RFU-STR-022	Issue 07 Date 13/11/2024

TITLE	
TESTING in the Context of TSI Conformity Assessment	
ORIGINATOR	**SUBJECT RELATED TO**
NB RAIL STRATEGY SUBGROUP	IOD 2016/797 Modules Decision 2010/713/EU ERA Assessment Scheme All TSIs
AMENDMENT RECORD: ISSUE 06: IOD REFERENCES UPDATE ISSUE 07: COMPLETE UPDATE INCLUDING NEW TITLE AND SEPARATION BETWEEN EVALUATION TESTING & EVIDENCE TESTING	

DESCRIPTION AND BACKGROUND EXPLANATION

References

Reference documents used in this RFU (without TSI references):

/D01/ IOD: Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union, amended by (EU) 2020/700

/D02/ Module decision 2010/713/EU: Commission decision of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council

/D03/ ERA AS: Technical document; Requirements for conformity assessment bodies seeking notification, MNB – ERA Assessment Scheme 000MRA1044 ver 1.1 and 2.0

/D04/ EN ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories

/D05/ EN ISO/IEC 17065:2012: Conformity assessment – Requirements for bodies certifying products, processes and services

/D06/ EU Blue Guide: The 'Blue Guide' on the implementation of EU product rules 2022 (2022/C 247/01) of 29.06.2022

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General Background

Testing is an important and necessary element for the activities of

- design organisations and their subcontractors,
- manufacturers and their subcontractors,
- keepers, RUs and IMs and their subcontractors,
- conformity assessment bodies (e.g. NoBos, DeBos)

to determine physical properties or functional properties of the Object of Assessment.

Within the IOD /D01/, the module decision /D02/ and the various TSIs the term ‘test/ testing’ is not yet used in a systematic way.

Many different words are used in these documents to demand the determination of physical properties or functional properties such as test, check, product check, examination, final product test(ing), final (product) inspection, inspection, monitoring to ensure conformity, design control, design verification, quality control, quality assurance.

It remains frequently unclear, whether a specific test activity shall be performed by the NoBo or by others (e.g. by the manufacturer or their subcontractors). This RFU aims to clarify this aspect.

For the determination of functional properties there is an area of overlap between the two evaluation activities “testing” and “inspection” (see section 2.4 or 2.6). Unless a TSI specifically demands testing, either activity may be used to determine such functional properties.

Note: In many cases the TSIs and the modules decision /D02/ do not prohibit, and in some cases even encourage, that NoBo and Applicant agree on whether a specific evaluation activity shall be performed by testing or by inspection.

RFU PROPOSAL

1 Definitions

1.1 Introduction

When testing is used, despite some similarities between the different testing activities mentioned in background explanation, it is possible to distinguish between two different

formats of testing. The naming of these two different formats is based on the ISO 17065 /D05/ and the ERA Assessment scheme /D03/:

- Evidence Testing: see /D03/ Annex E, figure 1, Evidence. The creation of evidence is an activity performed or at least controlled by the applicant.
- Evaluation Testing: see /D03/ & /D05/ section 7.4, Evaluation. The performance of evaluations is performed or at least controlled by the NoBo.

1.2 Evidence Testing

This includes testing that is performed or controlled by Design Organisations, Manufacturers, Keepers, RUs and IMs and their subcontractors.

Such testing is typically supporting the internal interests of these organisations to obtain evidence on certain physical or functional properties of the objects which they design, produce, trade, operate, maintain, etc.

This format of testing is frequently used during research and development, verification&validation, production control, product performance demonstration, staff training, staff competency assessment, evidencing fulfilment of contractual obligations, maintenance activities etc.

The resulting test reports may not in all cases be intended for use in NoBo conformity assessment activities. However, there may be cases where these reports need to be included within the set of documented project evidence that is presented to the NoBo (e.g. during a NoBo inspection activity – module SB- or during a NoBo audit – module SH1- of the manufacturer's routine testing during production control).

To allow clear identification of this kind of testing, it is in this document termed EVIDENCE TESTING or EVIDENCE TEST.

Note: Based on experience it is understood that the organisations which perform Evidence Testing apply

- *in most cases the relevant requirements of ISO 9001 for testing,*
- *only in a few cases the relevant requirements of ISO 17025 for testing.*

1.3 Evaluation Testing

This includes testing that is performed under conditions that shall be performed or at least be ‘controlled’ by the NoBo. ‘Controlled’ means in this context:

Irrespective which test lab performs the test, the NoBo shall examine if all evaluation tests to be used in its NoBo activities have been carried out according to the requirements of

ERA Assessment Scheme /D03/ version 1.1 section 7.4, subsection "*Testing*" or to version 2.0 Annex F.

These sections of /D03/ refer to the applicable requirements of ISO 17025 /D04/.

Where the outcome of this examination by the NoBo is not positive, the test result shall not be used by the NoBo.

This format of testing shall be performed where it is required as part of the NoBo's conformity assessment activities – more precisely: where it is part of the NoBo 'evaluation' activities – to determine one or more physical properties or functional properties of an Object of Assessment according to a defined test procedure.

To allow clear identification of this format of testing, it is in this document termed EVALUATION TESTING or EVALUATION TEST.

2 Distinction between Evaluation Tests, Evidence Tests, Inspections and Alternative Means

The following diagram (flow chart plus explanations) explains how determinations of physical properties or functional properties associated with the Object of Assessment are to be performed through

- an EVALUATION TEST or
- an EVIDENCE TEST or
- an INSPECTION or
- an ALTERNATIVE MEANS

An Alternative Means is an evaluation method that may be performed instead of an Evaluation Test or Evidence Test. It may only be requested by the applicant, if the specific Alternative Means is permitted by a TSI clause or by an associated detailed conformity assessment requirement.

Note: Typical Alternative Means permitted by TSIs are simulations, calculations, waiving of tests if certain design conditions are fulfilled.

The final decision on whether the assessment of physical or functional properties of the Object of Assessment fulfils all conditions defined in this RFU remains with the NoBo.

In some cases, the fulfilment of the conditions is directly obvious (e.g. where conditions A1 and A2 both result in a 'yes'). However, there are many situations where this is not directly obvious (e.g. where a TSI requires a type test (A1 >yes), but the TSI does not include a type test procedure (A2 >no) and the applicant has selected subsequently the option of performing an EVIDENCE TEST in B3). In such situations the NoBo shall document the

reasoning for the acceptability of the applied combinations of conditions from the diagram below within their project records.

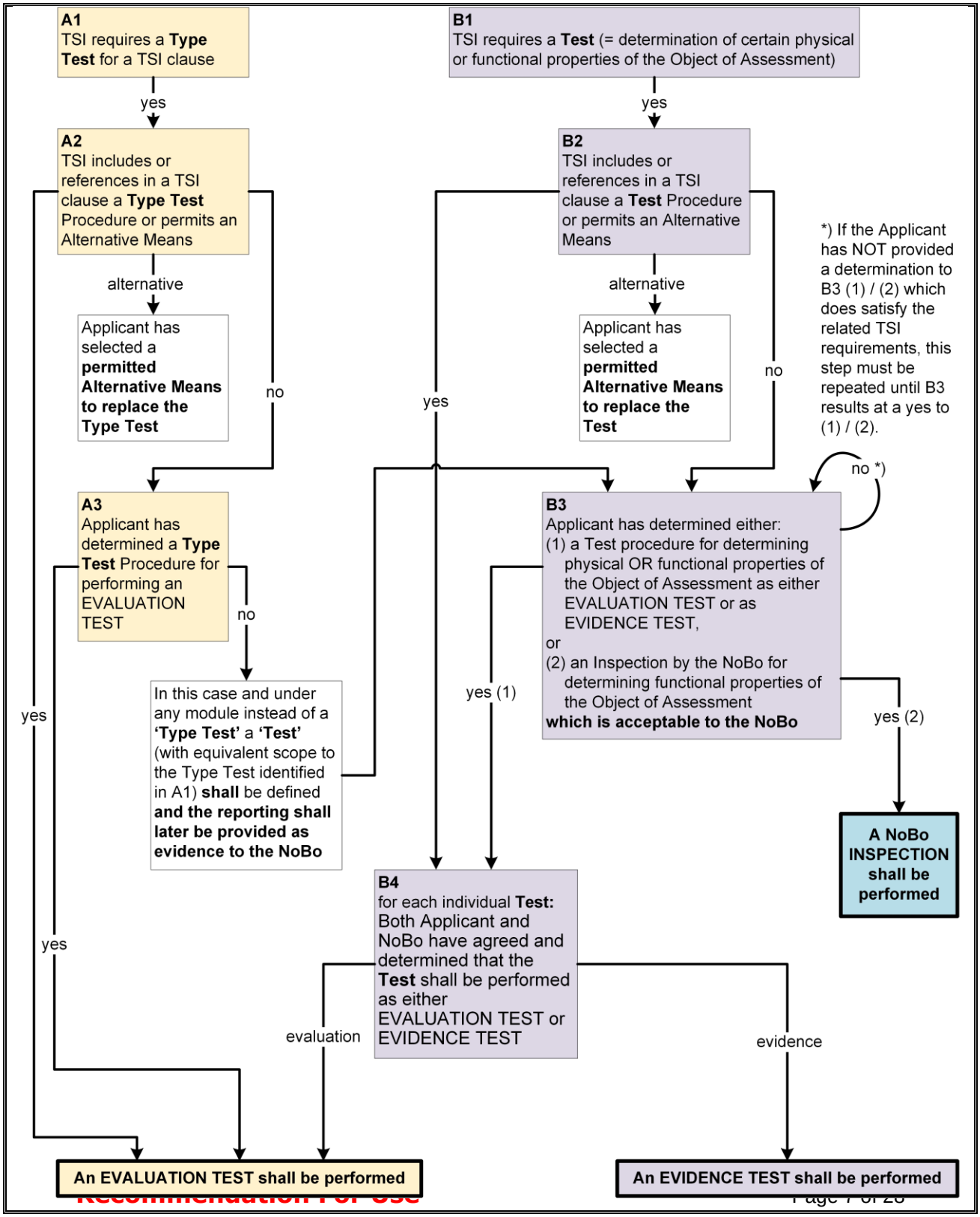
Note: It is common practice, that the Applicant already provides a reasoning on the proposed set of conditions, so that the NoBo may directly confirm this proposal where it is plausible and conforms fully to the selected Module, the applicable TSIs and this RFU.

Where the Applicants proposal on conditions and the reasoning is not plausible or missing, the NoBo shall establish the conditions and decide on that basis.

The following diagram is applicable for all Modules for ICs and for subsystems.

For the avoidance of doubt: There is no different approach or dispensation from Evaluation Testing included in the definitions of IOD /D01/, module decision /D02/, ERA AS /D03/ for the different modules e.g. SF, SG or SH1.

Neither H-type modules nor the Technical Opinion from ERA attached to RFU-STR-059 permit a dispensation from applying Annex F of ERA AS /D03/ for Evaluation Tests. In H-type modules the application of Annex F must be ensured through the QMS of the applicant. This shall be audited by the NoBo.


A1
TSI requires a **Type Test** for a TSI clause
yes
A2
TSI includes or references in a TSI clause a **Type Test** Procedure or permits an Alternative Means
alternative
Applicant has selected a **permitted Alternative Means to replace the Type Test**
no
A3
Applicant has determined a **Type Test** Procedure for performing an EVALUATION TEST
no
In this case and under any module instead of a **'Type Test'** a **'Test'** (with equivalent scope to the Type Test identified in A1) **shall** be defined **and the reporting shall later be provided as evidence to the NoBo**
yes
yes
An EVALUATION TEST shall be performed
B1
TSI requires a **Test** (= determination of certain physical or functional properties of the Object of Assessment)
yes
B2
TSI includes or references in a TSI clause a **Test** Procedure or permits an Alternative Means
alternative
Applicant has selected a **permitted Alternative Means to replace the Test**
no
yes
B3
Applicant has determined either:
(1) a Test procedure for determining physical OR functional properties of the Object of Assessment as either EVALUATION TEST or as EVIDENCE TEST,
or
(2) an Inspection by the NoBo for determining functional properties of the Object of Assessment
which is acceptable to the NoBo
no *)
*) If the Applicant has NOT provided a determination to B3 (1) / (2) which does satisfy the related TSI requirements, this step must be repeated until B3 results at a yes to (1) / (2).
yes (1)
yes (2)
A NoBo INSPECTION shall be performed
B4
for each individual **Test:** Both Applicant and NoBo have agreed and determined that the **Test** shall be performed as either EVALUATION TEST or EVIDENCE TEST
evaluation
evidence
An EVALUATION TEST shall be performed
An EVIDENCE TEST shall be performed

2.1 Condition A1: TSI requires a Type Test for a TSI clause

Where a TSI requires for one or more specified TSI clause(s) that a "Type Test" shall be performed, condition A1 is fulfilled.

Note: General statements on type testing without referring to a specific TSI clause do not fulfil condition A1.

Condition A1 is normally a high-level indication. There is often no information given at this level, which specific physical or functional properties of the Object of Assessment shall be subject to type testing. The identification of the precise properties follows within the subsequent conditions.

Instead of the term 'Type Test' the TSI CCS (EU) 2023/1695 in section (6.2.4.1) uses different wording which is giving the same effect:

- *"a representative specimen of the interoperability constituent has been submitted to a full set of test sequences […]"*

and

- *"these tests were carried out in a laboratory accredited […] and the standards referred to in Appendix A, Table A 4 […]" (Note: the referred standard is ISO 17025)*

2.2 Condition A2: TSI defines a Type Test Procedure or permits an Alternative Means

This condition is fulfilled (= "yes" or "alternative"), if the TSI clause, to which condition A1 has referred, defines for specific properties of the Object of Assessment a documented technical procedure for type testing or for the Alternative Means either

- within the TSI text

or

- within a document referenced within the TSI that shall be applied with this TSI clause.

2.3 Condition A3: Applicant has determined a Type Test Procedure

The Applicant has determined to the TSI clause, to which Condition A1 has referred, a 'Detailed Conformity Assessment Requirement' that defines for specific properties of the Object of Assessment a documented technical procedure for Type Testing.

Note: The approach on how the applicant shall/may define such Detailed Conformity Assessment Requirements is explained in the Blue Guide /D06/. A summary of this is

contained in RFU-STR-088 of NB-Rail. For subsystems CCO and RST additionally the requirements capture process according to (EU) 2018/545 applies.

2.4 Condition B1: TSI requires determination of certain physical or functional properties

This condition B1 is fulfilled, wherever a TSI requires the evaluation of

- certain defined physical properties (e.g. length, mass, speed, retardation)

  or

- certain defined functional properties (e.g. on/off status of an interface, a telegram can / cannot be received)

of the Object of Assessment (by the TSI demanding a 'test' / 'check'/ "assessment" / etc.) unless that evaluation is already subject to condition A1.

Note: There is usually no indication given at this level, which specific properties of the Object of Assessment shall be subject to evaluation. The decision, whether this evaluation shall apply testing or inspection follows within the subsequent conditions B2 and B3.

2.5 Condition B2: TSI includes or references a Test Procedure

The TSI clause, to which Condition B1 has referred, defines for specific properties of the Object of Assessment a documented technical test procedure either

- within the TSI text

  or

- within a document referenced within the TSI that shall be applied with this TSI clause.

2.6 Condition B3: Applicant has proposed a Test Procedure or Inspection

The applicant has determined to the TSI clause, to which Condition A1 or B1 has referred, a 'Detailed Conformity Assessment Requirement' that defines for specific properties of the Object of Assessment

- a documented test procedure for either an Evaluation Test or an Evidence Test,

  or

- the performance of an Inspection by the NoBo. This option is only permitted for the evaluation of functional properties and where the TSI does not specifically require testing or measurement.

2.7 Condition B4: Performance of Evaluation Tests

This is relevant for all modules, and specifically for modules CF / SF / SG.

If the conditions B2 and B3 have resulted in the need to perform testing, it shall be determined in condition B4 whether this testing shall be performed through either Evidence Testing or Evaluation Testing.

This decision must fulfil all requirements of the applicable TSI(s) and Module(s). These requirements are diverse and depend in some cases on a joint decision between NoBo and applicant.

In some cases, a TSI (e.g. in section 6) may define additional definitions on this aspect for a specific module. Also the related TSI application guides may be consulted.

The NoBo shall determine, if all these requirements are fulfilled. The final decision on this fulfilment remains with the NoBo. See also section 5 below.

3 Performance of Evaluation Tests

3.1 General requirements

The requirements (acceptance criteria) of Annex F of the ERA AS /D03/ shall be fully respected. There are four possible options of how an Evaluation Test can be performed. A TSI clause may limit the options for a particular Evaluation Test (e.g. according to section 6.2.4.1 of TSI CCS (EU) 2023/1695 only options 1a and 2 are permitted).

Opt.	By whom	Internal/ external	Accreditation	Mandatory requirements	Traceability
1a	NoBo test lab (within the same legal entity of the NoBo CAB)	internal	accredited	17025 + ERA AS F.1	Evidence on the proper accreditation is sufficient
1b			non-accredited	17065 + ERA AS F.2	NoBo shall apply checklist according to Annex 2 of this RFU
2	applicant, manufacturer, design organizations, RU, IM, … test lab	external	accredited	17025 + ERA AS F.1	Evidence on the proper accreditation is sufficient
3	applicant, manufacturer, design organizations,		non-accredited	ERA AS F.2	NoBo shall apply checklist according to Annex 2 of this RFU

	RU, IM, … test lab				
4	Test Lab of another body as specified in the TSI			as specified in the TSI.	NoBo may apply checklist according to Annex 2 of this RFU

Notes:

- *'internal' means inside the same legal organisation of the NoBo*
- *'external' means a different legal organisation, not being the NoBo*
- *'test laboratory' (or test lab) means the organisation performing the test including its management system, its human resources and its test equipment/ material. It is not required that the test laboratory is performing tests only inside a laboratory building. In fact: mobile test lab activities are in the rail industry frequently performed (e.g. within a test train or at a trackside location). There is no minimum size of a test lab team (i.e. one competent tester with one calibrated mobile test equipment may be sufficient to perform testing).*
- *If an Evaluation Test was performed in the past or before the NoBo got involved, it may become very difficult and laborious to obtain all required information from the test lab, but also in this case: without all required information the NoBo shall not accept the test result.*

The NoBo has the full authority and duty to determine that Evaluation Testing is/was performed according to the requirements below. If these requirements are not fulfilled, the NoBo shall not include the Evaluation Test result into its conformity assessment.

The requirements for accredited evaluation tests are in detail:

- Performance of the Evaluation Test according to
  - ERA AS /D03/ Annex F.1 (accreditation to ISO 17025 /D04/)
  - together with the particular test requirements as defined in the applicable TSI related test procedures
  - and together with any specific test requirements as defined by conditions A2/ A3/ B2/ B3.
- Accreditation must be/ have been valid at the time of testing and reporting on the test.
- Accreditation must be granted by a signatory of the EA or ILAC multilateral agreement.

- Accreditation scope must include the applied technical standards. *Note: Any test following a technical standard not included in the accreditation scope is a non-accredited test.*
- Accreditation also applies to past tests if the accreditation covered the applicable TSI requirements together with any specific test requirements as defined by conditions A2/ A3/ B2/ B3 and if the accreditation was valid at the time of testing and reporting (see ISO 17065 /D05/ section 7.4.5).

The requirements for non-accredited evaluation tests are in detail:

The Nobo shall evaluate (via Inspection and/or Audit) the performance (=planning, preparation, execution and reporting) of each different test activity performed by the non-accredited testing laboratory according to

- ERA AS /D03/ Annex F.2 (lists the relevant requirements of ISO 17025 /D04/) via a checklist in Annex 2 of this RFU
- the particular test requirements as defined in the applicable TSI related test procedures
- any specific test requirements as defined by conditions A2/ A3/ B2/ B3.

either

- when a test activity is performed for the first time and afterwards periodically at least every 24 months while the same test lab performs the same test activity,

or

- each time when a test activity is performed.

The following sections give additional explanations to the four options.

3.2 Option 1: Internal test lab of NoBo

This option 1 applies only to an internal test lab within the same legal entity as the NoBo, i.e. where the testing is performed using internal resources of the NoBo. The NoBo may hold accreditation to ISO 17025 for the testing or not. The NoBo shall as applicable follow all requirements for performing accredited or non-accredited testing.

This Option 1 excludes subcontracting or outsourcing of tests to external test labs, e.g. to a sister company of the NoBo (here Option 2 or 3 shall be applied).

3.3 Option 2: Accredited external test lab

The external test lab may (but is not required to) be subcontracted by the NoBo.

The accredited external test lab can e.g. be an internal lab of the applicant, design organization, manufacturer, infrastructure manager, railway undertaking or a significant subcontractor or any other test lab as long as it is properly accredited for this test in the framework of ISO17025 /D04/.

Note: If a test lab holds accreditation for ISO 17025 from national accreditation bodies that are not signatories of the EA or ILAC or for other areas (e.g. automotive or maritime test requirements), but not for TSI related test requirements, it is then not properly accredited as required for this Option 2.

3.4 Option 3: Non-accredited external test lab

For option 3 tests are performed by a non-accredited external test laboratory, or a test laboratory with a different scope of accreditation.

Note: Where an Applicant proposes to use this Option 3 first to NoBo A and later to NoBo B, and where the Applicant (together with the external test lab) has already completely and positively answered the checklist in Annex 2 of this RFU to NoBo A, it is highly recommended that the Applicant provides all the same answers and the associated evidence and the assessment results of Nobo A subsequently to NoBo B, in order to allow NoBo B to come to the same conclusion as NoBo A in the most efficient way. The NoBo B may ask for updated or additional evidence. The final decision on whether the evidence is also complete and positive for the project of NoBo B remains fully with NoBo B.

3.5 Option 4: Another body, only if this option is specified in the TSI

The tests may be performed by a non-accredited external test laboratory, or a test laboratory with a different (non-relevant) scope of accreditation. This option 4 must be explicitly permitted by a TSI. Where this option applies, the assessment of the test laboratory by the NoBo according to Annex 2 is not mandatory.

Note: Examples for this option are TSI ENE (EU) 1301/2014 as amended clause 6.2.2.1 or TSI INF (EU) 1299/2014 as amended clause 6.2.2.1 when applying module SG or clause 6.2.4.8.

4 Conditions for Replacing Evaluation Tests with Alternative Means

Alternative Means to Evaluation Tests shall only be acceptable, if such an Alternative Means is permitted and defined within the definition of Evaluation Tests and/or their documented test procedure or documented type test procedure within

a) the text of a TSI clause,
b) the text of a document referenced from a TSI clause,
c) the text of a Detailed Conformity Assessment Requirement that the applicant has determined to be used with a TSI clause (applicable in case of conditions A3 or B3 and:)

Note: In some cases specific conditions are given, under which an Evaluation Test can as Alternative Means be waived (=not be done).

The applicant is expected to propose a reasoning for selection of the Alternative Means approach and the NoBo shall assess whether this reasoning applies in the current project. The NoBo shall document the argumentation for its application within the project records.

Examples for Alternative Means defined in different TSI are given below.

For CCO or CCT subsystems or ICs:

No cases identified yet. This section may be updated in a future issue.

For ENE subsystems or ICs:

In TSI ENE (EU) 1301/2014 (as amended), clause §6.2.4.5 -5 states: “For operational speeds up to 120 km/h (AC systems) and up to 160 km/h (DC systems), measurement of the dynamic behaviour is not mandatory. In this case alternative methods of identifying construction errors shall be used, such as measurement of OCL geometry according to point 4.2.9.”

For INF subsystems or ICs:

No cases identified yet. This section may be updated in a future issue.

For RST subsystems or ICs:

Typical conditions for alternative means which may be contained in the TSIs or the associated detailed conformity assessment requirements are:

- a previous Evaluation Test result for a different (but technically fully representative) Object of Assessment is available and a Type Test procedure defines conditions, which if fulfilled, permit that the previous test result may be used for this Object of Assessment (= no new Evaluation Testing is required);
- if certain conditions are fulfilled, a simulation or calculation or Verification & Validation activity may be used instead of Evaluation Testing;
- no testing is required, if certain design parameters are fulfilled.

5 Conditions for using Evidence Test Reports as documented evidence during NoBo Inspections / Audits

According to the ERA AS /D03/ the reporting derived from Evidence Testing (or from Evaluation Testing) shall never become direct input to NoBo certification activities. The NoBo shall route such documented evidence always to their inspection or audit teams in order to determine if test performance and results are suitable.

Using the flow chart contained in section 2 above, in many cases

(1) the text of TSI clauses,

(2) the text in documents referenced by those TSI clauses,

(3) the text in other associated detailed conformity assessment requirements

requires that the applicant provides certain Evidence Test reports as part of the set of evidence to demonstrate conformity of the object of assessment with points (1)-(3) to the NoBo.

Depending on the applicable module, such Evidence Test reports will be required by the NoBo as necessary input to their inspection or their audit activities.

The NoBo shall in all such cases (similar to any other documented evidence received in the format of drawings, calculations, etc.) evaluate and decide whether the Evidence Testing reports are suitable to be used within the NoBo inspection or audit activities.

Such an Evidence Test report shall only be considered as suitable if

- **the test performance** (including e.g. test method, measurement equipment calibration, validation of programmable measurement equipment, selection of test samples, reporting, competence and impartiality of the test team, etc.)

and

- **the test results**

conform with the requirements contained in points (1)-(3) above.

As the NoBo will retain the responsibility for having done their inspection / audit completely and correctly, the NoBo can also ask

- for further / improved Evidence Testing performance and reporting (e.g. test with calibrated measuring equipment if calibration is deemed necessary by the NoBo; improved reporting to document the full test mesthod)
- Additional spot check Evidence Testing of certain properties of the Object of Assessment
- additional inspection / audit by the NoBo to evaluate, if the test performance and the test results fully conform with the points (1)-(3) above

to support its judgement.

6 Measuring Aids and Measuring Equipment

Note on Measuring Aids

During an inspection or auditing activity – not during an Evaluation Test activity (!) – a NoBo expert may use "measuring aids" to support the judgement of that expert.

Such a measuring aid is not a measuring equipment. It shall therefore never be used in a case where it has a significant influence on the results of any testing, inspection or auditing performed by the NoBo.

Note on Measuring Equipment

This concerns measuring equipment used during Evaluation Testing.

One relevant requirement contained in ERA AS /D03/ Ver 1.1 or 2.0 in connection with the applicable requirements of ISO 17025 /D04/ defines that Evaluation Testing shall only be performed with measuring equipment. Such equipment shall be calibrated. The calibration shall be traceable to a national standard (e.g. the national standard for length that is established in France).

The evidence of the calibration shall guarantee the metrological traceability according to ISO 17025 /D04/.

Calibrations performed by accredited calibration labs under ISO 17025 /D04/ can be deemed to satisfy this requirement, if the calibration has been done under this accreditation. There shall be a process to manage calibration, use, maintain, store calibrated measuring equipment. There shall be a process to follow up previous testing (and re-test as required), if the next calibration shows a defect or drift of values.

THIS RFU WAS AGREED ON
PLENARY MEETING 072

RFU-STR-022	Issue 07 Date 13/11/2024

THIS RFU ENTERS INTO FORCE ON
27/11/2024 (DATE OF PUBLICATION) FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.
RFU APPLICATION IS MANDATORY STARTING FROM
01/03/2025 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 072 – 13/11/2024: NO COMMENTS

ANNEX 1

Annex 1: Examples for different conditions of the diagram

The examples quoted in Annex 1 are valid at the time of publication of this issue of the RFU.

Condition A1

Examples that fulfil condition A1:

- TSI Loc&Pas (EU) No 1302/2014 (as amended) defines in Table H.1 several 'Type Tests'
- TSI INF (EU) No 1299/2014 (as amended) defines in Table 36 several 'Type Tests'
- TSI PRM (EU) No 1300/2014 (as amended) defines in Table D1 several 'Type Tests'
- TSI WAG (EU) No 321/2013 (as amended) defines in Table F.1 several 'Type Tests'
- TSI NOI (EU) No 1304/2014 (as amended) defines in Appendix C several 'Type Tests'
- TSI CCS (EU) 2023/1695 in Table 6.1.1 requires together with clause 6.2.4.1 for on-board ETCS IC an evaluation test that fulfils condition A1
- TSI CCS (EU) 2023/1695 clause 6.3.2.3. Conditions for using modules for On-board and Trackside Subsystems states: "*With reference to point 4.2 of Module SB (type-examination), design review is requested. With reference to point 4.2 of Module SH1 (full quality management system with design examination), an additional type test is required.*"
  Note: Neither the application of Module SB nor the additionally requested 'type test' for Module SH1 fulfil conditions A2 and A3 because in both cases no specific TSI clause is indicated to which the type test applies. This leads to condition B3.

Condition A2

Examples to explain the concept:

- In TSI CCS (EU) 2023/1695, 6.2.4.1 Mandatory tests for the on-board ETCS, in combination with 4.2.2 On-Board ETCS functionality, "[…] The requirements for tests are specified in Appendix A, Table A 1, 4.2.2 c. […]" which refers to Subset-076.

Note: This particular TSI clause limits the permitted options for Evaluation Testing in chapter 3 of this RFU to options 1a and 2.

- In TSI INF (EU) No 1299/2014 (as amended) TYPE TEST (tab. 36 of Appendix A) Characteristic to be assessed "The Rail" following §6.1.5.1 according to EN 13674-1:2011 +A1:2017 referenced in Appendix T, index [7].
- In TSI ENE (EU) No 1301/2014 (as amended) TEST are required by clause §6.1.4.1-1 (d) related to IC verification process. It defines the needing of tests according to Appendix E, index [9].
- In Appendix D, D.1 the TSI WAG (EU) No 321/2013 (as amended), includes. a mandatory reference to documented technical procedures for type testing within EN14363:2016+A2:2022 which relate to several TSI clauses:
  - 4.2.3.5.2
  - 6.2.2.2 (which is connected to 4.2.3.5.1)
  - 6.2.2.3 (which is connected to 4.2.3.5.2)
  - C.20.

Condition B1

Examples that fulfil condition B1:

- TSI INF (EU) No 1299/2014 (as amended) defines tests in table 37 under the heading 'ASSEMBLY BEFORE PUTTING INTO SERVICE' (with application of 6.2.2.1 for module SG)
- TSI PRM (EU) No 1300/2014 (as amended) defines tests in Table E.1: 'Inspection' that may require testing but each point needs to be looked at separately, starting with B1
- TSI CCS (EU) 2023/1695 defines in table 6.1.1: test/check that may require testing but each point needs to be looked at separately, starting with B1 except for on-board ETCS for which a type test that fulfills condition A1 is required in clause 6.2.4.1
- TSI CCS (EU) 2023/1695 defines in table 6.2.1: test/check that may require testing but each point needs to be looked at separately, starting with B1
- TSI CCS (EU) 2023/1695 defines in table 6.3 tests/checks that may require testing but each point needs to be looked at separately, starting with B1

Condition B2

Examples to explain the concept:

- In TSI PRM (EU) No 1300/2014 (as amended) regarding the spoken information as characteristic to be assessed:

  4.2.1.11. Spoken information

  (1) The spoken information shall have a minimum STI-PA level of 0,45, in accordance with the specification referenced in Appendix A, index 5. This index refers to a documented test procedure.

  In TSI ENE (EU) No 1301/2014 (as amended) tests are required by clause §6.2.4.5 -2 related to SS verification process. It defines the needing of tests according to Appendix E, index [9].

Condition B3

Examples to explain the concept:

- In TSI PRM (EU) No 1300/2014 (as amended), section 6.2.1 EC verification (general), fourth paragraph:

  "*For the infrastructure subsystem, the objective of inspection by a notified body is to ensure that the requirements of the TSI are fulfilled. The inspection is performed as a visual examination; in case of doubt, for the values verification, the notified body can ask the applicant to perform measurements. In case different methods are possible (e.g. for contrast), the measurement method shall be the one used by the applicant.*

  The approval process and the contents of the assessment shall be agreed between the applicant and a notified body in accordance with the requirements set out in this TSI."

  The Applicant may therefore propose either a test procedure for an EVALUATION TEST or an EVIDENCE TEST. The Applicant may not propose an INSPECTION.

- TSI CCS (EU) 2023/1695 clause 6.2.2 requires for ICs:

  "The following clarifications apply to the use of some of the modules:

  (1) with reference to Chapter 2 of the 'Module CB', 'EC'-type examination shall be carried out through a combination of production type and design type;

  (2) with reference to Chapter 3 of the 'Module CF' (product verification) statistical verification is not allowed, i.e. all interoperability constituents shall be individually examined."

The Applicant may therefore propose either a test procedure for an EVALUATION TEST or an EVIDENCE TEST or an INSPECTION through the NoBo.

- For subsystems, the TSI CCS (EU) 2023/1695 clause 6.3.2.3 requires:

  "With reference to point 4.2 of Module SH1 (full quality management system with design examination), ***an additional type test*** *is required."*

  Despite defining a "type test", there is no test procedure defined. The Applicant may therefore propose either a test procedure for an EVALUATION TEST or an EVIDENCE TEST or an INSPECTION through the NoBo.

Condition B4

Examples from the module decision /D02/ where the notified body and the applicant shall align their decision:

- /D02/ Module CF, section 4.1
- /D02/ Module CF, section 5.2
- /D02/ Module SF, section 4.2
- /D02/ Module SG, section 5.1, first paragraph
- /D02/ Module SG, section 5.3

Examples for requirements that must be considered within B4 by Applicant and NoBo

- /D02/ Module SG, section 5.1, third, fourth and fifth paragraph

  The conditions to entrust checking and test must be similar to the conditions, respected by a notified body to subcontract activities (see § 6.5 of the Blue Guide /D06/ and section 6.2.2 of ISO 17065 /D05/ and section 6.2.2 of the ERA AS /D03/) "*or, when this is specified by the relevant TSI(s)"* (e.g. by TSI INF (EU) No 1299/2014 as amended, section 6.2.2.1 or by TSI ENE (EU) No 1301/2014 as amended, section 6.2.2.1), "*by (or on the behalf of) the applicant*. *The notified body will then decide as to whether it shall use the results of these checks or tests."*

  The extent to which the evidence originating from other parties is taken into account by the notified body shall be justified by documented analysis using the factors listed in /D02/ Module SG, section 5.2

- /D02/ Module SG, section 5.2

  The accreditation standard is ISO 17025 /D04/. The certificate of accreditation must be valid at the time of testing and reporting.

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- /D02/ Module SG, section 5.2

  "In all cases, the notified body keeps the responsibility of final results of the examinations, tests and checks."

  Therefore, the NoBo decides which evaluation test results and which evidence test results may be accepted.

ANNEX 2

Annex 2: Checklist to evaluate non-accredited test labs

One of the checklist options below shall be used by the NoBo to evaluate non-accredited tests. It shall assure that the applicable requirements of ISO 17025 /D04/ are respected. As long as all content of the Checklist is present the NoBo may use a different format (e.g. an electronic checklist).

Checklist Option 1 (based on the structure of ISO 17025)

EVALUATION OF NON-ACCREDITED EXTERNAL TEST LAB – CHECKLIST AND REPORT	
Project Data	
NoBo	
Evaluation of external test lab was performed by (Name / Date)	
Quality Reviewer of this evaluation report (Name / Date)	
Object(s) of Assessment (Name/Type/Version/ Variant/Serial Number/ etc.)	
Test Laboratory (Name, Location)	
Test Requirements	*Description of test requirements e.g. stopping distance testing according to standard EN XYZ:2022, ch.5.3, Test option C.* *Make a systematic list in case of multiple test requirements.*
Test Specification / Procedure in use	*Reference to test specification / procedure e.g. 'Brake Stopping Distance Type Test' Doc-ID 123345, Ver.1.* *Make a systematic list in case of multiple test specifications / procedures.*
Date of On-Site Evaluation of Test Laboratory	*YYYY-MM-DD*
Evaluation Result	*e.g. The test lab has for the aforementioned test specification/ procedure (NOT) demonstrated conformity with the relevant requirements of ISO 17025:2017 together with the above mentioned test requirements.*

Note: For copyright reasons it is not possible to replicate in the following checklist of this RFU the actual content of the listed sections of ISO17025 within the column "Requirement". This column is therefore left empty.

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Clause of ISO 17025	Requirement (text)	Evidence	NOT Acc. / Acceptable
4.1			
4.2			
5.1			
5.4			
5.5			
5.6			
5.7			
6.2			
6.3			
6.4			
6.5			
6.6			
7.1			
7.2			
7.3			
7.4			
7.6			
7.7			
7.8			
7.10			
7.11			

Checklist Option 2 (clustered into coherent topics)

EVALUATION OF NON-ACCREDITED EXTERNAL TEST LAB – CHECKLIST AND REPORT	
Project Data	
NoBo	
Evaluation of external test lab was performed by (Name / Date)	
Quality Reviewer of this evaluation report (Name / Date)	
Object(s) of Assessment (Name/Type/Version/ Variant/Serial Number/ etc.)	
Test Laboratory (Name, Location)	
Test Requirements	*Description of test requirements e.g. stopping distance testing according to standard EN XYZ:2022, ch.5.3, Test option C.* *Make a systematic list in case of multiple test requirements.*
Test Specification / Procedure in use	*Reference to test specification / procedure e.g. 'Brake Stopping Distance Type Test' Doc-ID 123345, Ver.1.* *Make a systematic list in case of multiple test specifications / procedures.*
Date of On-Site Evaluation of Test Laboratory	*YYYY-MM-DD*
Evaluation Result	*e.g. The test lab has for the aforementioned test specification/ procedure (NOT) demonstrated conformity with the relevant requirements of ISO 17025:2017 together with the above mentioned test requirements.*

No.	Requirements of Annex F of ERA Assessment Scheme		
1	**Management of Test Lab Organisation (ISO/IEC 17025, 4.1 + 4.2+ 5.1 + 5.4 + 5.5 + 5.6 + 5.7 + 6.2 + 6.3 + 7.2 + 7.3 + 7.4 + 7.7))**	**Evidence**	**NOT Acc. / Acceptable**
1.1	Has the laboratory a legal entity, or a defined part of a legal entity + a responsible management + identifiable facilities/ locations?		
1.2	Is there an organisation structure with management + set up and continuous improvement of the test lab QMS + technical operations + support services + personnel with assigned responsibilities & duties (to include development of test methods, test execution, reporting of results)?		
1.3	Is the laboratory management committed to impartiality (e.g. Policy)? *Note: The test lab shall apply the impartiality (including independence of laboratory personnel) requirements of ISO/IEC 17025. It shall not be required to apply the same requirements that apply to the NoBo itself.*		
1.4	Are (potential) risks to impartiality identified (to include risk from ownership, governance, management, personnel, shared resources,		

	finances, contracts, marketing/branding, and payment of sales commission) + are suitable mitigations identified? *Note: The test lab shall apply the impartiality (including independence of laboratory personnel) requirements of ISO/IEC 17025. It shall not be required to apply the same requirements that apply to the NoBo itself.*		
1.5	Are the tests covered by this evaluation performed impartially (there are no unacceptable commercial, financial or other pressures)? *Note: The test lab shall apply the impartiality (including independence of laboratory personnel) requirements of ISO/IEC 17025. It shall not be required to apply the same requirements that apply to the NoBo itself.*		
1.6	Are there documented procedures as required for the scope of tests covered by this analysis for: calibration of equipment + qualification of personnel + sampling methods + identification/ handling/ transport/ treatment + testing methods (e.g: test specifications/ procedures/ method statements) + test conditions + follow up in case of equipment failing the next calibration? Have the testing methods been validated?		
1.7	Informative Question: Does the test laboratory hold any relevant accreditations/certifications covering its activities, e.g. ISO 9001 certification, accreditation to others or any relevant accreditations/certifications for similar activities e.g. automotive or naval testing (specify the details)?		
1.8	Do the documented procedures clearly describe the required test equipment and/or instrumentation + its operation?		
1.9	Does the test lab ensure the validity of results and inhibits reporting of incorrect results by • monitoring trends of measurements between calibrations, • cross checking measurements between different measurement equipment and different test laboratories, • appropriate functional checks of the measurement equipment?		
1.10	Are there legally enforceable commitments in place between the test lab and all staff and subcontractors to ensure confidentiality of client information?		
1.11	Is there an applied QMS + is the QMS continuously improved + are there Management Reviews to discuss the QMS's effectiveness + is the laboratory management committed to meet the needs and expectations of interested parties, such as customers, authorities, etc. and has the lab established the resulting requirements?		
2	**Contract review (ISO/IEC 17025, 7.1)**	**Evidence**	**NOT Acc. / Acceptable**
2.1	Is there a procedure to ensure that the the test lab only enters into contracts where test requirements are clear + can be met by the test lab's staff and equipment resources + any subcontracting is agreed with the client + the test method is meeting the client's requirements + the client is informed if an unsuitable / outdated requirement was made + the client is offered access during the testing + requirements for package/ storage/		

	transport of the Object of Assessment? (this shall apply also to later contract modifications)		
2.2	Are there records retained on the contract review?		
3	**Competence and Impartiality of Personnel (ISO/IEC 17025, 6.2)**	**Evidence**	**NOT Acc. / Acceptable**
3.1	Is the personnel undertaking the testing impartially (impartiality shall include neutrality and sufficient independence from design, manufacturing, construction, marketing and maintenance of the object of assessment)?		
3.2	Is there evidence that the personnel carrying out the test have received adequate training + were regularly competency assessed? Are systematic records on this available?		
4	**Test Facilities and Equipment (including those rented or provided by subcontractors) (ISO/IEC 17025, 6.3 + 6.4 + 6.5 + 6.6 + 7.6 + 7.7 + 7.11)**	**Evidence**	**NOT Acc. / Acceptable**
4.1	Do facilities & equipment and their associated records allow traceability (e.g. HW&SW versions, manufacturer, type, serial no., location, current and previous calibration intervals, calibration results, previous defects&repair)?		
4.2	Are facilities & equipment available, adequate + do they provide the required accuracy + are they checked to be correctly set up and fit for service before use (are associated requirements defined and applied, e.g. environmental conditions, access control, storage, transport, maintenance, calibration, measures against deterioration of equipment)?		
4.3	Is there a calibration and a maintenance programme (suitable intervals, pass/fail criteria) + is there a process for follow up of non-conforming work performed with defective equipment (e.g. after a failed calibration)?		
4.4	Is calibrated equipment labelled to give identity, status & validity of its calibration?		
4.5	Is evidence on calibration demonstrating metrological traceability to a national 'measurement standard' (e.g. a nationale physical reference kilogram or meter) and therefore to International System of Units (SI)? *Note: Calibration repots made by calibration labs under accreditation to ISO 17025:2017 with a related accreditation mark present on the report are suitable evidence in this regard*.		
4.6	If applicable: Are only suitable externally provided products and services used (e.g. rented equipment, sub-supplied services, measurement standards) + are suppliers selected against defined criteria + monitored?		
4.7	Are test conditions and test results systematically recorded + are these records used to detect trends/ defects (e.g. misalignment, drift of results), by e.g. re-testing with different equipment or by another lab?		
4.8	Has the measurement uncertainty been identified and documented for each measurement activity?		
4.9	Is the information management system (paper or IT-based) of the test lab including the records and any subsequent modifications?		

4.10	Is the information management system (paper or IT-based) of the test lab protected against unauthorised access + tempering + loss + loss of data integrity +		
4.11	Where electric/ electronic/ programmable equipment is used during the testing: Is the programmed equipment validated?		
5	**Test Execution (ISO/IEC 17025, 7.3 + 7.4)**	**Evidence**	**NOT Acc. / Acceptable**
5.1	Was sampling, handling of test items and testing performed by competent personnel according to documented processes and defined method(s) with adequate equipment?	Add YOUR test execution observations here.	
5.2	Was the measured information recorded correctly and without unnecessary delay?	Add YOUR test execution observations here.	
6	**Test Reporting (ISO/IEC 17025, 7.8 + 7.10)** **(this may be documented after desktop assessment of the report)**	**Evidence**	**NOT Acc. / Acceptable**
6.1	Does the test report include the information on sampling and testing (document control to enable a completeness check (e.g. page x/y), date of report, test lab name and address, person authorising the report, client, test location, environmental conditions, relevant dates, test object, information supplied by the client to the test lab, test requirements, sampling and test methods used, sample treatment, test results, measurement uncertainty, personnel, equipment used, indication of results provided by other test labs, deviations from intended plan/ method, calibration & metrological traceability, relevant equipment failures/ repair/ adjustment)?		
6.2	Are reports prepared, quality reviewed and authorised by competent personnel?		
6.3	Is there a procedure for amendment / correction of reports where necessary?		
6.4	Is non-conforming work managed (identification of impact on previous test reports, correction, corrective actions)?		