First Committee Draft (1CD)

Project:	Revision of OIML Document (OIML D 30:2008)
Title:	Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology
Date:	12 June 2019
Document number:	OIML-CS_SC7_P1_N004 (marked)
Supersedes document:	OIML-CS_SC7_P1_N002
Project Group:	OIML-CS/SC 7/p 1
Convenership:	OIML-CS Management Committee
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Circulated to P- and O-members and liaison international bodies and external organizations for:

☐ Discussion at (date and place of meeting):

☒ Comments by: **12 September 2019**

☐ Vote (P-members only) and comments by:

INTERNATIONAL DOCUMENT

OIML D 30

Edition 201x (E)

20190612 FIRST COMMITTEE DRAFT (1 CD)

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/IEC 17025 à 'lévaluation des Laboratoires d'Essais intervenant en métrologie légale

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Organisation Internationale de Métrologie Légale

International Organization of Legal Metrology

Contents

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.

This publication - reference OIML D 30, Edition 201x (E) - was developed by Project Group 1 in the OIML Certification System (OIML-CS) Management Committee (OIML-CS/SC 7). It was approved for final publication by the International Committee of Legal Metrology at its xx meeting in 201x. It replaces the previous edition dated 2008.

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 17025:2017 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 2017.

This Document gives guidance and interpretations relating to the application of ISO/IEC 17025 to the assessment of any Testing Laboratories involved in legal metrology testing. These Testing Laboratories may be:

- internal or third-party (subcontracting) Testing Laboratories of a national issuing authority;
- internal or third-party (subcontracting) Testing Laboratories of an inspection body, for instance those responsible for initial verification;
- internal, third-party (subcontracting) or Manufacturer Testing Laboratories (MTLs) of an OIML Issuing Authority when implementing the OIML Certification System (OIML-CS).

Note: In the OIML-CS the terms “Test Laboratory” and “Test Laboratories” are used in place of the terms “Testing Laboratory” and “Testing Laboratories”.

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-CS;
- 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 issuing authorities or by OIML Issuing Authorities for assessing their third-party (subcontracting) or manufacturer testing laboratories.

This Document has been developed in cooperation with the International Laboratory Accreditation Cooperation (ILAC), which is an Organization in Liaison with the OIML. Consequently, this Document should be used for accreditation assessments and any appropriate evaluation of testing laboratories on the basis on the Memorandum of Understanding signed between ILAC, the IAF and the OIML in October 2018.

This Document does not include the text of ISO/IEC 17025. Numbers and titles of ISO/IEC 17025 clauses and subclauses are associated with the relevant OIML Guidance which is identified with the letter “G” (for Guidance) followed by the relevant subclause 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 and approval of Testing Laboratories)

Under the OIML-CS, the relevant Testing Laboratories are those that have been designated by an OIML Issuing Authority and approved by the OIML-CS Management Committee.

Note 2 (Applicability)

When used in connection with the OIML-CS, the guidance in this Document is applicable to any testing laboratory that has been approved to perform testing and examinations, including internal testing laboratories of the OIML Issuing Authority, third-party (subcontracting) testing laboratories and manufacturer testing laboratories (MTLs).

In addition, the guidance in this Document is applicable to any testing laboratory that may wish to apply to be approved under the OIML-CS.

Note 3 (Issuing a partial test report)

Test reports may be partial test reports when several Testing Laboratories perform tests and examinations. In such a case, each Testing Laboratory issues a partial test report, which includes the results of the tests and examinations that it performs.

When tests and examinations are performed on the basis of an OIML Recommendation within the OIML-CS, the test report is drawn up according to the format specified in the relevant OIML Recommendation for the applicable tests and examinations that the Testing Laboratory performs.

~~*Note 4 (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 OIML Issuing Authority responsible for defining the tests and examinations to be performed.~~

~~On the basis of the contract signed by the OIML 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 OIML 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.~~

Interpretation of Sections of ISO/IEC 17025:2017

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 OIML-CS, the tests and examinations to be considered are those required by the relevant OIML Recommendation. The acceptance of test results between countries is formalized through the Declarations signed by the OIML Issuing Authorities, Utilizers and Associates.

1 Scope

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

G.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.

2 Normative References

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

G.2-1 In addition:

- OIML V 1: International vocabulary of terms in legal metrology (VIML) (bilingual French-English), 2013
- OIML G 1-100: Evaluation of measurement data - Guide to the expression of uncertainty in measurement, 2008
- OIML G 1-101: Evaluation of measurement data – Supplement 1 to the “Guide to the expression of uncertainty in measurement” Propagation of distributions using a Monte Carlo method, 2008
- OIML G 1-102: Evaluation of measurement data - Supplement 2 to the “Guide to the expression of uncertainty in measurement” Extension to any number of output quantities, 2011
- OIML G 1-104: Evaluation of measurement data – An introduction to the “Guide to the expression of uncertainty in measurement” and related documents, 2009
- OIML G 1-106: Evaluation of measurement data – The role of measurement uncertainty in conformity assessment, 2012
- OIML B 18: Framework for the OIML Certification System (OIML-CS), 2018
- 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 and G.3-2)

G.3-1 For the purpose of this Document, the relevant definitions given in ISO/IEC 17000:2004, in the VIM, and in the VIML apply. General definitions related to quality are given in ISO 9000:2015. Where different definitions are given in ISO 9000:2015, the definitions in ISO/IEC 17000:2004, in the VIM, and in the VIML are preferred.

G.3-2 In addition:

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

Note 1: Additional test reports are issued under the OIML-CS.

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 the tests and examinations it performs.

~~**type (pattern) evaluation (VIML, 2.04)**~~

~~conformity assessment procedure on one or more specimens of an identified type (pattern) of measuring instruments which results in an evaluation report and / or an evaluation certificate~~

~~*Note 1:* "Pattern" is used in legal metrology with the same meaning as "type".~~

~~*Note 2*: for the purposes of the OIML-CS, "evaluation report" should be read as "OIML type evaluation report".~~

Declaration (OIML B 18, 3.10)

Document that is signed by OIML Issuing authorities, Utilizers and associates accepting to abide by the rules of the OIML-CS. The scope of certification and/or acceptance of OIML type evaluation reports issued with an OIML Certificate under Scheme A or B are detailed in separate annexes which form part of the Declaration

OIML Certificate (OIML B 18, 3.25)

Type Examination certificate, issued by an OIML Issuing authority, attesting the conformity of a type of a measuring instrument or module with the relevant requirements of an OIML Recommendation at the time of testing and evaluation

OIML Certification System (OIML-CS) (OIML B 18, 3.26)

system for issuing, registering and using OIML Certificates and associated OIML type evaluation reports for types of measuring instruments (including families of measuring instruments, modules or families of modules), based on the requirements in the relevant OIML Recommendation(s)

OIML Issuing Authority (OIML B 18, 3.27)

certification body from an OIML Member State issuing OIML Certificates and associated OIML type evaluation reports in accordance with Scheme A or Scheme B

~~**Test Laboratory (OIML B 18, 3.38)**~~

~~laboratory performing certain or all tests on a type of measuring instrument. A Test Laboratory is designated by an OIML Issuing Authority and accepted by the OIML CS Management Committee~~

~~*Note 1:* A Test Laboratory may be an internal Test Laboratory of an OIML Issuing Authority, a third-party Test Laboratory or a Manufacturer's Test Laboratory (MTL).~~

~~*Note 2:* The OIML Issuing Authority, and not the Test Laboratory, is responsible for issuing the OIML type evaluation report.~~

~~*Note 3:* In the OIML-CS the term "Test Laboratory" is used instead of the term "Testing Laboratory".~~

OIML test report (OIML B 18, 3.29)

report issued by a test laboratory that includes the results of the tests and examinations it carried out on the basis of the relevant OIML Recommendation during OIML type evaluation on identified sample(s) of given type of measuring instrument or module

Note: Unless the OIML Recommendation states otherwise, several test reports may be issued if several test laboratories are involved in covering all of the tests and examinations specified in the relevant OIML Recommendation.

OIML type evaluation (OIML B 18, 3.30)

type evaluation conducted on the basis of the relevant OIML Recommendation(s)

OIML type evaluation report (OIML B 18, 3.31)

report issued by an OIML Issuing Authority participating in the OIML-CS that assesses the conformity of the type of a measuring instrument or module to the requirements in the relevant OIML Recommendation and, if applicable, to the additional national requirements specified in the Declaration

Test Laboratory (OIML B 18, 3.38)

laboratory performing certain or all tests on a type of measuring instrument. A Test Laboratory is designated by an OIML Issuing Authority and accepted by the OIML-CS Management Committee

Note 1: A Test Laboratory may be an internal Test Laboratory of an OIML Issuing Authority, a third-party Test Laboratory or a Manufacturer's Test Laboratory (MTL).

Note 2: The OIML Issuing Authority, and not the Test Laboratory, is responsible for issuing the OIML type evaluation report.

Note 3: In the OIML-CS the term "Test Laboratory" is used instead of the term "Testing Laboratory".

~~**Declaration (OIML B 18, 3.10)**~~

~~Document that is signed by OIML Issuing authorities, Utilizers and associates accepting to abide by the rules of the OIML-CS. The scope of certification and/or acceptance of OIML type evaluation reports issued with an OIML Certificate under Scheme A or B are detailed in separate annexes which form part of the Declaration~~

~~**OIML Certificate (OIML B 18, 3.25)**~~

~~Type Examination certificate, issued by an OIML Issuing authority, attesting the conformity of a type of a measuring instrument or module with the relevant requirements of an OIML Recommendation at the time of testing and evaluation~~

type (pattern) evaluation (VIML, 2.04)

conformity assessment procedure on one or more specimens of an identified type (pattern) of measuring instruments which results in an evaluation report and / or an evaluation certificate

Note 1: "Pattern" is used in legal metrology with the same meaning as "type".

Note 2: for the purposes of the OIML-CS, "evaluation report" should be read as "OIML type evaluation report".

~~**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~~

~~*Note 1*: Additional test reports are issued under the OIML-CS.~~

~~*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 the tests and examinations it performs.~~

4 General requirements

4.1 Impartiality

4.1.1 No OIML Guidance

4.1.2 No OIML Guidance

4.1.3 No OIML Guidance

4.1.4 No OIML Guidance

4.1.5 ~~No OIML Guidance~~

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

G.4.1.5-1 For the purposes of the OIML-CS, when a risk to impartiality is identified regarding any process that may influence an OIML Certificate, the OIML Issuing Authority shall be notified.

4.2 Confidentiality

4.2.1 No OIML Guidance

4.2.2 No OIML Guidance

~~**OIML Guidance to Section 4.2.2 (G.4.2.2-1)**~~

~~G.4.2.2-1 Where the testing laboratory is required to release confidential information the OIML Issuing Authority shall be notified.~~

4.2.3 No OIML Guidance

4.2.4 No OIML Guidance

5 Structural requirements

5.1 No OIML Guidance

5.2 No OIML Guidance

5.3 No OIML Guidance

~~**OIML Guidance to Section 5.3 (G.5.3-1)**~~

~~G.5.3-1 Under the OIML-CS the range of testing activities will be documented in the Declaration of the OIML Issuing Authority.~~

5.4

OIML Guidance to Section 5.4 (G.5.4-1)

G.5.4-1 Under the OIML-CS, the expression “customer’s facility” includes a manufacturer’s testing laboratory where the personnel of the testing laboratory conduct tests. ~~In particular, this requirement applies when testing laboratory personnel use a manufacturer’s test facility to perform type approval tests and/or examinations.~~

5.5

OIML Guidance to Section 5.5 (G.5.5-1)

G.5.5-1 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.

5.6 No OIML Guidance

5.7 No OIML Guidance

6 Resource requirements

6.1 General

No OIML Guidance

6.2 Personnel

6.2.1 No OIML Guidance

6.2.2 No OIML Guidance

~~**OIML Guidance to Section 6.2.2 (G.6.2.2-1)**~~

~~G.6.2.2-1 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.~~

6.2.3

OIML Guidance to Section 6.2.3 (G.6.2.3-1 and 6.2.3-2)

G.6.2.3-1 The personnel in charge of type evaluation testing and examinations shall be aware of the following:

- relevant OIML Publications;
- these guidelines;
- applicable OIML-CS Procedural Documents (only for activities associated with the OIML-CS).

G.6.2.3-2 OIML Publication D 14 gives guidelines for the training of legal metrology personnel.

6.2.4 No OIML Guidance

6.2.5 ~~No OIML Guidance~~

OIML Guidance to Section 6.2.5 (G.6.2.5-1 and 6.2.5-2)

G.6.2.5-1 This Guidance is related to 6.2.5 c). Training methods for the personnel should include participation in international work in the field of legal metrology (e.g. development of OIML Publications). This may include participating in national committees supporting the development of OIML publications.

G.6.2.6~~5~~-1~~1~~2 This Guidance is related to 6.2.5 e).Competence of the personnel responsible for tests and examinations shall be evaluated and validated by the technical management of the testing laboratory.

6.2.6

OIML Guidance to Section 6.2.6 (G.6.2.6-1 ~~to~~and G.6.2.6-~~3~~2)

~~G.6.2.6-1 Competence of the personnel responsible for tests and examinations shall be evaluated and validated by the technical management of the testing laboratory.~~

G.6.2.6-~~2~~1 Documented information shall be available~~A list shall be kept up to date~~, indicating for each category of measuring instrument the:

- personnel ~~qualified~~ authorized to carry out tests and/or examinations;
- personnel ~~qualified~~ authorized 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.6.2.6-~~3~~2 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.

6.3 Facilities and environmental conditions

6.3.1 No OIML Guidance

~~**OIML Guidance to Section 6.3.1 (G.6.3.1-1)**~~

~~G.6.3.1-1 Standards and test equipment shall be used in the same environmental conditions as those for 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.~~

6.3.2 ~~No OIML Guidance~~

OIML Guidance to Section 6.3.2 (G.6.3.2-1)

G.6.3.2-1 When applicable, the testing laboratory shall consider the environmental conditions specified in OIML Recommendations.

6.3.3

OIML Guidance to Section 6.3.3 (G.6.3.3-1)

G.6.3.3-1 In particular, information related to rain, wind, etc. shall be recorded in the case of tests performed outdoors.

6.3.4 No OIML Guidance

6.3.5

OIML Guidance to Section 6.3.5 (G.6.3.5-1)

G.6.3.5-1 This requirement also applies when the testing laboratory performs tests at the ~~uses the~~ customer's (manufacturer's), or other, facilities~~test facilities~~.

6.4 Equipment

6.4.1 No OIML Guidance

6.4.2

OIML Guidance to Section 6.4.2 (G.6.4.2-1)

G.6.4.2-1 This requirement also applies when the testing laboratory uses the customer's (manufacturer's) ~~test~~ facilities.

6.4.3 No OIML Guidance

6.4.4 No OIML Guidance

6.4.5

OIML Guidance to Section 6.4.5 (G.6.4.5-1 and G.6.4.5-2)

G.6.4.5-1 See 7.6.3.

G.6.4.5-2 Standards and test equipment shall be used in the same environmental conditions as those for 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.

6.4.6 No OIML Guidance

6.4.7 No OIML Guidance

6.4.8 No OIML Guidance

6.4.9 No OIML Guidance

6.4.10 No OIML Guidance

6.4.11 No OIML Guidance

6.4.12 No OIML Guidance

6.4.13 No OIML Guidance

6.5 Metrological traceability

6.5.1 No OIML Guidance

6.5.2

OIML Guidance to Section 6.5.2 (G.6.5.2-1 to G.6.5.2-3)

G.6.5.2-1 Any external calibration shall be performed by an accredited calibration laboratory or by a national metrology institute. When used in connection with the OIML-CS, in the case of an accredited calibration laboratory, the respective accreditation body shall be a signatory to the ILAC Mutual Recognition Arrangement or to a regional arrangement recognized by ILAC ~~a full Member of ILAC~~.

G.6.5.2-2 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 cases, 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.6.5.2-3 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.

6.5.3 No OIML Guidance

6.6 Externally provided products and services

6.6.1

OIML Guidance to Section 6.6.1 (G.6.6.1-1 ~~and G.6.6.1-2~~)

G.6.6.1-1 Under the OIML-CS, a~~Testing laboratories involved in the type evaluation process are designated by the OIML Issuing Authority and approved by the OIML-CS Management Committee.~~

~~G.6.6.1-2~~ ~~A~~ testing laboratory is not authorized to use externally provided testing services without the prior approval of the OIML Issuing Authority.

6.6.2

OIML Guidance to Section 6.6.2 (G.6.6.2-1)

G.6.6.2-1 Not applicable (see 6.6.1).

6.6.3

OIML Guidance to Section 6.6.3 (G.6.6.3-1)

G.6.6.3-1 Not applicable (see 6.6.1).

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1

OIML Guidance to Section 7.1.1 (G.7.1.1-1 to G.7.1.1-4)

G.7.1.1-1 Where a contract between a testing laboratory and the manufacturer is necessary, the OIML Issuing Authority should review and endorse the contract with respect to the proposed testing to ensure it is relevant and supports the type evaluation of the instrument. It is recommended that testing not commence until the IA has endorsed the proposed testing specified in the contract~~shall authorize each contract before signing (see also Explanatory Note 4)~~.

G.7.1.1-2 This Guidance is related to 7.1.1 a). In the case of OIML type evaluation, the testing and examination test procedures defined in the relevant OIML Recommendation shall be used and understood. When used in connection with the OIML-CS, any additional national testing requirements shall be understood where they are applied.

G.7.1.1-3 This Guidance is related to 7.1.1 b). This requirement also applies if any test is performed by the testing laboratory which uses the manufacturer's test facilities.

G.7.1.1-4 This Guidance is related to 7.1.1 d). 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 OIML-CS, those defined in the additional national requirements according to the scope of the Declaration.

7.1.2 No OIML Guidance

7.1.3

OIML Guidance to Section 7.1.3 (G.7.1.3-1)

G.7.1.3-1 Not applicable (see 7.8.3.1).

7.1.4 No OIML Guidance

7.1.5

OIML Guidance to Section 7.1.5 (G.7.1.5-1)

G.7.1.5-1 Any deviation from the contract shall be submitted to the OIML Issuing Authority for ~~approval~~endorsement.

7.1.6 No OIML Guidance

7.1.7 No OIML Guidance

7.1.8 No OIML Guidance

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 No OIML Guidance

~~**OIML Guidance to Section 7.2.1.1 (G.7.2.1.1-1 to G.7.2.1.1-4)**~~

~~G.7.2.1.1-1 These procedures shall ensure that the testing laboratory verifies that the sample(s) to be tested and/or examined are those validated by the OIML Issuing Authority.~~

~~G.7.2.1.1-2 Selection of instruments to be tested amongst a family is considered as sampling.~~

~~G.7.2.1.1-3 These procedures shall indicate how adjustments and modifications of the sample(s) authorized by the OIML Issuing Authority are taken into account during tests and examinations.~~

~~G.7.2.1.1-4 These requirements also apply when tests are performed using the manufacturer's test facilities.~~

7.2.1.2 No OIML Guidance

7.2.1.3

OIML Guidance to Section 7.2.1.3 (G.7.2.1.3-1)

G.7.2.1.3-1 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 specified by Utilizers and Associates in their Declarations.

7.2.1.4

OIML Guidance to Section 7.2.1.4 (G.7.2.1.4-1)

G.7.2.1.4-1 See 7.2.1.3.

7.2.1.5 No OIML Guidance

7.2.1.6

OIML Guidance to Section 7.2.1.6 (G.7.2.1.6-1)

G.7.2.1.6-1 Not applicable (see 7.2.1.3).

7.2.1.7

OIML Guidance to Section 7.2.1.7 (G.7.2.1.7-1)

G.7.2.1.7-1 Not applicable (see 7.2.1.3).

7.2.2 Validation of methods

7.2.2.1 No OIML Guidance

~~**OIML Guidance to Section 7.2.2.1 (G.7.2.2.1-1)**~~

~~G.7.2.2.1-1 Validation of methods is under the responsibility of higher authorities, e.g. the CIML for OIML Recommendations.~~

7.2.2.2

OIML Guidance to Section 7.2.2.2 (G.7.2.2.2-1)

G.7.2.2.2-1 Not applicable (see 7.2.1.3 and 7.2.2.1).

7.2.2.3

OIML Guidance to Section 7.2.2.3 (G.7.2.2.3-1)

G.7.2.2.3-1 Not applicable (see 7.2.1.3 and 7.2.2.1).

7.2.2.4

OIML Guidance to Section 7.2.2.4 (G.7.2.2.4-1)

G.7.2.2.4-1 Not applicable (see 7.2.1.3 and 7.2.2.1).

7.3 Sampling

7.3.1

OIML Guidance to Section 7.3.1 (G.7.3.1-1 and G.7.3.1-2)

G.7.3.1-1 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 OIML Issuing Authority.

G.7.3.1-2 If sampling is requested for legal metrological control, then this is under the responsibility of the OIML Issuing Authority.

7.3.2

OIML Guidance to Section 7.3.2 (G.7.3.2-1)

G.7.3.2-1 Not applicable (see 7.3.1)

7.3.3 ~~No OIML Guidance~~

OIML Guidance to Section 7.3.3 (G.7.3.3-1)

G.7.3.3-1 Not applicable (see 7.3.1)

7.4 Handling of test or calibration items

7.4.1

OIML Guidance to Section 7.4.1 (G.7.4.1-1)

G.7.4.1-1 Provisions shall be made to ensure that the sample to be examined and/or tested is the one validated by the OIML Issuing Authority.

Such provisions may consist of receiving the sample from the OIML Issuing Authority or of receiving it in sealed packaging. In this case the testing laboratory shall register the seal position when the packaging is received.

7.4.2 No OIML Guidance

7.4.3

OIML Guidance to Section 7.4.3 (G.7.4.3-1)

G.7.4.3-1 The procedures of the testing laboratory shall indicate that the OIML Issuing Authority is consulted in such a case.

7.4.4

OIML Guidance to Section 7.4.4 (G.7.4.4-1)

G.7.4.4-1 Provisions for the transportation, conditioning, handling and installation for testing shall be determined with the agreement of the OIML Issuing Authority.

7.5 Technical records

7.5.1 No OIML Guidance

7.5.2 No OIML Guidance

7.6 Evaluation of measurement uncertainty

7.6.1 No OIML Guidance

7.6.2 ~~No OIML Guidance~~

OIML Guidance to Section 7.6.2 (G.7.6.2-1)

G.7.6.2-1 If the relevant OIML Recommendation does not address how to take measurement uncertainty into account, the laboratory should refer to the applicable international standards (such as ISO and IEC) or other internationally established methods and practices.

7.6.3

OIML Guidance to Section 7.6.3 (G.7.6.3-1 to G.7.6.3-3)

G.7.6.3-1 Testing laboratories shall include in these procedures the confirmation of the acceptable uncertainties of measurement with the requirements of the relevant OIML Recommendation.

G.7.6.3-2 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.

G.7.6.3-3 If the relevant OIML Recommendation does not address how to take measurement uncertainty into account, the laboratory should refer to the applicable international standards (such as ISO and IEC) or other internationally established methods and practices~~If the relevant OIML Recommendation does not address how to take~~

~~measurement uncertainty into account, the OIML Issuing Authority is responsible for providing guidance to the testing laboratory~~.

7.7 Ensuring the validity of results

7.7.1 No OIML Guidance

7.7.2

OIML Guidance to Section 7.7.2 (G.7.7.2-1)

G.7.7.2-1 This ~~shall~~ may include participation in inter-laboratory comparisons organized by the BIML~~, if necessary~~.

7.7.3 No OIML Guidance

7.8 Reporting of results

7.8.1 General

7.8.1.1 No OIML Guidance

7.8.1.2

OIML Guidance to Section 7.8.1.2 (G.7.8.1.2-1 to G.7.8.1.2-3)

G.7.8.1.2-1 Each Testing Laboratory issues a partial test report and/or an additional test report corresponding to the tests and examinations it performed.

Where applicable, the 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.

G.7.8.1.2-2 The test report (including partial test reports and additional test reports) shall indicate:

- whether the tests carried out were split 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~~ compatible and interrelated type approval process.

G.7.8.1.2-3 When used in connection with the OIML-CS, the test report format specified in the Utilizer or Associate Declaration shall be used to issue the additional test report(s).

7.8.1.3 Not applicable

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1

OIML Guidance to Section 7.8.2.1 (G.7.8.2.1-1 to G.7.8.2.1-3)

G.7.8.2.1-1 This Guidance is related to 7.8.2.1 g). The description shall include where tests were split between several samples.

G.7.8.2.1-2 This Guidance is related to 7.8.2.1 k). Testing laboratories shall indicate the verifications performed to ensure that the tested and/or examined samples are those validated by the OIML Issuing Authority.

G.7.8.2.1-3 Test reports issued under the OIML-CS shall not bear the OIML or the OIML-CS logo.

7.8.2.2 No OIML Guidance

7.8.3 Specific requirements for test reports

7.8.3.1

OIML Guidance to Section 7.8.3.1 (G.7.8.3.1-1 and G.7.8.3.1-2)

G.7.8.3.1-1 This Guidance is related to 7.8.3.1 b). Statements of conformity related to the conformance of the instrument with the relevant OIML Recommendation are not allowed in OIML test reports. The OIML Issuing Authority is solely responsible for drawing conclusions on the conformance of the instrument with the relevant requirements (e.g. OIML Recommendation).

G.7.8.3.1-2 This Guidance is related to 7.8.3.1 d). Opinions and interpretations related to the conformance of the instrument with the relevant OIML Recommendation are not allowed in OIML test reports. The OIML Issuing Authority is solely responsible for drawing conclusions on the conformance of the instrument with the relevant requirements (e.g. OIML Recommendation).

7.8.3.2

OIML Guidance to Section 7.8.3.2 (G.7.8.3.2-1)

G.7.8.3.2-1 Under the OIML-CS the OIML Issuing Authority is responsible for providing or endorsing the sample(s).

7.8.4 Specific requirements for calibration certificates

7.8.4.1

OIML Guidance to Section 7.8.4.1 (G.7.8.4.1-1)

G.7.8.4.1-1 Not applicable

7.8.4.2

OIML Guidance to Section 7.8.4.2 (G.7.8.4.2-1)

G.7.8.4.2-1 Not applicable

7.8.4.3

OIML Guidance to Section 7.8.4.3 (G.7.8.4.3-1)

G.7.8.4.3-1 Not applicable

7.8.5 Reporting sampling – specific requirements

OIML Guidance to Section 7.8.5 (G.7.8.5-1)

G.7.8.5-1 ~~See 7.8.3.2-1~~Not applicable.

7.8.6 Reporting statements of conformity

7.8.6.1

OIML Guidance to Section 7.8.6.1 (G.7.8.6.1-1)

G.7.8.6.1-1 See 7.8.3.1-1

7.8.6.2

OIML Guidance to Section 7.8.6.2 (G.7.8.6.2-1)

G.7.8.6.2-1 See 7.8.3.1-1

7.8.7 Reporting opinions and interpretations

7.8.7.1

OIML Guidance to Section 7.8.7.1 (G.7.8.7.1-1)

G.7.8.7.1-1 See 7.8.3.1-2

7.8.7.2

OIML Guidance to Section 7.8.7.2 (G.7.8.7.2-1)

G.7.8.7.2-1 See 7.8.3.1-2

7.8.7.3

OIML Guidance to Section 7.8.7.3 (G.7.8.7.3-1)

G.7.8.7.3-1 See 7.8.7.1-2

7.8.8 Amendments to reports

7.8.8.1 No OIML Guidance

7.8.8.2 No OIML Guidance

7.8.8.3 No OIML Guidance

7.9 Complaints

7.9.1 No OIML Guidance

7.9.2 No OIML Guidance

7.9.3 No OIML Guidance

7.9.4 No OIML Guidance

7.9.4 No OIML Guidance

7.9.5

OIML Guidance to Section 7.9.5 (G.7.9.5-1)

G.7.9.5-1 Where the testing laboratory receives a complaint relating to technical activities under the OIML-CS, the OIML Issuing Authority shall be informed of the complaint. The provisions of ISO/IEC 17025:2017, 4.3.1 shall be observed.

7.9.6 No OIML Guidance

7.9.7

OIML Guidance to Section 7.9.7 (G.7.9.7-1)

G.7.9.7-1 For a complaint relating to technical activities under the OIML-CS, the testing laboratory shall notify the OIML Issuing Authority of the end of the complaint handling. The provisions of ISO/IEC 17025:2017, 4.3.1 shall be observed.

7.10 Nonconforming work

7.10.1

OIML Guidance to Section 7.10.1 (G.7.10.1-1)

G.7.10.1-1 For a decision to be taken, the OIML 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.

7.10.2 No OIML Guidance

7.10.3 No OIML Guidance

7.11 Control of data and information management

7.11.1 No OIML Guidance

7.11.2 No OIML Guidance

7.11.3 No OIML Guidance

7.11.4 No OIML Guidance

7.11.5 No OIML Guidance

7.11.6 No OIML Guidance

8 Management system requirements

8.1 Options

8.1.1 General

No OIML Guidance

8.1.2 Option A

No OIML Guidance

8.1.3 Option B

OIML Guidance to section 8.1.3 (G.8.1.3-1)

G.8.1.3-1 If the testing laboratory adopts Option B, the OIML Guidance given below for Option A is relevant and applicable.

8.2 Management system documentation (Option A)

8.2.1 No OIML Guidance

~~**OIML Guidance to Section 8.2.1 (G.8.2.1-1)**~~

~~G.8.2.1-1 In particular, the testing laboratory shall keep updated documentation on:~~

- ~~the legal and contractual requirements applicable to its activity as a testing laboratory for an OIML Issuing Authority;~~
- ~~the requirements applicable to the measuring instruments by reference to which the testing and examination is carried out (e.g. OIML Recommendation R xxx, national regulation no. yyy);~~
- ~~any relevant general or technical standard pertaining to its certification activity.~~

8.2.2 No OIML Guidance

8.2.3 No OIML Guidance

8.2.4

OIML Guidance to section 8.2.4 (G.8.2.4-1 to G.8.2.4-3)

G.8.2.4-1 When participating in the OIML-CS~~The testing laboratory does not have to assess, record and monitor by itself the participants in a mutual acceptance or recognition agreement or arrangement, but~~, the testing laboratory:

- ~~shall establish procedures for the operation of such agreements shall be documented;~~
- procedures for the participation of the testing laboratory in the operation and supervision of ~~such agreements~~the OIML-CS ~~shall be established~~; and
- ~~shall conduct lists of participants in such agreements and reports on the operation of these agreements shall be kept updated;~~
- periodic reviews of the participation of the testing laboratory in the OIML-CS~~se agreements shall be conducted~~.

G.8.2.4-2 Processes and systems include in particular:

- procedures for identification, storage of equipment submitted to testing and examination and of associated documentation;
- description of the test equipment and facilities, procedures for their maintenance and traceability;
- procedures for defining and planning tests and examinations;
- test procedures;
- criteria and procedures for dealing with nonconformities of products submitted to testing and examination, including procedures for any exception to the rule defined;

G.8.2.4-3 Processes and procedures shall conform to the requirements of the appropriate regulations, OIML Publications and standards.

8.2.5 No OIML Guidance

8.3 Control of management system documents (Option A)

8.3.1

OIML Guidance to section 8.3.1 (G.8.3.1-1)

G.8.3.1-1 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). This applies in particular to the documentation on procedures mentioned in 8.2.4, which shall be appropriately updated and available.~~the legal and contractual requirements applicable to its activity as a testing laboratory for an OIML Issuing Authority;
- the requirements applicable to the measuring instruments by reference to which the testing and examination is carried out (e.g. OIML Recommendation R xxx, national regulation no. yyy);
- any relevant general or technical standard pertaining to its testing activity; and
- the documentation on procedures mentioned in 8.2.4.

8.3.2 No OIML Guidance

8.4 Control of records (Option A)

8.4.1 No OIML Guidance

8.4.2 No OIML Guidance

~~**OIML Guidance to section 8.4.2 (G.8.4.2-1)**~~

~~G.8.4.2-1 Records related to OIML test reports shall be kept available for as long as the OIML Certificate remains registered.~~

8.5 Actions to address risks and opportunities (Option A)

8.5.1 No OIML Guidance

8.5.2 No OIML Guidance

8.5.3 No OIML Guidance

8.6 Improvement (Option A)

8.6.1 No OIML Guidance

8.6.2

OIML Guidance to section 8.6.2 (G.8.6.2-1)

G.8.6.2-1 ~~Under the OIML-CS, the OIML Issuing Authority is the customer.~~From the point of view of the testing laboratory, the "customer" is the OIML Issuing Authority. However, in practice the manufacturer requesting type approval tests and examinations is the "customer" of the testing laboratory. Feedback shall be sought from both the OIML Issuing Authority and the manufacturer.

8.7 Corrective actions (Option A)

8.7.1

OIML Guidance to section 8.7.1 (G.8.7.1-1 and G.8.7.1-2)

G.8.7.1-1 This applies to nonconformities in the operation of the management system and procedures (e.g. procedures in case of unexpected events during the tests), not to nonconformities of products submitted to testing and examination.

G.8.7.1-2 The actions shall include informing the OIML Issuing Authority when the nonconformity affects the results of a test whose results were used to issue an OIML Certificate.

8.7.2 No OIML Guidance

8.7.3 No OIML Guidance

8.8 Internal audits (Option A)

8.8.1 No OIML Guidance

8.8.2

OIML Guidance to section 8.8.2 (G.8.8.2-1)

G.8.8.2-1 For testing laboratories which are Test Laboratories under the OIML-CS the internal audit programme shall take into consideration ~~the requirements of OIML-CS Procedural Document PD-03 and~~ the requirement for the associated OIML Issuing Authority to report annually to the OIML-CS Management Committee.

8.9 Management reviews (Options A)

8.9.1

OIML Guidance to section 8.9.1 (G.8.9.1-1)

G.8.9.1-1 For testing laboratories which are Test Laboratories under the OIML-CS the management review shall take into consideration ~~the requirements of OIML-CS Procedural Document PD-03 and~~ the requirement for the associated OIML Issuing Authority to report annually to the OIML-CS Management Committee.

8.9.2 No OIML Guidance

~~**OIML Guidance to Section 8.9.2 (G.8.9.2-1)**~~

~~G.8.9.2-1 This Guidance relates to 8.9.2 g). Audits performed on Testing Laboratories by the external OIML Issuing Authority are considered as assessments by external bodies and their results should be taken into account in the management review of the Testing Laboratory.~~

8.9.3

OIML Guidance to Section 8.9.3 (G.8.9.3-1)

G.8.9.3-1 The outputs from management reviews related to management requirements and metrological and technical requirements shall be submitted to the OIML Issuing Authority as far as OIML activities are concerned.