



TC 3/SC 5/p 5
New publication: Guide for the application of ISO/IEC 17065
Title: <i>“OIML D xx - Guide for the application of ISO/IEC 17065 to the assessment of measuring instrument certification bodies in legal metrology”</i>
TC 3/SC 5/p 5 Project Group Convener: BIML Mr. Paul Dixon

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE
Committee Draft (1 CD) – MARKED
Date: 27 July 2017
Reference number: TC3_SC5_P5_N006 Circulated to P- and O-members for:
<input type="checkbox"/> discussion at (date and place of meeting):
<input checked="" type="checkbox"/> votes and comments by: 27 October 2017

INTERNATIONAL
DOCUMENT

OIML D xx

Edition 20xx (E)

COMMITTEE DRAFT (1 CD)

Guide for the application of ISO/IEC 17065 to the
assessment of measuring instrument certification
bodies in legal metrology

Guide pour l'application de la Norme ISO/IEC 17065 à l'évaluation des
organismes de certification des instruments de mesure en métrologie
légale

OIML D xx Edition
20xx (E)



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.

This [publication Document](#) - reference OIML D xx, Edition 20xx (E) - was developed by [Project Group 5 in the OIML Technical Subcommittee TC 3/SC 5 Conformity assessment](#). It was approved for final publication by the International Committee of Legal Metrology [at its xx meeting](#) in 20xx.

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:

Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

Preamble

This Document gives interpretation and specific requirements related to the application of ISO/IEC 17065:2012 *Conformity assessment - Requirements for bodies certifying products, processes and services* to the assessment of bodies that are responsible for ~~type evaluation~~ the national type approval of measuring instruments ~~or the (e.g. issuing of OIML Certificates under the OIML Certification System (OIML-CS) of conformity e for~~ types of measuring instruments).

The edition of ISO/IEC 17065 referred to in this Document is 2012.

Taking into account that ~~national type evaluation~~ type approval of measuring instruments and the issuing of OIML Certificates may be considered as product certification, this Document may be used:

- by peer assessment or accreditation assessors when interpreting ISO/IEC 17065 for legal metrology applications in connection with the OIML-CS;
- for the assessment of national issuing authorities responsible for national type approval of measuring instruments conducted by an accreditation body in the field of legal metrology (e.g. by an IAF Full Member signatory to the IAF Multilateral Recognition Arrangement (MLA));
- ~~for the accreditation of national bodies responsible for type evaluation of measuring instruments, when required by the national legal metrology regulation;~~
- ~~for the accreditation of OIML Issuing Authorities when required by the OIML Member;~~
- on a voluntary basis for the implementation of ISO/IEC 17065 by national ~~bodies issuing authorities~~ responsible for the national type evaluation approval of measuring instruments ~~or by OIML Certificate Issuing Authorities.~~

ISO/IEC 17065 calls for the implementation of ISO/IEC 17025 for testing activities associated with the product certification activity. A separate Document (OIML D 30) is available for the application of ISO/IEC 17025 to type testing of measuring instruments.

In view of the specific regulatory nature of the certification activity, certain guidance in this Document may be applicable either to the certification body that conducts the national type approval or issues the OIML Certificate or to a regulatory designating authority. In particular, depending on the organization of legal metrology in a country, the regulatory designating authority (e.g. the government) may be responsible for suspending or withdrawing certification. The quality system of the certification body shall clearly identify the responsibilities and the way in which they are shared.

The issuing of OIML Certificates under the OIML-CS is classified to Scheme type 1a defined in ISO/IEC 17067.

In cases where ISO/IEC 17065 is deemed not to be the most appropriate Standard, national authorities may decide to implement other Standards (e.g. ISO/IEC 17020 *General criteria for the operation of various types of bodies performing inspection*).

This Document was developed in cooperation with ILAC and the IAF, which are Organizations in liaison with the OIML. Consequently, this Document should be used for accreditation assessments and any appropriate evaluation of certification bodies on the basis of the Memorandum of Understanding signed between ILAC, the IAF and the OIML in October 2014.

This Document does not include the text of ISO/IEC 17065. Numbers and titles of ISO/IEC 17065 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 17065. 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 17065". OIML Guidance to the introduction of ISO/IEC 17065 is identified by "G.0-x".

Explanatory notes

Note 1 (Certification Bodies)

In the context of the OIML ~~-CS-Basic Certificate System~~, Certification Bodies are those OIML Issuing Authorities that have been ~~designated by CIML Members~~approved by the OIML-CS Management Committee.

~~For the implementation of the OIML Mutual Acceptance Arrangement (MAA), Certification Bodies are Issuing Participants that have been duly registered in the appropriate Declaration(s) of Mutual Confidence.~~

Note 2 (Applicability of requirements)

When used in conjunction with the OIML ~~-CS-Basic Certificate System and the MAA~~, the guidance in this Document is applicable to OIML Issuing Authorities which are responsible for issuing OIML Certificates and associated OIML type evaluation reports of Conformity resulting from type evaluations of measuring instruments on the basis of the relevant OIML Recommendation(s).

Interpretation of Sections of ISO/IEC 17065:2012

Conformity assessment - Requirements for bodies certifying products, processes and services

Introduction

OIML Guidance to the Introduction (G.0-1 to G.0-3)

G.0-1 Issuing national type ~~approval~~evaluation certificates or OIML Certificates are product certification activities. In these cases, certification is limited to compliance of types of instruments, families of types, and types of modules of instruments, but it covers neither the conformity of individual products, surveillance of production, nor quality systems for production.

This Document does not cover the case where the certification is granted based on the quality system of the manufacturer for the design of the products. Nevertheless, this Document covers the case where results of tests performed by the manufacturer, including under the OIML-CS, are taken into account to demonstrate the conformity.

It should be remembered that national type ~~evaluation—approval~~ certificates, and OIML Certificates and their associated OIML type evaluation reports, of Conformity are issued on the basis of tests and examinations.

This Document is limited to legal metrology requirements and does not cover other requirements which may be applicable to measuring instruments such as health and safety requirements.

G.0-2 This Document includes amplifications of ISO/IEC 17065 which are considered necessary for the specific applications mentioned in its preamble.

G.0-3 The form of the assertion of conformity is defined:

- in the national legal metrology regulations for national type ~~evaluations~~approvals;
- in OIML Publication B ~~183~~ for OIML Certificates under the OIML-CS;
- ~~in OIML Publication B 10 for OIML MAA Certificates;~~
- in the relevant OIML Recommendations for OIML type Eevaluation ~~R~~reports.

Even if the results of tests performed by the manufacturer, including under the OIML-CS, are taken into account for the assertion of the conformity, national type ~~evaluations—approval~~ and the issuing of OIML ~~Certification-Certificates~~ are considered as third-party product certification.

1 Scope

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

- G.1-1 ~~————~~“Certification bodies” are national ~~type evaluation bodies~~issuing authorities and OIML Issuing Authorities under the OIML-CS.
- G.1-2 ~~————~~“Third-party conformity assessment” is ~~national OIML~~ type ~~evaluation approval~~ and issuing OIML certificatess-issuing.
- G.1-3 The word “product” shall be understood as meaning the measuring instrument type (including ~~range of models and/or family(ies)~~ families of measuring instruments, modules, or families of modules) subject to ~~OIML national~~ type ~~evaluation approval or issuing OIML certificates~~. Processes and services are not relevant to ~~national OIML~~ type approval and issuing OIML ~~Cevaluation and certificates-issuing~~.

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
 - ISO/IEC Guide 99 International vocabulary of metrology - Basic and general concepts and associated terms (VIM), 2007
 - 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 3: OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments, 2011~~
 - ~~OIML B 10 (Amended 2012): Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (Integrating the changes in the 2012 Amendment), 2011~~18: Framework for the OIML Certification System (OIML-CS), 2016
 - 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.3-3)

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:

National Issuing Authority (OIML B 18)

Certifying body or person in an OIML Member State or Corresponding Member that is responsible for national type approval and that issues national/regional Type Approval Certificates for specific categories of measuring instruments or modules on the basis of examination and testing under its own control.

Type evaluation (VIML 2.5)

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

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

Type approval (VIML 2.6)

Decision of legal relevance, based on the evaluation report that the type of a measuring instrument complies with the relevant statutory requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time.

Note: For the purposes of this Document, the "type approval" is named "national type evaluation approval". Consequently "national type approval evaluation" in the sense of this Document includes evaluation (examination and testing), review and decision.

Evaluator

~~Person on the staff of the certification body who is in charge of the type evaluation of a measuring instrument.~~

Supervisor

~~Person on the managerial staff or appropriate internal committee of the certification body who is in charge of validating the work of evaluators and who has an appropriate knowledge of legal metrology.~~

G.3-3 For legal metrology this applications, "client" must be understood as the "applicant" for national type evaluation approval or for OIML ~~T~~ certification. Although the instrument may be manufactured by another company, the applicant has to assume responsibility for compliance.

4 General requirements

4.1 Legal and contractual matters

4.1.1 Legal responsibility

OIML Guidance to section 4.1.1 (G.4.1.1-1)

G.4.1.1-1 When a certification body is a service of a public administration, it may happen that the legal entity is the whole administrative body to which it belongs (see also IAF GD 5). [In this case the administrative body shall comply with the requirements in section 5.1.3 of ISO/IEC 17065.](#)

4.1.2 Certification agreement

4.1.2.1 No OIML Guidance

4.1.2.2 ~~No~~**OIML Guidance to section 4.1.2.2 (G.4.1.2.2-1)**

~~This applies in~~ **G.4.1.2.2-1** Provisions shall ensure that the manufacturer is informed of its responsibilities and that any modification to an approved type shall be notified to the certification body before being implemented.

~~In the present legal metrology procedures, changes in the standards do not affect type evaluation or OIML Certificates previously granted.~~

4.1.3 Use of license, certificates and marks of conformity**4.1.3.1****OIML Guidance to section 4.1.3.1 (G.4.1.3.1-1)**

G.4.1.3.1-1 For OIML Certificates, see OIML Basic Publication B ~~18 Framework for the 3-OIML Certificateion System (OIML-CS) for Measuring Instruments and when applicable OIML Basic Publication B 10 Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations~~. For type national type approval~~evaluations~~, these elements are generally described in national regulations.

4.1.3.2 No OIML Guidance

4.2 Management of impartiality

4.2.1 No OIML Guidance

4.2.2 No OIML Guidance

4.2.3 No OIML Guidance

4.2.4 No OIML Guidance

4.2.5 No OIML Guidance

4.2.6**OIML Guidance to section 4.2.6 (G.4.2.6-1)**

G.4.2.6-1 The certification body may be a service of a public administration or of a public institute. “Any part of the same legal entity” may be other services of public administrations, of the same public institute or of other public institutes. In all these cases, this requirement may be fulfilled by organizational procedures which guarantee impartiality.

4.2.7 No OIML Guidance

4.2.8 No OIML Guidance

4.2.9 No OIML Guidance

4.2.10 No OIML Guidance

4.2.11 No OIML Guidance

4.2.12 No OIML Guidance

4.3 Liability and financing

4.3.1 No OIML Guidance

4.3.2

OIML Guidance to section 4.3.2 (G.4.3.2-1)

G.4.3.2-1 Although financial resources of public administrations and public bodies are generally decided by the annual budget of the State, public administrations and public bodies are deemed to fulfil this requirement.

4.4 Non-discriminatory conditions

4.4.1 No OIML Guidance

4.4.2 No OIML Guidance

4.4.3 No OIML Guidance

4.4.4 No OIML Guidance

4.5 Confidentiality

4.5.1 No OIML Guidance

4.5.2 No OIML Guidance

4.5.3 No OIML Guidance

4.6 Publicly available information

OIML Guidance to section 4.6 (G.4.6-1 and G.4.6-4)

G.4.6-1 When International Recommendations or standards ~~and national regulations~~ are not strictly equivalent to national regulations, the manufacturer shall be made aware or informed of the fact that national type ~~approval~~evaluation will be performed according to the International Recommendation or standard, or to the national requirements, or both.

G.4.6-2 The certification body shall provide to applicants a list of product documentation required for processing the certification.

G.4.6-3 For a) some of these conditions result from laws, regulations or OIML Publications. The certification body shall clearly refer to these sources and, when necessary, summarize them in a document provided to manufacturers.

G.4.6-4 ~~OIML Issuing Authorities under the OIML-CS Participants in a Declaration of Mutual Confidence under the OIML-MAA_~~ shall keep the ~~OIML-CS Management Committee~~ BIML informed of any evolution related to items a) and c).

5 Structural requirements

5.1 Organisational structure and top management

5.1.1

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

G.5.1.1-1 Threats to impartiality may result from organizational provisions or from the status of the certification body (e.g. public administration).

5.1.2

OIML Guidance to section 5.1.2 (G.5.1.2-1)

G.5.1.2-1 When a certification body is a service of a public administration, it may happen that the legal entity is the whole administrative body to which it belongs (see also IAF GD 5).

5.1.3

OIML Guidance to section 5.1.3 (G.5.1.3-1 to G.5.1.3-32)

G.5.1.3-1 Policy matters may be decided by regulatory designating authorities (e.g. laws, ministerial decisions). The policy should include a commitment to approve only types of measuring instruments that fulfil the full set of applicable requirements for national type approval~~evaluation~~.

G.5.1.3-2 Supervision of the implementation of policies may be the responsibility of regulatory designating authorities; ~~however, the certification body must have procedures to demonstrate that this policy is implemented~~. This is also applicable to supervision of the finances of the certification body.

~~G.5.1.3-3 Definitions of evaluator and supervisor have been introduced to define two different levels in the process (test and examination and, decision).~~

5.1.4 No OIML Guidance

5.2 Mechanism for safeguarding impartiality

5.2.1

OIML Guidance to section 5.2.1 (G.5.2.1-1)

G.5.2.1-1 The mechanism which safeguards impartiality may result from general provisions concerning the organization of public administrations.

5.2.2 No OIML Guidance

5.2.3 No OIML Guidance

5.2.4

OIML Guidance to section 5.2.4 (G.5.2.4-1)

G.5.2.4-1 For the purposes of legal metrology, a mechanism which includes all interested parties such as manufacturers, users and consumers ~~is~~may not ~~be~~ applicable.

6 Resource requirements

6.1 Certification body personnel

6.1.1 General

6.1.1.1 No OIML Guidance

6.1.1.2 ~~No OIML Guidance~~

OIML Guidance to Section 6.1.1.2 (G.6.1.1.2-1)

G.6.1.1.2-1 ~~For the purposes of legal metrology, personnel shall have sufficient knowledge of national requirements and/or the OIML-CS and relevant OIML Recommendations if part of an OIML Issuing Authority. Evaluations shall be performed by evaluators having the required competence. The outcome of these tasks shall be validated by a supervisor.~~

~~A list shall be kept up to date, indicating for each category of measuring instruments:~~

- ~~• the qualified supervisor;~~
- ~~• the qualified evaluator;~~
- ~~• staff in the process of being qualified.~~

6.1.1.3 No OIML Guidance

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1

OIML Guidance to Section 6.1.2.1 (G.6.1.2.1-1 and G.6.1.2.1-4)

G.6.1.2.1-1 The appropriate requirements of OIML D 14 *Training of legal metrology personnel - Qualification - Training programs* ~~should be followed~~can be used to provide guidance.

G.6.1.2.1-2 Participation in international work (~~Regional~~regional and OIML) is an important element to build ~~_____~~competence.

G.6.1.2.1-3 Staff ~~that are~~ in the process of being qualified/~~trained~~ shall only be in charge of simple or well described activities, ~~or they shall work under the supervision of a competent person. They can participate in, but not be responsible for, testing.~~

G.6.1.2.1-4 Competence of personnel for tests and examinations is addressed in ISO/IEC 17025.

6.1.2.2**OIML Guidance to Section 6.1.2.2 (G.6.1.2.2-1 to G.6.1.2.2-2)**

G.6.1.2.2-1 Elements of experience could include: participation in international work on legal metrology (regional and OIML).

- ~~participation in international work on legal metrology (Regional and OIML);~~
- ~~participation as assessor or as technical expert in audits and in peer assessments.~~

Participation in these activities shall be recorded.

G.6.1.2.2-2 Records shall be kept of the qualifications of the personnel involved in ~~the~~ evaluation, review and decision makings.

6.1.3 Contract with the personnel

No OIML Guidance

6.2 Resources for evaluation**6.2.1 Internal resources****OIML Guidance to section 6.2.1 (G.6.2.1-1)**

G.6.2.1-1 The results of type evaluation (tests and examinations) which are used to ~~perform~~ issue national type approvals and to issue OIML Certificates shall be carried out by testing laboratories which conform to ISO/IEC 17025. A separate OIML Document gives comments on and interpretation of the implementation of ISO/IEC 17025. All the requirements of ISO/IEC 17025 shall be fulfilled by testing laboratories. For the issuing of OIML Certificates under Scheme A of the OIML-CS the scope of accreditation for the testing laboratory shall include the relevant OIML Recommendation.

6.2.2 External resources (outsourcing)**6.2.2.1****OIML Guidance to section 6.2.2.1 (G.6.2.2.1-1)**

G.6.2.2.1-1 Subcontracted bodies must in particular comply with ISO/IEC 17025 and other applicable documents. The certification body shall ensure this either by assessing its subcontractors by reference to these standards or by asking subcontractors to be adequately accredited. For the issuing of OIML Certificates under Scheme A of the OIML-CS, where accreditation is chosen, the scope of accreditation should cover the relevant OIML Recommendations.

6.2.2.2**OIML Guidance to section 6.2.2.2 (G.6.2.2.2-1 to G.6.2.2.2-2)**

G.6.2.2.2-1 Where the laboratory that performed the tests is not fully independent of the manufacturer, applicable criteria are those defined in the appropriate OIML Publication(s). Such a situation shall be clearly indicated in the type evaluation report. The manufacturer must provide evidence that the equipment submitted to tests is the

equipment submitted to type evaluation and that it has not been adjusted or modified in a non-authorized way.

- G.6.2.2.2-2 The certification body must have documented evidence that the equipment submitted to tests is the equipment submitted to type evaluation and that it has not been adjusted or modified in a non-authorized way.

6.2.2.3 No OIML Guidance

6.2.2.4

OIML Guidance to section 6.2.2.4 (G.6.2.2.4-1 to G.6.2.2.4-4)

- G.6.2.2.4-1 Only tasks that are clearly identified and described may be outsourced. Except for particular cases, this leads outsourcing to be limited to tests and examinations for which procedures are available and validated by the certification body.

- G.6.2.2.4-2 ~~In the event of there being several subcontracting laboratories, one of them is identified as the principal testing laboratory and is responsible for issuing the evaluation report.~~ In the case of an OIML ~~T~~certification type Evaluation, the OIML Issuing Authority is responsible for issuing the OIML ~~E~~type Evaluation ~~R~~report which will include all the test reports issued by ~~each the~~ subcontracting testing laboratory(ies).

- G.6.2.2.4-3 Subcontracting in series (i.e. subcontractors sub-contracting to other subcontractors) is prohibited and shall be detailed in the agreement with the subcontractor.

- G.6.2.2.4-4 When mutual agreements are signed for acceptance or recognition of test and examination results or evaluations, the requirements given in 6.2.24.4.a) and 6.2.24.4.b) still apply. This means that the certification body endorses responsibility for any accepted test and examination result or evaluation, and remains responsible for the decision of granting or refusing its own certification.

Acceptance of another country's national type approval evaluations or an of OIML Certificates and/or OIML type evaluation report as fulfilling national requirements on type evaluation is a regulatory issue and is usually not a responsibility of certification bodies.

Under the OIML-CS, a Utilizer does not have to provide a reason if they choose not to accept test results from a Manufacturer Test Laboratory.

7 Process requirements

7.1 General

7.1.1

OIML Guidance to section 7.1.1 (G.7.1.1-1 to G.7.1.1-6)

- G.7.1.1-1 For legal metrology, the certification scheme relates to the national type approval evaluation of measuring instruments and the issuing of OIML Certificates in accordance with the OIML ~~CS Basic and MAA Certificate Systems~~.

- G.7.1.1-2 National Ttype approval evaluation and issuing OIML Certifications includes testing, examinations and evaluation of the instrument.

G.7.1.1-3 ~~National type approval~~ and OIML ~~certification type evaluation~~ do not include testing or inspection of samples taken from the market. According to the national regulation or the OIML requirements, it may involve sampling from the manufacturers stock.

G.7.1.1-4 ~~National type approval evaluation~~ and OIML ~~certification type Evaluation~~ include design evaluation, in particular for the following aspects:

- suitability for use;
- sealing;
- checking facilities.

G.7.1.1-5 For Note 1, the activities of surveillance of production, or with the assessment and surveillance of the client's management system, are related to other national/regional legal metrology procedures.

G.7.1.1-6 Requirements pertaining to matters other than legal metrology (e.g. electrical safety) shall not be taken into account in national type approval evaluations or OIML certification Type Evaluations.

7.1.2

OIML Guidance to section 7.1.2 (G.7.1.2-1)

G.7.1.2-1 The requirements shall result from documents accessible to the public (laws, regulations, OIML publications, standards, etc.).

G.7.1.2-2 The word "standard" shall be understood as follows:

- For national type approval evaluations, - a set of regulations establishing the legal requirements for the instrument and standards that may be referred to in these regulations;
- For OIML Certification, - the applicable OIML Recommendations and the standards that may be referred to in these Recommendations.

Other applicable general regulatory legal metrology texts and OIML publications (on legal units, traceability, etc.) are also part of the applicable standards.

7.1.3 No OIML Guidance

7.2 Application

OIML Guidance to section 7.2 (G.7.2-1 and G.7.2-2)

G.7.2-1 The manufacturer shall indicate the ~~standard~~ national regulation and/or the OIML Recommendation according to which it applies for certification.

G.7.2-2 Minimum required information may be defined in the national regulation and/or the OIML Recommendation ~~standards~~. Additional necessary information shall be defined by the certification body.

7.3 Application review

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 The review of the application includes:

- eligibility of the type of measuring instrument for certification;
- agreement on the reference standards (applicable sets of requirements) and/or; OIML Recommendation (where applicable);
- capability of the certification body and of its subcontractors;
- acceptance of subcontractors by the applicant.

G.7.3.1-2 National Iaws and regulations may require that the application be submitted in a specific language.

7.3.2 No OIML Guidance

7.3.3 No OIML Guidance

7.3.4 No OIML Guidance

7.3.5 No OIML Guidance

7.4 Evaluation

7.4.1

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

G.7.4.1-1 National issuing authorities~~Type evaluation bodies~~ and OIML Issuing Authorities are responsible for:

- ~~for~~ checking that the sample(s) to be examined and tested complies(y) with the description in the application;
- ~~for~~ the configuration control of the sample(s) to be examined and/or tested;
- ~~for~~ allowing the subcontracting laboratory(ies) to verify that the sample(s) to be examined and/or tested are those validated by the national issuing authority~~type evaluation body~~ or the OIML Issuing Authority.

7.4.2 No OIML Guidance

7.4.3 No OIML Guidance

7.4.4

OIML Guidance to section 7.4.4 (G.7.4.4-1 to G.7.4.4-3)

G.7.4.4-1 Certification bodies that are OIML Issuing Authorities~~Participants~~ under the OIML ~~MAA- CS~~ and which use test results from Manufacturer Test Laboratories shall have procedures in place to ensure controlled supervision. The requirements for MTLs are detailed in OIML-CS Procedural Document PD-04.

G.7.4.4-2 When the certification body does not perform (or does not require) all the examinations and tests on each sample of measuring instruments (in particular in the case of families of instruments), or when adjustments and/or modifications are made in the course of type evaluation, the certification body shall conduct sufficient examinations and tests to demonstrate that ~~the measuring~~each instrument ~~tested~~ fulfils the whole set of requirements applicable to its category.

G.7.4.4-3 Any adjustment or modification during the type evaluation process shall be authorized by the certification body. Such adjustment or modification may be performed by the manufacturer. ~~In such a case, the certification body or the designated laboratory shall witness them to be sure that they conform to the authorization of the certification body.~~

During the type evaluation process ~~t~~The manufacturer is not authorized to perform any adjustment and/or modification ~~out of this supervision~~ without supervision authorization of the certification body.

After modification and/or adjustment, the certification body shall decide if complementary additional tests are required. If a modification/adjustment has been accepted without performing additional tests, the reason for such a decision shall be recorded.

7.4.5

OIML Guidance to section 7.4.5 (G.7.4.5-1)

G.7.4.5-1 Test results used under the ~~MAA-OIML-CS~~ shall comply with the requirements of OIML B 108.

7.4.6 No OIML Guidance

7.4.7 No OIML Guidance

7.4.8 No OIML Guidance

7.4.9

OIML Guidance to section 7.4.9 (G.7.4.9-1 to G.7.4.9-54)

G.7.4.9-1 When they exist, formats specified in the national regulations, OIML Recommendations and Documents, and standards, shall be used. This is the case for example, of OIML ~~type e~~ Evaluation ~~R~~ report ~~and test report F~~ formats for the OIML-~~CS-Certificate-System~~.

G.7.4.9-2 When the evaluation report includes two or more parts (examination report(s), test report(s), evaluation report) this shall be indicated.

G.7.4.9-3 The evaluation report shall highlight any necessary justifications showing that the requirements have been met.

G.7.4.9-4 The evaluation report shall allow clear identification of the certified instrument(s) and of the technical documentation on which the evaluation has been based.

~~G.7.4.9-5 — The evaluation report shall indicate the names of the evaluators and of the supervisor.~~

7.5 Review

7.5.1 No OIML Guidance

7.5.2 No OIML Guidance

7.6 Certification decision

7.6.1

OIML Guidance to section 7.6.1 (G.7.6.1-1 to G.7.6-3)

G.7.6.1-1 The certification body shall not delegate any power to subcontractors to draw conclusions on conformity from the test and examination results.

7.6.2**OIML Guidance to section 7.6.2 (G.7.6.2-1 to G.7.6.2-2)**

G.7.6.~~42-12~~ Only information related to the evaluation process is relevant.

G.7.6.~~42-32~~ Special provisions shall be considered when some of these decisions belong to regulatory designating authorities (e.g. governmental).

7.6.3 No OIML Guidance

7.6.4 No OIML Guidance

7.6.5 No OIML Guidance

7.6.6 No OIML Guidance

7.7 Certification documentation

7.7.1

OIML Guidance to section 7.7.1 (G.7.7.1-1)

G.7.7.1-1 For OIML Certificates, the certification documents are described in OIML B ~~3~~ *OIML Certificate System for Measuring Instruments* and OIML B ~~1018~~ *Framework for the OIML Certification System (OIML-CS)* and OIML-CS Procedural Document *PD-05a Mutual Acceptance Arrangement on OIML Type Evaluations*.

7.7.2 No OIML Guidance

7.7.3 No OIML Guidance

7.8 Directory of certified products

OIML Guidance to section 7.8 (G.7.8-1)

G.7.8-1 The BIML maintains a database, accessible on the OIML website, of OIML Certificates that have been issued and registered. The OIML Certificates on the OIML website provide information on the scope of certification and their validity. This database may fulfil the requirement. ~~However, it is the responsibility of the OIML Issuing Authority to provide the BIML with copies of the OIML Certificates issued and to check whether the database is up to date. Only registered certificates are valid.~~

7.9 Surveillance

7.9.1

OIML Guidance to section 7.9.1 (G.7.9.1-1)

G.7.9.1-1 Surveillance on products in use is not covered by ~~required in~~ the OIML CS ~~Certificate Systems~~.

7.9.2

OIML Guidance to section 7.9.2 (G.7.9.2-1)

G.7.9.2-1 Not applicable

7.9.3

OIML Guidance to section 7.9.3 (G.7.9.3-1)

G.7.9.3-1 Not applicable

7.9.4

OIML Guidance to section 7.9.4 (G.7.9.4-1)

G.7.9.4-1 Not applicable

|

7.10 Changes affecting certification

7.10.1

~~No OIML Guidance~~

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

G.7.10.1-1 Under the OIML-CS, examples of changes affecting certification are:

- revision of the OIML Recommendation;
- inclusion of a new measuring instrument category;
- a change to the proposed transition of a measuring instrument category from Scheme B to Scheme A;
- moving an instrument category from Scheme A back to Scheme B.

7.10.2

OIML Guidance to section 7.10.2 (G.7.10.2-1 to G.7.10.2-3)

G.7.10.2-1 The evaluation procedures shall be drawn up in such a way that their outcome, together with the already available evaluation reports, can demonstrate the compliance of each instrument with all the requirements.

G.7.10.2-2 Changes affecting certification can include:

- extension of the characteristics of a certified instrument;
- extension to a family of instruments or extension of a family of instruments,
Example: the type evaluation certificate concerns for instance a turbine gas meter with a maximum flow rate of 160 m³/h. The applicant requests for an extension of this Certificate to include the complete family of turbine gas meters with maximum flow rate from 60 m³/h to 1 000 m³/h;
- where applicable, extension of an OIML Certificate to another manufacturers (under the responsibility of the same applicant);
Example: the applicant is ~~a~~ company A and the manufacturer is ~~a~~ company B. The applicant requests for an extension to add an additional manufacturer which is ~~a~~ company C. The OIML Certificate~~type evaluation certificate~~ shall be modified to include company C as an additional manufacturer;
- transfer to a new applicant or evolution in the applicant's data.
Example: the applicant sells its activity to another company. The type evaluation certificate shall be modified to be transferred to the new company as the new applicant.

G.7.10.2-3 Applying for complimentary certifications on a certified product is under the responsibility of the manufacturer.

7.10.3 No OIML Guidance

7.11 Termination, reduction, suspension or withdrawal of certification

7.11.1 No OIML Guidance

7.11.2 No OIML Guidance

7.11.3

OIML Guidance to section 7.11.3 (G.7.11.3-1)

G.7.11.3-1 For OIML Certificates, in the event that an OIML type evaluation report is issued on the basis of incorrect technical conclusions or procedures ~~Certificate is terminated, suspended or withdrawn the Issuing Authority shall notify the BIML so that the registration of the the~~ OIML Certificate ~~will~~ can be ~~deregistered/amended accordingly on from~~ the OIML website.

G.7.11.3-2 In the case of regulatory certification, the procedures to terminate, suspend or withdraw certification shall be done in cooperation with regulatory designating authority and in accordance with the rules defined by the regulatory designating authority.

7.11.4 No OIML Guidance

7.11.5 See applicable OIML Guidance to sections 7.4 and 7.6.

7.11.6

OIML Guidance to section 7.11.6 (G.7.11.6-1)

G.7.11.6-1 For OIML Certificates, in the event that an OIML Certificate is reinstated after suspension the OIML Issuing Authority shall notify the BIML so that the OIML Certificate can be registered on the OIML website

7.12 Records

7.12.1 No OIML Guidance

7.12.2 No OIML Guidance

7.12.3

OIML Guidance to section 7.12.3 (G.7.12.3-1 to G.7.12.3-2)

G.7.12.3-1 “cycle” means “the validity period of the national type approval certificate”.

G.7.12.3-2 Records related to OIML type evaluation reports and test ~~R~~reports shall be kept available by the OIML Issuing Authority as long as the OIML Certificate remains registered.

7.13 Complaints and appeals

7.13.1

OIML Guidance to section 7.13.1 (G.7.13.1-1 to G.7.13.1-2)

G.7.913.1-1 In some cases, appeal procedures may be the responsibility of regulatory designating authorities. However, they must be described.

G.7.13.1-2 Under the OIML-CS, the OIML Issuing Authority shall have an appeals procedure. The OIML-CS also incorporates a Board of Appeal.

7.13.2 No OIML Guidance

- 7.13.3 No OIML Guidance
- 7.13.4 No OIML Guidance
- 7.13.5 No OIML Guidance
- 7.13.6 No OIML Guidance
- 7.13.7 No OIML Guidance
- 7.13.8 No OIML Guidance
- 7.13.9 No OIML Guidance



8 Management system requirements

8.1 Options

8.1.1 General

~~No OIML Guidance~~ **OIML Guidance to section 8.1.1 (G.8.1.1-1)**

G.8.1.1-1 Option A and Option B referred to in this section should not be confused with Scheme A and Scheme B of the OIML-CS.

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 ~~Certification~~certification ~~Body~~body adopts Option B, the OIML Guidance given below for Option A is relevant and applicable.

8.2 General management system documentation (Option A)

8.2.1

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

G.8.2.1-1 In particular, the certification body shall keep updated documentation on:

- the legal and contractual requirements applicable to its activity as a national issuing authority~~type approval body~~ and/or as an OIML Issuing Authority;
- the requirements applicable to the measuring instruments by reference to which the certification is carried out (e.g. OIML Recommendation R XX, national regulation no. xx);
- 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.8.2.4-43)

G.8.2.4-1 ~~The role and responsibilities of evaluators and supervisors shall be clearly described.~~

~~G.8.2.4-2~~ The certification body does not have to assess, record and monitor by itself the participants in a mutual acceptance or recognition agreement or arrangement, but:

- procedures for the operation of such agreements shall be documented;
- procedures for the participation of the certification body in the operation and supervision of such agreements shall be established;

- 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 certification body in these agreements shall be conducted.

G.8.2.4-~~32~~ Processes and systems include in particular:

- procedures for identification, storage of equipment submitted to certification 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 certification, including procedures for any exception to the rule defined;
- procedures for accepting and handling test reports and results received from applicants, from subcontractors or from signatories of a mutual arrangement/agreement.

G.8.2.4-~~43~~ 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 documents (Option A)**8.3.1****OIML Guidance to section 8.3.1 (G.8.3.1-1)**

G.8.3.1-1 This applies in particular to the documentation on procedures mentioned in 8.2.4, which shall be appropriately updated and available.

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 ~~type evaluation reports and test reports~~ shall be kept available ~~by the OIML Issuing Authority~~ for as long as the OIML Certificate remains registered.

8.5 Management review (Options A)**8.5.1 General**

8.5.1.1 No OIML Guidance

8.5.1.2 No OIML Guidance

8.5.2 Review inputs

No OIML Guidance

8.5.3 Review outputs

No OIML Guidance

8.6 Internal audits (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 For certification bodies that are ~~OIML Issuing Authorities~~ ~~Participants~~ under the OIML ~~MAA-CS~~ the internal audit programme shall take into consideration the requirements of OIML Basic Publication B 18 ~~and OIML-CS Procedural Document PD-030~~.

8.6.3**OIML Guidance to section 8.6.3 (G.8.6.3-1)**

G.8.6.3-1 For certification bodies that are OIML Issuing Authorities~~Participants~~ under the OIML ~~MAA-CS~~ the internal audit programme shall take into consideration the requirements of OIML Basic Publication B 180 and the requirement to report annually to the OIML-CS Management Committee~~on Participation Review~~.

8.6.4 No OIML Guidance

8.7 Corrective actions (Option A)**8.7.1****OIML Guidance to section 8.7.1 (G.8.7.1-1)**

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

8.7.2 No OIML Guidance

8.7.3 No OIML Guidance

8.7.4 No OIML Guidance

8.8 Preventive actions (Option A)

8.8.1 No OIML Guidance

8.8.2 No OIML Guidance

8.8.3 No OIML Guidance