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Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology

Guide pour l'application de la Norme ISO/CEI 17025 à l'évaluation des Laboratoires d'Essais intervenant en métrologie légale



Organisation Internationale de Métrologie Légale

International Organization of Legal Metrology

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Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The main categories of OIML publications are:

- International Recommendations (OIML R), which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;
- International Documents (OIML D), which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;
- International Guides (OIML G), which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- International Basic Publications (OIML B), which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML publishes or participates in the publication of **Vocabularies** (**OIML V**) and periodically commissions legal metrology experts to write **Expert Reports** (**OIML E**). Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

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OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization's headquarters:

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Preamble

ISO/IEC 17025:2005 is an International Standard which sets out criteria for the competence of testing and calibration laboratories. The edition of ISO/IEC 17025 referred to in this Document is 2005.

This Standard is in particular used by National Accreditation Bodies for accrediting testing laboratories.

This Document aims to be a guide for assessing the conformity to ISO/IEC 17025 of any Testing Laboratories involved in legal metrology testing. These Testing Laboratories may be:

- subcontracting Testing Laboratories of a national type approval body;
- subcontracting Testing Laboratories of an inspection body, for instance responsible for initial verification;
- subcontracting Testing Laboratories of an OIML Issuing Authority when implementing the OIML Basic Certificate System and the OIML Mutual Acceptance Arrangement (MAA).

It may be used in particular:

- by peer assessment or accreditation assessors when interpreting ISO/IEC 17025 for legal metrology applications in connection with the OIML Mutual Acceptance Arrangement (MAA);
- for the assessment of testing laboratories conducted by an accreditation body in the field of legal metrology (e.g. an ILAC full Member, signatory of the ILAC MRA);
- on a voluntary basis for the implementation of ISO/IEC 17025 by national type approval bodies or by OIML Issuing Authorities for assessing their subcontracting testing laboratories.

This Document has been developed in cooperation with ILAC, which is a Liaison Institution, and the purpose is for it to be adopted by both organizations (OIML and ILAC). Consequently, this Document should be used for accreditation assessments and for peer assessments under the OIML MAA on the basis on the Memorandum of Understanding signed between ILAC and the OIML in November 2006.

This Document does not include the text of ISO/IEC 17025. Numbers and titles of ISO/IEC 17025 sections are associated with the relevant OIML Guidance which is identified with the letter "G" (for Guidance) followed by the relevant section number of ISO/IEC 17025. A chronological number is also given (e.g. G.1.1-1) which signifies "OIML Guidance number 1 to section 1.1 of ISO/IEC 17025". OIML Guidance to the introduction of ISO/IEC 17025 is identified by G.0-x.

Explanatory notes

Note 1 (Designation of the Testing Laboratories)

For the OIML Basic Certificate System and for the implementation of the MAA, the relevant Testing Laboratories are designated by the Issuing Authority (see 3.3.1 of OIML B 3 and 3.13 of OIML B 10-1).

Note 2 (Signature of a Declaration of Mutual Confidence)

The implementation of the OIML MAA for a category of measuring instruments leads to the signature of a Declaration of Mutual Confidence (DoMC). A DoMC is managed by an ad-hoc committee which is called the Committee on Participation Review (CPR).

Note 3 (Applicability)

When used in connection with the MAA, the guidance in this Document is applicable to any body that performs tests and examinations under the DoMC (e.g. Testing Laboratories) and Issuing Authorities when they carry out tests and/or examinations.

However, since tests performed by manufacturers are excluded from the scope of the MAA, manufacturers' testing laboratories are not addressed in this Document.

Note 4 (Issuing a Partial Test Report)

Test Reports may be Partial Test Reports when tests and examinations are subcontracted to several Testing Laboratories. In such a case, a Partial Test Report, which includes the results of the tests and examinations that it performs, is issued by each Testing Laboratory.

When tests and examinations are performed on the basis of an OIML Recommendation within the OIML Basic Certificate System or the OIML MAA, the Report is drawn up according to the Format specified in the relevant Recommendation for the applicable tests and examinations that the Testing Laboratory performs.

Note 5 (Contracts)

Each application for type approval should lead to one contract only, covering all the tests and examinations to be performed. This contract shall be signed by the Issuing Authority responsible for defining the tests and examinations to be performed.

On the basis of the contract signed by the Issuing Authority, each Testing Laboratory is responsible for reviewing the request considering the tests and examinations it performs. From the point of view of the Testing Laboratory, the "customer" should be the Issuing Authority. However in practice, the manufacturer requesting the type approval is the "customer" of each Testing Laboratory involved in the type approval tests and examinations.

Note 6 (Audits performed on Testing Laboratories)

The additional audits mentioned in 4.11.5 may be internal or external. The Issuing Authority may require such an additional audit.

According to the fifth bullet of 4.15.1, audits performed on Testing Laboratories by the external Issuing Authority or carried out under the MAA are considered as assessments by external bodies and their results should be taken into account in the management review of the Testing Laboratory.

Interpretation of Sections of ISO/IEC 17025:2005

General requirements for the competence of testing and calibration laboratories

Introduction

OIML Guidance to the Introduction (G.0-1 and G.0-2)

- G.0-1 For the purpose of this Document, the relevant terms and definitions given in chapter 3 apply.
- G.0-2 When used in connection with the MAA, the tests and examinations to be considered are those required by the relevant OIML Recommendation and, if applicable, the additional tests approved by the CPR. The acceptance of testing results between countries is formalized through the Declarations of Mutual Confidence (DoMCs).

1 Scope

1.1

OIML Guidance to Section 1.1 (G.1.1-1 to G.1.1-3)

- G.1.1-1 This Document is applicable to all testing laboratories involved in legal metrology and in particular to those involved in type evaluation tests and examinations.
- G.1.1-2 The Issuing Authority is responsible for the correct selection of the sample(s) to be tested and for the correct application of test methods related to tests and examinations to be carried out according to the appropriate requirements (see also G.5.4.1-1 and G.5.4.1-2).
- G.1.1-3 When used in connection with the MAA requirements, applicable testing methods are those defined in the relevant OIML Recommendation and in the DoMC for additional tests approved by the CPR.
- 1.2 No OIML Guidance
- 1.3 No OIML Guidance
- **1.4** No OIML Guidance
- 1.5 No OIML Guidance
- **1.6** No OIML Guidance

2 Normative references

OIML Guidance to Section 2 (G.2-1)

G.2-1 In addition:

- ISO/IEC Guide 99 International vocabulary of metrology Basic and general concepts and associated terms (VIM), 2007
- OIML G 1: Guide to the expression of uncertainty in measurement (GUM), 1995
- OIML B 3: OIML Certificate System for Measuring Instruments, 2003
- OIML B 10-1: Framework for a Mutual Acceptance Arrangement on OIML type evaluations (OIML MAA), 2004
- OIML B 10-2: Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations, 2004
- OIML D 14: Training and qualification of legal metrology personnel, 2004
- OIML D 19: Pattern evaluation and pattern approval, 1988

3 Terms and definitions

OIML Guidance to Section 3 (G.3-1)

G.3-1 In addition:

Type evaluation (VIML 2.5)

Systematic examination and testing of the performance of one or more specimens of an identified type of measuring instrument against documented requirements, the results of which are contained in the evaluation report, in order to determine whether the type may be approved.

Examination (OIML B 3)

Visual inspection of an instrument or device and relevant documentation to ensure that some specified requirements are met.

Conformity (OIML B 3)

Fulfilment by a measuring instrument type of metrological and technical requirements as specified in the relevant Recommendation.

Issuing Authority

Any Authority that is responsible for issuing Certificates within a specified system of legal metrology control.

Note: In the case of type evaluation, an Issuing Authority may be a national Type Approval Body and/or, for the implementation of the OIML Mutual Acceptance Arrangement (MAA), an OIML Issuing Authority according to 2.13 of OIML B 3 and 3.11 of B 10-1.

Testing Laboratory

Any necessary specialized laboratory or laboratories designated by the Issuing Authority to carry out examination and testing of a sample or samples of a measuring instrument submitted for evaluation, with the Issuing Authority assuming responsibility for the evaluation report.

Note 1: When used in connection with the MAA, a Testing Laboratory may be part of the organization containing the OIML Issuing Authority, or a subcontracting Testing Laboratory of the OIML Issuing Authority.

Note 2: A Testing Laboratory may be a subcontractor of an inspection body.

Evaluation Report

Report, issued by an Issuing Authority, that includes the Partial Test Reports or the Test Report and assesses the conformity of the measuring instrument to the stated requirements.

OIML Evaluation Report

Report, drawn up according to the Test Report Format specified in the relevant Recommendation that includes the Partial Test Reports or the Test Report and assesses the conformity of the type of measuring instrument to all the requirements in the relevant OIML Recommendation

- Note 1: The OIML Evaluation Report is issued by the OIML Issuing Authority.
- Note 2: The OIML Evaluation Report is currently designated as "Test Report" in OIML B 3 and as "OIML Test Report" in OIML B 10-1.

Additional Test Report

Report issued by a Testing Laboratory that includes the results of additional tests and examinations, additional to those in the OIML Recommendation, accepted in the scope of a Declaration of Mutual Confidence (DoMC).

- Note 1: Additional Test Reports are issued under the Mutual Acceptance Arrangement (MAA).
- Note 2: In the event that several Testing Laboratories are involved in the additional tests and examinations, each Testing Laboratory issues an Additional Test Report corresponding to those tests and examinations it performs.

Complete Evaluation Report

Report, issued by the OIML Issuing Authority, composed of the OIML Evaluation Report and of the Additional Test Reports.

Note: Complete Evaluation Reports are issued under the Mutual Acceptance Arrangement (MAA).

Abbreviations:

MAA: Mutual Acceptance ArrangementDoMC: Declaration of Mutual ConfidenceCPR: Committee on Participation Review

- 4 Management requirements
- 4.1 Organization
- **4.1.1** No OIML Guidance
- **4.1.2** No OIML Guidance
- 4.1.3

OIML Guidance to Section 4.1.3 (G.4.1.3-1)

G.4.1.3-1 In particular, this requirement applies when Testing Laboratory personnel use a manufacturer's test facility to perform type approval tests and/or examinations.

4.1.4

OIML Guidance to Section 4.1.4 (G.4.1.4-1)

G.4.1.4-1 In the event that the Testing Laboratory provides consultancy services for the design of measuring instruments, people responsible for testing shall not be under the responsibility of managerial personnel in charge of giving such advice.

If the operators are in charge of both tests and of advising on the design of measuring instruments, they shall not take part in the tests of those measuring instruments for which they provided advice.

4.1.5

OIML Guidance to Section 4.1.5 d) (G.4.1.5-1)

- G.4.1.5-1 Such policies shall be evaluated even if they have been evaluated prior to the accreditation or peer assessment process by Issuing Authorities when they designate Testing Laboratories.
- **4.1.6** No OIML Guidance
- 4.2 Management system
- **4.2.1** No OIML Guidance
- 4.2.2

OIML Guidance to Section 4.2.2 b) (G.4.2.2-1)

- G.4.2.1-1 In addition, the laboratory's policy shall include a statement that the testing process is in accordance with the instructions of the Issuing Authority. When used in connection with the MAA, the statement shall specify that the testing process is in accordance with the relevant test procedures listed by the CPR.
- **4.2.3** No OIML Guidance

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4.2.5

OIML Guidance to Section 4.2.5 (G.4.2.5-1)

- G.4.2.5-1 In the case of OIML Type Evaluations, technical procedures shall be in accordance with those defined in the relevant OIML Recommendation and, when used in connection with the MAA, with those defined in the DoMC for additional tests validated by the CPR.
- **4.2.6** No OIML Guidance
- **4.2.7** No OIML Guidance
- 4.3 Document control
- 4.3.1 General

OIML Guidance to Section 4.3.1 (G.4.3.1-1)

- G.4.3.1-1 The Testing Laboratory shall maintain updated documentation on the legal and contractual requirements applicable to its activity of evaluation testing and examinations (e.g. OIML Recommendations).
- 4.3.2 Document approval and issue
- **4.3.2.1** No OIML Guidance
- **4.3.2.2** No OIML Guidance
- **4.3.2.3** No OIML Guidance
- 4.3.3 Document changes
- **4.3.3.1** No OIML Guidance
- **4.3.3.2** No OIML Guidance
- **4.3.3.3** No OIML Guidance
- **4.3.3.4** No OIML Guidance
- 4.4 Review of request, tender or contract
- 4.4.1

OIML Guidance to Section 4.4.1 (G.4.4.1-1 to G.4.4.1-4)

G.4.4.1-1 In the event that, due to the organization of legal metrology in a country, a contract between each Testing Laboratory and the manufacturer is necessary, each contract shall be authorized by the Issuing Authority before being signed (see also Explanatory Note 5).

- G.4.4.1-2 This Guidance is related to 4.4.1 a). In the case of OIML Type Evaluation, examination and test procedures defined in the relevant OIML Recommendation shall be used and understood. When used in connection with the MAA, additional national testing requirements approved by the CPR shall also be used and understood.
- G.4.4.1-3 This Guidance is related to 4.4.1 b). This requirement also applies if any test is performed by the Testing Laboratory which uses the manufacturer's test facilities.
- G.4.4.1-4 This Guidance is related to 4.4.1 c). In the case of OIML Type Evaluation, the requirements to be met are those defined in the relevant OIML Recommendation and, when used in connection with the MAA, those defined in the additional requirements according to the scope of the DoMC.
- **4.4.2** No OIML Guidance
- 4.4.3

OIML Guidance to Section 4.4.3 (G.4.4.3-1)

G.4.4.3-1 Not applicable (see 4.5.1)

4.4.4

OIML Guidance to Section 4.4.4 (G.4.4.4-1)

G.4.4.4-1 Any deviation from the contract shall be submitted to the Issuing Authority for approval.

4.5 Subcontracting of tests and calibrations

4.5.1

OIML Guidance to Section 4.5.1 (G.4.5.1-1 and G.4.5.1-2)

- G.4.5.1-1 Testing Laboratories involved in the type evaluation process are designated by the Issuing Authority.
- G.4.5.1-2 A Testing Laboratory is not authorized to subcontract any test or examination without the prior approval of the Issuing Authority.

4.5.2

OIML Guidance to Section 4.5.2 (G.4.5.2-1)

G.4.5.2-1 Not applicable (see 4.5.1)

4.5.3

OIML Guidance to Section 4.5.3 (G.4.5.3-1)

G.4.5.3-1 Not applicable (see 4.5.1)

4.5.4

OIML Guidance to Section 4.5.4 (G.4.5.4-1)

- G.4.5.4-1 Not applicable (see 4.5.1). This responsibility belongs to the Issuing Authority when designating Testing Laboratories.
- 4.6 Purchasing services and supplies
- **4.6.1** No OIML Guidance
- 4.6.2

OIML Guidance to Section 4.6.2 (G.4.6.2-1)

- G.4.6.2-1 See 5.4.5.1 and 5.4.6.
- **4.6.3** No OIML Guidance
- **4.6.4** No OIML Guidance
- 4.7 Service to the customer
- 4.7.1

OIML Guidance to Section 4.7.1 (G.4.7.1-1)

- G.4.7.1-1 Any clarification of the customer's request is under the responsibility of the Issuing Authority. See also 5.4.1.
- **4.7.2** No OIML Guidance
- 4.8 Complaints

No OIML Guidance

- 4.9 Control of nonconforming testing and/or calibration work
- 4.9.1

OIML Guidance to Section 4.9.1 (G.4.9.1-1)

- G.4.9.1-1 For a decision to be taken, the Issuing Authority shall be informed of any non-conformance of test and examination results with the applicable requirements and of any non-conformance in the implementation of test and examination procedures.
- **4.9.2** No OIML Guidance

4.10 Improvement

No OIML Guidance

4.11 Corrective action

4.11.1

OIML Guidance to Section 4.11.1 (G.4.11.1-1)

- G.4.11.1-1 This procedure shall include cooperation with the Issuing Authority in the event of non-conforming work.
- **4.11.2** No OIML Guidance
- **4.11.3** No OIML Guidance
- **4.11.4** No OIML Guidance
- **4.11.5** No OIML Guidance See Explanatory Note 6.
- 4.12 Preventive action
- **4.12.1** No OIML Guidance
- **4.12.2** No OIML Guidance
- 4.13 Control of records
- **4.13.1** General
- **4.13.1.1** No OIML Guidance
- 4.13.1.2

OIML Guidance to Section 4.13.1.2 (G.4.13.1.2-1)

- G.4.13.1.2-1 In the case of OIML Type Evaluation, technical records related to type evaluation tests and examinations shall be maintained available as long as the OIML Certificate remains registered.
- **4.13.1.3** No OIML Guidance
- **4.13.1.4** No OIML Guidance
- 4.13.2 Technical records
- **4.13.2.1** No OIML Guidance
- **4.13.2.2** No OIML Guidance

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- 4.14 Internal audits
- **4.14.1** No OIML Guidance
- **4.14.2** No OIML Guidance
- **4.14.3** No OIML Guidance
- **4.14.4** No OIML Guidance
- 4.15 Management reviews
- **4.15.1** No OIML Guidance See Explanatory Note 6.
- 4.15.2

OIML Guidance to Section 4.15.2 (G.4.15.2-1)

G.4.15.2-1 The findings from management reviews related to management requirements and metrological and technical requirements shall be submitted to the Issuing Authority.

- 5 Technical requirements
- 5.1 General
- 5.1.1

OIML Guidance to Section 5.1.1 (G.5.1.1-1)

- G.5.1.1-1 These factors shall also include control of the configuration of the measuring instrument during the various tests.
- **5.1.2** No OIML Guidance
- 5.2 Personnel
- 5.2.1

OIML Guidance to Section 5.2.1 (G.5.2.1-1 and 5.2.1-2)

G.5.2.1-1 Training methods for the personnel should include participation in international work in the field of legal metrology (e.g. development of OIML Publications).

This includes work for the OIML performed at the national level.

- G.5.2.1-2 This Guidance is related to Note 2. In particular, this note is applicable to the personnel responsible for:
 - the examinations (which are part of the evaluation);
 - the statement of the compliance of test results with the requirements (see 5.10.5).

5.2.2

OIML Guidance to Section 5.2.2 (G.5.2.2-1)

- G.5.2.2-1 The personnel in charge of type evaluation testing and examinations shall be aware of the following:
 - relevant OIML Publications;
 - these guidelines;
 - applicable Declarations of Mutual Confidence.

OIML Publication D 14 gives guidelines for the training of legal metrology personnel.

- **5.2.3** No OIML Guidance
- **5.2.4** No OIML Guidance

5.2.5

OIML Guidance to Section 5.2.5 (G.5.2.5-1 to G.5.2.5-3)

- G.5.2.5-1 Competence of the personnel responsible for tests and examinations shall be evaluated and validated by the Testing Laboratory's technical management (see 4.1.5 f)).
- G.5.2.5-2 A list shall be kept up to date, indicating for each category of measuring instrument:
 - personnel qualified to carry out tests and/or examinations;
 - personnel qualified to give an opinion on the statement of compliance/non-compliance of the results with requirements;
 - personnel responsible for training;
 - managerial personnel responsible for validating technical work.
- G.5.2.5-3 Personnel in the process of being qualified shall only be in charge of simple or well described activities. They can participate in, but not be responsible for, testing.

5.3 Accommodation and environmental conditions

5.3.1

OIML Guidance to Section 5.3.1 - second paragraph (G.5.3.1-1)

G.5.3.1-1 Standards and test equipment shall be used in the same environmental conditions as those of their calibration. Otherwise, appropriate corrections or new uncertainty calculations shall be performed. In the event that this is not possible, test results shall not be valid. The policy related to this matter shall be documented.

5.3.2

OIML Guidance to Section 5.3.2 (G.5.3.2-1)

- G.5.3.2-1 In particular, information related to rain, wind, etc. shall be recorded in the case of tests performed outdoors.
- **5.3.3** No OIML Guidance
- **5.3.4** No OIML Guidance
- **5.3.5** No OIML Guidance
- 5.4 Test and calibration methods and method validation

5.4.1 General

OIML Guidance to Section 5.4.1 (G.5.4.1-1 to G.5.4.1-4)

- G.5.4.1-1 These procedures shall ensure that the Testing Laboratory verifies that:
 - the sample(s) to be examined and/or tested are those validated by the Issuing Authority;
 - the configuration of the sample(s) to be examined and/or tested is the original one.
- G.5.4.1-2 Selection of instruments to be tested amongst a family is considered as sampling.
- G.5.4.1-3 These procedures shall indicate how adjustments and modifications of the sample(s) authorized by the Issuing Authority are taken into account during tests and examinations.
- G.5.4.1.4 These requirements also apply when tests are performed using the manufacturer's test facilities.

5.4.2 Selection of methods

OIML Guidance to Section 5.4.2 (G.5.4.2-1)

G.5.4.2-1 See 4.2.2.

In the case of OIML Type Evaluation, the test and examination procedures shall conform to those defined in the applicable OIML Recommendation and, if applicable, to the additional procedures included in the DoMC when used in connection with the MAA.

5.4.3 Laboratory-developed methods

OIML Guidance to Section 5.4.3 (G.5.4.3-1)

G.5.4.3-1 Not applicable (see 5.4.2).

5.4.4 Non standardized methods

OIML Guidance to Section 5.4.4 (G.5.4.4-1)

G.5.4.4-1 Not applicable (see 5.4.2). Test methods approved by the CPR are considered as standardized methods.

5.4.5 Validation of methods

5.4.5.1

OIML Guidance to Section 5.4.5.1 (G.5.4.5.1-1)

G.5.4.5.1-1 Validation of methods is under the responsibility of higher authorities (e.g. the CIML for OIML Recommendations and the CPR for additional tests).

5.4.5.2

OIML Guidance to Section 5.4.5.2 (G.5.4.5.2-1)

G.5.4.5.2-1 Not applicable (see 5.4.2 and 5.4.5.1).

5.4.5.3

OIML Guidance to Section 5.4.5.3 (G.5.4.5.3-1)

G.5.4.5.3-1 See 5.4.5.1.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 No OIML Guidance

5.4.6.2

OIML Guidance to Section 5.4.6.2 (G.5.4.6.2-1 to G.5.4.6.2-3)

- G.5.4.6.2-1 Testing laboratories shall include in these procedures the confirmation of the acceptable uncertainties of measurement with the requirements of the relevant OIML Recommendation.
- G.5.4.6.2-2 If the laboratory is accredited by a recognized accreditation body, the adequacy of the uncertainty calculations is deemed to be demonstrated if the scope of the accreditation includes type approval testing according to the appropriate requirements. This implies that the laboratory is capable of performing uncertainty calculations and ensuring the

appropriate ratio of uncertainty to maximum permissible error is met. In that case, according to OIML B 10-1, no peer assessment is required.

- G.5.4.6.2-3 If the relevant OIML Recommendation does not address how to take measurement uncertainty into account, the Issuing Authority is responsible for providing guidance to the Testing Laboratory.
- **5.4.6.3** No OIML Guidance
- 5.4.7 Control of data
- **5.4.7.1** No OIML Guidance
- **5.4.7.2** No OIML Guidance
- 5.5 Equipment
- 5.5.1

OIML Guidance to Section 5.5.1 (G.5.5.1-1)

G.5.5.1-1 The last sentence of the requirement applies when the Testing Laboratory uses the manufacturer's test facilities.

5.5.2

OIML Guidance to Section 5.5.2 (G.5.5.2-1)

- G.5.5.2-1 See 5.4.6.2.
- **5.5.3** No OIML Guidance
- **5.5.4** No OIML Guidance
- **5.5.5** No OIML Guidance
- **5.5.6** No OIML Guidance
- **5.5.7** No OIML Guidance
- **5.5.8** No OIML Guidance

5.5.9

OIML Guidance to Section 5.5.9 (G.5.5.9-1)

- G.5.5.9-1 Also applies when the Testing Laboratory uses the manufacturer's test facilities.
- **5.5.10** No OIML Guidance
- **5.5.11** No OIML Guidance

5.5	1	2.	No	OIV	AT (Guid	dance
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- 5.6 Measurement traceability
- 5.6.1 General
- **5.6.2** Specific requirements
- 5.6.2.1 Calibration
- 5.6.2.1.1

OIML Guidance to Section 5.6.2.1.1 (G.6.2.1.1-1)

- G.6.2.1.1-1 5.6.2.1 of ISO/IEC 17025 is related to calibration laboratories, which are not the object of this Document. See 5.6.2.2.1.
- 5.6.2.1.2 No OIML Guidance
- **5.6.2.2** Testing
- 5.6.2.2.1

OIML Guidance to Section 5.6.2.2.1 (G.5.6.2.2.1-1 to G.5.6.2.2.1-3)

- G.5.6.2.2.1-1 Any external calibration shall be performed by an accredited calibration laboratory or by a national metrology institute. When used in connection with the MAA, in the case of an accredited calibration laboratory, the respective accreditation body shall be a full Member of ILAC.
- G.5.6.2.2.1-2 In the event that the acceptance criteria are either stability, or based on a fault determination, traceability may not be necessary for all the quantities concerned. In such a case the repeatability of the test equipment is much more important than the accuracy of the indicated value, since the requirement is based on differences in errors. To this end, a calibration certificate from an accredited laboratory or from a national metrology institute may not be necessary.
- G.5.6.2.2.1-3 In the event that the uncertainty calculation demonstrates that the contribution of some components is not significant, an external calibration by an accredited laboratory or by a national metrology institute may not be required.
- 5.6.2.2.2 No OIML Guidance
- 5.6.3 Reference standards and reference materials
- **5.6.3.1** Reference standards

No OIML Guidance

5.6.3.2 Reference materials

No OIML Guidance

5.6.3.3 Intermediate checks

No OIML Guidance

5.6.3.4 Transport and storage

No OIML Guidance

5.7 Sampling

5.7.1

OIML Guidance to Section 5.7.1 (G.5.7.1-1 and G.5.7.1-2)

G.5.7.1-1 In general there is no sampling in the sense of ISO/IEC 17025 in the type evaluation process in legal metrology.

Nevertheless, OIML Recommendations may require a selection of samples amongst a family of measuring instruments.

Such a selection is done under the responsibility of the Issuing Authority.

G.5.7.1-2 If sampling is requested for legal metrological control, then this is under the responsibility of the Issuing Authority.

5.7.2

OIML Guidance to Section 5.7.2 (G.5.7.2-1)

- G.7.2-1 Not applicable (see 5.7.1)
- **5.7.3** No OIML Guidance

5.8 Handling of test and calibration items

5.8.1

OIML Guidance to Section 5.8.1 (G.5.8.1-1)

G.5.8.1-1 Provisions shall be made to ensure that the sample to be examined and/or tested is the one validated by the Issuing Authority.

Such provisions may consist in receiving the sample from the Issuing Authority or in receiving it in sealed packaging. In this case, the Testing Laboratory shall register the seal position when the packaging is received.

5.8.2 No OIML Guidance

5.8.3

OIML Guidance to Section 5.8.3 (G.5.8.3-1)

G.5.8.3-1 The procedures of the Testing Laboratory shall indicate that the Issuing Authority is consulted in such a case.

5.8.4

OIML Guidance to Section 5.8.4 (G.5.8.4-1)

- G.5.8.4-1 Provisions for transportation, conditioning, handling, and installation for testing shall be determined with the agreement of the Issuing Authority.
- 5.9 Assuring the quality of test and calibration results

5.9.1

OIML Guidance to Section 5.9.1 (G.5.9.1-1)

- G.5.9.1-1 Such procedures shall include participation in interlaboratory comparisons organized by the BIML, if necessary.
- **5.9.2** No OIML Guidance
- 5.10 Reporting the results
- **5.10.1** General

OIML Guidance to Section 5.10.1 (G.5.10.1-1 to G.5.10.1-4)

G.5.10.1-1 Each Testing Laboratory issues a Partial Test Report and/or an Additional Test Report which corresponds to the tests and examinations it performed.

Relevant parts of the Test Report Format given in the applicable OIML Recommendation shall be used by each Testing Laboratory for issuing the Test Report, if applicable.

The results of examinations in the Partial Test Report shall be provided using the applicable checklists in the relevant OIML Recommendation.

- G.5.10.1-2 The test report (Test Report, Partial Test Report, Additional Test Report) shall indicate:
 - whether the tests carried out were split up between two or more samples;
 - whether adjustments and/or modifications were performed during tests;
 - the reason why some tests were not performed, in particular in the case of a complementary Type Approval process.
- G.5.10.1-3 When used in connection with the MAA, the Test Report Format specified in the applicable procedures approved by the CPR shall be used to issue the Additional Test Report(s).

G.5.10.1-4 The third paragraph is not applicable.

5.10.2 Test reports and calibration certificates

OIML Guidance to Section 5.10.2 (G.5.10.2-1 and G.5.10.2-2)

- G.5.10.2-1 This Guidance is related to 5.10.2 f). The description shall include where tests were split up between several samples.
- G.5.10.2-2 This Guidance is related to 5.10.2 h). Testing Laboratories shall indicate the verifications performed to ensure that the tested and/or examined samples are those validated by the Issuing Authority.

5.10.3 Test reports

5.10.3.1

OIML Guidance to Section 5.10.3.1 (G.5.10.3.1-1 to G.5.10.3.1-3)

- G.5.10.3.1-1 This Guidance is related to 5.10.3.1 b). The Test Report Format of the relevant OIML Recommendation specifies the way in which the interpretations shall be indicated (pass/fail).
- G.5.10.3.1-2 This Guidance is related to 5.10.3.1 c). The information may be provided in the form of a ratio between the expanded uncertainty and the maximum permissible error. The coverage factor shall always be indicated.
- G.5.10.3.1-3 This Guidance is related to 5.10.3.3 e). For example, information related to the environmental conditions under which the tests were performed outdoors (see 5.3.2).
- **5.10.3.2** No OIML Guidance

5.10.4 Calibration certificates

5.10.4.1

OIML Guidance to Section 5.10.4.1 (G.5.10.4.1-1)

G.5.10.4.1-1 Not applicable

5.10.4.2

OIML Guidance to Section 5.10.4.2 (G.5.10.4.2-1)

G.5.10.4.2-1 Not applicable

5.10.4.3

OIML Guidance to Section 5.10.4.3 (G.5.10.4.3-1)

G.5.10.4.3-1 Not applicable

5.10.4.4

OIML Guidance to Section 5.10.4.4 (G.5.10.4.4-1)

G.5.10.4.4-1 Not applicable

5.10.5 Opinions and interpretations

OIML Guidance to Section 5.10.5 (G.5.10.5-1)

G.5.10.5-1 See 5.10.3.1 d)

Opinions and interpretations related to the conformance of the instrument with the relevant OIML Recommendation are not allowed in Test Reports (Partial Test Report, Additional Test Report).

The Issuing Authority is solely responsible for drawing conclusions on the conformance of the instrument with the relevant requirements (e.g. OIML Recommendation).

5.10.6 Testing and calibration results obtained from sub-contractors

OIML Guidance to Section 5.10.6 (G.5.10.6-1)

G.5.10.6-1 In the event of tests and/or examinations performed by several Testing Laboratories, each Testing Laboratory shall establish a Test Report (Partial Test Report, Additional Test Report). Each Test Report is then a part of the Evaluation Report or OIML Evaluation Report and, if applicable, Complete Evaluation Report.

5.10.7 Electronic transmission of results

No OIML Guidance

5.10.8 Format of reports and certificates

OIML Guidance to Section 5.10.8 (G.5.10.8-1)

G.5.10.8-1 See 5.10.1.

5.10.9 Amendments to test reports and calibration certificates

No OIML Guidance