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**ACCREDITATION AND MONITORING OF NOTIFIED BODIES IN THE
EUROPEAN UNION AND RELEVANCE TO COTIF**

Discussion document prepared by the OTIF Secretariat

1. INTRODUCTION

In accordance with ATMF Articles 3a and 6, vehicles which are either admitted to operation in accordance with ATMF or authorised for placing in service in the EU in accordance with equivalent technical provisions can be operated internationally. It follows that admissions (COTIF) and authorisations (EU) have a similar value for the use of vehicles in international transport. It is therefore necessary that vehicles admitted under COTIF or under EU law are designed, built and inspected with equivalent precision and care; COTIF contains several provisions that aim to ensure this. Nevertheless, the responsibilities concerning inspection and certification of vehicles before they can be used are not identical between the legal systems of the EU and COTIF. Despite the differences, which are explained in this paper, the results of the conformity assessment should be the same.

The EU is currently in the process of improving the systematic oversight on conformity assessment bodies. This paper discusses the extent to which these developments are relevant to COTIF and how the results could be put to use for non-EU OTIF Member States.

In order for the international approval of railway vehicles in accordance with ATMF to function properly, each State is responsible for implementing the conformity assessment processes in accordance with COTIF. Trust between the authorities of the different States should be established and maintained so that approvals issued by one State are not questioned by another. This paper proposes lines of actions that aim at building a basis for this trust.

This document does not suggest that new regulations be developed.

1.1. EU CONFORMITY ASSESSMENT

EU States have agreed on unifying, to a certain extent, their railway markets by setting out harmonised product requirements and conformity assessment methods. The EU has implemented a system with third party assessments, where the applicant (e.g. the manufacturer) can only request authorisation from the competent authority (the National safety authority, or in the future the EU agency for railways) after the vehicle has been assessed by a notified body (third party assessor). In this model the notified body assesses compliance of the vehicle with the applicable rules.

Some non-EU OTIF Member States have concluded agreements with the EU under which they apply the same railway related rules. Examples are Switzerland and Norway.

Notification of conformity assessment bodies is a national competence, albeit the requirements are harmonised at EU level. Some States use accreditation¹ to check the competences of Notified Bodies, but this is not mandatory. Notified Bodies may offer their services in any EU State and the certificates issued are valid across the EU.

At time of writing 63 notified bodies are listed² as being competent to carry out assessments in the EU in the field of railway interoperability. Notified Bodies operate on an EU-wide open market and enter into a contractual relation with the applicant, which is their customer.

Despite being competitors in an open market, Notified Bodies are required to coordinate between themselves by sharing experiences with a view to harmonising the quality of their work. The coordination is organised by the NB-Rail coordination group.

¹ Accreditation is the process where the competences of a Notified Body are checked by the unique national Accreditation Body. Accreditation Bodies have a wide scope related to the certification/registration of quality systems, products, services, personnel, environmental management systems and are not limited to accrediting railway related organisation. Accreditation is not unique to EU States, but is a concept that is used by many States around the globe.

² http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=30

1.2. COTIF CONFORMITY ASSESSMENT

COTIF is a Convention between sovereign States, in which they agree, by applying ATMF, that each State recognises the validity of certificates issued by another State.

ATMF Article 5 is compatible with the division of tasks applicable in the EU (third party assessment), but also permits the State's competent authority to carry out the assessments itself. The competent authority is a government body, independent from any railway undertaking, infrastructure manager, vehicle keeper, ECM, or designer or manufacturer of railway material. In case the competent authority itself carries out the assessments, it must fulfil the requirements concerning independence and qualifications that would otherwise be applicable to the notified body.

In accordance with the provisions in point 1.3.2 of the UTP GEN-D, an EU Notified Body is considered as also having the competence to carry out assessments in the scope of COTIF. Whether or not a Notified Body can offer its services in a non-EU OTIF Member State depends on the provisions in force in each of these States.

2. IMPROVING CONSISTENCY OF ASSESSMENTS IN THE EU

2.1. COORDINATION OF NOTIFIED BODIES

Article 44 of Directive (EU) 2016/797 required the EU Commission to ensure coordination and cooperation between bodies notified under this directive.

Article 30.6 of the above-mentioned directive contains an obligation for conformity assessment bodies to participate in the activities of the notified conformity assessment bodies' coordination group. The tasks of NB rail as a coordination group have been defined in their operating rules (being finalised).

In addition the NOBOs have organised themselves in an association. According to its website³:

The NB-Rail Association is an international non-profit organization of the notified bodies for interoperability in the railway sector. The association is installed to support and to complement the activities of NB-Rail coordination group with activities not mandated in the mentioned basics. The detailed objectives are:

- a) *to relate with the railway relevant professional organizations and associations like UNIFE, CER, UIC, CEN, CENELEC and others as well as with official bodies like the European Rail Agency ERA, the European Commission – here also with other General Directorates than DG Move – the European parliament and the Council and their representatives and make the work of the NB-Rail coordination group visible to those organizations, associations and stakeholders;*
- b) *to establish the association as a representative body with these organizations, associations and agencies, as Article 28 of Directive 2008/57/EC does not provide for establishing the NB-Rail coordination group as a stakeholder;*
- c) *to support the coordination of the notified bodies to harmonize the procedures for conformity assessment and suitability for the use of interoperability constituents as well as the procedures for the assessment of the subsystems;*
- d) *to make proposals and ensure co-ordination and development of studies and scientific enquiries to improve the quality, effectiveness and efficiency of notified bodies certification;*
- e) *to ensure cooperation in the standardization of the notification scheme for notified bodies;*

³ http://nb-rail.eu/as/as_en.html

- f) *to ensure cooperation for the improvement and the standardization of information systems which hold data on certifications and which are used to improve certification consistency;*
- g) *to provide easy access to NB-Rail public documents via an internet web page;*
- h) *to share information regarding the objectives and organize conferences or workshops.*

The results of discussions between Notified Bodies in the scope of NB-Rail meetings are set out in documents called Recommendations for Use (RFU). If NB-Rail identifies a problem in applying the legal provisions, it can address its concerns to the EU Commission in the form of Questions & Clarification (Q&C). Both types of documents, RFU and Q&C, are publicly available on the NB-Rail website.

2.1. ACCREDITATION SCHEME FOR NOTIFIED BODIES

Over the years, feedback on the EU system from Notified Bodies has suggested that the quality of work of different Notified Bodies is not always the same. This is illustrated in the Agency report “*Sectorial scheme for accreditation of notified bodies under Directive 2008/57/EC ANALYSIS OF CURRENT SITUATION ERA/ADV/2014-15/REP-001 V 2.0⁴*” which quotes in chapter 3:

“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 NB-Rail 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”.

In reply to these concerns, in 2015 the Agency, at the request of the European Commission, developed an accreditation scheme for Notified Bodies. The Scheme is intended to be used by accreditation bodies when evaluating the competencies of (aspirant) NoBo. The Scheme is based on the EN ISO/IEC 17000 series and therefore has a strong international basis.

The results of the Agency’s work are set out in the above-mentioned report, which is public. The scheme formally refers only to accreditation and not to recognition, but obviously could also be used for the latter.

2.2. NOTIFIED BODIES AND THE 4TH RAILWAY PACKAGE

Chapter VI of Directive (EU) 2016/797 on the interoperability of the rail system within the EU contains provisions relating to assessment bodies, including Notified Bodies, but also the notifying authorities. It contains new obligations concerning the participation of Notified Bodies in the notified conformity assessment bodies’ coordination group.

Regulation (EU) 2016/796 on the EU Agency for Railways sets out in Article 34 the future tasks for the Agency concerning the monitoring of notified bodies. Against this background, and to prepare

⁴ <http://www.era.europa.eu/Document-Register/Pages/ERA-ADV-2014-15.aspx>

itself for future tasks, in 2016 the EU Agency started developing processes to gather information about Notified Bodies, analysing this data and using it to assess effectively the performance of Notified Bodies and report on the results. During this preparatory phase, the EU Agency is assisted by a task force, to develop a system for monitoring notified bodies. OTIF is invited to participate in this taskforce with observer status.

In the future execution of the performance assessment, the EU Agency intends to work together with notifying authorities competent in the State of the Notified Body concerned.

3. CONSISTENCY OF THE WORK OF OTIF ASSESSING ENTITIES

In principle, there should be no differences between the results of assessments performed by any EU notified body or any OTIF assessing entity. Logically, this would mean that the professional qualifications and assessment methods should also be similar between EU Notified Bodies and non-EU assessing entities. It is for this reason that the provisions in force in the EU and COTIF have been harmonised. The COTIF provisions are set out in ATMF Article 5, UTP GEN-D Article 1.3 and UTP GEN-E.

EU experience shows that without proper coordination and without detailed requirements to be met by the Notified Bodies, the results of the assessments may vary. There is no reason to assume that the situation would be different for non-EU assessing entities. This would suggest that these assessing entities could also benefit from coordination and some form of monitoring.

The institutional organisation of assessing entities in non-EU States may however vary and in some cases differ from the EU. In several non-EU States, for example, the conformity assessment is the responsibility of a State organ, such as the Railway Directorate of the Transport Ministry.

In the context of OTIF, each State is sovereign and responsible for ensuring that its Competent Authority and Assessing Entities meet the requirements as defined in COTIF. There is no provision in COTIF that regulates a harmonised external or peer-to-peer evaluation of the verification of State entities. There is also no single supervisory authority which oversees the activities and performances of assessing entities; each State has to ensure for its assessing entity(/ies) that all rules are complied with.

Nevertheless, ATMF Article 5 § 6 sets out that:

A Contracting State shall ensure the consistent supervision of the assessing entities indicated in § 2 and shall withdraw the competence from an assessing entity which no longer meets the criteria referred to in § 3, in which case it shall immediately inform the Secretary General thereof.

This can be understood to mean that some kind of coordination would be required in order to obtain ‘consistent’ supervision. However, it is within the responsibility of each State to ensure this. In addition, point 1.3.5 of UTP GEN-D sets out that:

The Committee of Technical Experts shall set up an assessing entity coordination group which shall discuss any matter relating to the application of the procedures for assessing conformity or suitability for the use of interoperability constituents (chapter 2) and the procedures for assessing conformity of subsystems with the applicable UTP(s) (chapter 3).

Such a coordination group has not been set up at the time of writing. Setting up such a group for non-EU assessing entities only would seem suboptimal; synergies with the coordination of Notified Bodies at EU level should be sought.

In accordance with ATMF Article 5 § 7,

should a State consider that an assessing entity or competent authority of another State, does not meet the criteria, the matter has to be transferred to the Committee of Technical Experts which, within four months, shall inform the Contracting State in question of any changes that are necessary for the assessing entity or authority to retain the status conferred upon it. In relation to this, the Committee of Technical Experts may decide to instruct the State to suspend or withdraw technical certificates made on the basis of work done by the assessing entity or by the authority in question.

At the time of writing, these correcting provisions have never been put into practice. This article could however justify some sort of coordinated monitoring, because it allows one State to report on the performance of the competent authority and assessing entity of another State. Coordinated monitoring could be explained as a systematic way of implementing this Article. Arbitration in case of concerns is carried out at the level of the Committee of Technical Experts.

Both for the work of EU Notified Bodies and for State related Assessing Entities, it is common to rely on external experts and test institutes, such as laboratories, universities or research centres. It seems justified to aim for the harmonisation of qualifications for any of these experts and institutes and to aim to apply the same basic procedures in all OTIF Contracting States.

4. PROPOSED WAY FORWARD

Taking into account all of the above, the OTIF Secretariat suggests the following course of action:

1. To establish a link between NB-Rail and the non-EU assessing entities, with the assistance of the EU Commission. After discussion in WG TECH 30, this link was established. Since then, NB-Rail has been invited to participate in OTIF technical meetings and the non-EU assessing entities will be invited to participate in NB-Rail meetings concerning the assessment of rolling stock.
2. To publish and promote the existing accreditation scheme for Notified Bodies among non-EU Competent Authorities as an example of best practice, with the suggestion that they use the scheme *mutatis mutandis* to verify the competences of persons and organisations working in the field of UTP conformity assessment. This action could be carried out by the OTIF Secretariat in coordination with the European Union Agency for Railways.
3. To follow closely the development of the monitoring scheme for Notified Bodies and to keep WG TECH updated on the results. This action could be carried out by the OTIF Secretariat in coordination with the European Union Agency for Railways.
4. Once the work is finished at EU level, to make available to non-EU Competent Authorities the experience and best practices concerning implementation of the monitoring scheme at EU level and to promote using them as a basis for consistently monitoring the quality of conformity assessment at national level by non-EU OTIF Contracting States. This action could be carried out by the OTIF Secretariat in coordination with the European Union Agency for Railways.
5. To discuss whether and how coordinated monitoring of assessing entities should be established within the framework of COTIF.
6. To consider the need for changes to the UTP GEN-E on assessing entities, in relation to the EU changes within the 4th Railway Package. This task is part of a wider activity to consider the need to align COTIF and the EU provisions as part of the 4th Railway Package.
