BASIC
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OIML B 10-2

Edition 2004 (E)

Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations

Listes de Contrôle pour les Autorités de Délivrance et les Laboratoires d'Essais effectuant des Essais de Type OIML

OIML B 10-2 Edition 2004 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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Foreword

The *OIML Certificate System for Measuring Instruments* was introduced in 1991 to facilitate harmonizing approval procedures and lowering costs associated with the international trade of measuring instruments subject to legal control. The *System* provides the possibility for a manufacturer to obtain an OIML Certificate and a Test Report indicating that a given instrument type complies with the requirements of relevant OIML International Recommendations that are applicable within the *System*.

The *System* was established to take into account the general principles applicable to testing, certification, conformity assessment, accreditation and related subjects as laid down by other International Organizations such as ISO, IEC and ILAC. A decision of the Tenth International Conference of Legal Metrology in 1996 confirmed and enhanced these objectives and also included reference to the WTO in the context of the TBT Agreement. In 2002 the *System* was revised (OIML B 3 (formerly P 1): *OIML Certificate System for Measuring Instruments* - Edition 2003) to extend the scope of application to categories of measuring instruments including families of measuring instruments, modules, and families of modules.

OIML Certificates and Test Reports may be provided by OIML Member States that have established Issuing Authorities responsible for processing applications by manufacturers that request certification of their instrument types.

The OIML Basic Publication B 10-1 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations* (Edition 2004), or MAA, was developed to further enhance the climate for mutual confidence and recognition of test results between OIML Members by providing a means whereby national metrology services can more directly assess testing and certification capabilities through internationally accepted means, such as laboratory accreditation and peer review. The MAA is designed to do this in an efficient manner that minimizes the need for multiple independent bilateral arrangements between Members. By accommodating certain agreed upon additional requirements, beyond those in the relevant OIML Recommendation, the MAA is designed to potentially expand the customer base of testing laboratories, and provide instrument manufacturers the "one-stop-testing" they desire. While OIML Certificates and Test Reports will continue to be accepted by national metrology services on a voluntary basis, the MAA is intended to greatly strengthen the commitment of the signatories.

These generic *Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations* are intended for guidance in initially carrying out and recording the results of internal assessments of the capabilities of Issuing Authorities and Testing Laboratories, to be used by legal metrology experts along with other information to provide the basis for establishing the extent of external assessment necessary for confidence in competence among Participants.

The Checklists developed would be based on the requirements for assessing the competence of Issuing Authorities according to ISO/IEC Guide 65 and for assessing the competence of Testing Laboratories according to ISO/IEC 17025.

This publication - reference OIML B 10-2 Edition 2004 (E) - was developed by the OIML Technical Subcommittee TC 3/SC 5 Conformity Assessment. It was approved for final publication by the International Committee of Legal Metrology in 2003.

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Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations

1 Scope

1.1 These Checklists provide guidance for conducting and recording the results of an assessment of the competence of Testing Laboratories and of Issuing Authorities that participate in a Declaration of Mutual Confidence (DoMC) under the "Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations" (OIML MAA) **[1]**. They are intended for use by either a team assigned to carry out a peer assessment of competence or, if applicable, for an internal audit of the operation of Issuing Authorities according to the requirements of ISO/IEC Guide 65:1996 "General requirements for bodies operating product certification systems" **[6]**. They may also be used for assessing the competence of Testing Laboratories according to the requirements of ISO/IEC 17025:1999 "General requirements for the competence of testing and calibration laboratories" **[5]**.

Note: Clauses 3 and 4 of these Checklists are intended as specific references to relevant clauses of ISO/IEC Guide 65:1996 as indicated in square brackets [ ] and ISO/IEC 17025:1999 as indicated in parenthesis ( ), respectively. However, the requirements of ISO/IEC Guide 65 and ISO/IEC 17025 are the governing documents through reference.

The use of these Checklists is voluntary.

1.2 More specific Checklists may need to be developed on the basis of these generic Checklists for a given category of measuring instrument covered. Such Checklists, therefore, may require and include additional or supplementary clauses for clarity and completeness and would be agreed upon for use by prospective or existing participants in a DoMC for their use.

1.3 The persons involved in an assessment and who would complete these Checklists are expected to have appropriate experience and training as follows:

- The assessment team of an accreditation body that carries out an assessment of the Testing Laboratory or Laboratories of an Applicant shall include at least one member who is an expert in legal metrology examination and testing for the category of instruments or devices covered. The accreditation body shall meet the requirements of ISO/IEC Guide 58 **[7]** and Guide 61 **[8]**. It shall participate in a mutual recognition agreement among accrediting bodies in the participating states or within regions that include the intended participants in a proposed or existing DoMC as, for example, participation in the "ILAC Mutual Recognition Arrangement" (ILAC Arrangement).
- The legal metrology experts that carry out a peer assessment of the Testing Laboratory or Laboratories shall be identified and assigned by the Committee on Participation Review for the category of instruments covered in a DoMC. In addition to having an expert on examination and testing, at least one expert shall be familiar with the requirements of quality systems.

2 Terminology

The definitions given in the OIML MAA **[1]** are applicable here.

3 Checklist applicable to Issuing Authorities

3.1 **Certifying body** [4]

3.1.1 General provisions [4.1]

a) Identify the relevant OIML Recommendation: Number: R ..... Edition: .....

b) The body has issued OIML Certificates for the relevant category of measuring instruments or modules:

☐ Yes ☐ No

If "Yes", indicate the number of Certificates issued: .....

Comments: .....

.....

.....

c) A documented policy exists to provide equal access and treatment for all applicants for type evaluation:

☐ Yes ☐ No

Comments: .....

.....

.....

d) Identity of the Issuing Authority

Name: .....

Contact person: .....

Address: .....

.....

Telephone: ..... Fax: ..... E-mail: .....

3.1.2 Organization [4.2]

An organization chart with the description of the responsibilities and functions of all sub-units is publicly available:

☐ Yes ☐ No

Comments: .....

.....

.....

3.1.3 Operations [4.4]

In addition to evaluating a measuring instrument to the requirements of the cited OIML Recommendation, the body would be willing to evaluate a type submitted for additional, but not substantially different tests required by other participants in a DoMC:

☐ Yes ☐ No

If yes, identify the tests.

Comments: .....

.....

.....

3.1.4 Subcontracting [4.4]

a) The body also performs the role of a Principal laboratory:

☐ Yes ☐ No

Comments: .....

.....

.....

b) The body designates the Principal laboratory:

☐ Yes ☐ No

If "Yes", the Principal laboratory is responsible for both examination and testing:

☐ Yes ☐ No

Give the number and identify the Principal laboratory, identifying the subcontracting laboratories with it, available for this category of measuring instruments.

.....

.....

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Comments: .....

.....

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c) The body designates all laboratories that are authorized for examination and testing of a measuring instrument type:

☐ Yes ☐ No

Comments: .....

.....

.....

d) The body authorizes a Principal laboratory to subcontract some testing related to the type evaluation of a measuring instrument:

☐ Yes ☐ No

If "Yes", the Principal laboratory is held responsible for all tests performed:

☐ Yes ☐ No

Comments: .....

.....

.....

e) A written procedure is followed in assessing the competence of the Principal laboratory and any subcontracting laboratories:

☐ Yes ☐ No

Comments: .....

.....

.....

f) If applicable, an applicant for type evaluation testing shall be informed of the details regarding any subcontractor involved:

☐ Yes ☐ No

Comments: .....

.....

.....

g) The body has a clear policy concerning subcontracting:

☐ Yes ☐ No

Comments: .....

.....

.....

3.1.5 Quality system [4.5]

The body has a quality system documented in a quality manual:

☐ Yes ☐ No

Comments: .....

.....

.....

The manual contains or refers to the following:

a) A quality statement:

☐ Yes ☐ No

Comments: .....

.....

.....

b) The legal status of the body and its parent responsible body:

☐ Yes ☐ No

Comments: .....

.....

.....

c) Names, qualifications, experience, and titles of all senior managers and other certification personnel:

☐ Yes ☐ No

Comments: .....

.....

.....

d) An organizational chart showing lines of authority:

☐ Yes ☐ No

Comments: .....

.....

.....

e) A description of the organization:

☐ Yes ☐ No

Comments: .....

.....

.....

f) Policy and procedures for conducting management reviews:

☐ Yes ☐ No

Comments: .....

.....

.....

g) Administrative procedures including document control:

☐ Yes ☐ No

Comments: .....

.....

.....

h) The operational and functional duties of all senior managers and other personnel:

☐ Yes ☐ No

Comments: .....

.....

.....

i) The procedure for the recruitment, selection, and training of certification personnel and monitoring performance:

☐ Yes ☐ No

Comments: .....

.....

.....

j) The identity of subcontractors and the procedures for assessing, recording, and monitoring their competence:

☐ Yes ☐ No

Comments: .....

.....

.....

k) The procedures for handling non-conformities and any necessary corrective or preventive actions:

☐ Yes ☐ No

Comments: .....

.....

.....

l) Conditions for issue, retention, and withdrawal of Certificates and Test Reports:

☐ Yes ☐ No

Comments: .....

.....

.....

m) Control over the use of Certificates and Test Reports:

☐ Yes ☐ No

Comments: .....

.....

.....

n) The policy and procedures for handling appeals, complaints and disputes:

☐ Yes ☐ No

Comments: .....

.....

.....

o) The procedures for conducting internal audits:

☐ Yes ☐ No

Comments: .....

.....

.....

3.1.6 *Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification* [4.6]

a) The body has documented procedures to grant, maintain, withdraw, or suspend certification:

☐ Yes ☐ No

Comments: .....

.....

.....

b) The body has documented procedures to re-evaluate changes in the design of the measuring instrument or module, changes in the performance or test requirements, changes in the ownership, structure or management of the manufacturer, or information indicating that the measuring instrument or module no longer complies with the certification requirements:

☐ Yes ☐ No

Comments: .....

.....

.....

c) The body has a clear and appropriate policy concerning what tests to perform in the case of a request for an extension or modification of the scope of a certificate:

☐ Yes ☐ No

Comments: .....

.....

.....

3.1.7 Internal audits and management reviews [4.7]

a) The body has procedures for carrying out periodic internal audits and management reviews at defined intervals:

☐ Yes ☐ No

The frequency of the audits and reviews is .....

Comments: .....

.....

.....

b) The results of the audits and reviews are documented and are available for responsible personnel, and corrective action is taken in a timely and appropriate manner:

☐ Yes ☐ No

Comments: .....

.....

.....

3.1.8 Documentation [4.8]

The body makes available existing documents and, at regular intervals, updates all documents describing the scope of its activities:

☐ Yes ☐ No

Comments: .....

.....

.....

Such documents would include the following information:

a) Its authority to operate:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Its certification rules and procedures:

☐ Yes ☐ No

Comments: .....

.....

.....

c) The evaluation procedures and certification process:

☐ Yes ☐ No

Comments: .....

.....

.....

d) Fees charged for evaluations and certifications:

☐ Yes ☐ No

Comments: .....

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.....

e) The rights and duties of customers (manufacturers and suppliers):

☐ Yes ☐ No

Comments: .....

.....

.....

f) Procedures handling complaints, appeals and disputes:

☐ Yes ☐ No

Comments: .....

.....

.....

g) A directory of certified measuring instrument and module types and their manufacturers or suppliers:

☐ Yes ☐ No

Comments: .....

.....

.....

h) Procedures for establishing, maintaining, and controlling the distribution of documents and data to authorized personnel and manufacturers as required in relation to relevant certification activities:

☐ Yes ☐ No

Comments: .....

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.....

3.1.9 Records [4.9]

a) The body has procedures for identifying, filing, accessing, and disseminating Test Reports and Certificates issued:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Records are identified, managed, and disposed of in such a way as to ensure integrity of the process and confidentiality of the information:

☐ Yes ☐ No

Comments: .....

.....

.....

c) A policy is established for retaining records:

☐ Yes ☐ No

If "Yes", for how long? .....

Comments: .....

.....

.....

3.1.10 Confidentiality [4.10]

a) The body has arrangements for safeguarding the confidentiality of certification information that shall not be disclosed to a third party without written consent from the manufacturer or supplier:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Information is disclosed to a third party only as specified by law, and the manufacturer or supplier is informed of such disclosures:

☐ Yes ☐ No

Comments: .....

.....

.....

3.2 Certification body personnel [5]

a) The body has documents defining the duties and responsibilities of all personnel:

☐ Yes ☐ No

Comments: .....

.....

.....

b) The body has defined criteria for assessing the competence of its own and contracted personnel with regard to responsibilities directly related to the certification process:

☐ Yes ☐ No

Comments: .....

.....

.....

c) Information regarding the name, position, educational qualifications, professional status, experience and training, and performance appraisal is maintained on file:

☐ Yes ☐ No

Comments: .....

.....

.....

3.3 Changes in the certification requirements [6]

a) The body has procedures to give public notice of any intended changes in its certification requirements and shall provide any views expressed by interested parties to those responsible for consideration before changes are implemented:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Consideration is given to views expressed by interested parties in changes in the certification requirements.

☐ Yes ☐ No

Comments: .....

.....

.....

3.4 Appeals, complaints and disputes [7]

a) The body has documented procedures for addressing appeals, complaints, and disputes:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Records are maintained of appeals, complaints, and disputes and any subsequent remedial actions and their effectiveness:

☐ Yes ☐ No

Comments: .....

.....

.....

3.5 Application for certification [8]

a) The body has procedures for providing applicants up-to-date information regarding the certification program:

☐ Yes ☐ No

Comments: .....

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b) Applicants are given the necessary rules to comply with regarding the use of Test Reports and Certificates as concerns advertising and making claims regarding the certification of their measuring instruments and modules:

☐ Yes ☐ No

Comments: .....

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c) The body requires an official application form to be completed by the applicant or a duly authorized representative of the applicant:

☐ Yes ☐ No

Comments: .....

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.....

d) The application requires at least the following information: corporate identity, including name and address, and specifications of the measuring instrument or module type including the necessary documentation to be evaluated:

☐ Yes ☐ No

Comments: .....

.....

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3.6 **Preparation for evaluation** [9]

a) The body has a procedure for reviewing each application with the customer prior to a type evaluation to ensure that the requirements are understood, that any differences in understanding are resolved, and that it has the capability of performing the requested evaluation:

☐ Yes ☐ No

Comments: .....

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3.7 **Evaluation** [10]

a) The body identifies the designated Testing Laboratories in which the sample or samples of the measuring instrument or module type is/are to be evaluated:

☐ Yes ☐ No

Comments: .....

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.....

b) The body has a clear and appropriate policy when deciding which tests to perform on each instrument in the case of a family of instruments:

☐ Yes ☐ No

Comments: .....

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(c) The body has a clear and appropriate policy concerning the possibilities of making adjustments or modifications to instruments during the course of evaluation:

☐ Yes ☐ No

Comments: .....

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(d) The body has a clear and appropriate policy concerning what action to take (i.e. to retest totally or not) in the case where the instrument has failed the first evaluation:

☐ Yes ☐ No

Comments: .....

.....

.....

(e) The body has a clear and appropriate policy concerning how to report these specific cases in order to attest confidence in the fact that the instrument is capable of fulfilling all the applicable requirements without unauthorized adjustment or modification (see also 3.8):

☐ Yes ☐ No

Comments: .....

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3.8 Report on evaluation [11]

a) The body receives a report on an evaluation from the designated Testing Laboratory in the format specified in the relevant OIML Recommendation and in any other applicable documents:

☐ Yes ☐ No

Comments: .....

.....

.....

b) The body promptly informs the applicant about the report and identifies any non-conformities that require addressing and any further evaluations that may be necessary:

☐ Yes ☐ No

Comments: .....

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.....

c) The body validates a report that contains complete information about the way that the test(s) were distributed for each instrument, when applicable:

☐ Yes ☐ No

Comments: .....

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(d) When all tests are not performed on each instrument submitted, a clear explanation of the reason(s) is provided:

☐ Yes ☐ No

Comments: .....

.....

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3.9 **Decision on certification** [12]

a) The body makes a decision, or judgement, to issue a Certificate of Conformity of a measuring instrument or module type based on a review of the Test Report of the examination and testing results and any other relevant information:

☐ Yes ☐ No

Comments: .....

.....

.....

b) The body does not delegate its authority to grant, maintain, extend, suspend, or withdraw a certification:

☐ Yes ☐ No

Comments: .....

.....

.....

c) The body provides a Test Report and, if requested, a Certificate of Conformity to the manufacturer or supplier of the measuring instrument or module that includes the applicant's name and address, the identity of the instrument type evaluated, the relevant OIML Recommendation, and the effective date:

☐ Yes ☐ No

Comments: .....

.....

.....

3.10 Surveillance [13]

a) The body has documented procedures to enable any surveillance to be carried out and documented in accordance with criteria of the certification system:

☐ Yes ☐ No

Comments: .....

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b) The body requires the manufacturer or supplier to inform it of any significant changes that may affect the conformity of the measuring instrument or model type and determine whether any announced changes require further investigation:

☐ Yes ☐ No

Comments: .....

.....

.....

3.11 Use of licenses, Certificates and marks of Conformity [14]

a) The body has documented procedures for control of the ownership, use, and display of its Certificates and marks of conformity:

☐ Yes ☐ No

Comments: .....

.....

.....

3.12 Complaints to manufacturers or suppliers [15]

a) The body requires the manufacturer or supplier to keep a record for at least 10 years of all complaints received with regard to the compliance of a certified measuring instrument or module with requirements and make these records and actions known to the body when requested in response to complaints:

☐ Yes ☐ No

Comments: .....

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.....

3.13 Identity of the person responsible for completing the Checklist

a) Name: .....

Signature: .....

Title: .....

Address: .....

Telephone: ..... Fax: ..... E-mail: .....

b) Brief statement of background and experience:

.....

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c) Comments attached:

☐ Yes ☐ No

If "Yes", identify the specific clauses to which the comments apply and identify those clauses in the attached comments:

.....

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.....

d) Names, addresses, and brief statement of background and experience of any other members of the assessment team:

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4 Checklist applicable to Testing Laboratories

4.1 General information

a) Identify the relevant OIML Recommendation: Number: ..... Edition: .....

b) Identity of the Testing Laboratory:

Name or Department (if applicable):.....

Contact person: .....

Address.....

Telephone: ..... Fax: ..... E-mail: .....

c) Identify the Issuing Authority that has authorized the Testing Laboratory to carry out the evaluation according to the relevant Recommendation:

Name:.....

Contact person: .....

Address: .....

.....

Telephone: ..... Fax: ..... E-mail: .....

d) The Testing Laboratory is legally authorized to conduct examinations as well as the required testing:

☐ Yes ☐ No

Comments: .....

.....

.....

e) The Testing Laboratory has issued OIML Test Reports for the relevant category of measuring instruments or modules:

☐ Yes ☐ No

If "Yes", indicate the number of Certificates and Test Reports issued: .....

Date of the first issued ..... and of the last issued .....

Comments: .....

.....

.....

f) A written policy exists to provide equal access and treatment for all applicants for type evaluation:

☐ Yes ☐ No

Comments: .....

.....

.....

4.2 Management requirements (4)

4.2.1 *Organization* (4.1)

a) The Testing Laboratory has the managerial and technical staff with the authority and resources needed to carry out type evaluation for the category of measuring instruments and devices identified:

☐ Yes ☐ No

Comments: .....

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.....

b) The Testing Laboratory has documented policies and procedures to ensure that its management and personnel are free from any undue internal or external pressure or influence that might adversely affect the quality of their work:

☐ Yes ☐ No

Comments: .....

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.....

c) The Testing Laboratory has documented policies and procedures to prevent involvement in any activities that would reduce confidence in its competence, impartiality, or operational integrity:

☐ Yes ☐ No

Comments: .....

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.....

d) The Testing Laboratory has a documented organizational management structure that defines the interrelationships between quality management, technical operations and support services:

☐ Yes ☐ No

Comments: .....

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.....

e) The Testing Laboratory has documented procedures to ensure adequate supervision of the type evaluation staff by persons familiar with the requirements, examinations, test procedures, and the recording of the results:

☐ Yes ☐ No

Comments: .....

.....

.....

f) The Testing Laboratory has an identified technical manager who has overall responsibility for the technical operations and provision of the resources needed to ensure the required quality of type evaluations:

☐ Yes ☐ No

Comments: .....

.....

.....

g) The Testing Laboratory has an identified quality manager who has defined responsibility and authority for ensuring the implementation at all times of the quality system and who has direct access to the highest level of management at which decisions are made on laboratory policy or resources:

☐ Yes ☐ No

Comments: .....

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h) The Testing Laboratory has designated deputies for the technical and quality managers:

☐ Yes ☐ No

Comments: .....

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4.2.2 Quality system (4.2)

The Testing Laboratory has an established, implemented, and maintained quality system as documented in a quality manual that defines the policies and objectives of the system and encompasses in its scope the carrying out of type evaluation of the category of measuring instruments indicated:

☐ Yes ☐ No

Comments: .....

.....

.....

The manual includes at least the following:

a) A policy statement that provides the overall objective of the quality system and the requirement that all personnel concerned with testing activities become familiar with the quality documentation and implement the policies and procedures in their work:

☐ Yes ☐ No

Comments: .....

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b) A reference to the supporting procedures and technical procedures and an outline of all relevant documentation in the quality system:

☐ Yes ☐ No

Comments: .....

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.....

c) A definition of the roles and responsibilities of the technical and quality managers:

☐ Yes ☐ No

Comments: .....

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4.2.3 Document control (4.3)

a) The Testing Laboratory has documented procedures for control of all documents both internal and external that are a part of the quality system:

☐ Yes ☐ No

Comments: .....

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b) A readily available, up-to-date list of approved documents in the quality system is maintained:

☐ Yes ☐ No

Comments: .....

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.....

c) Procedures are available to ensure that current editions of authorized documents are available where needed and are periodically revised to ensure continuing suitability and compliance with requirements:

☐ Yes ☐ No

Comments: .....

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.....

d) Procedures are available to ensure that obsolete documents are promptly removed and, if retained for legal or other purposes, are suitably marked:

☐ Yes ☐ No

Comments: .....

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.....

e) Procedures are available for the review and approval of clearly indicated changes in documents as well as access by designated personnel to pertinent background information that was the basis for the changes:

☐ Yes ☐ No

Comments: .....

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.....

f) Quality system documents are uniquely identified including the date of issue or revision, number of pages, and the authority that issued the documents:

☐ Yes ☐ No

Comments: .....

.....

.....

g) If applicable, procedures are established that describe how to make and control changes in documents maintained in computerized systems:

☐ Yes ☐ No

Comments: .....

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4.2.4 Review of requests, tenders, and contracts (4.4)

a) The Testing Laboratory has procedures for review of a request from a customer for type evaluation to ensure that all necessary documentation has been submitted for review:

☐ Yes ☐ No

Comments: .....

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b) Estimates are given to a customer regarding the time required for conducting a complete evaluation, and the evaluation fee is confirmed:

☐ Yes ☐ No

Comments: .....

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c) Procedures are given to a customer regarding receiving updates on, and answering questions about, the status of an evaluation:

☐ Yes ☐ No

Comments: .....

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4.2.5 Sub-contracting of tests (4.5)

a) The Testing Laboratory identifies the subcontracting laboratory, which is authorized by the Issuing Authority, and the schedule for any of the required testing that will be carried out:

☐ Yes ☐ No

Comments: .....

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b) The Testing Laboratory is responsible for the test results provided by a subcontractor and incorporates those results in the final Test Report:

☐ Yes ☐ No

Comments: .....

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4.2.6 Purchasing services and supplies (4.6)

a) The Testing Laboratory has policies and procedures for the selection and purchasing of all services and supplies necessary for type evaluations:

☐ Yes ☐ No

Comments: .....

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.....

b) Records are maintained of services and supplies, including their suppliers, necessary for testing the identified category of measuring instruments or modules:

☐ Yes ☐ No

Comments: .....

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.....

4.2.7 Services to the customer (4.7)

a) The Testing Laboratory has procedures for providing customers clarification of all evaluation requirements:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Customers are permitted access to monitor testing under appropriate safeguards for ensuring the confidentiality of work for other customers and no undue influence on the decisions of management or testing personnel:

☐ Yes ☐ No

Comments: .....

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.....

4.2.8 Complaints (4.8)

a) The Testing Laboratory has established procedures for resolving complaints, disputes, and appeals regarding type evaluations and Test Reports:

☐ Yes ☐ No

Comments: .....

.....

.....

b) Records are maintained for at least 10 years of all complaints and their resolutions, and corrective actions taken:

☐ Yes ☐ No

Comments: .....

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.....

4.2.9 Control of nonconforming testing (4.9)

a) The Testing Laboratory has policies and procedures for taking action when the testing or the preparation of the Test Report does not conform to its procedures or the requirements of the relevant Recommendation:

☐ Yes ☐ No

Comments: .....

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.....

b) Corrective actions are specified when nonconforming tests are identified as arising from doubt in implementing appropriate policies and procedures:

☐ Yes ☐ No

Comments: .....

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.....

4.2.10 Corrective action (4.10)

a) The Testing Laboratory has policies and procedures for corrective action by designated persons when departures from policies and procedures in the quality system or from the testing and Test Report procedures are identified:

☐ Yes ☐ No

Comments: .....

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b) Procedures are specified for recording and monitoring any corrective action taken:

☐ Yes ☐ No

Comments: .....

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4.2.11 Preventive action (4.11)

a) The Testing Laboratory has procedures for initiating corrective actions for problems that might cause nonconforming testing as soon as such problems are identified:

☐ Yes ☐ No

Comments: .....

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4.2.12 Control of records (4.12)

a) The Testing Laboratory has established and maintains control procedures for identifying, filing, accessing, and disseminating to authorized persons reports of type evaluation:

☐ Yes ☐ No

Comments: .....

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b) Quality system records including reports and corrective or preventive actions based on reports of internal audits and management reviews are maintained for at least 5 years:

☐ Yes ☐ No

Comments: .....

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4.2.13 Internal audits (4.13)

a) The Testing Laboratory conducts periodic audits at least once a year by trained personnel to verify compliance with all procedures necessary to demonstrate competence in type evaluation testing:

☐ Yes ☐ No

Comments: .....

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b) The quality manager plans and organizes internal audits on a predetermined schedule or as requested by management:

☐ Yes ☐ No

The audit period is .....

Comments: .....

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c) The personnel involved in internal audits are identified and trained and are independent of the activity audited to the extent practical:

☐ Yes ☐ No

Comments: .....

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4.2.14 Management reviews (4.14)

The laboratory management has a documented schedule and procedure for the laboratory management to review the quality system and testing activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes and improvements:

☐ Yes ☐ No

Comments: .....

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4.3 Technical requirements

4.3.1 *Personnel* (5.2)

a) The Testing Laboratory has a record of the current job description for managerial, technical and key support personnel involved in testing:

☐ Yes ☐ No

Comments: .....

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b) The laboratory management has established personnel records providing evidence that the staff involved in required type evaluations is qualified and maintains competence through experience, education, training, and appropriate supervision:

☐ Yes ☐ No

Comments: .....

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c) The Testing Laboratory has established a schedule for continuous training for all personnel involved in testing necessary to maintain competence:

☐ Yes ☐ No

Comments: .....

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4.3.2 Accommodation and environmental conditions (5.3)

The Testing Laboratory has the necessary and appropriate facilities for power, lighting, temperature, and humidity, and other controls necessary to carry out the required type evaluations:.....

☐ Yes ☐ No

Comments: .....

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The ability to determine applicable influence quantities according to the relevant OIML Recommendation are checked, for example, as follows:

a) Specified range of temperature:

☐ Yes ☐ No

Comments: .....

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b) Specified range of humidity:

☐ Yes ☐ No

Comments: .....

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c) Electrical supply variations:

☐ Yes ☐ No

Comments: .....

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d) Electromagnetic compatibility:

☐ Yes ☐ No

Comments: .....

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e) Electrical shock:

☐ Yes ☐ No

Comments: .....

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f) Mechanical vibration and shock:

☐ Yes ☐ No

Comments: .....

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4.3.3 Test methods (5.4)

a) The Testing Laboratory has available for the personnel involved in testing all test methods including those necessary for sampling, if required, as specified in the relevant OIML Recommendation and any referenced supplementary documents:

☐ Yes ☐ No

Comments: .....

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b) The Testing Laboratory has procedures for estimating the uncertainty in measurement for on-site calibrations of working standards necessary to carry out the tests required by the relevant OIML Recommendation, and for establishing traceability to national standards of the value of measurement standards and measurement results.

☐ Yes ☐ No

Comments: .....

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c) Calculations and data transfers are checked for validity and, where necessary, confidentiality for recording, storage, and retrieval:

☐ Yes ☐ No

Comments: .....

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4.3.4 Equipment (5.5)

a) The Testing Laboratory has for the relevant type evaluation all necessary and appropriate equipment that is clearly identified:

☐ Yes ☐ No

Comments: .....

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b) Documented procedures are available for the appropriate operation and maintenance of equipment:

☐ Yes ☐ No

Comments: .....

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c) Records are maintained of repairs and calibrations with established schedules for the equipment:

☐ Yes ☐ No

Comments: .....

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4.3.5 Measurement traceability (5.6)

a) The Testing Laboratory has the necessary reference and working measurement standards and/or reference materials for calibrations and the relevant type evaluation testing:

☐ Yes ☐ No

Comments: .....

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b) Records are maintained of the calibrations, with appropriate schedules, and of the traceability of the values of measurement standards and certified reference materials and all pertinent measurement results:

☐ Yes ☐ No

Comments: .....

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c) The Testing Laboratory has documented procedures for the safe handling, transport, storage and use of measurement standards and reference materials:

☐ Yes ☐ No

Comments: .....

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4.3.6 Sampling (5.7)

The Testing Laboratory has available the necessary documented sampling procedures as specified in the relevant OIML Recommendation and in any referenced supplementary document:

☐ Yes ☐ No ☐ Not applicable

Comments: .....

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4.3.7 Handling and transportation of test items (5.8)

a) The Testing Laboratory has documented procedures for the transport, handling, protection, and storage of a sample or samples of measuring instruments or module types received and evaluated:

☐ Yes ☐ No

Comments: .....

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b) A thorough visual examination is carried out of the external condition and packaging of the sample or samples as received and before returned to customers:

☐ Yes ☐ No

Comments: .....

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4.3.8 Assuring the quality of test results (5.9)

The Testing Laboratory has programs for monitoring the quality of test results:

☐ Yes ☐ No

Comments: .....

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Such programs may be the following:

a) Maintaining records of data using quality control standards:

☐ Yes ☐ No

Comments: .....

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b) Laboratory intercomparisons:

☐ Yes ☐ No

Comments: .....

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c) Exchange of information and test data with other Testing Laboratories:

☐ Yes ☐ No

Comments: .....

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4.3.9 Reporting the results (5.10)

a) The Testing Laboratory prepares the reports on the type evaluation according to (i) the Test Report Format of the relevant OIML Recommendation and (ii) any necessary additional documents, provided that the latter do not contain substantially different requirements:

☐ Yes ☐ No

Comments: .....

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b) The origin of any test results provided by a subcontracting laboratory is clearly identified:

☐ Yes ☐ No

Comments: .....

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c) Test Reports are securely transmitted to the Issuing Authority for evaluation and possible certification:

☐ Yes ☐ No

Comments: .....

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4.4 Identity of the person responsible for completing the checklist:

a) Name: .....

Signature: .....

Title: .....

Address: .....

Telephone: ..... Fax: ..... E-mail: .....

b) Brief statement of background and experience: .....

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c) Additional comments attached:

☐ Yes ☐ No

If "Yes", identify the specific clauses to which the comments apply and identify those clauses in the attached comments:

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d) Names, addresses, and brief statement of background and experience of any other members of the assessment team:

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References

[1] OIML B 10-1 (2004), Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations

[2] OIML B 3 (ex P 1) (2003), OIML Certificate System for Measuring Instruments (Second Edition)

[3] OIML V 1 (2000), International Vocabulary of Terms in Legal Metrology (VIML)

[4] ISO/IEC Guide 2:1996, Standardization and related activities - General vocabulary

[5] ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories

[6] ISO/IEC Guide 65:1996, General requirements for bodies operating product certification systems

[7] ISO/IEC Guide 58:1993, Calibration and testing laboratory accreditation systems - General requirements for operation and recognition

[8] ISO/IEC Guide 61:1996, General requirements for assessment and accreditation of certification/registration bodies

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