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RECOMMENDATION FOR USE

NB-RAIL COORDINATION GROUP

Administrative Decision according to Interoperability Directive (EU) 2016/797 art. 30.6

Co-funded by the European Union

RFU-STR-022	Issue 06 Date 23/06/2020

TITLE	
USE OF TEST RESULTS FROM TESTING BODIES OTHER THAN NOTIFIED BODIES	
ORIGINATOR	**SUBJECT RELATED TO**
NB RAIL STRATEGY SUBGROUP	IOD 2008/57 and IOD 2016/797 ALL TSI ASSESSMENT MODULES
AMENDMENT RECORD: ISSUE 06, IOD REFERENCES UPDATE	

DESCRIPTION AND BACKGROUND EXPLANATION

Scope

This RFU addresses conformity assessment in relation to Directives 2008/57/EC and (EU) 2016/797, the TSIs in force and the assessment modules as defined in Decision 2010/713/EU.
This RFU consider also the Technical Document 'MNB – Assessment scheme 000MRA1044 ver 1.1' established by the European Union Agency for Railway (ERA) on the requirements for conformity assessment bodies seeking notification, referenced as "Assessment Scheme" in this document.
It sets criteria that notified bodies must consider to enable test results, collected by other testing bodies, to be used to support notified body assessments without the need to repeat those tests. This RFU is applicable to Subsystems and Interoperability Constituents. It covers partial and complete tests.

Note: decision 2010/713/EU introduced new modules to be applied with those TSIs entered into force after 01/01/2011, providing a "correlation table" in Annex 3 so to understand the correlation existing with the "old" modules. Some modules changed their names, some not; therefore, this RFU will refer to those modules which changed their names in the following way: "module H1/CH" means the "old" module H1, renamed as CH by the Decision 2010/713/EU.

Introduction

This RFU shall apply to testing activities performed by both accredited and not accredited test laboratories which are carried out within the scope of NoBo evaluation activities. It does not apply to tests performed by the applicant when he applies modules H2/CH1 or SH2/SH1 for the conformity assessment process. Modules H2/CH1 and SH2/SH1 clearly assume "tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility". So there, in this case the notified body is therefore not responsible for the execution of the tests, only for the assessment of the quality management system applied for the tests and the use of the test results in the conformity assessment and verification. Quality of these test results is

considered covered by the Quality Management System of the manufacturer / contracting entity, being an integral part of modules H2/CH1 and SH2/SH1 conformity assessment.

On the other side, modules B/CB, SB, F/CF, SF and SG imply that notified bodies must carry out / have carried out all tests that form part of conformity assessment. In some TSIs module SG recognises that notified bodies may accept evidence of tests from other bodies, under certain circumstances. The text of the modules SG varies and is inconsistent between the TSIs concerned; in module SG as defined in Decision 2010/713/EU clarification and explanation of conditions, documentation and responsibilities are given.
Notified bodies prefer testing to be carried out by accredited test laboratories. In practice, however, many tests can be carried out credibly only by the manufacturer during the course of the contract, and sometimes the utilisation of other not accredited laboratories is requested by the applicant as well.
Whilst the manufacturer or supplier might demonstrate competence and adequate pro cesses, its test department cannot be deemed independent. This should be afforded by the Notified Body's assessment and/or monitoring of the test.
MNB – Assessment scheme part 2.B Requirements §7.4 deals with the requirements related to the 'Evaluation' performed by the NoBo.

Note 1: application of the Assessment Scheme is mandatory for the following three cases, as determined by EA and ERA:

1. since 01/01/2018 – for newly accredited NoBos
2. 16/06/2019 – for recognized NoBos (assessed through monitoring by ERA)
3. 01/01/2018 – 01/07/2020 for accredited NoBos (depending on the date when the ERA Assessment scheme is added to the accreditation scope)

Note 2: a new revision of EN ISO/IEC 17025 has been published in 2017. References here and in the ERA Assessment Scheme should be interpreted also to include the similar references according to the latest EN ISO/IEC 17025 standard revision.

RFU PROPOSAL

Acceptance of Tests Performed by other testing bodies

Annex VIII of the Directive 2008/57/EC or Chapter VI of (EU) 2016/797 in connection with MNB – Assessment Scheme defines the minimum criteria for bodies undertaking verification tasks.

Note: The Assessment Scheme uses the term CAB for Conformity Assessment Body. CAB performing activities as a notified body are called NoBo. In this case CAB can be understood to mean "NoBo".

Section 7.4.TEST related to testing requires that:
'the evaluation activities related to testing shall follow the applicable requirements of ISO/IEC 17025. The CAB shall ensure that the test used in its evaluation activities have been carried out according the following acceptance criteria:

- *In competent, independent and reproducible manner according to the requirements of ISO/IEC 17025, and*
- *in accordance with the applicable requirements of normative documents for products and their manufacturing process.*

The *CAB* shall have documented methods to ensure these above criteria according to the following possibilities:

- Accredited test;
- Non-accredited test.'

Notified bodies must apply similar criteria to testing bodies in order to accept the test results from these organisations to support their assessment activities. When modules B/CB, SB, F/CF, SF and SG are chosen by the applicant, the NoBo keeps the responsibility of final results of the tests and checks, even when tests are contracted by manufacturers and/or applicants directly to accredited test laboratories.

If the testing body is **accredited for the relevant scope against EN ISO/IEC 17025**, it is assumed that both acceptance criteria are satisfied. In 7.4. TEST.A – Accredited test the following is stated:

'An accredited test shall be accepted only if:

- *the test report includes a valid assessment mark and/or the assessment ID number, and*
- *if the CAB has received a copy of assessment (*) certificate (can be also provided electronically via website) of the laboratory performing the test, including its annex. The performed test must have been performed within the scope and subject to the rules of this assessment.'*

(*): the word "assessment" should in this context be understood as "accreditation"

So the notified body shall check that no conflict of interest exists, that accreditation covers the testing being performed and that accreditation is current.
This case applies also to those tests already performed in the past (before the applicant's request), provided that the scope of the test performed covered the TSI requirements and the accreditation was in force at the time of the tests execution.

On the contrary, if the testing body (manufacturer or other) **is not accredited against the EN ISO/IEC 17025** (or the accreditation does not cover the test methods required by the relevant TSI), the notified body shall confirm that the systems for control of

competence, independence, testing and material handling processes, facilities and equipment and other processes relevant to the contribution to the subsystem are controlled.
The following basic criteria shall be checked before the tests are performed - this means that the NoBo cannot accept results of tests already performed in the past except where such a check has been performed by another IOD NoBo under the same conditions and that the documented result of such a check is accompanying the test report.

The NoBo shall check and keep the records to demonstrate that the laboratory com plies with the requirements of EN ISO/IEC 17025 as below, see Section 7.4.TEST.B – Non-accredited test:

- *'CAB staff who assesses the testing laboratories have the adequate competence;*
- *CAB keeps records to demonstrate the performed assessment towards the laboratory for compliance with requirements of EN ISO/IEC 17025:2005 (remark: in the assessment scheme the 17025:2005 is referenced, below the references to the 17025:2017 are added in brackets) as below:*
  - Point 4.1 (4.1 + 5) Organisation
  - Point 4.5 (6.6) Subcontracting of tests and calibrations
  - Point 4.9 (7.10) Control of nonconforming testing and/or calibration work
  - Point 5.2 (6.2) Personnel
  - Point 5.3 (6.3) Accommodation and environmental conditions
  - Point 5.4 (7.2) Test and calibration methods and method validation
  - Point 5.5 (6.4) Equipment
  - Point 5.6 (6.5) Measurement traceability
  - Point 5.7 (7.3) Sampling
  - Point 5.8 (7.4) Handling of test and calibration items
  - Point 5.9 (7.7) Assuring the quality of test and calibration results
  - Point 5.10 (7.8) Reporting the results
- *the testing laboratory presents all records of a specific test under request by the CAB;*
- *competence and independence of the laboratory personnel are evaluated and recorded;*
- *participation to interlaboratory comparison or proficiency-testing programmes is recorded (if available);*
- *CAB assesses periodically, at least every 24 months, the laboratory to demonstrate that its competence is maintained, as far as required for the purpose of the certification.*

The above list can be amended by a TSI if the TSI permits certain testing by non-accredited test laboratories (e.g. by infrastructure manager's maintenance teams). In this case, the TSI may provide alternative requirements to those mentioned above in

this section.'

In all cases (testing body being accredited against EN ISO/IEC 17025 or not), the No Bo shall consider the appropriateness of the arrangements and decide the level of witnessing required; where the risk does not justify high cost it may not be necessary for the notified body to participate fully in the tests. They may be able to intervene on a limited sample basis only. For instance, tests are often possible only as an integral and continuous part of production.

THIS RFU WAS AGREED ON

PLENARY MEETING 059

THIS RFU ENTERS INTO FORCE ON

23/06/2020 (DATE OF PUBLICATION)

FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.

RFU APPLICATION IS MANDATORY STARTING FROM

23/06/2020

AT THIS DATE ANY PREVIOUS VERSIONS OF THIS RFU WILL BE WITHDRAWN.

RFUS SHALL BE APPLIED BY ALL NOBOS. PLEASE REFER TO RFU-STR-702, CHAPTER 3 OF THE SECTION "DESCRIPTION AND BACKGROUND EXPLANATION", FOR THE LEGAL BASIS SUPPORTING THIS OBLIGATION.

ERA COMMENTS

PLE 059 – 17/06/2020: NO COMMENTS