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

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

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Guide pour l'application du Guide ISO/CEI 65 à l'évaluation des organismes de certification des instruments de mesure en métrologie légale.

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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; 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 Basic Publications (OIML B), which define the operating rules of the various OIML structures and systems;

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.

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

Additionally, the OIML 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 to metrological authorities, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus they do not necessarily represent the views of the OIML.

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SCOPE

This document gives interpretation and specific requirements related to the application of ISO/IEC Guide 65 (1996) to assessment of bodies who are responsible for ~~delivering~~-type approval evaluation of measuring instruments (e.g. OIML Certificates of conformity of types of measuring instruments).

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

~~It~~ may be used:

- for the accreditation of national type approval bodies when required by the national legal metrology regulation,
- for the accreditation of OIML ~~Certificate~~-Issuing Authorities when required by the CIML Member,
- on a voluntary basis for the implementation of ISO/IEC Guide 65 by national type approval bodies 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).

<p style="text-align: center;">ISO GUIDE 65 General requirements for bodies operating product certification systems</p>	<p style="text-align: center;">Specific requirements and comments related to type approval and OIML Certificates</p>
<p>Introduction</p> <p>Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing, while still others comprise type testing only.</p> <p>This Guide specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.</p> <p>The requirements contained in this Guide are written, above all, to be considered as general criteria for organizations operating product certification systems; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account.</p> <p>Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents will, in many cases, require their own explanatory documentation.</p> <p>While this Guide is concerned with third-parties providing product certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.</p> <p>The diversity in certification systems may at first seem unnecessary and even confuses newcomers in the field, clients and operators alike. The ISO/IEC publication Certification and related activities is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community.</p>	<p>Issuing type approval 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 approval 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.</p> <p>This document includes amplifications of ISO Guide 65 which are considered necessary for the specific applications mentioned in its scope.</p> <p>The form of the assertion of conformity is defined:</p> <ul style="list-style-type: none"> - in the national legal metrology regulations for type approvals; - in the OIML pPublication B 3 for OIML Certificates; - <u>in the relevant OIML Recommendations for Evaluation Reports.</u> <p>Even if results of tests performed by the manufacturer are taken into account for the assertion of the conformity, type approvals and OIML Certification are third-party product certification.</p>

<p style="text-align: center;">ISO GUIDE 65 General requirements for bodies operating product certification systems</p>	<p style="text-align: center;">Specific requirements and comments related to type approval and OIML Certificates</p>
<p>1 Scope</p>	
<p>1.1 This Guide specifies general requirements that a third-party operating a product certification system shall meet if it is to be recognized as competent and reliable.</p> <p>In this Guide the term “certification body” is used to cover any body operating a product certification system. The word “product” is used in its widest sense and includes processes and services; the word “standard” is used to include other normative documents such as specifications or technical regulations.</p>	<p>The third-parties are national type approval bodies and OIML Issuing Authorities.</p> <p>The word “standard” shall be understood as follows:</p> <ul style="list-style-type: none"> - for type approvals, 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. <p>Other applicable general regulatory legal metrology texts and OIML publications (on legal units, traceability, etc.) are also part of the applicable standards.</p>
<p>1.2 The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both, as described in ISO/IEC Guide 53:</p> <p>a) type testing or examination;</p> <p>b) testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;</p> <p>c) testing or inspection of every product or of a particular product, whether new or already in use;</p> <p>d) batch testing or inspection;</p> <p>e) design appraisal.</p> <p><i>NOTE 1</i> <i>ISO/IEC Guide 28 may be consulted for a model of one form of a third-party product certification system.</i></p>	<p>Type approval and OIML Certificate issuing include only activities a, b and e. Activities c and d are related to other legal metrology procedures.</p> <p>a) Type approval and OIML Certification includes tests, examinations and evaluation of the instrument.</p> <p>b) Type approval 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.</p> <p>e) Type approval and OIML Type Evaluation include design evaluation, in particular for the following aspects:</p> <ul style="list-style-type: none"> • suitability for use, • sealing, • checking facilities.
<p>2 References</p>	
<p>ISO 8402:1994, Quality management and quality assurance — Vocabulary.</p> <p>ISO 10011-1:1990, Guidelines for auditing quality systems — Part 1: Auditing.</p> <p>ISO/IEC Guide 2:1996, Standardization and related activities — General vocabulary.</p>	<p>In addition:</p> <p>OIML V 1: International vocabulary of terms in legal metrology (VIML) (bilingual French-English), 2000</p> <p>OIML V 2: International vocabulary of basic and general terms in metrology (VIM) (bilingual French-English), 1993</p>

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<p>ISO/IEC Guide 7:1994, Guidelines for drafting of standards suitable for use for conformity assessment.</p> <p>ISO/IEC Guide 23:1982, Methods of indicating conformity with standards for third-party certification systems.</p> <p>ISO/IEC Guide 25:1990, General requirements for the competence of calibration and testing laboratories.</p> <p>ISO/IEC Guide 27:1983, Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.</p> <p>ISO/IEC Guide 28:1982, General rules for a model third-party certification system for products.</p> <p>ISO/IEC Guide 39:1988, General requirements for the acceptance of inspection bodies.</p> <p>ISO/IEC Guide 53:1988, An approach to the utilization of a supplier's quality system in third-party product certification.</p> <p>ISO/IEC Guide 62:1996, General requirements for bodies operating assessment and certification/registration of quality systems.</p>	<p>OIML G 1: Guide to the expression of uncertainty in measurement (GUM), 1995</p> <p>OIML B 3: OIML Certificate System for Measuring Instruments, 2003</p> <p>OIML B 10-1: Framework for a Mutual Acceptance Arrangement on OIML type evaluations (OIML MAA), 2004</p> <p>OIML B 10-2: Checklists for Issuing Authorities and testing laboratories carrying out OIML type evaluations, 2004</p> <p>OIML D 14: Training of legal metrology personnel - Qualification - Training programs, 2004</p> <p>OIML D 19: Pattern evaluation and pattern approval, 1988</p> <p>IAF GD 5:2006: IAF Guidance on the application of ISO/IEC Guide 65:1996</p> <p>ISO/IEC Guide 25 now corresponds to ISO/IEC 17025.</p> <p>Note :</p> <p>ISO 8402:1994 now corresponds to ISO 9000:2000</p> <p>ISO 10011-1:1990 now corresponds to ISO 19011:2002</p> <p>ISO/IEC Guide 2:1996 now corresponds to ISO/IEC Guide 2:2004</p> <p>ISO/IEC Guide 7:1982 now corresponds to ISO/IEC Guide 2:1994</p> <p>ISO/IEC Guide 28:1982 now corresponds to ISO/IEC Guide 28:2004</p> <p>ISO/IEC Guide 39 now corresponds to ISO/IEC 17020</p> <p>ISO/IEC Guide 53:1988 now corresponds to ISO/IEC Guide 53:2005</p>
<p>3 Definitions</p>	
<p>For the purposes of this Guide, the relevant definitions given in ISO/IEC Guide 2 and ISO 8402 apply, together with the following definition.</p>	<p>For the purpose of this Guide, the relevant definitions given in the ISO/IEC 17000, VIM and VIML apply. General definitions related to quality are given in ISO 9000. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000, VIM and VIML are preferred.</p>

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	<p>Type (pattern) evaluation (VIML 2.5) Systematic examination and testing of the performance of one or more specimens of an identified type (pattern) 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.</p> <p><i>NOTE</i> “Pattern” is used in legal metrology with the same meaning as “type”; in the entries below, only “type” is used.</p> <p>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.</p> <p>Evaluator Person on the staff of the certification body who is in charge of the type evaluation of a measuring instrument.</p> <p>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.</p>
<p>3.1 supplier: The party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.</p>	<p>For this application, "supplier" must be understood as "applicant" for type approval or for OIML Type Evaluation. Although the instrument may be manufactured by another company, the applicant has to assume responsibility for compliance.</p>
<p>4 Certification body</p>	
<p>4.1 General provisions</p>	
<p>4.1.1 The policies and procedures under which the certification body operates and their administration shall be non-discriminatory and shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this Guide.</p>	
<p>4.1.2 The certification body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification be conditional upon the number of certificates already issued.</p>	

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<p>4.1.3 The criteria against which the products of a supplier are evaluated shall be those outlined in specified standards. Requirements for standards suitable for this purpose are contained in ISO/IEC Guide 7. If explanation is required as to the application of these documents for a specific certification system, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the certification body.</p>	<p>These criteria shall result from documents accessible to the public (laws, regulations, OIML publications, standards, etc.).</p>
<p>4.1.4 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the certification being considered.</p>	<p>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.</p>
<p>4.2 Organization</p>	
<p>The structure of the certification body shall be such as to foster confidence in its certifications. In particular, the certification body shall:</p> <p>a) be impartial;</p> <p>b) be responsible for decisions relating to its granting, maintaining, extending, suspending and withdrawing of certification;</p> <p>c) identify the management (committee, group or person) which shall have overall responsibility for all of the following:</p> <ol style="list-style-type: none"> 1) performance of testing, inspection, evaluation and certification as defined in this Guide, 2) formulation of policy matters relating to the operation of the certification body, 3) decisions on certification, 4) supervision of the implementation of its policies, 5) supervision of the finances of the body, 6) delegation of authority to committees or individuals as required to undertake defined 	<p>a) Impartiality may result from organizational provisions or from the status of the certification body (e.g. public administration).</p> <p>b) In some cases, withdrawing and/or suspending certifications may be the responsibility of higher authorities.</p> <p>c2) Policy matters may be decided by higher authorities (e.g. laws, ministerial decisions). <u>The policy should include a commitment to approve only types of measuring instruments that fulfil the full set of applicable requirements for type approval.</u></p> <p>c4) Supervision of the implementation of policies may be the responsibility of higher administrative authorities; however the certification body must have procedures to demonstrate that this policy is implemented.</p> <p>c5) Similar comment as for c4.</p>

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<p>activities on its behalf,</p> <p>7) technical basis for granting certification;</p> <p>d) have documents which demonstrate it is a legal entity;</p> <p>e) have a documented structure which safeguards impartiality including provisions to ensure the impartiality of the operations of the certification body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system;</p> <p>f) ensure that each decision on certification is taken by a person(s) different from those who carried out the evaluation;</p> <p>g) have rights and responsibilities relevant to its certification activities;</p> <p>h) have adequate arrangements to cover liabilities arising from its operations and/or activities;</p> <p>i) have the financial stability and resources required for the operation of a certification system;</p> <p>j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing certification functions relating to the type, range and volume of work performed, under a responsible senior executive;</p> <p>k) have a quality system giving confidence in its ability to operate a certification system for products;</p> <p>l) have policies and procedures that distinguish between product certification and any other activities in which the certification body is engaged;</p> <p>m) together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the certification process;</p> <p>n) have formal rules and structures for the appointment and operation of any committees which are involved in the certification process; such committees shall be free from any commercial, financial and other pressures that might influence decisions; a structure where members are chosen to provide a balance of interests where no single interest predominates will be deemed to satisfy this provision;</p>	<p>d) 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.</p> <p>e) This structure may result from general provisions concerning the organization of public administrations. <u>For the purpose of legal metrology a decision committee which includes all the interested parties such as manufacturers, users and consumers is not applicable.</u></p> <p>f) This is the reason why definitions of evaluator and supervisor have been introduced.—(To be discussed)</p> <p>i) 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.</p>

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<p>o) ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications, and it shall not</p> <p>1) supply or design products of the type it certifies,</p> <p>2) give advice or provide consultancy services to the applicant as to methods of dealing with matters which are barriers to the certification requested,</p> <p>3) provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification process and decisions;</p> <p>p) have policies and procedures for the resolution of complaints, appeals and disputes received from suppliers or other parties about the handling of certification or any other related matters.</p>	<p>o) 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.</p>
<p>4.3 Operations</p>	
<p>The certification body shall take all steps necessary to evaluate conformance with the relevant product standards according to the requirements of specific product certification system (see clause 3). The certification body shall specify the relevant standards or parts thereof and any other requirements such as sampling, testing and inspection requirements which form the basis for the applicable certification system.</p> <p>In conducting its certification operations, the certification body shall observe, as appropriate, the requirements for the suitability and competence of body(ies) or person(s) carrying out testing, inspection and certification/registration as specified in ISO/IEC Guides 25, 39 and 62.</p>	<p>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.</p> <p>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.</p> <p>The manufacturer is not authorized to perform any adjustment and/or modification out of this supervision.</p> <p>After modification and/or adjustment, the certification body shall decide if complementary test are required.</p> <p>The results of tests and examinations which are used to perform type evaluation shall be carried out by testing laboratories whose quality system conforms to ISO/IEC 17025 requirements. 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 the testing laboratories.</p>

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<p>4.4 Subcontracting</p> <p>When a certification body decides to subcontract work related to certification (e.g. testing or inspection) to an external body or person, a properly documented agreement covering the arrangements including confidentiality and conflict of interest shall be drawn up. The certification body shall</p> <p>a) take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, suspending or withdrawing certification;</p> <p>b) ensure that the subcontracted body or person is competent and complies with the applicable provisions of this Guide and other standards and guides relevant to testing, inspection or other technical activities (see clause 2), and is not involved either directly or through the person's employer with the design or production of the product in such a way that impartiality would be compromised;</p> <p>c) obtain the applicant's consent.</p> <p><i>NOTES :</i></p> <p>2 <i>Where work related to certification has been undertaken prior to the application for certification, the body may take account of it, provided it can take responsibility as detailed in 4.4 a) and satisfy itself regarding the matters detailed in 4.4 b).</i></p> <p>3 <i>The requirements given in 4.4 a) and b) are also relevant, by extension, when a certification body uses, for granting its own certification, work performed by another certification body with which it has signed an agreement.</i></p>	<p>a) The certification body shall not delegate any power to subcontractors to draw conclusions on conformity from the test and examination results.</p> <p>b) 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.</p> <p>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.</p> <p>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 (e.g. OIML Test Report).</p> <p>Subcontracting in series (subcontractors subcontracting to other subcontractors) is prohibited.</p> <p>Where the laboratory that performed the tests is not fully independent of the manufacturer, <u>applicable criteria are those defined in the appropriate OIML Publications.</u> this Such a situation shall be clearly indicated in the type evaluation report. In such a case, this laboratory must be accredited to perform these tests and <u>The manufacturer</u> 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. (To be discussed)</p> <p>Note 2: In addition, 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-authorized way.</p>

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	<p>Note 3: 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.</p> <p>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.</p>
<p>4.5 Quality system</p>	
<p>4.5.1 The management of the certification body having executive responsibility for quality shall define and document its policy for quality and its objectives for, and commitment to, quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.</p>	
<p>4.5.2 The certification body shall operate an effective quality system in accordance with the relevant elements of this Guide and appropriate for the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the certification body staff. The certification body shall ensure effective implementation of the documented quality system, procedures and instructions. The certification body shall designate a person having direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority for</p> <p>a) ensuring that a quality system is established, implemented and maintained in accordance with this Guide, and</p> <p>b) reporting on the performance of the quality system to the body's management for review and as a basis for improvement of the quality system.</p>	<p>In particular, the certification body shall keep updated documentation on:</p> <ul style="list-style-type: none"> - 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.
<p>4.5.3 The quality system shall be documented in a quality manual and associated quality procedures, and the manual shall contain or refer to at least the following:</p> <p>a) a quality policy statement;</p>	

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<p>b) a brief description of the legal status of the certification body, including the names of its owners and, if different, names of the persons who control it;</p> <p>c) the names, qualifications, experience and terms of reference of the senior executive and other certification personnel, both internal and external;</p> <p>d) an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive;</p> <p>e) a description of the organization of the certification body, including details of the management (committee, group or person) identified in 4.2 c), its constitution, terms of reference and rules of procedure;</p> <p>f) the policy and procedures for conducting management reviews;</p> <p>g) administrative procedures including document control;</p> <p>h) the operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;</p> <p>i) the procedure for the recruitment, selection and training of certification body personnel and monitoring of their performance;</p> <p>j) a list of its approved subcontractors and the procedures for assessing, recording and monitoring their competence;</p> <p>k) its procedures for handling nonconformities and for assuring the effectiveness of any corrective and preventive actions taken;</p>	<p>h) the role and responsibilities of evaluators and supervisors shall be clearly described.</p> <p>j) 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:</p> <ul style="list-style-type: none"> - 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. <p>k) 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.</p>

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<p>l) the procedures for evaluating products and implementing the certification process, including</p> <p style="padding-left: 40px;">1) the conditions for issue, retention and withdrawal of certification documents,</p> <p style="padding-left: 40px;">2) controls over the use and application of documents employed in the certification of products;</p> <p>m) the policy and procedure for dealing with appeals, complaints and disputes;</p> <p>n) its procedures for conducting internal audits, based on the provisions of ISO 10011-1.</p>	<p>l) This includes in particular:</p> <ul style="list-style-type: none"> - 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. <p>These procedures shall conform to the requirements of the appropriate regulations, OIML Publications and standards.</p>
<p>4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification.</p>	
<p>4.6.1 The certification body shall specify the conditions for granting, maintaining and extending certification and the conditions under which certification may be suspended or withdrawn, partially or in total.</p>	<p>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.</p>
<p>4.6.2 The certification body shall have procedures to:</p> <p>a) grant, maintain, withdraw and, if applicable, suspend certification ;</p> <p>b) extend or reduce the scope of certification;</p>	<p>a) The procedures to withdraw or suspend certification may be out of the scope of responsibility of the certification body and may be decided by higher authorities.</p> <p>b) This applies in particular to:</p> <ul style="list-style-type: none"> - extension of the characteristics of a certified instrument, - extension to a family of instruments or extension of a family of instruments, <p>Example: the type approval certificate concerns for instance a turbine gas meter with a maximum flow rate of $160 \text{ m}^3/\text{h}$. The applicant requests for an extension of this Certificate to include the complete family of turbine gas meters with maximum flow rate from $60 \text{ m}^3/\text{h}$ to $1000 \text{ m}^3/\text{h}$.</p> <ul style="list-style-type: none"> - extension to other manufacturers (under the responsibility of the same applicant),

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<p>c) re-evaluate, in the event of changes significantly affecting the product's design or specification, or changes in the standards to which compliance of the product is certified, or changes in the ownership, structure or management of the supplier, if relevant, or in the case of any other information indicating that the product may no longer comply with the requirements of the certification system.</p>	<p>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 approval certificate shall be modified to include company C as an additional manufacturer.</p> <p style="text-align: center;">- transfer to a new applicant or evolution in the applicant's data.</p> <p>Example: the applicant sells its activity to another company. The type approval certificate shall be modified to be transferred to the new company as the new applicant.</p> <p>c) 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 approval or OIML Certificates previously granted.</p>
<p>4.7 Internal audits and management reviews</p>	
<p>4.7.1 The certification body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is implemented and is effective .The certification body shall ensure that:</p> <p>a) personnel responsible for the area audited are informed of the outcome of the audit; b) corrective action is taken in a timely and appropriate manner; and c) the results of the audit are documented.</p>	
<p>4.7.2 The body's management with executive responsibility shall review its quality system at defined intervals which are sufficiently short to ensure its continuing suitability and effectiveness in satisfying the requirements of this Guide and the stated quality policy and objectives. Records of such reviews shall be maintained.</p>	
<p>4.8 Documentation</p>	
<p>4.8.1 The certification body shall provide (through publications, electronic media or other means), update at regular intervals, and make available on request, the following:</p> <p>a) information about the authority under which the certification body operates; b) a documented statement of its product certification system, including its rules and procedures for granting, maintaining, extending, suspending and withdrawing certification; c) information about the evaluation procedures and</p>	<p>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.</p>

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<p>certification process related to each product certification system;</p> <p>d) a description of the means by which the organization obtains financial support and general information on the fees charged to applicants and to suppliers of certified products;</p> <p>e) a description of the rights and duties of applicants and suppliers of certified products, including requirements, restrictions or limitations on the use of the certification body's logo and on the ways of referring to the certification granted;</p> <p>f) information about procedures for handling complaints, appeals and disputes;</p> <p>g) a directory of certified products and their suppliers.</p>	<p>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.</p>
<p>4.8.2 The certification body shall establish and maintain procedures to control all documents and data that relate to its certification functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the certification body or suppliers when they are required to perform any function relating to the certification body's activities.</p>	<p>This applies in particular to the documentation on procedures mentioned in 4.5.3.1), which shall be appropriately updated and available.</p>
<p>4.9 Records</p>	
<p>4.9.1 The certification body shall maintain a record system to suit its particular circumstances and to comply with existing regulations. The records shall demonstrate that the certification procedures have been effectively fulfilled, particularly with respect to application forms, evaluation reports, surveillance activities and other documents relating to granting, maintaining, extending, suspending or withdrawing certification. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. The records shall be kept for a period of time so that continued confidence may be demonstrated for at least one full certification cycle, or as required by law.</p>	<p>Note: “full certification cycle” means “the validity period of the type approval certificate”.</p>

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<p>4.9.2 The certification body shall have a policy and procedures for retaining records for a period consistent with its contractual, legal or other obligations. The certification body shall have a policy and procedures concerning access to these records consistent with 4.10.1.</p> <p><i>NOTE 4</i> <i>The question of the length of time for retention of records requires specific attention in the light of legal circumstances and recognition arrangements.</i></p>	<p>Records related to OIML Test Reports shall be kept available as long as the OIML Certificate remains registered.</p>
<p>4.10 Confidentiality</p>	
<p>4.10.1 The certification body shall have adequate arrangements consistent with applicable laws to safeguard confidentiality of the information obtained in the course of its certification activities at all levels of its organization, including committees and external bodies or individuals acting on its behalf.</p>	
<p>4.10.2 Except as required in this Guide or by law, information gained in the course of certification activities about a particular product or supplier shall not be disclosed to a third-party without the written consent of the supplier. Where the law requires information to be disclosed to a third-party, the supplier shall be informed of the information provided as permitted by the law.</p>	
<p>5 Certification body personnel</p>	
<p>5.1 General</p>	
<p>5.1.1 The personnel of the certification body shall be competent for the functions they perform, including making required technical judgements, framing policies and implementing them.</p>	<p>Evaluations shall be performed by evaluators having the required competence. The outcome of these tasks shall be validated by a supervisor.</p> <p>A list shall be kept up-to-date, indicating for each category of measuring instruments:</p> <ul style="list-style-type: none"> - the qualified supervisor, - the qualified evaluator, - staff in the process of being qualified.
<p>5.1.2 Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.</p>	<p>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.</p> <p>Records <u>shall be kept</u> of their qualifications -shall be kept of the personnel involved in the evaluations.</p> <p>Competence of personnel for tests and examinations is addressed in ISO/IEC 17025.</p>

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<p>5.2 Qualification criteria</p>	
<p>5.2.1 In order to ensure that evaluation and certification are carried out effectively and uniformly, the minimum relevant criteria for the competence of personnel shall be defined by the certification body.</p>	<p>The appropriate requirements of OIML D 14 "Training of legal metrology personnel - Qualification - Training programs" should be followed.</p> <p>Participation in international work (Regional and OIML) is an important element to build competence.</p>
<p>5.2.2 The certification body shall require its personnel involved in the certification process to sign a contract or other document by which they commit themselves</p> <p>a) to comply with the rules defined by the certification body, including those relating to confidentiality and independence from commercial and other interest; and</p> <p>b) to declare any prior and/or present association on their own part, or on the part of their employer, with a supplier or designer of products to the evaluation or certification of which they are to be assigned.</p> <p>The certification body shall ensure that, and document how, any contracted personnel for their own part, and on the part of their employer if any, satisfy all the requirements for personnel outlined in this Guide.</p>	
<p>5.2.3 Information on the relevant qualifications, training and experience of each member of the personnel involved in the certification process shall be maintained by the certification body. Records of training and experience shall be kept up to date, in particular the following:</p> <p>a) name and address;</p> <p>b) organization affiliation and position held;</p> <p>c) educational qualification and professional status;</p> <p>d) experience and training in each field of the certification body's competence;</p> <p>e) date of most recent updating of records;</p> <p>f) performance appraisal.</p>	<p>Elements of experience include:</p> <ul style="list-style-type: none"> - participation in international work on legal metrology (Regional and OIML), - participation as assessor or as technical expert in audits and in peer assessments. <p>Participation in these activities shall be recorded.</p>
<p>6 Changes in the certification requirements</p>	
<p>The certification body shall give due notice of any changes it intends to make in its requirements for certification. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following decision on, and publication of, the changed requirements, it shall verify that each supplier makes any necessary adjustments within such time as, in the opinion of the certification body, is reasonable.</p>	

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<p>7 Appeals, complaints and disputes</p>	
<p>7.1 Appeals, complaints and disputes brought before the certification body by suppliers or other parties shall be subject to the procedures of the certification body.</p>	<p>In some cases, appeal procedures may be the responsibility of higher authorities. However they must be described.</p>
<p>7.2 Each certification body shall:</p> <p>a) keep a record of all appeals, complaints and disputes and remedial actions relative to certification;</p> <p>b) take appropriate subsequent action;</p> <p>c) document the action taken and its effectiveness.</p>	
<p>8 Application for certification</p>	
<p>8.1 Information on the procedure</p>	
<p>8.1.1 The certification body shall provide to applicants an up-to-date detailed description of the evaluation and certification procedures, appropriate to each certification scheme, and the documents containing the requirements for certification, the applicants' rights and duties of suppliers which have certified products (including fees to be paid by applicants and suppliers of certified products).</p>	<p>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.</p> <p>The certification body shall provide to applicants a list of product documentation required for processing the certification.</p>
<p>8.1.2 The certification body shall require that a supplier:</p> <p>a) always complies with the relevant provisions of the certification programme;</p> <p>b) makes all necessary arrangements for the conduct of the evaluation, including provision for examining documentation and access to all areas, records (including internal audit reports) and personnel for the purposes of evaluation (e.g. testing, inspection, assessment, surveillance, reassessment) and resolution of complaints;</p> <p>c) makes claims regarding certification only in respect of the scope for which certification has been granted;</p> <p>d) does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification which the certification body may consider misleading or unauthorized;</p> <p>e) upon suspension or cancellation of certification, discontinues its use of all advertising matter that contains any reference thereto and returns any certification documents as required by the</p>	

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<p>certification body;</p> <p>f) uses certification only to indicate that products are certified as being in conformity with specified standards;</p> <p>g) endeavours to ensure that no certificate or report nor any part thereof is used in a misleading manner;</p> <p>h) in making reference to its product certification in communication media such as documents, brochures or advertising, complies with the requirements of the certification body.</p>	
<p>8.1.3 When the desired scope of certification is related to a specific system or type of system operated by the certification body, any explanation needed shall be provided to the applicant.</p>	
<p>8.1.4 If requested, additional application information shall be provided to the applicant.</p>	
<p>8.2 The application</p>	
<p>8.2.1 The certification body shall require completion of an official application form, signed by a duly authorized representative of the applicant, in which or attached to which are the following:</p> <p>a) the scope of the desired certification;</p> <p>b) a statement that the applicant agrees to comply with the requirements for certification and to supply any information needed for evaluation of products to be certified.</p>	
<p>8.2.2 The applicant, as a minimum, shall provide the following information:</p> <p>a) corporate entity, name, address and legal status;</p> <p>b) a definition of the products to be certified, the certification system, and the standards against which each product is to be certified if known to the applicant.</p>	<p>b) The manufacturer shall indicate the standard according to which it applies for certification.</p> <p>Minimum required information may be defined in standards. Additional necessary information shall be defined by the certification body.</p>
<p>9 Preparation for evaluation</p>	
<p>9.1 Before proceeding with the evaluation, the certification body shall conduct, and maintain records of, a review of the application for certification to ensure that:</p> <p>a) the requirements for certification are clearly</p>	<p>This includes:</p> <ul style="list-style-type: none"> - 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

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<p>defined, documented and understood;</p> <p>b) any difference in understanding between the certification body and the applicant is resolved; and</p> <p>c) the certification body has the capability to perform the certification service with respect to the scope of the certification sought and, if applicable, the location of the applicant's operations and any special requirements such as the language used by the applicant.</p>	<p>subcontractors,</p> <ul style="list-style-type: none"> - acceptance of subcontractors by the applicant. <p>Laws and regulations may require that the application be submitted in a specific language.</p>
<p>9.2 The certification body shall prepare a plan for its evaluation activities to allow for the necessary arrangements to be managed.</p>	<p>Type approval bodies and OIML Issuing Authorities are responsible:</p> <ul style="list-style-type: none"> - for the compliance of the sample(s) to be examined and tested with 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 approval body or the OIML Issuing Authority.
<p>9.3 The certification body shall assign personnel appropriately qualified to perform the tasks for the specific evaluation. Personnel shall not be assigned if they have been involved in, or been employed by a body involved in, the design, supply, installation or maintenance of such products in a manner and within a time period which could conflict with impartiality.</p>	
<p>9.4 To ensure that a comprehensive and correct evaluation is carried out, the personnel involved shall be provided with the appropriate working documents.</p>	
<p>10 Evaluation</p>	
<p>The certification body shall evaluate the products of the applicant against the standards covered by the scope defined in its application against all certification criteria specified in the rules of the scheme.</p>	
<p>11 Evaluation report</p>	
<p>The certification body shall adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that:</p> <p>a) personnel appointed to evaluate the conformance of the products shall provide the certification body with a report of findings as to the conformity with all the certification requirements;</p> <p>b) a full report on the outcome of the evaluation is promptly brought to the applicant's notice by the certification body, identifying any nonconformities that have to be discharged in order to comply with all of the certification requirements and the extent of further evaluation or testing required. If the applicant</p>	<p>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 Test Report Formats for the OIML Certificate System.</p> <p>When the evaluation report includes two or more parts (examination report(s), test report(s), evaluation report) this shall be indicated.</p> <p>The evaluation report shall highlight any necessary justifications showing that the requirements of 4.3 and 4.4 have been met.</p> <p>The evaluation report shall allow clear identification</p>

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<p>can show that remedial action has been taken to meet all the requirements within a specified time limit, the certification body shall repeat only the necessary parts of the initial procedure.</p>	<p>of the certified instrument(s) and of the technical documentation on which the evaluation has been based.</p> <p>The evaluation report shall indicate the names of the evaluators and of the supervisor. (To be discussed)</p>
<p>12 Decision on certification</p>	
<p>12.1 The decision as to whether or not to certify a product shall be taken by the certification body on the basis of the information gathered during the evaluation process and any other relevant information.</p>	<p>Only information related to the evaluation process is relevant.</p>
<p>12.2 The certification body shall not delegate authority for granting, maintaining, extending, suspending or withdrawing certification to an outside person or body.</p>	<p>Special provisions shall be considered when some of these decisions belong to higher authorities (e.g. governmental).</p>
<p>12.3 The certification body shall provide to each supplier offering certified products, formal certification documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal certification documents shall permit identification of the following:</p> <p>a) the name and address of the supplier whose products are the subject of certification;</p> <p>b) the scope of the certification granted, including, as appropriate,</p> <ol style="list-style-type: none"> 1) the products certified, which may be identified by type or range of products, 2) the product standards or other normative documents to which each product or product type is certified, 3) the applicable certification system; <p>c) the effective date of certification, and the term of the certification if applicable.</p>	<p>For OIML Certificates, the certification documents are described in OIML B 3 "OIML Certificate System for Measuring Instruments".</p>
<p>12.4 In response to an application for amendment to the scope of a certificate already granted, the certification body shall decide what, if any, evaluation procedure is appropriate in order to determine whether or not the amendment should be made and shall act accordingly.</p>	<p>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.</p> <p>See also 4.6.2</p>
<p>13 Surveillance</p>	
<p>13.1 The certification body shall have documented procedures to enable surveillance to be carried out in accordance with the criteria applicable to the relevant</p>	<p>Surveillance is not required in the OIML Certificate System.</p> <p>Surveillance is generally not required in type</p>

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certification system.	approval systems.
<p>13.2 The certification body shall require the supplier to inform it about any of the changes cited in 4.6.2 c), such as intended modification to the product, manufacturing process or, if relevant, its quality system, which affect the conformity of the product. The certification body shall determine whether the announced changes require further investigations. If such is the case, the supplier shall not be allowed to release certified products resulting from such changes until the certification body has notified the supplier accordingly.</p>	Applying for complementary certifications on a certified product is under the responsibility of the manufacturer.
<p>13.3 The certification body shall document its surveillance activities.</p>	Not applicable.
<p>13.4 Where the certification body authorizes the continuing use of its mark on products of a type which have been evaluated, the certification body shall periodically evaluate the marked products to confirm that they continue to conform to the standards.</p>	Not applicable.
<p>14 Use of licences, certificates and marks of conformity</p>	
<p>14.1 The certification body shall exercise proper control over ownership, use and display of licences, certificates and marks of conformity.</p>	<p>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.</p> <p>For type approvals, these elements are generally described in national regulations.</p>
<p>14.2 Guidance on the use of certificates and marks permitted by the certification body may be obtained from ISO/IEC Guide 23.</p>	
<p>14.3 Incorrect references to the certification system or misleading use of licences, certificates or marks, found in advertisements, catalogues, etc., shall be dealt with by suitable action.</p> <p><i>NOTE 5 Such actions are addressed in ISO/IEC Guide 27 and can include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.</i></p>	
<p>15 Complaints to suppliers</p>	
<p>The certification body shall require the supplier of certified products to:</p> <p>a) keep a record of all complaints made known to the supplier relating to a product's compliance with requirements of the relevant standard and to make these records available to the certification body when requested;</p>	

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b) take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification; c) document the actions taken.	