INTERNATIONAL DOCUMENT

# OIML D 37

Edition 2022 (E)

# Guide for the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities under the OIML Certification System

Guide pour l'application de la Norme ISO/IEC 17020 à l'évaluation des Autorités de Délivrance OIML dans le Système de Certification OIML

OIML D 37 Edition 2022 (E)

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

# Contents

# Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organisation whose primary aim is to harmonise the regulations and metrological controls applied by the national metrological services, or related organisations, 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 Document - reference OIML D 37, Edition 2022 (E) - was developed by Project Group 6 in the OIML Certification System Management Committee. It was approved for final publication by the International Committee of Legal Metrology at its 57th meeting in October 2022.

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

OIML B 18:2022 *Framework for the OIML Certification System (OIML-CS)* specifies that OIML Issuing Authorities are required to demonstrate their competence through compliance with either ISO/IEC 17065:2012 *Conformity assessment — Requirements for bodies certifying products, processes and services*, or ISO/IEC 17020:2012 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection* (with additional requirements as specified in OIML-CS Procedural Document PD-03 *Application and approval of OIML Issuing Authorities, Utilizers and Associates*). PD-03 details the requirements and procedures for the assessment and approval of OIML Issuing Authorities under the OIML-CS.

ISO/IEC 17065, is the preferred standard to be applied by OIML Issuing Authorities to demonstrate their competence under the OIML-CS. A separate Document (OIML D 32:2018 *Guide for the application of ISO/IEC 17065 to assessment of certification bodies in legal metrology*) is available for the application of ISO/IEC 17065 to the assessment of conformity assessment bodies ("certification bodies") that are responsible for the issuing of OIML certificates under the OIML-CS.

The issuing of OIML certificates under the OIML-CS is classified as Scheme type 1a defined in ISO/IEC 17067 *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*.

The ISO Committee on Conformity Assessment (ISO/CASCO) has developed International Standards and Guides to support conformity assessment. The basic concept under these standards is the *Functional Approach* as described in ISO/IEC 17000:2020, Annex A, which divides conformity assessment into three functions:

- selection;
- determination; and
- review, decision and attestation.

Under this functional approach, ISO/IEC 17020 is classified as a standard for the "determination" function. To support the use of ISO/IEC 17020 by OIML Issuing Authorities to demonstrate competence, the requirements from ISO/IEC 17065 relating to the "selection" and "review, decision and attestation" functions are also applicable. Further information on the *Functional Approach* and how it is applied to conformity assessment under the OIML-CS is provided in Annex A of OIML B 18.

This Document gives guidance and interpretations related to the application of ISO/IEC 17020 (Part I), and subclauses 4.1.2, 4.1.3, 4.4, 4.6, 7.4, 7.5, 7.6, 7.11 and 7.13.6 of ISO/IEC 17065 (Part II), to the assessment of OIML Issuing Authorities that are responsible for the issuing of OIML certificates under the OIML Certification System (OIML-CS).

ISO/IEC 17020 calls for the implementation of the applicable requirements of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* 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.

This Document was 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 certification bodies on the basis of 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 17020 or ISO/IEC 17065. Numbers and titles of ISO/IEC 17020 and ISO/IEC 17065 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 17020 and ISO/IEC 17065. A chronological number is also given (e.g. G.1.1-1) which signifies "OIML guidance number 1 to subclause 1.1 of ISO/IEC 17020". OIML guidance to the introduction of ISO/IEC 17020 is identified by "G.0-x".

# Explanatory notes

*Note 1 (Inspection)*

The ‘inspection’ of a measuring instrument and the ‘type evaluation’ of a measuring instrument are equivalent for the purposes of the OIML-CS.

*Note 2 (Inspection Bodies)*

In the context of the OIML-CS, an Inspection Body is an OIML Issuing Authority that has been approved by the OIML-CS Management Committee.

*Note 3 (Applicability of requirements)*

The guidance and interpretations in this Document are applicable only to OIML Issuing Authorities which are responsible for issuing OIML-CS certificates and associated OIML type evaluation reports resulting from type evaluations of measuring instruments on the basis of the relevant OIML Recommendation(s).

# Part I - Guidance and Interpretation of Clauses and Subclauses of ISO/IEC 17020:2012 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

## Introduction

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

G.0-1 Issuing OIML-CS certificates is the activity of examination of products, the determination of their conformity with requirements, and the reporting of the results. In this case, the activity is limited to compliance of types of instruments, families of types, and types of modules of instruments. This activity does not cover the conformity of individual products, surveillance of production, or quality systems for production.

This Document does not cover the case where the examination of products and the determination of their conformity with requirements is 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 can be taken into account to demonstrate the conformity.

OIML-CS certificates and their associated OIML type evaluation reports, are issued on the basis of tests and examinations.

This Document is limited to legal metrology requirements under the OIML-CS 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 elaborations of ISO/IEC 17020 in Part I, and certain clauses and sub-clauses of ISO/IEC 17065 in Part II, 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 OIML Publication B 18 for OIML-CS certificates and in the relevant OIML Recommendations for OIML type evaluation reports.

The test results that are taken into account for the assertion of the conformity can be obtained from tests performed by the manufacturer (a manufacturer test laboratory), a third-party test laboratory or an internal test laboratory inside the Inspection Body. Irrespective of the origin of the test results, the issuing of OIML-CS certificates is considered as third-party inspection (performed by a type A inspection body).

## 1 Scope

**OIML guidance to clause 1 (G.1-1 to G.1-3)**

G.1-1 Only a type A inspection body (see G.4.1.6-1) is permitted to be an OIML Issuing Authority under the OIML-CS.

G.1-2 “Inspection Bodies” are OIML Issuing Authorities under the OIML-CS (see G.3.5-1).

G.1-3 "Inspection" relates to the issuing of OIML-CS certificates and OIML type evaluation reports under the OIML-CS when the relevant requirements of ISO/IEC 17065 are also applied (see Part II).

## 2 Normative References

**OIML guidance to clause 2 (G.2-1)**

G.2-1 In addition:

- OIML V 1:2013 *International vocabulary of terms in legal metrology (VIML) (bilingual French-English)*
- OIML V 2-200:2012 *International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM)*
- OIML G 1-100:2008 *Evaluation of measurement data - Guide to the expression of uncertainty in measurement*
- OIML G 1-101:2008 *Evaluation of measurement data – Supplement 1 to the "Guide to the expression of uncertainty in measurement" Propagation of distributions using a Monte Carlo method*
- OIML G 1-102:2011 *Evaluation of measurement data - Supplement 2 to the "Guide to the expression of uncertainty in measurement" Extension to any number of output quantities*
- OIML G 1-104:2009 *Evaluation of measurement data – An introduction to the "Guide to the expression of uncertainty in measurement" and related documents*
- OIML G 1-106:2012 *Evaluation of measurement data – The role of measurement uncertainty in conformity assessment*
- OIML G 19:2017 *The role of measurement uncertainty in conformity assessment decisions in legal metrology*
- OIML B 18:2022 *Framework for the OIML Certification System (OIML-CS)*
- OIML D 14:2004 *Training and qualification of legal metrology personnel*
- OIML D 19:1988 *Pattern evaluation and pattern approval*
- ILAC P15 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*

## 3 Terms and definitions

**OIML guidance to clause 3 (G.3-1 and G.3-2)**

G.3-1 For the purpose of this Document, the relevant definitions given in ISO/IEC 17000:2020 *Conformity assessment – Vocabulary and general principles*, in the VIM, and in the VIML apply. General definitions related to quality are given in ISO 9000:2015 *Quality management systems - Requirements*. Where different definitions are given in ISO 9000:2015, the definitions in ISO/IEC 17000:2020, in the VIM, and in the VIML are preferred.

G.3-2 In addition:

**OIML certificate (OIML B 18)**

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

**regulatory designating authority**

governmental or public body that is tasked with designating an inspection body

**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".

**type approval (VIML 2.05)**

decision of legal relevance, based on the review of type evaluation report, that the type of a measuring instrument complies with the relevant statutory requirements and results in the issuance of the type approval certificate

*Note*: For the purposes of the OIML-CS, "type approval certificate" should be read as "OIML certificate".

**3.1 inspection**

**OIML guidance to subclause 3.1 (G.3.1-1)**

G.3.1-1 Inspection is the examination of a product (see G.3.2-1) and determination of its conformity with the applicable OIML Recommendation(s).

**3.2 product**

**OIML guidance to subclause 3.2 (G.3.2-1)**

G.3.2-1 The word "product" shall be understood as meaning the measuring instrument type (including families of measuring instruments, modules, or families of modules) subject to inspection/evaluation for the issuance of OIML certificates.

**3.3 process**

**OIML guidance to subclause 3.3 (G.3.3-1)**

G.3.3-1 Processes are not relevant to issuing OIML certificates.

**3.4 service**

**OIML guidance to subclause 3.4 (G.3.4-1)**

G.3.4-1 Services are not relevant to issuing OIML certificates.

**3.5 inspection body**

**OIML guidance to subclause 3.5 (G.3.5-1)**

G.3.5-1 For the purposes of the OIML-CS, an Inspection Body is an OIML Issuing Authority approved by the OIML-CS Management Committee. The Inspection Body has used compliance with ISO/IEC 17020 and the additional requirements specified in OIML-CS Procedural Document PD-03 *Application and approval of OIML Issuing Authorities, Utilizers and Associates* to demonstrate their competence.

### 3.6 inspection system

No OIML guidance

### 3.7 inspection scheme

**OIML guidance to subclause 3.7 (G.3.7-1)**

G.3.7-1 For the purposes of the OIML-CS, the specified requirements are those in OIML Recommendations and the rules and procedures are those detailed in OIML B 18 and the OIML-CS Operational and Procedural Documents.

### 3.8 impartiality

No OIML guidance

### 3.9 appeal

No OIML guidance

### 3.10 complaint

No OIML guidance

## 4 General requirements

### 4.1 Impartiality and independence

**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

**4.1.6**

**OIML guidance to subclause 4.1.6 (G.4.1.6-1)**

G.4.1.6-1 The Inspection Body must be a third-party (type A) inspection body to be an OIML Issuing Authority under the OIML-CS.

### 4.2 Confidentiality

**4.2.1** No OIML guidance

**4.2.2** No OIML guidance

**4.2.3** No OIML guidance

# 5 Structural requirements

## 5.1 Administrative requirements

**5.1.1**

**OIML guidance to subclause 5.1.1 (G.5.1.1-1)**

G.5.1.1-1 When the Inspection Body is a service of a public administration, it may happen that the legal entity is the whole administrative body to which it belongs.

**5.1.2** No OIML guidance

**5.1.3** No OIML guidance

**5.1.4** No OIML guidance

**5.1.5**

**OIML guidance to subclause 5.1.5 (G.5.1.5-1)**

G.5.1.5-1 Provisions shall ensure that the client is informed of its responsibilities and that any modification to an approved type shall be notified to the Inspection Body before being implemented.

## 5.2 Organization and management

**5.2.1**

**OIML guidance to subclause 5.2.1 (G.5.2.1-1)**

G.5.2.1-1 Threats to impartiality may result from organisational provisions or from the status of the Inspection Body.

**5.2.2** No OIML guidance

**5.2.3** No OIML guidance

**5.2.4**

**OIML guidance to subclause 5.2.4 (G.5.2.4-1)**

G.5.2.4-1 When the Inspection Body is a service of a public administration, it may happen that the legal entity is the whole administrative body to which it belongs.

**5.2.5** No OIML guidance

**5.2.6** No OIML guidance

**5.2.7** No OIML guidance

# 6 Resource requirements

## 6.1 Personnel

**6.1.1**

**OIML guidance to subclause 6.1.1 (G.6.1.1-1 and G.6.1.1-2)**

G.6.1.1-1 For the purposes of the OIML-CS, personnel shall have sufficient knowledge of the OIML-CS Procedural Documents and the relevant OIML Recommendations.

G.6.1.1-2 The Inspection Body shall also define and document the competence requirements for all personnel involved in the review and certification decision (according to the additional requirements in Part II of this document).

**6.1.2** No OIML guidance

**6.1.3**

**OIML guidance to subclause 6.1.3 (G.6.1.3-1 and G.6.1.3-2)**

G.6.1.3-1 Participation in international work (regional and OIML) is an important element to build competence.

G.6.1.3-2 Competence of personnel for tests and examinations is addressed in ISO/IEC 17025.

**6.1.4** No OIML guidance

**6.1.5**

**OIML guidance to subclause 6.1.5 (G.6.1.5-1)**

G.6.1.5-1 The appropriate requirements of OIML D 14 *Training of legal metrology personnel - Qualification - Training programs* can be used to provide guidance.

**6.1.6**

**OIML guidance to subclause 6.1.6 (G.6.1.6-1)**

G.6.1.6-1 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.

**6.1.7** No OIML guidance

**6.1.8** No OIML guidance

**6.1.9** No OIML guidance

**6.1.10**

**OIML guidance to subclause 6.1.10 (G.6.1.10-1 and G.6.1.10-2)**

G.6.1.10-1 Elements of experience could include participation in international work on legal metrology (regional and OIML). Participation in these activities shall be recorded.

G.6.1.10-2 Records shall be kept of the qualifications of the personnel involved in evaluation, review and decision making.

**6.1.11** No OIML guidance

**6.1.12** No OIML guidance

**6.1.13** No OIML guidance

## 6.2 Facilities and equipment

**OIML guidance to subclause 6.2 (G.6.2-1 and G.6.2-2)**

The following guidance relates to subclause 6.2 as a whole, so specific guidance for each individual subclause (6.2.1 to 6.2.15) is not provided.

G.6.2-1 The results of type evaluation (tests and examinations) which are used to issue OIML certificates shall be carried out by testing laboratories which conform to ISO/IEC 17025. A separate OIML Document (OIML D 30) gives guidance on the application of ISO/IEC 17025 to testing laboratories involved in legal metrology testing. The applicable requirements of ISO/IEC 17025 will be fulfilled by testing laboratories which have been approved by the OIML-CS Management Committee. These testing laboratories therefore fulfil the requirements of 6.2 and so guidance is not provided for 6.2.1 to 6.2.15. Instead, ISO/IEC 17025 and OIML D 30 should be consulted for further information.

G.6.2-2 For the issuing of OIML certificates under Scheme A of the OIML-CS the scope of accreditation or peer assessment for the testing laboratory shall include the applicable OIML Recommendations. Where the test laboratory is accredited, the Accreditation Body that carries out the assessment of the testing laboratory shall be a signatory of a mutual recognition arrangement among Accrediting Bodies (regional or international), for instance the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement).

## 6.3 Subcontracting

**6.3.1**

**OIML guidance to subclause 6.3.1 (G.6.3.1-1 to G.6.3.1-4)**

G.6.3.1-1 Subcontracted testing laboratories shall comply with the applicable requirements of ISO/IEC 17025. The Inspection Body shall determine this either by assessing its subcontractors against the applicable requirements of this standard (in which case the Inspection Body shall demonstrate its competence to carry out such an assessment) or by asking subcontracted testing laboratories to be accredited or peer assessed. Where

accreditation is chosen, the Accreditation Body that carries out the assessment of the Test Laboratory shall be a signatory of a mutual recognition arrangement among Accrediting Bodies (regional or international), for instance the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement). For the issuing of OIML Certificates under Scheme A of the OIML-CS, where accreditation is chosen, the scope of accreditation shall cover the relevant OIML Recommendations. Where peer assessment is chosen, the scope of the peer assessment shall cover the relevant OIML Recommendations.

G.6.3.1-2 Where the laboratory that performed the tests is not fully independent of the manufacturer this 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 an unauthorised way.

G.6.3.1-3 The Inspection 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-authorised way.

G.6.3.1-4 Subcontracting in series (i.e. subcontractors subcontracting to other subcontractors) is prohibited and shall be detailed in the agreement with the subcontractor.

**6.3.2** No OIML guidance

**6.3.3**

**OIML guidance to subclause 6.3.3 (G.6.3.3-1)**

G.6.3.3-1 In the case of OIML certification, the OIML Issuing Authority is responsible for issuing the OIML type evaluation report which will include all the test reports issued by the subcontracted testing laboratory(ies).

**6.3.4**

**OIML guidance to subclause 6.3.4 (G.6.3.4-1)**

G.6.3.4-1 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 Inspection Body.

# 7 Process requirements

## 7.1 Inspection methods and procedures

**7.1.1**

**OIML guidance to subclause 7.1.1 (G.7.1.1-1)**

G.7.1.1-1 For the purposes of the OIML-CS, the methods and procedures are those defined in the applicable OIML Recommendations and the standards that may be referred to in these Recommendations.

**7.1.2**

**OIML guidance to subclause 7.1.2 (G.7.1.2-1 to G.7.1.2-3)**

G.7.1.2-1 OIML-CS certification does not include testing or inspection of samples taken from the market. According to the OIML requirements, it may involve sampling from the manufacturers stock.

G.7.1.2-2 Nevertheless, OIML Recommendations may require a selection of samples amongst a family of measuring instruments.

G.7.1.2-3 Such a selection is done under the responsibility of the OIML Issuing Authority.

**7.1.3** No OIML guidance

**7.1.4** No OIML guidance

**7.1.5** No OIML guidance.

**7.1.6**

**OIML guidance to subclause 7.1.6 (G.7.1.6-1 to G.7.1.6-5)**

G.7.1.6-1 Inspection Bodies that are OIML Issuing Authorities under the OIML-CS and which use test results from Manufacturer Test Laboratories shall have procedures in place to ensure controlled supervision. The requirements for Manufacturer Test Laboratories are detailed in OIML-CS Procedural Document PD-04 *Assessment and approval of Test Laboratories*.

G.7.1.6-2 When the Inspection 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 Inspection Body shall conduct sufficient examinations and tests to demonstrate that the measuring instrument fulfils the whole set of requirements applicable to its category.

G.7.1.6-3 During the type evaluation process the manufacturer is not authorized to perform any adjustment and/or modification without authorisation of the Inspection Body.

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

G.7.1.6-4 In the case of the recognition of a test report issued before the type approval application, the Inspection Body shall ensure that the instrument that was tested is identical to the instrument that is the subject of type approval.

G.7.1.6-5 Under the OIML-CS, test results used for issuing an OIML certificate shall comply with the requirements of OIML-CS Procedural Document PD-05 *Processing an OIML Type Evaluation Report and OIML Certificate*.

**7.1.7** No OIML guidance

**7.1.8** No OIML guidance

**7.1.9** No OIML guidance

## 7.2 Handling inspection items and samples

**7.2.1** No OIML guidance

**7.2.2** No OIML guidance

**7.2.3** No OIML guidance

**7.2.4** No OIML guidance

## 7.3 Inspection records

**7.3.1**

**OIML guidance to subclause 7.3.1 (G.7.3.1-1)**

G.7.3.1-1 OIML type evaluation report and test report formats specified in the applicable OIML Recommendations shall be used.

**7.3.2** No OIML guidance

## 7.4 Inspection reports and inspection certificates

**7.4.1**

**OIML guidance to subclause 7.4.1 (G.7.4.1-1 to G.7.4.1-4)**

G.7.4.1-1 Under the OIML-CS, the inspection report is the OIML type evaluation report and the inspection certificate is the OIML certificate. Both of these documents shall be issued in accordance with OIML-CS Procedural Document PD-05 *Processing an OIML type evaluation report and OIML certificate*. OIML certificates are registered with the BIML and are publicly available on the OIML website.

G.7.4.1-2 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.7.4.1-3 When the evaluation report includes two or more parts (examination report(s), test report(s), evaluation report) this shall be indicated.

G.7.4.1-4 The evaluation report shall highlight any necessary justifications showing that the requirements have been met.

**7.4.2**

**OIML guidance to subclause 7.4.2 (G.7.4.2-1)**

G.7.4.2-1 A template for an OIML-CS certificate can be downloaded from the OIML website. The template contains the information to be included.

**7.4.3**

**OIML guidance to subclause 7.4.3 (G.7.4.3-1)**

G.7.4.3-1 For OIML certificates, the certification documents are described in OIML B 18 *Framework for the OIML Certification System (OIML-CS)* and OIML-CS Procedural Document PD-05 *Processing an OIML type evaluation report and OIML certificate*.

**7.4.4**

**OIML guidance to subclause 7.4.4 (G.7.4.4-1)**

G.7.4.4-1 The OIML type evaluation report shall clearly identify the test reports that have been used to support the evaluation.

**7.4.5**

**OIML guidance to subclause 7.4.5 (G.7.4.5-1)**

G.7.4.5-1 Revisions to OIML certificates shall be issued in accordance with OIML-CS Procedural Document PD-05 *Processing an OIML type evaluation report and OIML certificate*.

## 7.5 Complaints and appeals

**7.5.1**

**OIML guidance to subclause 7.5.1 (G.7.5.1-1 and G.7.5.1-2)**

G.7.5.1-1 In some cases, appeal procedures may be the responsibility of regulatory designating authorities. However, they must be described.

G.7.5.1-2 Under the OIML-CS, the OIML Issuing Authority shall have an appeals procedure. The OIML-CS also incorporates a Board of Appeal.

**7.5.2** No OIML guidance

**7.5.3** No OIML guidance

**7.5.4** No OIML guidance

**7.5.5** No OIML guidance

## 7.6 Complaints and appeals process

**7.6.1** No OIML guidance

**7.6.2** No OIML guidance

**7.6.3** No OIML guidance

**7.6.4** No OIML guidance

**7.6.5** No OIML guidance

# 8 Management system requirements

## 8.1 Options

### 8.1.1 General

**OIML guidance to subclause 8.1.1 (G.8.1.1-1)**

G.8.1.1-1 Option A and Option B referred to in this subclause 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 subclause 8.1.3 (G.8.1.3-1)**

G.8.1.3-1 If the certification body 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**

**OIML guidance to subclause 8.2.1 (G.8.2.1-1)**

G.8.2.1-1 In particular, the Inspection Body shall keep updated documentation on:

- the legal and contractual requirements applicable to its activity as an OIML Issuing Authority;
- the requirements applicable to the measuring instruments by reference to which the type examination is carried out, e.g. OIML Recommendation R XXX.

**8.2.2** No OIML guidance

**8.2.3** No OIML guidance

**8.2.4**

**OIML guidance to subclause 8.2.4 (G.8.2.4-1 to G.8.2.4-3)**

G.8.2.4-1 The Inspection 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 Inspection 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 Inspection Body in these agreements shall be conducted.

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

- procedures for selection, identification, storage of equipment submitted to inspection and of associated documentation;
- description of the test equipment and facilities, procedures for their maintenance and metrological traceability;
- procedures for defining and planning tests and examinations;
- test procedures;
- criteria and procedures for dealing with nonconformities of products submitted to inspection, 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.8.2.4-3 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 documents (Option A)

**8.3.1**

**OIML guidance to subclause 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**

**OIML guidance to subclause 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-CS 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

**8.5.1.3** 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 subclause 8.6.2 (G.8.6.2-1)**

G.8.6.2-1 For Inspection Bodies that are OIML Issuing Authorities under the OIML-CS the internal audit programme shall take into consideration the requirements of OIML B 18 *Framework for the OIML Certification System (OIML-CS),* OIML-CS Procedural Documents PD-03 *Application and approval of OIML Issuing Authorities, Utilizers and Associates*, PD-05 *Processing an application for an OIML Type Evaluation Report and OIML certificate* and PD-07 *Transition Arrangements under the OIML-CS*, and the requirement to report annually to the OIML-CS Management Committee.

**8.6.3** No OIML guidance

**8.6.4** No OIML guidance

**8.6.5** No OIML guidance

## 8.7 Corrective actions (Option A)

**8.7.1**

**OIML guidance to subclause 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 inspection.

**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

## Annex A Independence requirements for inspection bodies

### A.1 Requirements for inspection bodies (Type A)

**OIML guidance to subclause A.1 (G.A.1-1)**

G.A.1-1 For b) the Inspection Body may be a service of a public administration or of a public institute. In this case, "a part of a legal entity" may be interpreted as 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 organisational procedures which guarantee independence.

### A.2 Requirements for inspection bodies (Type B)

**OIML guidance to subclause A.2 (G.A.2-1)**

G.A.2-1 A type B inspection body is not permitted to be an OIML Issuing Authority under the OIML-CS.

### A.3 Requirements for inspection bodies (Type C)

**OIML guidance to subclause A.3 (G.A.3-1)**

G.A.3-1 A type C inspection body is not permitted to be an OIML Issuing Authority under the OIML-CS.

# Part II - Guidance and Interpretation of Subclauses 4.1.2, 4.1.3, 4.4, 4.6, 5.2, 7.4, 7.5, 7.6, 7.11 and 7.13.6 of ISO/IEC 17065:2012 *Conformity assessment - Requirements for bodies certifying products, processes and services*

In addition to the requirements specified in ISO/IEC 17020, the requirements in the following clauses and subclauses of ISO/IEC 17065 also apply when assessing the competence of OIML Issuing Authorities under the OIML-CS.

### 4.1.2 Certification agreement

**4.1.2.1** No OIML guidance

**4.1.2.2**

**OIML guidance to subclause 4.1.2.2 (G.4.1.2.2-1)**

G.4.1.2.2-1 Provisions shall ensure that the client is informed of its responsibilities and that any modification to an approved type shall be notified to the Inspection Body before being implemented.

### 4.1.3 Use of license, certificates and marks of conformity

**4.1.3.1**

**OIML guidance to subclause 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 OIML Certification System (OIML-CS)*, OIML-CS Procedural Documents PD-05 and PD-06. Rules on the use of OIML logos, including the OIML-CS logo, can be found in OIML B 20:2019 *Rules for the use of OIML logos*.

**4.1.3.2** No OIML guidance

### 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

### 4.6 Publicly available information

**OIML guidance to subclause 4.6 (G.4.6-1 to G.4.6-3)**

G.4.6-1 The Inspection Body shall provide to applicants a list of product documentation required for processing the certification.

G.4.6-2 For a) some of these conditions result from OIML Publications. The Inspection Body shall clearly refer to these sources and, when necessary, summarise them in a document provided to clients.

G.4.6-3 For c) the client shall be informed of its responsibilities and that any modification to an approved type shall be notified to the Inspection Body before being implemented.

### 5.2 Mechanism for safeguarding impartiality

**5.2.1**

**OIML guidance to subclause 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** No OIML guidance

### 7.4 Evaluation

**7.4.1**

**OIML guidance to subclause 7.4.1 (G.7.4.1-1)**

G.7.4.1-1 Inspection Bodies are responsible for:

- checking that the sample(s) to be examined and tested complies(y) with the description in the application;
- the configuration control of the sample(s) to be examined and/or tested;
- allowing the subcontracting laboratory(ies) to verify that the sample(s) to be examined and/or tested are those validated by the Inspection Body.

**7.4.2** No OIML guidance

**7.4.3** No OIML guidance

### 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 subclause 7.6.1 (G.7.6.1-1)**

G.7.6.1-1 The Inspection 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 subclause 7.6.2 (G.7.6.2-1 and G.7.6.2-2)**

G.7.6.2-1 Only information related to the evaluation process is relevant.

G.7.6.2-2 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

### 7.11 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 subclause 7.11.3 (G.7.11.3-1 and G.7.11.3-2)**

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 the OIML certificate will be deregistered from the OIML website. The BIML will inform Utilizers and Associates under the OIML-CS of the deregistering of the OIML certificate.

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 the regulatory designating authority and in accordance with the rules defined by the regulatory designating authority.

**7.11.4** No OIML guidance

**7.11.5**

**OIML guidance to subclause 7.11.5 (G.7.11.5-1)**

G.7.11.5-1 See applicable OIML guidance to subclauses 7.4 and 7.6.

**7.11.6**

**OIML guidance to subclause 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.

## 7.13 Complaints and appeals

**…**

**7.13.6** No OIML guidance