 : Bilateral meetings

Name	Date
CER bilateral meeting 1	20th MAR 2015
CER bilateral meeting 2	10th APR 2015
NB-Rail bilateral meeting 1	13th APR 2015
NB-Rail bilateral meeting 2	2nd JUL 2015
NB-Rail bilateral meeting 3	23rd JUL 2015
UNIFE bilateral meeting	2nd OCT 2015
CER bilateral meeting 3	5th NOV 2015
NB-Rail bilateral meeting 4 (ph.conf)	23rd NOV 2015
NB-Rail bilateral meeting 5 (ph.conf)	8 th DEC 2015
NB-Rail bilateral meeting 6 (ph.conf)	10 th DEC 2015

NB-Rail bilateral meeting 7 (CCS)

16th DEC 2015

6 CONCLUSIONS OF THE AD HOC TASK FORCE

Throughout the ten months of activity of the ad hoc task force (from FEB 2015 to DEC 2015), several versions of the text of the accreditation scheme were discussed. The latest version sent as final to EC is the version 6.1.

ERA received comments from all stakeholders, which ERA analysed and provided replies. In most of the cases the comments were accepted. The complete list of comments received, including the ERA replies is stored in ERA Extranet and available upon request.

Nevertheless, a consensus on the accreditation scheme, especially concerning the chosen baseline standard EN ISO/IEC 17065:2012, has not been achieved during the course of the activity of the task force. During the meeting there were two specific objections as summarised here below:

- UNIFE is rejecting:
 - the choice of the EN ISO/IEC 17065:2012 as baseline standard. Especially UNIFE criticises the exclusion of the eligibility of in-house conformity assessment bodies to notified bodies (debate on Notified bodies being third party conformity assessment bodies or first- or second-party conformity assessment bodies).
 - The limitation to TYPE A inspection bodies in case of outsourced inspection activities. UNIFE would extend the outsourced inspection activities also to TYPE B and TYPE C inspection bodies.
- Some CER members believe that the baseline standard EN ISO/IEC 17065:2012 should be not applicable for infrastructure related activities. For those CER members if the subject of the certification is a line or a bridge it could not be assimilated to a product. For those CER members it is necessary to provide multiple choices depending on the activities of a NoBo.
- EBA is rejecting the limitation to TYPE A inspection bodies in case of outsourced inspection activities. UNIFE would extend the outsourced inspection activities also to TYPE B and TYPE C inspection bodies.

Unfortunately the comments from UNIFE and EBA regarding the limitation to type A inspection bodies as above mentioned arrived to ERA later than the final deadline (UNIFE position, via e-mail the 21st DEC 2015; EBA position via e-mail the 18th DEC 2015) and therefore they could not be processed.

ERA suggests to postpone the debate on this topic as an open point for further revision of the harmonised accreditation scheme.

Regarding the two above objections, the ERA position was clear and discussed several times with the support of presentations and documents:

- Baseline standard EN ISO/IEC 17065:2012 suits best to the purpose of railway notified bodies because the EC certificates cover products regardless if those products are small object, locomotives or entire railway lines;
- Notified bodies are third party conformity assessment, and
- In-house assessment bodies have different tasks rather than notified bodies (as defined by the modules decision 713/2010 and by the choice of modules in TSIs).

As part of the two above comments, the rest of the AHTF members were supporting the ERA proposal.

During the development of the accreditation scheme, ERA received several ideas, suggestions and contributions not strictly related to the scope of the project. Some of these contributions were related to a long-term vision on the conformity assessment for the railway sector.

In order to keep trace of these thoughts ERA invited the ad hoc task force members to produce a position paper on this topic; the position papers may contain elements not included in the scope of the project. For the sake of transparency, this report includes the positions paper received before the 15th DEC 2015 in Annex 1.

7 STAKEHOLDERS PERCEPTION

ERA has launched on the 13th NOV 2015 a survey to analyse the perception of the AHTF members (28 people) about the quality of the work performed. The survey was not intended to provide a technical analysis of the document produced by ERA, but to focus on the way how the work has been developed by ERA.

The survey was articulated in 4 set of questions plus a possibility to provide an additional comments on that set of questions. At the end of the survey, there was a possibility to provide a contribution on general topic.

It was possible to reply to questions with scores from 1 to 3, where:

- 1: low score
- 2: average score
- 3: high score

The four set of question were:

- 1) General management of the project;
- 2) Meetings management;
- 3) Technical content of the project, and
- 4) Overall logistics of meetings.

ERA has received 10 replies to this questionnaire, which is equal to 36% (=10/38) of the total.

7.1 Survey numeric results

The numeric findings have been assessed as:

- **ERA excellence:** average score greater than 2.8 (highlighted in yellow), and
- **ERA area of improvement:** average score lower than 2.

Table 4: Numeric results of the survey

1) General management of the project											Av
ERA Extranet space: user-friendliness	2	3	2	3	2	3	2	2	3	3	2,5
ERA management of the comments provided	3	3	3	3	3	3	3	3	3	2	2,9
Time allocated to provide comments	3	3	2	3	2	2	3	3	3	2	2,6
Quality of the documents provided	3	3	2	2	2	2	3	3	2	1	2,3
Planning of the meetings	3	3	2	3	2	3	3	3	3	2	2,7
Overall evaluation	3	3	3	3	3	3	3	3	3	2	2,9

2) Meetings management

Time allocation to breaks	3	1	2	3	2	3	3	3	3	3	2,6
Time allocation to debate items	3	2	2	3	1	3	3	3	3	3	2,6
Overall time management	3	3	2	3	2	3	3	3	3	3	2,8
ERA competence in chairing meetings	3	3	3	3	3	2	3	3	3	3	2,9

3) Technical content of the project

Impact assessment: quality of light impact assessment result	3	2	2	3	3	-	2	2	3	1	2,3
Impact assessment: added value of questionnaire	3	2	2	2	2	-	3	2	3	1	2,2
Added value of the technical discussions at meetings	3	1	3	3	2	2	3	3	3	2	2,5
Technical level of the documentation produced by ERA	3	3	3	2	3	2	3	3	3	2	2,7
Technical knowledge of the members of the Ad Hoc Task Force	3	2	3	2	2	3	3	3	3	3	2,7

Technical knowledge of the ERA staff	3	3	3	3	3	2	3	3	3	1	2,7
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4) Overall logistics of meetings

Coffee and lunch breaks: quality of sandwiches and refreshments	3	2	3	2	2	2	3	3	3	3	2,6
IT support in Lille (Internet connection, WiFi, etc)	3	3	3	-	2	3	2	3	3	-	2,7
Supporting tools in Lille (beamer, audio, lights ...)	3	3	3	3	3	3	3	2	3	3	2,9
Registration and administrative support	3	3	2	3	3	3	3	3	3	3	2,9
Agenda	3	3	2	3	2	3	3	3	2	3	2,7
Invitation (timing, content, flexibility, etc)	3	3	2	3	3	3	3	3	3	3	2,9
Overall organization	3	3	2	3	3	3	3	3	3	3	2,9

7.1.1 Conclusion on survey numeric results

ERA excellence

NOTE: same order as survey

- ERA management of the comments provided
- Overall evaluation
- Overall time management
- ERA competence in chairing meetings
- Supporting tools in Lille (beamer, audio, lights ...)
- Registration and administrative support
- Invitation (timing, content, flexibility, etc)
- Overall organization

Comment: This good results has been achieved following a structured approach to project management. Pending an appropriate ERA internal methodology for project management, the responsible for this project followed the guidelines provided by PM² the official methodology of the EC. This approach positively impacted also on the good team work amongst the ERA members and especially with the administrative assistance.

ERA area of improvements

There are no areas of improvements. The lowest score is 2.2 regarding the “Impact assessment: added value of questionnaire” which is however greater than 2.0 (minimum threshold).

7.2 Survey comments provided

This section is provided without any ERA analysis or explanation. The text included in this section is “copy/paste” from the comments received.

1.1) General management - additional comments

- well prepared meetings, good level of discussions.
- Overall better managed than many other ERA meetings.
- Too much time allocated to provide comments - this implied slow development process.
- The project was very professionally managed by the ERA officers in charge including the targeted working method and accurate/timely management of the document repository on the ERA Extranet.
- The performance has been exemplary, well done.
- General comment on the ERA Extranet: the Extranet continues to be confusing.
- The Extranet structure of the Adhoc Task Force does not correspond to the structure of other Extranet spaces.

- The planning of the meeting had been excellent

2.1) Meetings management - additional comments

- Breaks too long
- Maybe sometime a pre-bilateral meeting (like with NB Rail Participant) will be good as also to stop him sometimes in his arguments. That requires a good knowledge of the subject. For that point 3 is less valued.
- You should ensure the participants be back at the table in due time for efficient continuing. Sometimes that was not the case so the breaks had to be unnecessarily extended.

3.1) Technical content - additional comments

- Many of the AHTF gained more from attendance than they gave
- Since point 3.1 is asking about technical content: Our organisation disagrees with the content of the work. Core elements are not reflected in the report. This does NOT say anything about the technical competency of ERA staff. ERA staff ensured transparency.
- Impact assessment not really convincing as it could neither fully prove necessity for the scheme nor prove any benefit.

4.1) Overall logistics - additional comments

- Difficulties in reaching Lille by airplane, End times of the meeting too late in the afternoon
- Try and vary the food

5) Any additional comments you would like to provide us. Please be specific.

- Very interesting and satisfying work performed and the comparison had with members of the Task.
- Please see comment at 1.1
- To less time for that important project.
- Rename the category 3.1. I understand that the technical content of the report should not be judged?
- Excellent organisation and management

ANNEX 1 - POSITION PAPERS OF THE MEMBERS OF THE AHTF

ERA has requested the organisation members of the AHTF to provide their position papers on the accreditation scheme.

The following organisation replied:

- 1) CER;
- 2) UNIFE;
- 3) EIM;
- 4) NB-Rail association, and
- 5) Verband der TUV e. V.

Their position papers are annexed to this document.

Accreditation scheme for Notified Bodies

Brussels, 14 December 2015



Mr Josef Doppelbauer

Executive Director
European Railway Agency (ERA)
Executive Director

Dr Libor Lochman

Executive Director

Mrs Anna Gigantino

European Railway Agency (ERA)
Head of Interoperability Unit

Dear Josef,
Dear Anna,

I appreciate that in December 2015 the European Railway Agency (ERA) successfully concluded its final report proposing a sectoral accreditation scheme for Conformity Assessment Bodies (CABs) taking into account outcomes from the consultations with key representatives from the railway sector.

The Community of European Railway and Infrastructure Companies (CER) largely supports the proposal, in particular the necessity to have legally independent Conformity Assessment Bodies as outlined in version 5 of the Agency's accreditation scheme document, and believes that it should provide a good baseline for the accreditation of Conformity Assessment Bodies within the scope of the IOD going forward.

However, the selection of EN ISO/IEC 17065 as the most suitable standard upon which the accreditation scheme for NoBos should be based has not been clearly justified and therefore consensus has not been achieved. Product certification is one of the NoBo activities, but not the main activity of the NoBo. For example the main activity in the infrastructure domain is the subsystem verification, based in principle on an inspection. As a result of this, it is believed that it is necessary to make a difference in the choice of the accreditation scheme depending on the activities of the NoBo and also to consider appropriate and well-established EN standards, such as EN ISO/IEC 17020 and EN ISO/IEC 17021.

CER believes that the scheme should be reviewed and where necessary revised no later than two years from now so as to capitalise on return of experience and on the results of the ERA monitoring of NoBo work, and to explore opportunities to optimise requirements for accreditation of CABs which verify infrastructure-related subsystems and constituents. The requirements of RFUs (Requests for Understanding) should be incorporated into the scheme where appropriate.

In addition, whilst recognising that the mandate given by the European Commission and timelines set in the ERA 2015 work programme require focus on accreditation path only, CER believes that confidence in the NoBo accreditation processes and, where applicable, the related DeBo processes will not be achieved unless they become mandatory and all paths are harmonised to common and/or mutually recognised and accepted standards.

On a separate note, CER would like to express its appreciation for the very professional performance of the ERA officers in charge, the targeted working method and the accurate management of the document repository on the ERA extranet. The performance has been exemplary.

Yours sincerely,

In 2014, the European Railway Agency (ERA) was granted with a mandate from the European Commission to draft an European sectoral accreditation scheme (the Scheme) for Conformity Assessment Bodies (CABs) seeking accreditation as a Notified Body (NoBo) under the EU Railway Interoperability Directive 2008/57/EC (the IOD). For this purpose, an Ad Hoc Task Force group composed of key representatives and stakeholders from the European railway was formed in 2015.

At the beginning of the Task Force, ERA announced that it is neither ERA's request nor ERA's assignment to achieve a joint solution and common understanding on the subject matter. Because of this, the final ERA proposal of the Scheme does unfortunately not reflect the consensus and the common opinion of the members of the Task Force group.

UNIFE and its members have addressed its concerns over the proposed contents of the Scheme several times, in various ways, on different levels and at many occasions. However, those concerns were never genuinely taken into account and have never been considered in the Scheme up to the final draft provided in December 2015. It is therefore with great regret that UNIFE, who has always been in favor and supportive of setting up an European accreditation scheme, cannot promote or vindicate the final draft of the ERA Accreditation Scheme.

The current situation under the IOD: In-house Bodies as CABs

Under the regime and opportunities of the IOD, UNIFE members have successfully established and maintained independent internal conformity assessment bodies during the last couple of years (so-called in-house bodies or in-house CABs). Those in-house bodies are accredited in accordance to common European standards like EN ISO/IEC 17020, EN ISO/IEC 17021 or EN ISO/IEC 17025 and act as fully accepted Assessment Bodies (AsBo), Designated Bodies (DeBo) or Testing Bodies in accordance to the IOD today.

The concept of in-house bodies was originally adopted from the innovative European aircraft industry and once implemented it turned out to be a big success for the European railway industry as well. In-house CABs enable manufacturers and operators to preserve valuable technical knowledge and expertise, while at the same time providing a constant stream and backflow of necessary information by the use of independent assessments. They allow manufacturers and operators to build up learning organizations throughout a permanent return of first-hand experience, knowledge and continuous improvement, which makes it possible to optimize products, processes and projects on a daily basis.

Today in-house bodies are widely recognized and well respected for their technical competence and expertise. They form an integral part of the European vehicle authorization process and have an important strategic role strengthening the competitiveness of the European railway industry in the global context. Moreover, in-house bodies are fully in line with the intention and targets of the 4th Railway Package by significantly reducing the administrative barriers and costs for authorization as well as enhancing the time to market for new rail vehicles.

The future situation under the ERA Scheme: No In-house Bodies as CABs

With the Scheme, ERA decided to make use of EN ISO/IEC 17065 as the solely baseline standard for accreditation and to implemented extensive requirements for the organizational structure of NoBos. It seems however that those decisions have been made without adequately observing the status, circumstances and consequences in the Member States and in the European railway industry. Although ERA stated that the Scheme and its content would be in full line with the IOD and its criteria for NoBos, there are now restrictions under the Scheme – especially with regards to the activities and structure of NoBos – that have no valid or justified counterpart in the IOD. Those additional requirements interfere with already existing and well-established concepts for CABs in the Member States and put

the European railway industry on the back foot in comparison to other non-European railway industries.

Due to ERA's decision to base the Scheme solely upon EN ISO/IEC 17065 and to require NoBos to be a separated "third-party" legal entity, numerous existing CABs and all of today's in-house bodies will be entitled to shut down their current services; while many future entities will be prohibited from providing CAB-services at all.

The problem: Exclusion and Elimination of In-house Bodies

The problem is that any CAB seeking accreditation as a NoBo under the Scheme has to be a separate third-party legal entity. In-house bodies are identifiable and independent entities of an organization that provide impartial first-hand conformity assessments. However, they are not separated third-party legal entities. Because of this, any existing and accredited in-house body of today or any future in-house body would be excluded from becoming a NoBo under the ERA Scheme.

This provision of the Scheme regarding the legal structure and organization of a NoBo is not in line with the current NoBo criteria set out in the IOD (see Article 28 and Annex VIII). At no point or paragraph does the IOD require a NoBo to be a separated third-party legal entity.

Over the past years, in-house bodies did become accredited as CABs under the IOD. They have proven to perform well; executing their role to the highest professional standards and in the case of several Member States, contributed greatly to solve existing authorization issues. They are the missing link between National Safety Authorities and the operational stakeholders, like manufacturers and operators. In the context of growing international competition and the entry of non-European manufacturers and operators into the European market, in-house bodies offer and add an extremely important benefit to the local industries. Their competence, technical experience and integrity is out of the question, which makes them a fundamental part of the trust building process for the railway system in European Union. A backflip on these achievements might cost the EU railway sector dearly.

UNIFE proposal: Preserve In-House Bodies

An exclusion of all existing and future in-house bodies working as CABs under the IOD is simply not acceptable for UNIFE and its members. Today in-house bodies play a vital role in every rail vehicle development and/or vehicle modification process of manufacturers and operators. They form a fundamental part of vehicle authorization proceedings with the result that an exclusion would cause a major "bleeding" of valuable and needed technical expertise as well as a destruction of proven and well-established workflows.

1. UNIFE proposes to replace the implemented "third-party" requirement for CABs through the requirement to give proof of independency and impartiality as stated in EN ISO/IEC 17020.

In-house bodies can and will provide independency and impartiality, but they cannot be a separated third-party legal entity, because this would require to found a completely new company. There is no reason or evidence available that the required and necessary independency of CABs depend on their organizational structure. ERA's argument that CABs under the IOD have to be a third-party due to the provisions out of Decision No 768/2008/EC is invalid. Decision 768/2008/EC is a so-called "sui generis decision", which cannot be directly applied (see Section 1.2.2.2 of the Blue Guide). This Decision only comes into force, if it has explicitly been made applicable through a specific reference. This however is not the case in relation to the IOD, which therefore means that Decision 768/2008/EC is not applicable here. ERA should not establish any additional requirements within the Scheme that

- a) have no valid legal basis in the current IOD;
- b) endanger existing accreditations and services of established CABs under the IOD;

- c) annihilate well-accepted and acknowledged centers of competence, like in-house bodies;
- d) interfere with already existing and proven concepts in the Member States;
- e) interfere with the entrepreneurial freedom of manufacturers and operators; and
- f) relate only to the internal organizational structures of CABs with no clear benefits for competence and expertise.

2. UNIFE also proposes to base the Scheme not solely on EN ISO/IEC 17065, but also on other common EN standards, like EN ISO/IEC 17020, 17021 or 17025.

The selection of EN ISO/IEC 17065 as the most suitable standard upon which the Scheme for NoBos under the IOD should be based for all sub-systems has not been clearly justified by ERA and therefore consensus has not been achieved. ERA's argument that EN ISO/IEC 17065 is the sole and best suited standard, because NoBos would perform "product certification" is invalid. At no point does the IOD make use of the term "product certification" or requires NoBos specifically to perform "product certification". The certification activity is only one possible activity for a CAB and only one step in a longer process composed and accompanied by other activities like testing, inspection and/or quality management. For this reason, several stakeholders of the Task Force believe that the current Scheme makes little sense, especially for infrastructure related installations, vehicle modifications or railway products that are not related to typical manufacturing processes. Therefore, it is believed that it is necessary to make a difference in the choice of the applicable EN standard depending on the activities of the NoBo. ERA should make sure that any Scheme for the accreditation of CABs under the IOD adds real benefit and meets the needs of the European railway sector, which means in this case a parallel application of EN standards, like

- a) EN ISO/IEC 17020 for inspection activities;
- b) EN ISO/IEC 17021 for auditing of management systems;
- c) EN ISO/IEC 17025 for testing activities; or
- d) EN ISO/IEC 17065 for certification activities.

What needs to be done?!

1. Delete the requirement for separate "third-party" legal entities acting as CAB and replace it through the requirement of giving proof of independency and impartiality.
 - A third-party structure is no guarantee for independent operating principles and work flows. A specific proof of independency however will keep existing in-house bodies in service and will make sure that all CABs have to work as independent as needed.
2. Create generic criteria for NoBo accreditation under the IOD, which are not solely based on a single or one specific EN standard like EN ISO/IEC 17065.
 - The products and services of the European railway industry are various and so are the areas of operation of CABs. The parallel usage of different EN standards is essential to create the best possible CABs for the best European railway system.

The lack of consensus on the Scheme may lead to the Scheme not being adopted and the objectives of the project not to be achieved. Under the current Scheme, manufacturers, operators and Member States – whose existing accreditations are not based on the EN ISO/IEC 17065 standard and who work constantly with in-house bodies – will face significant costs, a loss of much needed expertise and changes of well-established concepts and working principles. Moreover, for many CABs and stakeholders the Scheme of ERA breaches the common understanding on a non-discriminatory access to the EU Single Market. UNIFE therefore believes that the Scheme should be reviewed and where necessary revised at the earliest opportunity.

Brussels, 15th December 2015

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Head of Interoperability Unit

Mr Luca Trinca
European Rail Agency (ERA)
Project Officer

Dear Josef,
Dear Anna,
Dear Luca,

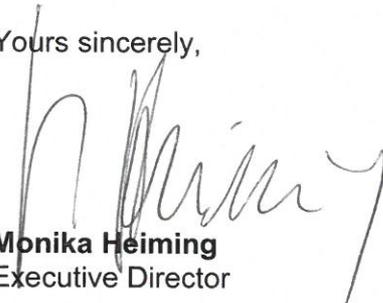
The European Railway Agency (ERA) has successfully concluded its proposal for a sectoral accreditation scheme for Conformity Assessment Bodies (CAB's), as mandated by the European Commission. The European Rail Infrastructure Managers (EIM) as a recognised body has actively followed this workstream.

EIM supports the proposal by ERA and agrees some form of accreditation of Conformity Assessment Bodies would be beneficial to the sector. EIM believes that in order for the scheme to achieve its goal to harmonise the requirements for Conformity Assessment Bodies to become NoBo and improve confidence in the quality of the NoBo process, the scheme will have to be adopted on a mandatory basis.

EIM supports the views raised by other sector stakeholders during the consultation that there should be a review of the scheme within 2 years of implementation. The aim of which is to return experience and ensure the scheme has achieved what it is intended to do while benefiting the sector and not becoming a barrier for sector entry.

Finally, EIM would like to voice its appreciation for the professional manner in which this workstream has been conducted by ERA and the project managers in charge.

Yours sincerely,



Monika Heimig
Executive Director



Mr. Luca Trinca
Interoperability Unit
Coordination Sector
European Railway Agency
120 rue Marc Lefrancq
F-59300 Valenciennes
France

16/12/2015

Subject: Accreditation Scheme

Dear Mr. Trinca!

The “report on the framework of the sectoral scheme for the accreditation of conformity assessment bodies for the purpose of notification under the Interoperability Directive 2008/57/EC” has been drafted and finalised during 2015 by ERA with intensive consultation of various stakeholders including NB-Rail. From the point of view of NB-Rail the final report perfectly fulfils the objectives of the accreditation scheme as listed hereunder.

- To harmonize the accreditation process for all accredited notified bodies
 - In a next step this scheme shall be extended to all notified bodies including the recognised bodies
- To increase the mutual trust amongst the relevant stakeholders in the EC certification process
- To ensure that CABs have the correct procedures and competence to perform NoBo activities as described in the EU railway legal framework
- To assure independent and impartial third-party assessment
- To harmonized the the competency assessment procedure of the notified bodies performed by the national accreditation bodies and national authorities

NB-Rail congratulates to the outstanding work that has been done and is happy to give any further support if needed.

Best regards

Christoph Handel
Chairman
NB-Rail AISBL
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1000 Brussel
Belgium

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Accreditation scheme – CAB under Directive 2008/57/EC

Dear Mr. Trinca:

The European Railway Agency has recently drafted and finalized the report on the framework of the sectoral scheme for the accreditation of conformity assessment bodies for the purpose of notification under the Interoperability Directive 2008/57/EC. Various stakeholders have been consulted intensively.

The system of accreditation is a suitable tool to manage risks by assuring that accredited bodies are competent, independent and impartial to carry out the work they have to undertake. Furthermore, accreditation is regarded as a means to secure national and international acceptance of certifications issued by accredited bodies.

VdTÜV e.V. congratulates to the outstanding work. From our point of view the final report perfectly fulfils the objectives of the accreditation scheme to guarantee common criteria for accreditation of bodies involved in the assessment as listed hereunder:

- To harmonize the accreditation process for all accredited notified bodies
 - In a next step this scheme shall be extended to all notified bodies including the recognized bodies;
- To increase the mutual trust amongst the relevant stakeholders in the EC certification process;
- To ensure that the conformity assessment bodies have the correct procedures and competence to perform Notified Body activities as described in the EU railway legal framework;
- To assure independent and impartial third-party assessment;
- To harmonize the competency assessment procedure of the notified bodies performed by the national accreditation bodies and national authorities.

In order to ensure consistency and quality and to be in line with Regulation (EC) 765/2008 of the European Parliament and the Council of 9 July 2008 VdTÜV e.V. highly recommends that this accreditation scheme shall be binding in its entirety and directly applicable in all Member States, either the member states uses its national accreditation body nor by recognition of another governmental organization, e.g. national safety agencies or ministry of transports.

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Does the European Railway Agency plan to recommend the European Commission to make the finalized accreditation scheme more legally binding and by this means to ensure harmonized requirements and methods for the accreditation of notified bodies in the entire Union? (common level-playing field) In addition, the EU Commission shall ensure that the accreditation scheme clearly states the requirements of the international Standard ISO/IEC 17020 type A according to the intention of Directive 2008/57/EC.

Thank you for consideration in advance!

Sincerely,

A handwritten signature in blue ink, appearing to read 'K. Brüggemann', followed by a long horizontal line.

Dr. Klaus Brüggemann
Managing Director