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NB-RAIL COORDINATION GROUP

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



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RFU-STR-022

Issue 09

Date 04/03/2026

TITLE

TESTING in the Context of TSI Conformity Assessment

ORIGINATOR

NB RAIL STRATEGY SUBGROUP

SUBJECT RELATED TO

IOD 2016/797, Modules Decision
2010/713/EU; ERA Assessment Scheme
000MRA1044 ver 2.0, All TSIs

AMENDMENT RECORD:

ISSUE 08: SMALL ADMINISTRATIVE UPDATES TO CORRECT TYPOS

ISSUE 09: REMOVAL OF CONNECTIONS BETWEEN EVALUATION TESTS AND EVIDENCE TESTS IN SECTION 2 (BASED ON ADVISE BY ERA), UPDATE OF REFERENCE TO CURRENT EU BLUE GUIDE, EDITORIAL IMPROVEMENT OF THE WORDING THROUGHOUT (WITHOUT A CHANGE OF CONTENT), REFERENCE AND EXTRACT CONSIDERING ERA AS VER. 2.0 ANNEX E, FIGURE 1 (NOTE 7) AND MODULE DECISION – MODULE SH1 CLAUSE 4.2. + INTRODUCTION, ADAPTATIONS DURING STR MEETING ON PHRASING/WORDING, NOTES UNDER 1.1 + 1.3 FINE TUNING + CASE 4 POINTING TO MODULE SG

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 V2.0
- /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, type test, 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 intending to reach a harmonised approach among the Notified Bodies.

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.



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RFU PROPOSAL

1 Definitions

1.1 Introduction

When tests are performed, despite some similarities between the different testing activities mentioned in 'General Background' above, 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.

'Controlled by XYZ' means, that the organisation XYZ must check and ensure that, even if a test is not performed by that organisation, that the test method, the preparation of the test object, the test equipment, the training of the test staff, etc. follows the respective requirements for this EVIDENCE or EVALUATION TEST.

Notes:

- *Generally speaking Evaluation Tests are indicated in the TSI as 'Type Test', but TSI may use other wording to indicate them.*
- *On the other hand, Evidence Tests are any other tests which are either indicated by a TSI or defined by the applicant, design organisation, manufacturer or subcontractor for the purpose of the conformity assessment by the NoBo.*

1.2 Evidence Testing

This includes all testing that can according to the applicable TSI(s) be controlled by Design Organisations, Manufacturers, Keepers, RUs and IMs and their subcontractors.

Such testing is generally supporting the internal interests of these organisations to obtain evidence on the fulfilment of 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.



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However, there are TSI parameters where EVIDENCE TEST reports need to be also included within the set of documented evidence that is provided to the NoBo within a project in order to serve as evidence within the NoBo's assessment activities (e.g. SHto evidence during a NoBo audit to module SD the manufacturer's internal testing activities during production control).

As clarified by /D03/ Annex E, figure 1 (Note 7):

"This testing is not associated with the CAB evaluation activities.

These testing activities are performed by the manufacturer and in some cases under the

control of the applicant and are not in the scope of the testing in Annex F, e.g.:

- › *production related (serial) tests under the control of the manufacturer;*
- › *final (commissioning) testing at the end of production under the control of the manufacturer or applicant;*
- › *type testing which as part of an H-type module performed under the control of the applicant.*

Information coming from this activity may be used by applicants as evidence input to the CAB evaluation activities. Predominantly this information is input to inspection and may also be input to auditing."

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

1.3 Evaluation Testing

This includes all tests that, according to an applicable TSI clause, shall be assessed by the NoBo (these not being necessarily executed by the NoBo, but at least controlled by it before inspection of the test results).

Irrespective of which test lab actually performs the Evaluation Test, the NoBo shall examine if all evaluation tests to be used in its NoBo conformity assessment activities have been



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carried out according to the requirements of ERA Assessment Scheme /D03/ V2.0 Annex F.

In case such a test would be excluded of the provision of the Annex F and falling under the provisions of the ERA Assessment Scheme /D03/ V2.0 Annex E for Evaluation Tests (the Applicant controlling the testing according to module CH1 or SH1), the inspection of such tests results remains a task to be performed by that Notified Body who has performed previously the audit of the related QMS (refer to RFU-STR-065) including the control measures for such testing. According to /D03/, those control measures are 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 by a TSI clause (or by an associated detailed conformity assessment requirement) 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.

Note: Based on experience it is understood that by far the large majority of Evaluation Tests present in projects is only controlled but not performed by the NoBos.

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 the method

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

An 'Alternative Means' is an evaluation method that may be performed instead of an Evaluation Test or Evidence Test. It may be proposed by the applicant, if such an Alternative Means is specifically permitted by a TSI clause (or by an associated detailed conformity assessment requirement).



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Note: Typical Alternative Means permitted by TSI clauses (or by associated detailed conformity assessment requirements) are e.g.

- *simulations,*
- *calculations,*
- *waiving of testing if certain design conditions are fulfilled.*

The final decision on whether a proposed method for the determination 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 in the flow chart 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)).

In such situations the NoBo shall document the reasoning for the acceptability of the applied method within their project records.

Note: It is common practice, that the Applicant already provides a reasoning on the proposed method, so that the NoBo may directly confirm this proposal where it is plausible and where it conforms fully to the selected Module, the applicable TSI clause, the associated detailed conformity assessment requirement and this RFU.

Where the Applicant's proposal on a method and the reasoning is not plausible or missing, the NoBo shall evaluate the situation and decide on that basis.

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

Note: For the avoidance of doubt: This diagram is combining all relevant definitions for the permitted methods of IOD /D01/, module decision /D02/, ERA AS /D03/ for any module e.g. SF, SG or SH1.



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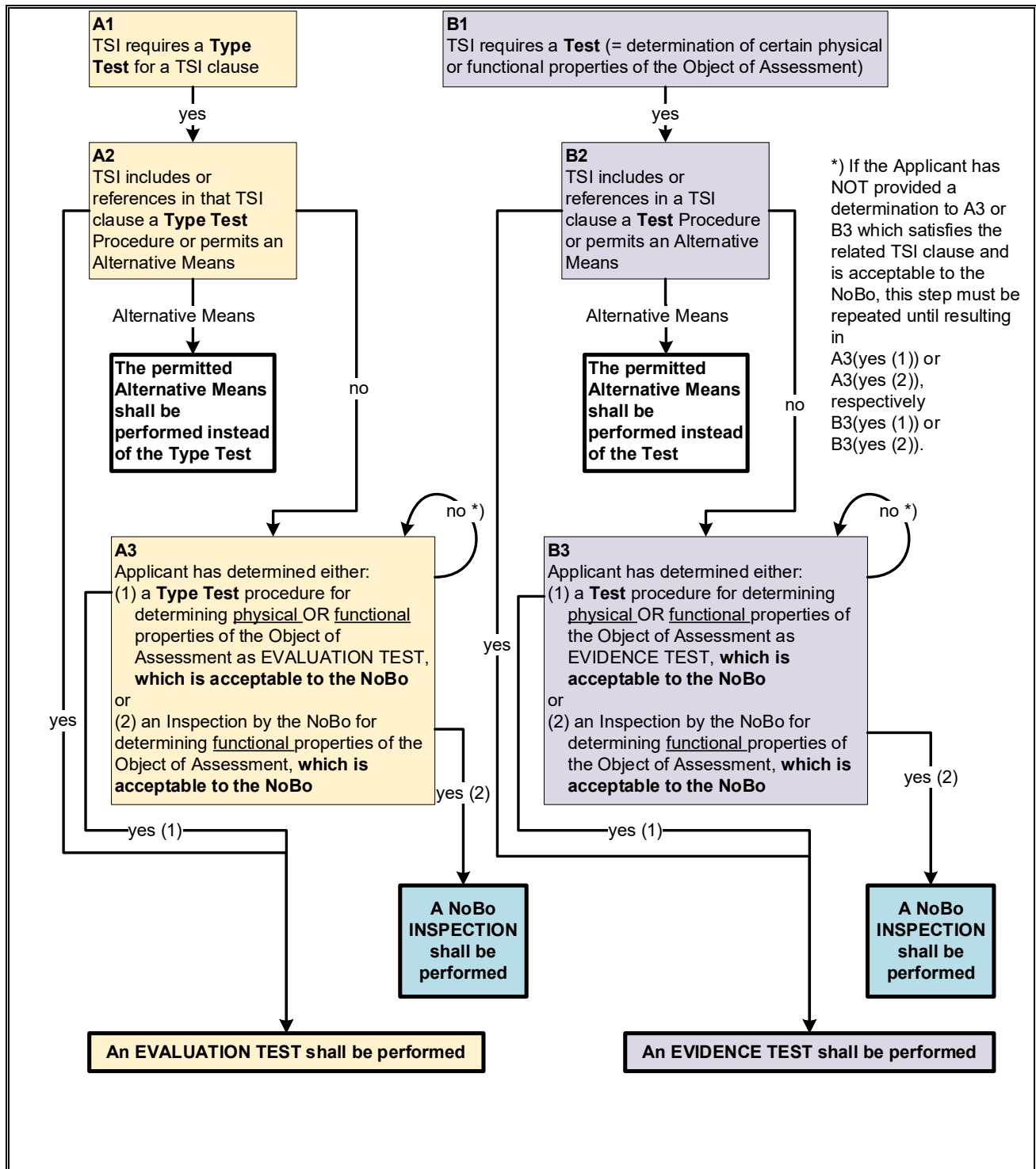


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2.1 Condition A1: The TSI requires a Type Test for a TSI clause

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: The TSI defines a Type Test Procedure or permits an Alternative Means

This condition is fulfilled, if the TSI clause, to which condition A1 has referred, defines for specific properties of the Object of Assessment

- (1) a documented technical procedure for type testing (=“yes”), or
- (2) a documented technical procedure for the Alternative Means that may be applied by the Applicant to replace the type testing (=“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: The Applicant has proposed a Type Test Procedure or proposed to perform a NoBo inspection

The applicant has determined to the TSI clause, to which Condition A1 has referred, a ‘Detailed Conformity Assessment Requirement’ that defines for a specific functional or physical property of the Object of Assessment



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- a documented test procedure that fulfils the TSI (=“yes1”),
- or
- the performance of an Inspection by the NoBo (=“yes2”). This option is only permitted for the evaluation of functional properties and only where the TSI does not specifically require a measurement of the property.

This decision by the applicant must fulfil all requirements of the applicable TSI(s) and Module(s). These requirements are diverse and can depend in some cases on a joint decision between NoBo and Applicant (e.g. as defined in Modules SG and SF).

In some cases, a TSI (e.g. in its section 6) may define additional definitions on this aspect for a specific Module.

Note: The applicant may also consult the related ERA TSI application guides, EU Blue Guide /D06/ and RFU-STR-088 for further information on this topic.

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

2.4 Condition B1: The TSI requires determination of certain physical or functional properties (other than through a ‘Type Test’)

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

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

or

- 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.

Condition B1 is often 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 testing. The identification of the precise properties follows within the subsequent conditions.

2.5 Condition B2: The TSI includes or references a Test Procedure

This condition is fulfilled, if the TSI clause, to which condition B1 has referred, defines for specific properties of the Object of Assessment

- (1) a documented technical procedure for testing (=“yes”), or
- (2) a documented technical procedure for the Alternative Means that may be applied by the Applicant to replace testing (=“Alternative Means”)



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either

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

Note: An Alternative Means can e.g. be a simulation, where this is permitted by the TSI or within a document referenced within the TSI that shall be applied with the applicable TSI clause.

2.6 Condition B3: The Applicant has proposed a Test Procedure or proposed to perform a NoBo Inspection

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

- a documented test procedure that fulfils the TSI (= "yes1"),

or

- the performance of an Inspection by the NoBo (= "yes2"). This option is only permitted for the evaluation of functional properties and only where the TSI does not specifically require a measurement of the property.

This decision by the applicant must fulfil all requirements of the applicable TSI(s) and Module(s). These requirements are diverse and can depend in some cases on a joint decision between NoBo and Applicant (e.g. as defined in Modules SG and SF).

In some cases, a TSI (e.g. in its section 6) may define additional definitions on this aspect for a specific Module.

Note: The applicant may also consult the related ERA TSI application guides, EU Blue Guide /D06/ and RFU-STR-088 for further information on this topic.

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

3 Options for the Performance of Evaluation Tests

3.1 General requirements



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The requirements for Evaluation Tests (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.

Be aware: A TSI clause may limit which options may be selected for a particular Evaluation Test (e.g. where section 6.2.4.1 of TSI CCS (EU) 2023/1695 applies, only options 1a and 2 are permitted).

Opt.	By whom	Internal/ external to the NoBo	Under Accreditation or not	Mandatory requirement s	Traceability for this Option
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	The NoBo <u>shall</u> apply a 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, RU, IM, ... test lab		non-accredited	ERA AS F.2	The NoBo* <u>shall</u> apply a checklist according to Annex 2 of this RFU
4	Test Lab of applicant or another body as specified in the TSI <i>(currently only related to TSI ENE and TSI INF under module SG)</i>			as specified in the TSI	The NoBo* may apply a checklist according to Annex 2 of this RFU

* In H-Type Modules, the NoBo shall audit during the QMS approval auditing that the Applicant/Auditee applies the provisions of Annex F of the /D03/ in combination with the Annex 2 of this RFU. (This ensures that the Applicant/Auditee applies the same level of control measures as a NoBo regarding Evaluation Tests).

Notes:



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- *'internal' means inside the same legal organisation of the NoBo (not through a sister company, etc.)*
- *'external' means a different legal organisation, not being the NoBo (e.g. a subcontractor of the NoBo or an independent test-lab contracted through the applicant)*
- *'test laboratory' (or test-lab) means the organisation performing the test including its management system, its human resources and its test equipment/ material. For the avoidance of doubt: It is not required that the test-lab 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.*

The NoBo has the full authority and duty to determine that any 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.

Note: If an Evaluation Test was performed in the past, even before the NoBo got involved, it may become very difficult and laborious to obtain all required information from the test-lab to determine if Annex F of the ERA AS /D03/ was applied. But also in this case: Without all required information the NoBo shall not accept the test result.

The requirements for accredited Evaluation Tests are combined from:

- Performance of the Evaluation Test according to
 - ERA AS /D03/ Annex F.1 in combination with the referenced sections of ISO 17025 /D04/
 - together with the particular test requirements as defined in the applicable TSI clauses defined under condition A1
 - and together with any specific test requirements as defined by conditions A2/ A3.
- Accreditation must be/ have been valid at the time of evaluation testing and reporting on the Evaluation 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 must also have applied to past Evaluation Tests.

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



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The NoBo shall during its conformity assessment project 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 one of the two checklists in Annex 2 of this RFU
- if the Evaluation Test applied the particular specific test requirements as defined in the applicable TSI related test procedures (condition A1/A2/A3)

either

- (a) when a test activity is performed for the FIRST TIME, and afterwards while the SAME test lab performs the SAME test activity using the SAME QMS PERIODICALLY at least every 24 months,

or

- (b) EACH TIME when a test activity is performed by that test-lab.

The following sections give additional explanations to the four options on performing Evaluation Tests.

3.2 Option 1: Internal accredited or non-accredited 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 evaluation testing or not. The NoBo shall as applicable follow all requirements for performing accredited or non-accredited testing as defined in section 3.1 of this RFU.

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 needs to 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/ according to section 3.1 of this RFU.

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, but Option 3 could be used.



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3.4 Option 3: Non-accredited external test lab

For option 3 Evaluation Tests are performed by a non-accredited external test laboratory, or by a test laboratory with a different scope of accreditation. In this case the Evaluation Test shall follow section 3.1 of this RFU.

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 complete and positive also 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

Here the Evaluation Tests may be performed by an accredited or a non-accredited external test-lab, or a test-lab 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-lab 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 or Evidence Tests with Alternative Means

Alternative Means to Evaluation Tests or Evidence Tests shall only be acceptable, if such an Alternative Means is permitted and defined within

- a) the text of a TSI clause (refer to condition A1 or B1),
- b) the text of a document referenced from that TSI clause (refer to condition A2 or B2),
- c) the text of a Detailed Conformity Assessment Requirement that the applicant has determined to be used with that TSI clause (refer to condition A3 or B3)

Note: In some cases when specific (design) conditions are fulfilled, an Evaluation Test can as an Alternative Means become completely waived (=no Evaluation or Evidence Test needs to be done).



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

Note: 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 of this RFU.

For ENE subsystems :

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 of this RFU.

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 Evaluation 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 by the OoA (=Product-Design).*

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

According to the ERA AS /D03/ the reporting derived from Evidence or Evaluation Testing shall never become a direct input to the NoBo certification activities. The NoBo shall route



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such reporting as documented evidence always to their inspection and/or audit teams in order to determine if test performance and test 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 associated detailed conformity assessment requirements**

requires that the Applicant provides certain Evidence or Evaluation Test reports to demonstrate conformity of the Object of Assessment with these points (1)-(3) to the NoBo.

Depending on the applicable Module(s), such Evidence or Evaluation Test reports will be required by the NoBo as necessary input to their inspection or to 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's inspection or audit activities.

Such an Evidence or Evaluation 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 or Evaluation Testing performance and reporting (e.g. evidence testing with calibrated measuring equipment if such calibration is deemed necessary by the NoBo; or improved reporting to document the full test method)
- for 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



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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 076

THIS RFU ENTERS INTO FORCE ON

04/03/2026 (DATE OF PUBLICATION)

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

RFU APPLICATION IS MANDATORY STARTING FROM

04/03/2027

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



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NONE



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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 without any requirements of the test to be performed as type test.*"

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.



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- 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

Example to explain the concept:



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In TSI ENE (EU) No 1301/2014 (as amended) tests are required by clause §6.2.4.5 -2 related to Subsystem verification process. It defines the need for 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 test procedure for an EVIDENCE TEST. The Applicant may not propose an INSPECTION, as the TSI requires the determination of a physical property through ‘measurement’.

- 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 EVIDENCE TEST or to perform an INSPECTION through the NoBo.



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ANNEX 2

Annex 2: Checklist to evaluate non-accredited test-labs that are intending to perform Evaluation Tests

One of the checklist options below shall be used by the NoBo to evaluate non-accredited test-labs, only where these are intended to perform Evaluation Tests. It shall assure that the applicable requirements of ERA AS /D03/ Annex F.2 in connection with 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	<i>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.</i>
Test Specification / Procedure in use	<i>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.</i>
Date of On-Site Evaluation of Test Laboratory	YYYY-MM-DD
Evaluation Result	<i>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.</i>



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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 and shall be filled by the NoBo.

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			



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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)?



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	<i>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.</i>		
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? <i>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.</i>		
1.5	Are the tests covered by this evaluation performed impartially (there are no unacceptable commercial, financial or other pressures)? <i>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.</i>		
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 <ul style="list-style-type: none"> • 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 test lab only enters into contracts where test requirements are clear + can be met by the test lab's staff and		



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	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)? <i>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.</i>		
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?		



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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 + tampering + 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)?		