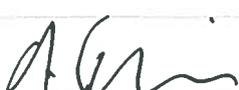
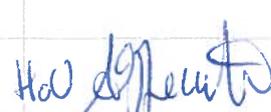


Report

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

LIGHT IMPACT ASSESSMENT

ERA/ADV/2014-15/REP-003 V 1.0

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1. Context and Problem Definition

1.1. Problem and problem drivers

The initiative addresses the following problems:

- NSAs and applicants expressed concerns about the low quality of work performed by some Notified Bodies which can delay the authorization process. E.g. a NSA might ask for additional plausibility checks if he questions the certificate of a Notified Body.
- A number of Notified Bodies within NB-Rail confirmed discrepancies in the quality of work among them and expressed concerns about competition distortion related to the services offered by them:

These problems result from different qualification requirements imposed by the notifying authority in the Member State where the Notified Body is registered.

A notified body must meet at least the minimum criteria in annex VIII of the Interoperability Directive. The notifying entity in each Member State might either directly recognize a conformity assessment body as a Notified Body or might notify a conformity assessment body if it is accredited to a specific standard. This accreditation presumes that the minimum criteria are met and it might impose additional requirements for the conformity assessment body depending which accreditation standard is chosen.

Competition distortion can result from the following situation:

A Notified Body accredited to EN ISO/IEC17065 can only accept test results in a technical file from an applicant, if the tests are performed by an accredited laboratory (EN ISO/IEC17025). If not, he has to accompany the tests and check if the requirements of EN ISO/IEC17025 are met during the tests. This would usually lead to extra costs for the Notified Body – in the worst case tests have to be repeated.

A recognized Notified Body has not this restriction, or at least these restrictions are not public accessible. This means that the recognised body might accept any test results in a technical file independent if they were performed by an accredited laboratory or not (without the need for accompanying tests).

1.2. Stakeholders affected

Applicants (Infrastructure Managers, Railway Undertakings and Suppliers) are impacted by the problem – either due to delays in the authorisation process or due to interoperability issues after the subsystem is placed into service.

NSAs are impacted as well – the problems could result in a higher workload for the authorisation due to additional plausibility checks.

Notified Bodies are impacted due to competition distortion

Looking forward to the 4RP, ERA might be impacted as well in both the authorisation of vehicle and in monitoring and auditing the NoBos.

1.3. Evidence and magnitude of the problem

The above mentioned problems were confidentially communicated between the concerned actors and ERA. The ERA study about “Real Authorisation Cases” from the Cross Acceptance Unit confirms a lack of trust in the work of some Notified Bodies by applicants and NSAs.

ERA sent out a questionnaire to all impacted stakeholders but did not receive any written feedback confirming the evidence of the problem.

The problems are considered to be a very sensitive issue.

Currently the quality of work is not being monitored by the Agency. For this reason any lack of quality of work cannot be identified and the resulting consequences cannot be measured.

In the framework of the project, such a monitoring scheme will be set up which will allow to assess the size of the impact of the problem in the future.

1.4. Baseline scenario

If no action will be taken, the above mentioned problems will still persist. At current stage it cannot be assessed if the size of the problem will rise in future. This can only be assessed by a system monitoring the quality of work of the Notified Body.

1.5. Subsidiarity and proportionality

EU action is needed in order to ensure that the notifying entity in each Member State notifies the conformity assessment body based on the same set of qualification requirements. In this context it is irrelevant if the accreditation ensures compliancy to these requirements or the notifying entity check compliancy to these requirements.

The Agency developed a number of TSIs and is now managing the content of all TSIs. ERA can be considered to be the right doctor at EU level, because Notified Bodies assess the conformity of a system or a component with the TSI.

For this reason, the Commission already provided a mandate to the Agency in order to draft an advice for an accreditation scheme. Nevertheless this mandate does not cover so far notification of conformity assessment bodies based on a recognition by the notifying entity.

2. Objectives

2.1. General and specific objectives

General objectives are:

- to increase trust in the work performed by Notified Bodies (from applicant's and NSA's point of view);
- to ensure fair competition framework conditions among Notified Bodies

The specific objectives are:

- to harmonize the requirements for Conformity Assessment Bodies to become Notified Bodies (The Notifying entity has to ensure that these requirements are met)

2.2. Link with Railway Indicators

Currently the quality of work of a Notified Body is not monitored, a monitoring system will be set up by the Agency.

Nevertheless there is already a link to one Railway Indicator:

RI 2.4 – Time required from contract signing to commercial use per vehicle category

3. Options

3.1. List of proposed options

Option 1:

Proposal of a voluntary accreditation scheme for Notified Bodies based on EN/ISO standard 17065

In this context "Voluntary" means:

Voluntary at Member State level, so that the notifying entity in each Member State decides the accreditation scheme by its own

Option 2:

As Option 1 – but mandatory (at EU level) accreditation scheme for Notified Bodies

Option 3:

As Option 2 – the requirements of the scheme are mandatory for all CABs if they are notified by the notifying entity (Notification based on Accreditation and Recognition)

3.2. Description of options

Option 1:

A voluntary accreditation scheme is proposed based on EN/ISO Standard 17065 including a specification of the required technical capacity of a conformity assessment body.

Notifying Entities can still notify conformity assessment bodies based on an accreditation referring to other standards as well (e.g. EN/ISO 17020/17021) or directly recognize them as notified bodies.

This option partly addresses the problem related to the quality of work of a Notified Body. Applicants might select Notified Bodies accredited according to the proposed scheme of the Agency in order to lower the risk for delays in the authorization process.

Option 2

Notifying Entities can either notify conformity assessment bodies based on an accreditation referring to the scheme proposed by the Agency or directly recognize them as Notified Bodies.

An accreditation based on other standards than the proposed scheme is not possible in the context of the notification of a conformity assessment body by the notifying entity of the Member State.

This option partly addresses both problems: the quality of work of a Notified Body as well as competition distortion among Notified Bodies:

As in Option 1, Applicants might select Notified Bodies accredited according to the proposed scheme of the Agency in order to lower the risk for delays in the authorization process.

In addition, all conformity assessment bodies notified based on an accreditation will offer a standardized assessment product.

Option 3

The requirements of the proposed accreditation scheme will replace the current minimum requirements for Notified Bodies in Annex VIII of the Interoperability Directive. A notifying entity has to ensure that any conformity assessment body meets these requirements if it is notified. Either the notifying entity notifies the conformity assessment body based on an accreditation according to the proposed scheme or this check is done by himself and he recognizes the conformity assessment body as Notified Body.

Only this option fully addresses both problems: the quality of work of a Notified Body as well as competition distortion among Notified Bodies:

Applicants can be sure that all Notified Bodies meet the same qualification requirements and offer standardized assessment product.

4. Impacts of the options

4.1. Identification of impacts

Option 1:

Applicants (railway undertakings, infrastructure managers, suppliers) might be positively impacted. They will profit from the lower risk of delays in the authorization process.

National Safety Authorities might be positively impacted as well – the workload in the framework of an authorization process might decrease due to less plausibility checks of the technical file.

Notified Bodies are not impacted.

Option 2:

- Applicants/ NSAs:

.. are positively impacted as in option 1, but in a stronger way. The likelihood to profit from lower risks of delays in the authorization process is higher because all accredited CABs notified by the notifying entity will offer a standardized assessment product and a similar level of quality of work.

- Notified Bodies:

.. currently accredited based on EN ISO/IEC17065 (28 out of 60) or EN ISO/IEC17020 including 17021 (23 out of 60) will profit from fair competition conditions resulting from the mandatory scheme.

Notified Bodies currently accredited only based on EN ISO/IEC17020 (approx. 12 out of 60) are negatively impacted by the scheme as they have to meet requirements for QMS audits as well.

Notified Bodies recognized by the notifying entity are not impacted.

- In-house Bodies of Suppliers:

UNIFE expressed concerns that their in-house bodies cannot be accredited according to the proposed scheme due to the fact that the scheme requires a separate legal entity to act as a Notified Body.

This requirement results from EC decision 768/2008 and is part of the revised IOD in the framework of the 4th railway package as well. For this reason there are additional costs expected to create a legal entity. But these additional costs cannot be linked to the scheme!

To reduce the impact, it was suggested to check the assignment of conformity assessment modules in the TSIs and apply modules from families A or C (where the applicant can assess conformity by himself) for components, where third party assessment is not considered to be beneficial.

Option 3

Compared to option 2 – it will provide most benefits for applicants as well as NSAs.

- Notified Bodies

In addition to option 2, recognized conformity assessment (18 out of 60) bodies might be negatively impacted if they do not currently meet the requirements of EN ISO/IEC17065

4.2. Assessment of impacts

Option 1:

The impact will be positive but at a very low level and might not be measurable.

Option 2:

- Applicant/NSA
 - Reduced authorization costs
 - Less interoperability issues after authorization
- Notified Bodies

for Notified Bodies currently accredited only based on EN ISO/IEC 17020

- Additional one-time costs for accreditation based on EN ISO/IEC 17065
- Increase in revenues – they can offer more conformity assessment products.

for Notified Bodies currently accredited only based on EN ISO/IEC 17065 or EN ISO/IEC 17020 or EN ISO/IEC 17021.

- Increase in revenues – due to fairer competition framework conditions.
- Suppliers
(if their in-house bodies would like to act as Notified Bodies as well)
- Costs to create a separate legal entity

(this impact cannot be assigned to the scheme)

Option 3:

As Option 2 – but benefits are expected at a higher level.

Recognized Notified Bodies might be negatively concerned as well in the same way as accredited Notified Bodies

The magnitude could not be estimated due to a lack of data. It might be possible once a monitoring scheme for the quality of work of Notified Bodies is set allowing to analyse the impact of quality of the assessment in the framework of the authorization process.

4.3. Uncertainties/risks

Option 1:

- No risks/ uncertainties

Option 2:

There might be the risk of cost increases in the framework of the authorization – where accredited Notified Bodies perform conformity assessment:

- There could be a cost increase for third party conformity assessment due to the fact the all accredited Notified Bodies have to meet all requirements of the scheme. Notified Bodies who are negatively impacted might increase prices in order to recover costs. In general this cost increase is expected to be at a very low level due to the fact, that total conformity assessment are around 1% of total project costs.
- There could be a project cost increase due to stricter requirements resulting from the conformity assessment. E.g. test results have to be performed by an accredited laboratory or have to be accompanied by Notified Bodies.

Competition Distortion is not mitigated because recognized Notified Bodies are not concerned at all.

Option 3:

- The identified risk in 2 applies to all authorization projects.
- The current mandate of the Agency only covers the accreditation scheme. Further legal instruments are necessary to make the requirements of this proposed scheme mandatory for all Notified Bodies.
- The scheme does not apply for all assessment bodies in the railway sector, e.g. Designated Bodies and CSM-RA are out of scope.

Due to the current scope of the mandate, all stakeholders are in favor of option 2. Option 1 is not supported by NB Rail because it will not bring any benefits for them.

There are no objections from stakeholders for option 3

5. Comparison of options

5.1. Comparative analysis

	<i>Option 1</i> <i>Voluntary</i> <i>Scheme</i>	<i>Option 2</i> <i>Mandatory</i> <i>Scheme</i>	<i>Option 3</i> <i>Mandatory</i> <i>for all</i> <i>Notified</i> <i>Bodies</i>
Effectiveness			
<i>Increase in Quality of Work of the Notified Body</i>	0/+	+	++
<i>Fair Competition Conditions under Notified Bodies</i>	0	+	++
Efficiency			
<i><Magnitude of benefits></i>	0	+	++

<Magnitude of costs>	0	-	-
<Externalities>	N/A	N/A	N/A
Coherence			
<i>Strategic compliance with removing technical barriers – Reduction of Authorization Time</i>	0	+	+

5.2. Preferred option(s)

Option 3 is the preferred option.

Nevertheless the current mandate addresses only accredited Notified Bodies.

For this reason Option 2 is the preferred “intermediate” option. Another mandate from the Commission should extend the scope to recognized Notified Bodies as well.

So far, the benefits could not be expressed in qualitative terms. For this reason a monitoring scheme is necessary to assess the impact of the scheme on the quality of work of Notified Bodies.

It is highly recommended to assess the impact of the scheme based in the proposed Railway Indicators as defined in chapter 6, after the scheme is in force and Notified Bodies are accredited to it.

6. Monitoring and evaluation

6.1. Monitoring indicators

The indicators for measuring the success of the accreditation scheme should be better analysed and finalized.

The following list is a stable proposal.

- Reduction of duration of first and additional APIS;
- Increased percentage of mutually recognised rolling stocks accepted at borders (e.g. WAG TSI clause 7.1.2)
- To measure the variance of price levels for a theoretical project (variance will decrease due to “standardization of the assessment product offered by Notified Bodies) Difference in price levels are still possible due to competition but not due to different assessment products
- To measure the preparation work for the technical file by the applicant (reduction expected)
- To assess customer satisfaction at NSA level/ applicant level/ RU level
 - The number of plausibility checks per technical file (NSA)
 - The number of interoperability issues of a subsystem assessed to be compliant to TSI
 - The perception of work of Notified Bodies (it should confirm increase in quality)

6.2. Future evaluations

N/A