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APPROVAL**

New Document

Guide for the application of ISO IEC Guide 65
to assessment of measuring instrument certification bodies
in legal metrology

DD 1 - Guide for the application of ISO IEC Guide 65 to assessment
of measuring instrument certification bodies in legal metrology
43rd CIML Meeting - Sydney 2008



ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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; the OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and intended to improve the work of the metrological services;
- **International Guides (OIML G)**, which are informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology;
- **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 are formed by the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations, International Documents and International Guides are published in French (F) and English (E) 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 G XX, edition 200X (E) - was developed by the OIML Technical TC 3/SC 5 *Conformity assessment*. It was approved for final publication by the International Committee of Legal Metrology in 200X.

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

This document gives interpretation and specific requirements related to the application of ISO/IEC Guide 65:1996 *General requirements for bodies operating product certification systems* to assessment of bodies who are responsible for type evaluation of measuring instruments (e.g. OIML Certificates of conformity of types of measuring instruments). ISO/IEC Guide 65 is used in the Document to designate its edition 1996.

Taking into account that type evaluation of measuring instruments may be considered as a product certification, this Guide may be used:

- 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 Guide 65 by national bodies responsible for type evaluation of measuring instruments or by OIML Certificate Issuing Authorities.

ISO/IEC Guide 65 calls for the implementation of ISO/IEC 17025 for testing activities associated with the product certification activity. A separate guide for the application of ISO/IEC 17025 to type testing of measuring instruments has been drawn up.

In view of the specific regulatory nature of the certification, certain requirements in this document may be applicable either to the certification body or to a higher authority. In particular, depending on the organization of legal metrology in a country, the higher 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 they are shared.

If ISO/IEC Guide 65 seems to not 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 has been developed in cooperation with ILAC and IAF, which are liaisons. 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, IAF and the OIML in November 2007.

This Document does not include the text of ISO/IEC Guide 65. Numbers and titles of ISO/IEC Guide 65 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 Guide 65 associated to a chronologic number (e.g. G.1.1-1 which corresponds to OIML Guidance number 1 to section 1.1 of ISO/IEC Guide 65). OIML Guidance to introduction of ISO/IEC Guide 65 are identified G.0-x.

EXPLANATORY NOTES

NOTE 1:

For the OIML Certificate System Certification Bodies are the Issuing Authorities designated by CILM Members and, for the implementation of the MAA, Certification Bodies are Issuing Participants in Declarations of Mutual Confidence.

NOTE 2:

When used in connection with the OIML Certificate System and the MAA, the requirements of this guide are applicable to OIML Issuing Authorities which are responsible for issuing OIML Certificates of Conformity resulting from type evaluations of measuring instruments on the basis of OIML Recommendations.

INTERPRETATION OF SECTIONS OF ISO/IEC Guide 65:1996

General requirements for bodies operating product certification systems

Introduction

OIML Guidance to introduction (G.0-1 to G.0-3)

- G.0-1 Issuing type evaluation certificates or OIML Certificates are product certification activities. In these cases, certification is limited to compliance of types of instruments, families of types, types of modules of instruments, and does not cover conformity of individual products, surveillance of production and 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 are taken into account to demonstrate the conformity. It should be remembered that type evaluation certificates and OIML Certificates 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 Guide 65 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 type evaluations;
 - in the OIML Publication B 3 for OIML Certificates;
 - in the relevant OIML Recommendations for Evaluation Reports.
- Even if results of tests performed by the manufacturer are taken into account for the assertion of the conformity, type evaluations and OIML Certification are third-party product certification.

1 Scope

1.1

OIML Guidance to section 1.1 (G.1.1-1 and G.1.1-2)

- G.1.1-1 Third-party certification bodies are national type evaluation bodies and OIML Issuing Authorities.
- G.1.1-2 The word “standard” shall be understood as follows:
- for type evaluations, set of regulations establishing the legal requirements for the instrument and standards that may be referred to in these regulations;
 - for OIML Certificates, the applicable OIML Recommendation 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.

1.2

OIML Guidance to section 1.2 (G.1.2-1 to G.1.2-4)

- G.1.2-1 Type evaluation and OIML Certificate issuing include only activities a, b and e. Activities c and d are related to other legal metrology procedures.
- G.1.2-2 Type evaluation and OIML Certification includes tests, examinations and evaluation of the instrument.
- G.1.2-3 Type evaluation and OIML Type Evaluation do not include testing or inspection of samples taken from the market. According to the regulation or the OIML requirements, it may involve sampling from the manufacturer's stock.
- G.1.2-4 Type evaluation and OIML Type Evaluation include design evaluation, in particular for the following aspects:
- suitability for use;
 - sealing;
 - checking facilities.

2 References

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

- G.2-1 In addition:
- OIML V 1: International vocabulary of terms in legal metrology (VIML) (bilingual French-English), 2000
 - 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 of legal metrology personnel - Qualification - Training programs, 2004
 - OIML D 19: Pattern evaluation and pattern approval, 1988
 - IAF GD 5:2006: IAF Guidance on the application of ISO/IEC Guide 65:1996
- G.2-2
- ISO/IEC Guide 25 now corresponds to ISO/IEC 17025:2005
 - ISO 8402:1994 now corresponds to ISO 9000:2000
 - ISO 10011-1:1990 now corresponds to ISO 19011:2002
 - ISO/IEC Guide 2:1996 now corresponds to ISO/IEC Guide 2:2004
 - ISO/IEC Guide 7:1982 now corresponds to ISO/IEC Guide 2:1994
 - ISO/IEC Guide 28:1982 now corresponds to ISO/IEC Guide 28:2004

- ISO/IEC Guide 39 now corresponds to ISO/IEC 17020:1998
- ISO/IEC Guide 53:1988 now corresponds to ISO/IEC Guide 53:2005

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 the ISO/IEC 17000:2004, VIM and VIML apply. General definitions related to quality are given in ISO 9000:2005. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000:2004, VIM and VIML are preferred.

G.3-2 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 instruments against documented requirements, the results of which are contained in the evaluation report, in order to determine whether the type may be approved.

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 purpose of this Document, the “type approval” is named “type evaluation”. Consequently “Type evaluation” in the sense of this Document includes examination, tests 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 this application, "supplier" must be understood as "applicant" for type evaluation or for OIML Type Evaluation. Although the instrument may be manufactured by another company, the applicant has to assume responsibility for compliance.

4 Certification body

4.1 General provisions

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 These criteria shall result from documents accessible to the public (laws, regulations, OIML publications, standards, etc.).

4.1.4

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

- G.4.1.4-1 Requirements pertaining to other than matters of legal metrology (e.g. electrical safety) shall not be taken into account in type approvals or OIML Type Evaluations.

4.2 Organization

OIML Guidance to section 4.2.) (G.4.2-1 to G.4.2-9)

- G.4.2-1 Impartiality may result from organizational provisions or from the status of the certification body (e.g. public administration).
- G.4.2-2 In case of regulatory certification, withdrawing and/or suspending certifications shall be done in cooperation with the regulatory designating authority and in accordance with the rules defined by the regulatory designating authority.
- G.4.2-3 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 type evaluation.
- G.4.2-4 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.4.2-5 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 GD5).
- G.4.2-6 The structure which safeguards impartiality may result from general provisions concerning the organization of public administrations.
For the purpose of legal metrology a decision committee which includes all the interested parties such as manufacturers, users and consumers is not applicable.
- G.4.2-7 Definitions of evaluator and supervisor have been introduced to define two different levels in the process (test and examination and, decision).
- G.4.2-8 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 the requirement defined in i).
- G.4.2-9 The certification body may be a service of a public administration or of a public institute. Related bodies 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 confidentiality, objectivity and impartiality.

4.3 Operations

OIML Guidance to section 4.3 (G.4.3-1 to G.4.3-3)

- G.4.3-1 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 or modifications are made in the course of type evaluation, the certification body shall demonstrate that each instrument tested fulfils the whole set of requirements applicable to its category.
- G.4.3-2 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. The manufacturer is not authorized to perform any adjustment and/or modification out of this supervision without supervision of the certification body. After modification and/or adjustment, the certification body shall decide if complementary test are required. If a modification/adjustment has been accepted without performing additional tests, the reason for such decision shall be recorded.
- G.4.3-3 The results of tests and examinations which are used to perform type evaluation shall be carried out by testing laboratories which conform to ISO/IEC 17025. A separate OIML document gives comments an interpretation of the implementation of ISO/IEC 17025. All the requirements of the ISO/IEC 17025 shall be fulfilled by testing laboratories.

4.4 Subcontracting

OIML Guidance to section 4.4 (G.4.4-1 to G.4.4-8)

- G.4.4-1 The certification body shall not delegate any power to subcontractors to draw conclusions on conformity from the test and examination results.
- G.4.4-2 Subcontracted bodies must in particular comply with ISO 17025 and other applicable Guides. The certification body shall ensure this either by assessing its subcontractors by reference to these standards or by asking subcontractors to be adequately accredited.
- G.4.4-3 Only tasks that are clearly identified and described may be subcontracted. Except for particular cases this leads subcontracting to be limited to tests and examinations for which procedures are available and validated by the certification body.
- G.4.4-4 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 case of an OIML Type Evaluation, the OIML Issuing Authority is responsible for issuing the OIML Evaluation Report which includes all the test reports issued by each subcontracting testing laboratories.
- G.4.4-5 Subcontracting in series (subcontractors sub-contracting to other subcontractors) is prohibited.
- G.4.4-6 Where the laboratory that performed the tests is not fully independent of the manufacturer, applicable criteria are those defined in the appropriate OIML Publications. 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 has not been adjusted or modified in a non-authorized way.

- G.4.4-7 In addition to note 2, the certification body must have documented evidence that the equipment submitted to tests is the equipment submitted to type evaluation and has not been adjusted or modified in a non-authorised way.
- G.4.4-8 When mutual agreements are signed for acceptance or recognition of test and examination results or evaluations, the requirements given in 4.4.a and 4.4.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 other countries' type approvals or of OIML Certificates as fulfilling national requirements on type approval is a regulatory issue and is usually not a responsibility of certification bodies.

4.5 Quality system

4.5.1.1.1 No OIML Guidance

4.5.2

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

G.4.5.2-1 In particular, the certification body shall keep updated documentation on:

- the legal and contractual requirements applicable to its activity as a 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 n° xx);
- any relevant general or technical standard pertaining to its certification activity.

4.5.3

OIML Guidance to section 4.5.3 (G.4.5.3-1 to G.4.5.3-5)

G.4.5.3-1 The role and responsibilities of evaluators and supervisors shall be clearly described.

G.4.5.3-2 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.4.5.3-3 Item k) 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.

G.4.5.3-4 Procedures defined in l) 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.4.5.3-5 Procedures shall conform to the requirements of the appropriate regulations, OIML Publications and standards.

4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification

4.6.1

OIML Guidance to section 4.6.1 (G.4.6.1-1)

G.4.6.1-1 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.

4.6.2

OIML Guidance to section 4.6.2 (G.4.6.2-1 to G.4.6.2-3)

G.4.6.2-1 In case of regulatory certification, the procedures to withdraw or suspend certification shall be done in cooperation with regulatory designating authorities.

G.4.6.2-2 Procedures indicated in b) apply in particular to:

- 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 60m³/h to 1000 m³/h;
- where applicable, extension to other 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 an additional manufacturer which is a company C. The 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.4.6.2-3 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.

4.7 Internal audits and management reviews

4.7.1 No OIML Guidance

4.7.2 No OIML Guidance

4.8 Documentation

4.8.1

OIML Guidance to section 4.8.1 (G.4.8.1-1 and G.4.8.1-2)

G.4.8.1-1 Participants in a Declaration of Mutual Confidence under the OIML MAA shall keep the BIML informed of any evolution related to items a, b, and c.

G.4.8.1-2 The BIML keeps a database of OIML Certificates issued. This database, accessible on the OIML web site, may fulfil item g. However it is the responsibility of OIML Issuing Authorities to provide the BIML with copies of the OIML Certificates issued and to check whether the database is up-to-date.

4.8.2

OIML Guidance to section 4.8.2 (G.4.8.2-1)

G.4.8.2-1 This applies in particular to the documentation on procedures mentioned in 4.5.3.l), which shall be appropriately updated and available.

4.9 Records

4.9.1

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

G.4.9.1-1 “full certification cycle” means “the validity period of the type approval certificate”.

4.9.2

OIML Guidance to section 4.9.2 (G.4.9.2-1)

G.4.9.2-1 Records related to OIML Test Reports shall be kept available as long as the OIML Certificate remains registered.

4.10 Confidentiality

4.10.1 No OIML Guidance

4.10.2 No OIML Guidance

5 Certification body personnel

5.1 General

5.1.1

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

G.5.1.1-1 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.

5.1.2

OIML Guidance to section 5.1.2 (G.5.1.2-1 to G.5.1.2-3)

G.5.1.2-1 Staff in the process of being qualified shall be in charge only of simple or well described activities. They can participate in, but not be responsible for, testing.

G.5.1.2-2 Records shall be kept of the qualifications of the personnel involved in the evaluations.

G.5.1.2-3 Competence of personnel for tests and examinations is addressed in ISO/IEC 17025.

5.2 Qualification criteria

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 The appropriate requirements of OIML D 14 "Training of legal metrology personnel - Qualification - Training programs" should be followed.

G.5.2.1-2 Participation in international work (Regional and OIML) is an important element to build competence.

5.2.2 No OIML Guidance

5.2.3

OIML Guidance to section 5.2.3 (G.5.2.3-1)

G.5.2.3-1 Elements of experience could include:

- 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.

6 Changes in the certification requirements

No OIML Guidance

7 Appeals, complaints and disputes

7.1

OIML Guidance to section 7.1 (G.7.1-1)

G.7.1-1 In some cases, appeal procedures may be the responsibility of higher authorities. However they must be described.

7.2 No OIML Guidance

8 Application for certification

8.1 Information on the procedure

8.1.1

OIML Guidance to section 8.1.1 (G.8.1.1-1 and G.8.1.1-2)

G.8.1.1-1 When International Recommendations or standards and national regulations are not strictly equivalent, the manufacturer shall be aware or informed of the fact that type evaluation will be performed according to the International Recommendation or standard or to the national requirements, or both.

G.8.1.1-2 The certification body shall provide to applicants a list of product documentation required for processing the certification.

8.1.2 No OIML Guidance

8.1.3 No OIML Guidance

8.1.4 No OIML Guidance

8.2 The application

8.2.1 No OIML Guidance

8.2.2

OIML Guidance to section 8.2.2 (G.8.2.2-1 and G.8.2.2-2)

G.8.2.2-1 The manufacturer shall indicate the standard according to which it applies for certification.

G.8.2.2-2 Minimum required information may be defined in standards. Additional necessary information shall be defined by the certification body.

9 Preparation for evaluation

9.1

OIML Guidance to section 9.1 (G.9.1-1 and G.9.1-2)

G.9.1-1 The preparation for evaluation includes:

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

G.9.1-2 Laws and regulations may require that the application be submitted in a specific language.

9.2

OIML Guidance to section 9.2 (G.9.2-1)

- G.9.2-1 Type evaluation bodies and OIML Issuing Authorities are responsible:
- 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 laboratorie(s) to verify that the sample(s) to be examined and/or tested are those validated by the Type evaluation body or the OIML Issuing Authority.

9.3 No OIML Guidance

9.4 No OIML Guidance

10 Evaluation

No OIML Guidance

11 Evaluation report

OIML Guidance to section 11 (G.11-1 to G.11-5)

- G.11-1 When they exist, formats specified in the regulations, OIML Recommendations and Documents, and standards, shall be used. This is the case for example, of OIML Evaluation Report Formats for the OIML Certificate System.
- G.11-2 When the evaluation report includes two or more parts (examination report(s), test report(s), evaluation report) this shall be indicated.
- G.11-3 The evaluation report shall highlight any necessary justifications showing that the requirements of 4.3 and 4.4 have been met.
- G.11-4 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.11-5 The evaluation report shall indicate the names of the evaluators and of the supervisor.

12 Decision on certification

12.1

OIML Guidance to section 12.1 (G.12.1-1)

- G.12.1-1 Only information related to the evaluation process is relevant.

12.2

OIML Guidance to section 12.2 (G.12.2-1)

- G.12.2-1 Special provisions shall be considered when some of these decisions belong to regulatory designating authorities (e.g. governmental).

12.3

OIML Guidance to section 12.3 (G.12.3-1)

- G.12.3-1 For OIML Certificates, the certification documents are described in OIML B 3 "OIML Certificate System for Measuring Instruments".

12.4

OIML Guidance to section 12.4 (G.12.4-1)

- G.12.4-1 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.
See also G.4.6.2-2 and G.4.6.2-3.

13 Surveillance

13.1

OIML Guidance to section 13.1 (G.13.1-1)

- G.13.1-1 Surveillance is not required in the OIML Certificate System. Surveillance is generally not required in type evaluation systems.

13.2

OIML Guidance to section 13.2 (G.13.2-1)

- G.13.2-1 Applying for complementary certifications on a certified product is under the responsibility of the manufacturer.

13.3

OIML Guidance to section 13.3 (G.13.3-1)

- G.13.3-1 Not applicable.

13.4

OIML Guidance to section 13.4 (G.13.4-1)

- G.13.4-1 Not applicable.

14 Use of licenses, certificates and marks of conformity

14.1

OIML Guidance to section 14.1 (G.14.1-1)

G.14.1-1 For OIML Certificates, see OIML document B 3 "OIML Certificate System for Measuring Instruments", and when applicable OIML documents on the implementation of the OIML MAA. For type evaluations, these elements are generally described in national regulations.

14.2 No OIML Guidance

14.3 No OIML Guidance

15 Complaints to suppliers

No OIML Guidance