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Type evaluation and type approval

Essai de modèle et approbation de modèle



Contents

[To be added]



Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonise the regulations and metrological controls applied by the national metrological services, or related organisations, of its Member States.

The main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to harmonise and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

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

Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

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TYPE¹ EVALUATION and TYPE APPROVAL

1 General

1.1 Introduction

1.1.1 This International Document is addressed primarily to three groups

- i. OIML Technical Committee and Subcommittee secretariats and Project Group (PG) conveners,
- ii. officials in Government administrations responsible for designing and developing Type Approval Control Systems, and
- iii. legal metrology officials

concerned with conformity assessment (including testing and type approval) of measuring instruments. PG conveners are responsible for the drafting of International Recommendations for measuring instruments subject to type evaluation and type approval. Government policy makers are responsible for designing and developing Type Approval Control Systems (hereafter referred to as “type approval control systems” or “type approval controls”). Legal metrology officials are responsible for the adoption and implementation of type evaluation and type approval requirements.

1.1.2 Because of its general nature, this International Document has wide applicability in such fields as trade, environmental protection or health. It includes advice, procedures, and influencing factors bearing on the conduct of type evaluation and on the type approval decision that follows it. It is intended to serve as a reference for authorities in developing and operating type approval controls on weighing and measuring instruments. This will assist industry by guaranteeing the quality of the products being sold as well as ensuring better protection for the consumers and eliminating fraudulent practices.

1.1.3 This Document should be capable of being used for the type approval of all measuring instruments that are controlled for legal metrology purposes. Typically, these are applied through national regulations that regulate the use of weighing and measuring instruments not only for their use in trade but also their use for purposes of health, safety and environmental protection and their use in official decision-making.

1.2 Relationship between type approval controls and verification

1.2.1 Type approval controls are different from, but complementary to, verification controls.

1.2.2 Verification is a process which is capable of being applied to every regulated instrument, or a representative sample determined by the legal metrology authorities. It requires relatively simple equipment, but it can only test for accuracy at current operating conditions and those features which can be checked by visual inspection. Verification does not guarantee that an instrument will continue to operate properly over its working lifetime.

1.2.3 Type approval controls, however, involve lengthy and rigorous testing of an instrument over a wide range of operating conditions using expensive equipment and skilled personnel. It is only economically viable to test a small number of instruments in this way, most usually the “type” which will form the basis for approval. This gives greater assurance that the instrument will work satisfactorily over its working lifetime. It has to be accompanied, however, by additional checks so that legal metrology authorities can be satisfied that all instruments of that type are satisfactory.

¹ Note that some earlier publications, including some of the most relevant OIML Documents, refer to “pattern evaluation” rather than “type evaluation, and “pattern approval” rather than “type approval”. The meaning is exactly the same and, in order to avoid confusion throughout this Document, the phrases “type evaluation” and “type approval” are used. Similarly, “type” is used in preference to “pattern”, but the two concepts are exactly the same.

1.2.4 There are two main interactions between type approval controls and verification. The first is that verification can be one of the means of policing type approval controls. Verification officers are in a good position to check whether an instrument is (or claims to be) of a type approved for use, either through labelling or accompanying documentation. Moreover, the data gathered during both the initial and subsequent verification of a larger number of copies of a given type will, when systematically analysed, often yield information not available from type evaluation. Such feedback can be used as the basis for revising the conditions of approval when the situation warrants this. Depending on circumstances, the experience gained during verifications may justify later changes in the type approval concerning instrument design, manufacturing process, application of the type, or required verification procedures; in extreme cases, it might even result in suspension or withdrawal of the approval.

1.2.5 Second, the type evaluation and type approval stages may themselves identify matters which verification officers should look out for and will inform decisions on matters such as reverification periods.

1.2.6 A companion OIML Document D 20 [2] is also available; it may prove to be useful when an appropriate balance between type evaluation and type approval and initial verification is being considered.

2 Terms and definitions

The terms in this Document are taken from the 2022 edition of the International Vocabulary of Legal Metrology (VIML) [3], where appropriate. Definitions of terms not found in the VIML [3] are provided with appropriate references where applicable.

2.1 accreditation

third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks
[ISO/IEC 17000:2020, 7.7] [VIML, A.19]

Note: ISO/IEC 17000:2020 defines “attestation” as “issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated”.

2.2 approval

permission for a product or process to be marketed or used for stated purposes or under stated conditions
[ISO/IEC 17000:2020, 9.1] [VIML, A.25]

2.4 certification

third-party attestation related to products, processes, systems or persons
[ISO/IEC 17000:2020, 7.6] [VIML, A.18]

Note: ISO/IEC 17000:2004 defines “attestation” as “issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated”.

2.5 conformity assessment

demonstration that specified requirements relating to a product, process, system, person or body are fulfilled
[ISO/IEC 17000:2020, 4.1] [VIML, A.1]

2.5 copy of a type

individual instrument which conforms, within specified limits, to a given type in all respects

Note: The word “type” or “pattern” has been commonly used to refer to the definitive model of a measuring instrument as well as to the class of instruments that conform to it. The instruments produced by the manufacturer to replicate the type constitute a different class. The question of whether an instrument of this class conforms to the type is normally the subject of initial verification. Type approval not only implies the recognition that the type conforms to requirements but, generally, also relates to the instruments of the class produced by the manufacturer; it usually conveys that these may be sold as legal for use and submitted for initial verification.

2.7 evaluation

judgment - based on the outcome of testing - on whether requirements have been met.

Note: This is not a defined term in either ISO/IEC 17000:2020 or the VIML. This definition has been developed from the definition of type evaluation (see 2.24) for the purpose of this International Document.

2.8 examination

review of documentation and/or visual inspection of an instrument prior to testing

Note: This is not a defined term in either ISO/IEC 17000:2020 or the VIML because it is a word used in many different contexts. This definition has been produced solely for the purpose of this International Document.

2.9 initial verification

verification of a measuring instrument which has not been verified previously
[VIML, 2.12]

2.10 inspection

examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements
[ISO/IEC 17000:2020, 6.3] [VIML, A.11]

2.10 jurisdiction

sphere within which a particular government or a given agency of such a government has power to make or enforce law or regulation

Examples: The spheres of legal authority of (1) a particular national government, (2) a particular provincial government, (3) the legal metrology agency of a particular country, and (4) the agency of a particular city government charged with enforcing pollution laws.

2.13**legal metrology**

practice and process of applying statutory and regulatory structure and enforcement to metrology

[VIML, 1.01]

2.14**legal metrology authority**

public (Government or local Government) body authorised by law on a national level to be responsible for legal metrological supervision as a whole or in part

[Modified from OIML D 9:2004, 2.15]

2.15**legal metrology official**

authorised employee or appointee of a legal metrology authority

Note: This is not a defined term in either ISO/IEC 17000:2020 or the VIML. This definition has been produced solely for the purpose of this International Document.

2.14**modification of a type**

change in a type that does or may alter some of its metrological or technical characteristics, its ranges, or its applicability

2.15**modified type**

with reference to a given type, one which has been subjected to modification

2.16**national issuing authority**

certifying body or person that is responsible for national type approval and that issues national/regional type approval certificates for specific categories of measuring instruments or modules on the basis of examination and testing under its own control

[Modified from OIML B 18:2022, 3.24]

2.17**request for type approval**

taken together, all the documents, instruments, fees, etc. submitted to the legal metrology authority when approval of a type is requested

2.20**subsequent verification**

verification of a measuring instrument after a previous verification

[VIML, 2.13]

2.21**testing**

determination of one or more characteristics of an object of conformity assessment, according to a procedure

[ISO/IEC 17000:2020, 6.2] [VIML, A.10]

2.20 testing laboratory

laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or products

[ISO Guide 2] [4]

2.23 type (of a measuring instrument or module)

definitive model of a measuring instrument or module (including a family of instruments or modules) of which all of the elements affecting its metrological properties are suitably defined

[VIML, 4.06]

2.24 type approval

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

[VIML, 2.05]

2.23 type approval process

sequence of all the steps taken in the course of the evaluation and approval or rejection of a type, starting with the submission of the request for type approval and culminating in a certificate or notice of type approval or rejection

2.24 type evaluation

conformity assessment procedure on one or more specimens of an identified type (pattern) of measuring instruments which results in an evaluation report and / or an evaluation certificate

[VIML, 2.04]

2.25 validity of type approval

period of time during which the type approval is recognised by the approving legal metrology authority as being in effect

2.26 verification

provision of objective evidence that a given item fulfils specified requirements

[VIM, 2.44] [5]

3 Design of type approval control systems

3.1 Introduction

3.1.1 Type evaluation and type approval are components of a system of legal metrology controls designed to provide government with the means for assuring the adequacy of measurements covered by law or regulation. Type evaluation (consisting of testing and examination) and type approval are quite distinct steps in the

metrological control system. Type evaluation is an objective process of determining facts concerning a model or range of instruments, whereas type approval is the decision, based on these facts and involving judgment, to permit or not to permit that model or range of instruments to be used for regulated purposes. The approving official (decision maker) will often not be the official(s) who carried out the evaluation. This Document has been drafted on the assumption that these officials will be distinct.

3.1.2 A type approval decision will relate to both the subject model or range and to the applicant who requests the type approval. It conveys license to the applicant to produce and/or sell instruments of a specific type with the implication that they are likely to conform to the approved type. It conveys to the users of these instruments and to verification officials that the model or range conforms to legal requirements and is adequate for use in approved applications. The type approval process, therefore, constitutes an important component of official efforts to assure the quality of measurements in certain areas of public concern.

3.1.3 Because many variables, conditions, and limitations bear on the manner of type evaluation, it becomes necessary to choose between available alternatives and to plan type evaluations to accommodate the particular cases at hand.

3.1.4 These choices will be affected by the nature of the instrument and its application, the resources available for type evaluation and approval, and applicable regulations or national practice. Beyond these factors there is usually some freedom of choice which can be turned to advantage in accommodating different situations as they present themselves. There have been important developments in type approval control systems over the past thirty years, including changes in the balance in emphasis and effort between type approval controls and initial verification. This Document covers some of the available alternatives. There have also been changes in cooperation between legal metrology authorities, including national issuing authorities and national responsible bodies, and manufacturers in the course of type evaluation and approval. Traditionally, manufacturers and legal metrology authorities have functioned more or less independently of each other, with the manufacturer designing and producing and the authority evaluating and approving. The burdens of the ever-increasing number, variety, and complexity of instruments require higher levels of government-manufacturer cooperation. Modern designs, complex electronic circuitry, software and fast-changing technology complicate the type approval process so that increasingly flexible approaches to it are necessary. At the same time, design criteria become more restrictive tools than before and represent only a last resort, whereas minimum performance criteria become more attractive in that they tend to remain applicable while not standing in the way to innovation.

3.1.5 In designing new type approval controls, there are three basic decisions that need to be made:

- a) Which instruments should be subject to type approval control;
- b) What performance requirements should be specified that approved instruments must conform to; and
- c) How type evaluation will be conducted.

3.2 Which instruments should be subject to type approval?

3.2.1 Legal metrology controls may focus on the measuring instruments used (traditional legal metrology), on the general qualifications of laboratories making measurements (laboratory accreditation), or on the ability to obtain acceptable measurement results (proficiency testing). While these approaches often exist side by side, type approval controls, and therefore also instruments subject to type approval, should be seen as part of traditional legal metrology.

3.2.2 Control of whole categories of measuring instruments may be required by law. While this most often involves type approval controls, in some cases verification without type approval is deemed to be sufficient. The requirement of type approval will usually stem from either the intended or the potential use of measuring

instruments in activities where the quality of measurement is of public concern. Such uses may be identified as the measurement of quantities related to specified classes of objects, commodities, phenomena, materials, or conditions. For example, type approval of taximeters is generally required because of their intended use in determining taxi fares. Type approval of volumetric measures might be required because of their potential use in commerce, even though some of these measures might only be used in households, laboratories, or factories.

3.2.3 At the same time, certain categories of measuring instruments used in fields of measurement involving the public, though subject to some forms of control, may not justify type approval controls - for instance conventional instruments of such design and construction material whose metrological qualities do not vary much with time or single instruments and systems composed of approved components. This would apply, for instance to liquid-in-glass thermometers or drinking measures for alcoholic beverages. In such cases there may still be regulations which specify detailed requirements as to the technical and metrological characteristics, and conceivably also as to the form, constituent materials, and construction of instruments not subject to type approval controls. There will also be requirements for verification even if some instruments are automatically accepted for initial verification.

3.3 What performance requirements should be specified?

Under the OIML Treaty there is an expectation that where type approvals controls are introduced or are planned the national regulations should be based on the relevant OIML Recommendations, where they exist. Quite apart from meeting OIML Member States' commitments under the OIML Treaty, there are several other advantages to this approach. It means that instruments manufactured to international standards are able to be used without costly modifications. It ensures that obligations under the World Trade Organisations Technical Barriers to Trade Agreement are complied with. In addition, as most of the relevant OIML Recommendations set out the test methods, a test report format and a type evaluation report format, it is easier to carry out the type evaluation phase.

3.4 How type evaluation will be conducted?

3.4.1 In determining how the type evaluation will be conducted for a particular category of instrument, there has to be regard to the fact that among OIML Member States and Corresponding Members, there are differences in the conditions under which legal metrology regulation takes place. Some countries have the capability to carry out the complete type evaluation and approval process, at least for some instruments, using their own facilities and staff. In the case of other countries where there may be limited resources, they will need to consider making partial or full use of evidence of third-party conformity assessment. In all cases, however, provided that the requirements are based on OIML Recommendations and provision is made for instruments with appropriate certificates issued under the OIML-CS, there will be harmonised access for compliant instruments in all countries, together with higher standards of protection than would be the case without type approval controls.

3.4.2 The three options can be summarised as follows:

- i. the type evaluation is based on all of the type evaluation tests being performed by the national issuing authority;
- ii. the type evaluation is based on a combination of type evaluation tests being performed by the national issuing authority and partial or limited evidence of third-party conformity assessment (including the use of independent test data);
- iii. the type evaluation is based solely on evidence of third-party conformity assessment.

3.4.3 Because type approval, regardless of how the type evaluation is conducted, offers the same level of protection and harmonised access, it is not the purpose of this Document to put forward one approach as being

preferable to another. The choice is entirely a matter for the authorities in the country or economy concerned. Moreover, even within a single jurisdiction it may be that the complete type evaluation and approval process using their own facilities and staff is applied to one set of regulated instruments, and the partial or full use of evidence of third-party conformity assessment is applied to other categories of instruments.

3.5 What constitutes a different type

When two types of instruments are very much alike, a decision must be made whether, from a legal metrology point of view, only one or two separate type approval processes must be followed. Guidelines intended to help with such decisions follow.

3.5.1 Different applicants or manufacturers

A type approval is granted to a specific applicant. Seemingly identical instruments submitted for type approval by different applicants, presumably produced by different manufacturers, should follow independent type approval processes.

3.5.2 Superficial differences between instrument types

Different instrument types produced by a particular manufacturer that are identical in design, materials, components and measurement ranges, but that differ superficially in their colour or other non-metrological characteristics can normally be regarded as being covered by a single type approval.

3.5.3 Different measurement ranges

Instruments of a specific manufacturer which differ in measuring range and/or in scale intervals of measured quantities can generally be considered as covered by the same type approval, provided that such differences preserve the performance of the instrument within permissible error limits.

3.5.4 Different components, materials, or manufacturing techniques

Instruments manufactured by a specific manufacturer which differ from one another by the fact that they contain nominally identical components or materials obtained from different suppliers, can generally be considered as covered by a single approval, if the various sources of supply do not influence the regulated metrological characteristics of the instruments. Similar considerations apply when the manufacturer employs different manufacturing techniques or, in electronic instruments, different wiring or layouts, to produce a single type of instrument. They also apply when different components are used as transducers between the measured quantity and the sensors of otherwise identical instruments. An example is load platforms of weighing instruments and connectors at the input of electronic instruments.

3.6 What constitutes a modified type

When a manufacturer makes changes in a type of instrument related to an approved type, approval of the modification may be necessary. The considerations in such cases are presented below.

3.6.1 Responsibility for determining occurrence of modifications

3.6.1.1 When a manufacturer makes a change in a type of instrument manufactured to replicate an approved type, three possibilities exist:

- the changed instrument is still a replication of the approved type;
- the change is sufficient to require approval of a modification of the type; or

- the change is so radical that a new type approval must be obtained as for a new type of instrument.

3.6.1.2 Guidelines concerning responsibility for taking action in such matters should be issued by the legal metrology authorities. These should address both the question of action threshold and the procedures to be followed by responsible parties. Action thresholds can be based on the considerations given in 3.5.

3.6.1.3 The following two possible procedures for use in such cases by grantees or manufacturers should be considered by the authorities; preferably they should have the option of using either one.

3.6.1.3.1 Notification of change in instrument type

The grantee of the original approval or the manufacturer notifies the legal metrology authorities that a change has been made or is contemplated for an instrument produced to replicate an approved type. They cite the existing type approval, detail the changes, and give any data, analysis, and conclusions concerning the technical or metrological consequences of the changes. On the basis of the notification, the authorities decide whether to require further action as regards approval of a type modification, or a new type approval, and inform the grantee or the manufacturer accordingly.

3.6.1.3.2 Request for approval of modification

The grantee of the original approval or the manufacturer, after taking account of official guidelines and deciding that a change is significant, requests approval of a type modification, or possibly a new type approval, citing the existing type approval, detailing the changes, and giving any data, analysis, and conclusions concerning the technical or metrological consequences of the changes.

3.6.2 Evaluation for modification of a type

3.6.2.1 When a manufacturer seeks approval of a modified type, the legal metrology authorities must first determine whether the changes constitute only a modification. Then, on the basis of both the previous evaluation of the original type and the modification as described in submitted documents or embodied in a submitted instrument, it must decide how to evaluate the modified type. Possibilities include only an evaluation of documents when the metrological consequences of the modification are quite predictable from these documents; a partial type evaluation when the modification clearly affects only specific characteristics or portions of the instrument; and a limited type evaluation when it seems necessary to check whether, or to what extent, the modification affects the various metrological characteristics of the type.

3.6.2.2 The evaluation of the modification can result in approval, modification of the approval, a new approval or the rejection of the modified type.

4 Operation of a type approval control system

4.1 Outline

A type approval, based on a type evaluation by the national issuing authority, will normally consist of the following steps. The national issuing authority should set out in formal documentation how each of the steps will be conducted, making clear the obligations on both applicants and legal metrology officials at each stage.

4.1.1 Applications for type approval

4.1.1.1 The administrative requirements should set out clearly the circumstances where an application for type approval must be made. Typically, these may include:

- category of instrument for which type approval is required by law or regulation;
- new type of instrument;
- existing type of instrument not previously approved for legal use;
- newly imported type of instrument;
- radically new intended application, within the jurisdiction, of an approved type;
- extension of application of a type;
- intended use of instrument type in a new jurisdiction (this does not necessarily imply import);
- modification of an instrument type replicating an approved type;
- previous type rejection or withdrawal of type approval, coupled with newly presented facts concerning the type, improvement of the instrument type, or a change in regulations.

4.1.1.2 The requirements should also describe the documentation, the conditions of the instrument to be submitted for approval, the expected timescales (service standards), and the fees which are payable, distinguishing between:

- Requests for full testing, evaluation and approval;
- Requests for evaluation and approval taking account of independent test data which is already available;
- Requests for approval based on a type evaluation which has already been obtained, e.g. an OIML certificate.

4.1.2 Initial examination of an application for type approval

4.1.2.1 Bilateral, regional, or international agreements between different countries may formally permit acceptance of instruments elsewhere.

4.1.2.2 The requirements should describe how the application will be examined prior to any testing or evaluation taking place and how incomplete or invalid applications will be dealt with.

4.1.3 Type evaluation

4.1.3.1 The requirements should describe how and by whom the type evaluation will be conducted. If testing of the instrument submitted and the conformity assessment judgment will be made by different individuals or organisations, this should be explained. The requirements should also make clear what forms of evaluation carried out in other jurisdictions (either OIML certificates or type approval decisions made by other authorities) may be acceptable.

4.1.3.2 It will usually be helpful to draw up an Evaluation Plan, though this may be an administrative practice rather than part of the published requirements. Steps in a typical evaluation plan are:

- tentative evaluation plan;
- identification of and arrangements for organisation, facilities, equipment, and personnel needed for evaluation;
- examination of submitted documents;
- revised evaluation plan;
- examination and tests of instruments and/or devices;
- report of evaluation, conclusions drawn, and recommendations.

4.1.4 Type approval

The administrative arrangements should describe how and by whom the approval stage will be conducted. It will normally be necessary to provide for the following steps:

- examination of report of evaluation in the light of applicable regulations and requirements;
- decision to grant or withhold type approval;
- framing of detailed conditions of type approval.

4.1.5 Communicating the approval decision

4.1.5.1 The published documentation should describe how a decision to grant approval will be communicated and any accompanying certificate will be issued. They should also describe how decisions to refuse approval, request modifications or request additional information will be communicated.

4.1.5.2 Where there are requirements to deposit a specimen instrument and device of the approved type with the national issuing authority, give public notice of the type approval and/or notify verification officials of the type approval, this should be made clear.

4.1.6 Continuing obligations on holders of type approvals

The system documentation should clearly set out the continuing obligations on manufacturers or others who receive a type approval certificate. This may include obligations to place a type approval marking on the instrument and obligations to notify the authorities of any modifications in the approved instruments.

4.2 Initial examination of an application for type approval

Before any testing or evaluation is carried out, especially if the applicant is to be charged for such work, the application should be examined to ensure that it complies with the regulations and is complete. It is important that those examining the application identify the relevant regulations and requirements.

4.2.1 Information included in the application

Applications or application forms may include the following information:

- name and address of applicant and applicant's representative;
- name and address of the manufacturer of the subject instrument;
- documents indicating the applicant's authority to represent the manufacturer;
- category of instrument and its general purpose;
- intended and other possible legal applications of the instrument;
- reference to regulations under which the type is to be approved;
- reference to those previous type approvals or rejections issued to the applicant or manufacturer, particularly from other jurisdictions, that may have a bearing on the present request
- manufacturer's designation and name for the instrument;
- manufacturer's specifications of metrological characteristics of the instrument that are regulated for the subject category of instrument;
- inventory of instruments, devices and materials, or of descriptive material, defining the type and submitted with the request.

4.2.2 Supporting documents

The national issuing authority can ask that certain documents be included with the request or the applicant may choose to submit them on an optional basis. These documents may include some or all of the following:

- description of the instrument, for example, detailed specifications relating to construction, assembly, adjustment, and internal operation of the instrument or to internal standards, safety devices, and self-adjusting mechanisms; also, assembly drawings, detailed drawings, layouts, and schematic diagrams (see 6.7);
- sales literature, photographs, drawings, and documents intended for users, including instructions for installation and preparation of an instrument for service, and operating, maintenance, and repair manuals;
- published papers describing the principle of operation of the instrument type or of primary devices;
- evidence of third-party conformity assessment, e.g. an OIML certificate and/or type evaluation report, type approval issued in another jurisdiction, tests carried out by a suitable testing laboratory.

4.2.3 Specimen instrument

Generally, one or more sample instruments or devices are submitted with the request for type approval; they constitute the “type”. A statement should accompany submitted instruments and devices which indicates whether they are prototypes, from a production line test run, or from an established production line. It is imperative in all cases that the samples are representative of the final production. In certain cases, definitive descriptions, such as engineering descriptions and assembly drawings, are submitted in lieu of actual equipment.

4.2.4 Consideration of the application for type approval

4.2.4.1 The following questions should be considered before evaluation takes place:

- Is the applicant properly authorised by the manufacturer and acceptable to the legal metrology authority?²
- Do regulations require type approval of the instrument, also taking account of its intended or potential application?
- Have all requested items of information, documents, instruments, etc, been submitted?
- Does the instrument or its description, submitted as the type, appear to be sufficiently definitive to serve as the type?

4.2.4.2 The decision to accept or refuse the request at this stage is based on a study of the documents submitted with the request for type approval. If the request is lacking in some details, the approval authority may ask that it be supplemented before the decision is taken. Even if it seems at this stage that the type does not meet requirements, the application should be accepted, except in cases where there has been a prior rejection of the subject type or of one closely related to it.

² Authorities may specify that only certain persons may submit requests for type approval, such as:

- a manufacturer
- a manufacturer's sales representatives
- a distributor of the manufacturer's instruments
- an assembler of systems constituted of subsystems produced by various manufacturers
- an importer
- certain officials of the foreign services or consulates of other jurisdictions

4.3 Type evaluation plan

4.3.1 Scope of evaluation plan

4.3.1.1 All applications for type approval should be subject to an evaluation plan drawn up specifically for that application.

4.3.1.2 The scope and nature of the evaluation plan should take into account:

- Whether the type submitted has been approved in one or more jurisdictions. Evidence of this may be an EU-type examination certificate, a test and/or type evaluation report produced by another authority, or another country's type approval certificate stating the relevant OIML Recommendation has been met.
- Whether a certificate and/or type evaluation report issued under the OIML-CS has been presented.

4.3.1.3 Both alternatives can be effective in reducing the workload of the approving authority and help to minimise the overall cost of the type approval process. Bilateral, regional, or international agreements between different countries may formally permit acceptance of instruments elsewhere.

4.3.1.4 Even in the absence of such agreements, the authorities may be authorised to accept data obtained in or conclusions drawn in the other jurisdiction. Also, the authority, encouraged by an approval in another jurisdiction, may conclude that partial or limited type evaluation will suffice to account for differences in the requirements of the two jurisdictions. Wherever possible, approving authorities should cooperate with each other in sharing results of type evaluation test data and should consider participation in formal arrangements for reciprocal acceptance of type approvals or acceptance of the test data leading to type approval.

4.3.2 Choice of organisation to evaluate the type

4.3.2.1 When new technologies are applied to measuring instruments or when a national issuing authority is faced with evaluating instrument categories with which it has not dealt previously, it may find that it lacks the facilities or personnel necessary to carry out some of the required type evaluations. In such cases it should turn for support to organisations that have the needed capabilities, including traceability to national standards. Depending on circumstances, such evaluation efforts may be cooperative; for instance, authority personnel might work side by side with the personnel of some other organisation to conduct tests at the latter's facility.

4.3.2.2 Categories of organisations that can be considered in these cases are listed below. Not all these categories of organisations will be available in every jurisdiction or for every type of instrument:

- other government laboratories of the same jurisdiction;
- laboratories of independent test organisations or of universities;
- laboratories of manufacturer or industry associations;
- government laboratories in other jurisdictions;
- manufacturer facilities.

4.3.3 Contents of an evaluation plan

4.3.3.1 The evaluation plan should be developed in some detail on the basis of the following:

- the intended or possible applications of the instrument type;
- the requirements of regulations concerning both the category of instrument and the applications;
- the tentatively decided modes of verifications;

- the amount of information and data submitted with the request;
- information already available from prior type evaluations of related instruments and devices;
- the facilities, equipment, and personnel available for type evaluation.

4.3.3.2 The tentative plan should specify, as relevant, the following:

- characteristics, parameters, and conditions to be tested or examined;
- the test methods to be used, document studies to be conducted, and inquiries to be made;
- the scope, extent, or limits of those tests, studies, and inquiries.

4.3.3.3 Such specifications can, for the most part, be assembled by reference to existing OIML Recommendations that contain requirements and tests applicable to type evaluation of the particular subject instrument or device.

4.3.3.4 The plan should also specify the sites at which testing is to be carried out – this may be the factory, a laboratory, or a user location, usually determined by the choice of testing organisation.

4.3.3.5 A full evaluation plan may include both a study of the documents furnished by the applicant and a testing phase which may include the testing of a prototype instrument, of preliminary production instruments, or of instruments from an established production line. To the extent that certain test protocols are required by regulation, these should be followed. Occasionally the evaluating officials may have to establish special test procedures for new generations of instruments or for special applications of instruments in order to determine compliance with requirements.

4.3.3.6 Of the possible steps that can be taken in the course of evaluation, in each particular case, only some of these will be found to apply or to be necessary. In some cases, the evaluation process should be stopped after one or more deficiencies of the type have been found that give ample ground for rejection.

4.4 Different kinds of type evaluation

The various kinds of type evaluation can be classified as to their extent and their purpose. These are outlined below.

4.4.1 Complete type evaluation

In a complete type evaluation, all relevant aspects of the type, including metrological characteristics and technical provisions, are evaluated to determine that the type complies with applicable regulations and that copies of the type can be expected to perform properly. Typically, a complete type evaluation is carried out when the type has not been previously evaluated by the national issuing authority, or there is no evidence of a third-party conformity assessment.

4.4.2 Partial type evaluation

In a partial type evaluation, only a limited number of selected characteristics of a type are evaluated to determine their compliance with applicable regulations. A partial type evaluation is typically carried out when an already approved type has been modified such that only certain of its characteristics can be expected to have been affected by the modification, for example, when a new indicating device has been incorporated.

4.4.3 Limited type evaluation

In a limited type evaluation all relevant aspects of a type are evaluated, but not as thoroughly as in a complete type evaluation, to determine which of these appear to have deviated from those found during a previous evaluation. Characteristics that appear to have deviated can then be subjected to a more thorough evaluation. A limited type

evaluation may be carried out when the results of a previous evaluation in another jurisdiction are available and a limited sub-set of the type evaluation tests are carried out to establish confidence in the previous results or to establish which of the characteristics of a type may have been affected by its modification.

4.5 Study of submitted documents

4.5.1 The documents to be examined in the light of the requirements laid down in regulations and for purposes of evaluation include the application for type approval, the type itself to the extent it is defined in documents, and any supporting documents. These documents should, as need arises, be referred to again in the course of any later tests.

4.5.2 If the type is presented in the form of documents, rather than as actual instruments, it should be determined that the information given defines a type sufficiently well. If this is not the case, further information should be sought, the submission of instruments should be required of the applicant, or rejection of the type should be recommended.

4.5.3 The conclusions of this examination should be summarised to become part of the report of the evaluation. This summary should make reference to the particular document, passage, or data on which important specific conclusions are based.

4.6 Conduct of the evaluation - testing phase

4.6.1 Metrological examination

The metrological examination includes the evaluation of instrument characteristics prescribed in the relevant OIML Recommendation. In addition to evaluation of metrological performance, the following instrument features might also be examined:

- scale interval;
- scale range;
- scale marks, spacing, and numbering;
- statement of scale units and of instrument constants;
- resolution and line widths of scale marks, recorder chart paper, or oscilloscope screens, least significant digit of a digital readout;
- potential for and provisions to minimise parallax;
- provisions for properly or uniquely applying the measured quantity to the instrument (loading) and potential for improper loading.

4.6.2 Technical examination

The relevant OIML Recommendation will cover all the important elements of the technical examination. Authorities should not add requirements for technical examination not specified in the OIML Recommendation. The following might also be considered for examination if not specified in the OIML Recommendation:

- mechanical adequacy of instrument supports and enclosure;
- location of controls with a view to error-free operation;
- adequacy of identification of controls;
- readability of scale and dial numbering;
- visibility of instrument readout for operator and customer;
- security from inadvertent disconnection of the connectors of communication lines;
- potential for and safeguards against operator fraud.

4.6.3 Administrative examination

The relevant OIML Recommendation may or may not prescribe an examination of the administrative features of the instrument. These might include:

- resistance to tampering of enclosure and external adjustments;
- provision of locks and of locations for seals, stamping, and calibration tags;
- placement of name plates;
- adequacy of name plates, including identification of manufacturer and type, serial number, and instrument rating;
- presence and prominence of important restrictions of use and other cautions;
- security of attachment of calibration or conversion charts to instrument.

4.6.4 Choice of test points

The relevant OIML Recommendation will normally include test methods which prescribe test points. These may include:

- points corresponding to commonly encountered values;
- end and mid-points and points of overlap of ranges;
- equally spaced or logarithmically spaced points in a range;
- points reflecting reference and extreme conditions;
- points near previously discovered resonances of an instrument;
- points located where theoretical analysis of the instrument's equations indicates poles, zeroes, or exceptionally high or low sensitivities.

4.7 Evaluation report

4.7.1 The conformity assessment stage of the evaluation should be based on a report of the objective findings of the examination stage and a report of the conclusions drawn. This will in turn lead to recommendations concerning type approval. While these may be given in a single document, it will often be advantageous to allocate them to separate documents as indicated below. Separate documents are especially appropriate when evaluation and approval are the responsibilities of different officials.

4.7.2 There are many reasons for writing and then maintaining these reports as a permanent record: the conclusions and recommendations are aimed at the approving official; the report of objective findings should be available for future reference in the event the findings are challenged; a modification or an extension of the approval or of the period of validity of the type is applied for; there is a change in related regulation, etc.

4.7.3 The report should be a permanent, objective record of the evaluation process and its results, against which possible future evaluations can be compared and which can support the type approval or rejection decision, if it is challenged (conceivably in court), by the applicant, manufacturers, or users. It should identify the values of measured metrological characteristics and their uncertainties and instruments, devices and salient documents examined, personnel and laboratories that carried out the evaluation, provide a summary of tests carried out, and list any special procedures, standards, and equipment used in the process. It should contain important data, ambient conditions, and the time data where taken or it should identify the place where such data are stored. To the extent that findings are not based on measurement but on visual inspection, they should be as objective as possible in each instance.

4.8 Conclusions and recommendations resulting from evaluation

On the basis that the personnel carrying out the type evaluation process do not make the approval decisions, the report giving conclusions and recommendations should provide the basis for such a decision, for a definition of the type, and for the contents of a type approval certificate or rejection. The report might be structured in five parts, as follows.

4.8.1 Summary of findings of evaluation

The summary should list the characteristics, attributes, and conditions of the instrument that are subject to regulation along with both the required limiting values or qualities and the corresponding values or qualities determined during the evaluation. Each item that demonstrates failure to meet requirements should be clearly identified as such. The list may be followed by a discussion of important conclusions to be drawn from it.

4.8.2 Recommendation of the examiner(s)

The recommendation can, for example, be one of the following:

- approval (unqualified);
- approval (qualified);
- rejection (unqualified); the main reasons for rejection should be given;
- recommendation that the type be rejected, but that it may be approved in the future, if specified modifications are made to satisfaction as may be demonstrated by a partial re-evaluation of the type; or
- recommendation that the type be rejected, that the applicant be adequately informed about its deficiencies, and that the type be accepted for a complete re-evaluation in the future, provided the applicant declares that the deficiencies have been corrected.

4.8.3 Definition of the type

The report should include a definition of the type. This definition may be in the form of the evaluator's description of the type, including a listing of characteristics and the values of the associated parameters with their maximum permissible uncertainties; it may be in the form of the manufacturer's description and drawings appended to the report; or it may be in the form of reference to a copy of the type deposited by the applicant. Combinations of the above and, perhaps, of reference to certain components of the instrument that have been deposited can also be used to define the type.

4.8.4 Additional basis for type approval certificate or rejection notice

A variety of information and recommendations, in addition to that mentioned above may be reported. Depending on the case at hand, the report may include appropriate items drawn from the following list:

- a) applications
 - approved ranges;
 - maximum and minimum capacity;
 - reference conditions;
 - normal conditions of use;
 - approved subjects of measurement: physical quantities, commodities, materials, objects, or phenomena which may be measured;
 - special restrictions on application.

- b) accuracy
 - accuracy class;
 - nominal instrument error(s);
 - maximum permissible error(s);
 - required use of calibration charts, corrections, or instrument constants.
- c) requirements on manufacturer
 - special requirements on manufacturing or quality control procedures, if applicable, under accreditation programs;
 - required inspections and tests in lieu of initial verification, including sampling plan;
 - required name plate information and stamps, marks, and seals affixed at the factory;
 - required availability for inspection by legal metrology authority of manufacturer's facilities.
- d) administrative requirements
 - required notification of legal metrology authority concerned or registration of instruments upon sale, purchase, installation, putting into use, recalibration, or repair of instruments;
 - required notification of legal metrology authority concerned upon changes in specified components or materials in the type of instrument (see 2.2.4).
- e) requirements for use
 - installation requirements;
 - requirements dealing with ambient influence quantities at site of installation or permanent use
 - legally required auxiliary equipment, identification of the measuring instruments in conjunction with which it may be legally used;
 - legally required maintenance procedures;
 - required interval and sources of recalibration and maximum permissible uncertainties of recalibration;
 - required procedures for use of instrument.

4.8.5 Proposed initial and subsequent verifications

The report should include recommendations concerning verifications in relation to the following items:

- characteristics to be verified;
- acceptable values and uncertainties of parameters of verified characteristics;
- maximum permissible error(s) of the type;
- intervals between verifications;
- verification sampling plans;
- verification procedures;
- required verification equipment and its characteristics and limits of error;
- required qualification of inspectors;
- manufacturer's role in initial verifications;
- sites of verifications;
- location of required marks and seals;
- possible exemption from verification.

4.9 Factors influencing type approval decisions

4.9.1 Type approval judgments are made with reference to the requirements laid down in law or regulation, keeping in mind the application of the type and, for example, the durability and reliability of instruments of the type. The type evaluation process that leads to the approval of a type, though generally carried out conscientiously, is based on a very small number of instruments and can generate only limited data. It follows that even the best judgment in granting type approval or setting the conditions of approval may sometimes later turn out to be less than optimum. Judgments that, in retrospect, prove to be faulty might, for example, relate to the incidence of failure or the rate of deterioration of the copies of a type or to the verification intervals or verification procedures which are made conditions of type approval. Because such judgments can in fact be too optimistic or too pessimistic, approval authorities should welcome opportunities to revise earlier type approval decisions so as to improve compliance with regulation or to reduce unnecessary work or expense.

4.9.2 The data gathered during both the initial and subsequent verification of a larger number of copies of a given type will, when systematically analysed, often yield information not available from type evaluation. Such feedback can be used as the basis for revising the conditions of approval when the situation warrants this. Depending on circumstances, the experience gained during verifications may justify later changes in the type approval concerning instrument design, manufacturing process, application of the type, or required verification procedures; in extreme cases, it might even result in withdrawal of the approval.

4.10 Decision considerations

The approving official decides whether to issue a type approval certificate or a rejection notice and conveys the decision to the applicant as appropriate, together with other documents that may be relevant. The type approval may be a full or a provisional approval as discussed below.

4.10.1 Full type approval

In general, type approval must be regarded as full or complete despite the fact that any one approval is subject to a variety of conditions which limit the scope of the approval. These conditions may be inclusive or exclusive as in “... only for use in measuring the volume of water ...” or “... not for use in measuring corrosive liquids ...”. The possible conditions of approval are many and include:

- restricted application of copies of the type;
- requirements or exemptions related to verifications of copies of the type;
- requirements concerning installation, safeguarding, or recalibration;
- period of validity of the type approval.

4.10.2 Provisional type approval

4.10.2.1 Under some circumstances a type may be approved for legal use before type evaluation has been completed. It is granted with the understanding that further evaluation will take place before (full) type approval can be considered.

4.10.2.2 Provisional type approval, for example, may be granted after only partial or limited type evaluation when an urgent need for use of copies of the type exists but the approval authority is temporarily unable to carry out a complete type evaluation. The approval should be qualified by obtaining written agreement from the applicant that existing copies of the type will be modified or retrofitted if required by the (full) type approval. A provisional approval could also be given when new technology is involved and the metrology service wishes to study the instrument in use.

4.11 Approval on the basis of an OIML certificate or other previous evaluation

4.11.1 Where an application for type approval is accompanied by either a certificate issued under the OIML-CS or evidence of other equivalent evaluation, the national issuing authority may, after checking the validity of the certificate, approve the type without requiring further evaluation.

4.11.2 Where a type has been tested or evaluated in another jurisdiction and it is shown that the type conforms to OIML Recommendations or national regulations, authorities may approve the type, affix the approval mark on the type, and issue the approval certificate to the applicant. If the type does not conform to either OIML Recommendations or national regulations, the authorities shall issue rejection notices, and return supporting documents and the submitted type back to the applicant.

5 Administrative Matters

5.1 Fees

Fees will usually be payable for all applications. They should be set in accordance with the requirements of the approval or registration authority and may be determined either from a fee schedule for the various categories of instrument or according to the actual work carried out by the authority or both. Where there is a fixed or initial fee, it will usually need to be submitted with the application.

5.2 Documents to be provided after approval decision

A type approval certificate, rejection notice, amendment to an existing approval certificate, or similar document reflecting the approval decision should be sent to the applicant at the earliest possible time. When the definition or description of the type is not part of the approval certificate, it should be the subject of a separate document which must accompany the certificate. The approving official should also consider sending to the applicant copies of, or excerpts from, the reports of type evaluation and of conclusions and recommendations. More detailed test data not contained in these reports may, when appropriate, also be conveyed.

5.2.1 Type approval certificate

A type approval certificate should contain the following information. Part of this information may, in certain instances, be conveyed by reference to more general official documents, such as regulations.

- identification of the application for type approval, applicant, manufacturer, and approving authority and official; regulations complied with and jurisdiction(s) where approval is valid; specific instruments, components, and salient documents examined;
- date of approval and, if applicable, of its expiration;
- comprehensive definition of the type and its variants; the definition may be the subject of an appended document;
- approved application of the type, its accuracy requirements on its manufacturer, administrative requirements, and requirements for its use. When, in lieu of initial verification, heavy reliance is placed on the manufacturer's quality control, inspections, and tests, a separate document may detail the requirements on the manufacturer.

5.2.2 Extension of type approval

An extension of type approval may be granted for a previously approved type when one or more of the original conditions of approval are extended. Typically, the original period of validity or the permitted application of the type are extended. The application may, for example, be extended to a higher point in the measurement range or to an additional class of merchandise. Normally the decision concerning an extension of type approval is based on only a partial type evaluation.

5.2.3 Amendment of type approval

A currently valid type approval may be amended, for example, because of changes in regulations, modification of a type, or extension of its application. The document approving a proposed amendment of type approval should include the following:

- identification of the currently valid type approval and of any prior amendments;
- reason for the amendment; and
- amended provisions of the approval, preferably also quoting verbatim any earlier provisions deleted or superseded by it.

5.2.4 Rejection notice

5.2.4.1 A rejection should be communicated to the applicant and include the following information:

- identification of the application for type approval, applicant, manufacturer, and rejecting authority and official; applicable regulations; specific instruments, components, and salient documents examined; and manufacturer's instrument type for which application was made;
- date of rejection; and
- characteristics and the values of their parameters found to be deficient as well as the corresponding acceptable values; other conditions not fulfilled.

5.2.4.2 When reasons for rejection are based on relatively small deficiencies or when deficiencies can be easily rectified, the notice may, at the option of the official, list changes in the type that would make it acceptable and, perhaps invite resubmission of the request after these changes have been made.

5.3 Type approval mark

5.3.1 Type approval may convey the privilege or the obligation to affix a type approval mark to instruments manufactured to replicate the type or to instruments of the type as demonstrated by verification. Typically, such marks identify the jurisdiction, type approval certificate number, and year of approval. In some instances, this mark must be supplemented with a mark indicating verification.

5.3.2 If authorities decide they wish to require that type approval marks, the regulations should make clear whether marks are to be affixed by the manufacturer, importer, or verifying official.

5.3.3 Any type approval mark should be visible, legible, and indelible; in some cases, its location on the instrument may be specified. When approval has been provisional or limited in some special way, the approval mark should convey this fact.

5.4 Validity of period of type approval

Depending upon applicable laws and regulations, type approval may be granted for an indefinite period or may lose validity at a predetermined time. The question of when and why a type approval may lose validity is discussed below.

5.4.1 Expiration of type approval

The expiration time of a type approval may be prescribed by regulation or may be set at the time of type approval on the judgment of the approving official acting within regulations. When or just before a type approval expires, extension of type approval may be requested. Some type approvals are given without a limit to the period of validity.

5.4.2 Withdrawal of type approval

Type approval may be withdrawn for various reasons. These include deficiencies in the type not discovered before approval; changes in regulations to take account of more stringent needs, advances in the state-of-the-art, or new technologies; unfulfilled stipulations of approval; and failure of too many copies of the subject type of instrument to replicate the type.

5.5 Public notices

Decisions of type approval, suspension or withdrawal should be announced in public notices at the earliest possible time. These notices may be in official periodicals or special bulletins or recognised websites. Decisions that should be announced include granting and withdrawal of type approval, extension of the application or the period of validity of a type, and, in some instances, approval of a modification of a type. Such notices should identify the instrument covered by the type approval, give its approved application, and state any requirements relating to its installation and use. Notices may also give additional details or indicate how such details can be obtained.

5.6 Documents conveyed to officials responsible for verifications

Approval authorities or officials responsible for type approval should notify verification authorities and verification officials of their approval decisions and they should furnish the latter with such information as will be necessary or helpful in carrying out verifications. Depending on the practice in a given jurisdiction, the approving official may prescribe or recommend how verifications are to be conducted or furnish information and data upon which the verification authorities can base their plans for verification. In any case, a copy of the type approval certificate should be made available. When the approving official prescribes or recommends the manner of verification, a document should be prepared covering such recommendations and conveyed to the appropriate officials.

5.7 Ownership of type approval certificate

A type approval certificate remains the property of the authority which issued it and its use by the person to which it is issued, for instance for marketing purposes, may be subject to conditions imposed by that authority. Where more than one certificate is issued to different applicants in respect of the same type, the same conditions should be applied to all certificates for that type.

5.8 Confidentiality of information

In the course of the control process, the approval or registration authority often obtains proprietary information related to the type or range, manufacturing techniques, etc. The authority must protect this information and carefully limit access to it, or to data concerning the type generated by the authority, to properly authorised organisations or individuals, e.g., the applicant, the manufacturer and certain officials of the verification authorities.

1 References

- [1] OIML B 18:2022 *Framework for the OIML Certification System (OIML-CS)*
- [2] OIML D 20:1988 *Initial and subsequent verification of measuring instruments and processes*
- [3] OIML V 1:2022 (E/F) *International vocabulary of terms in legal metrology (VIML)*
- [4] OIML V 2-200:2012 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)*
- [5] OIML B 3:2011 *OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments*
- [6] OIML B 10:2011 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations*

- [7] ISO/IEC 17065:2012 *Conformity assessment – Requirements for bodies certifying products, processes and services*
- [8] ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- [9] OIML-UNIDO Guidance Document *Certification of Measuring Instruments*
<https://www.oiml.org/en/oiml-cs/docs/oiml-unido-guidance-document-on-the-oiml-cs.pdf>

ANNEX (INFORMATIVE)

ADDITIONAL INFORMATION ON THE OIML CERTIFICATION SYSTEM (OIML-CS)

A.1 Background

The OIML-CS was launched on 1 January 2018 and replaced the previous OIML Basic Certificate System [5] and the OIML Mutual Acceptance Arrangement (MAA) [6].

A.2 Principles

The OIML-CS is a system for issuing, registering and using OIML certificates and their associated OIML type evaluation/test reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of OIML Recommendations.

It is a single Certification System comprising two Schemes: Scheme A and Scheme B.

The aim of the OIML-CS is to facilitate, accelerate and harmonise the work of national and regional bodies that are responsible for type evaluation and approval of measuring instruments subject to legal metrological control. In the same way, instrument manufacturers, who are required to obtain type approval in some countries in which they wish to sell their products, should benefit from the OIML-CS as it will provide evidence that their instrument type complies with the requirements of the relevant OIML Recommendation(s).

It is a voluntary system and OIML Member States and Corresponding Members are free to participate. Participating in the OIML-CS and signing the OIML-CS Declaration will commit, in principle, the signatories to abide by the rules of the OIML-CS. OIML B 18 [1] establishes these rules whereby signatories voluntarily accept and utilise OIML type evaluation and test reports, when associated with an OIML certificate issued by an OIML Issuing Authority, for type approval or recognition in their national or regional metrological controls.

A.3 Objectives and expected benefits

The objectives of the OIML-CS are

- a. to promote the global harmonisation, uniform interpretation and implementation of legal metrological requirements for measuring instruments and/or modules,
- b. to avoid unnecessary re-testing when obtaining national type evaluations and approvals, and to support the recognition of measuring instruments and/or modules under legal metrological control, while achieving and maintaining confidence in the results in support of facilitating the global trade of individual instruments, and
- c. to establish rules and procedures for fostering mutual confidence among participating OIML Member States and Corresponding Members in the results of type evaluations that indicate conformity of measuring instruments and/or modules, under legal metrological control, to the metrological and technical requirements established in the applicable OIML Recommendation(s).

The various stakeholders may benefit from the OIML-CS:

- a. for national legal metrology authorities from countries in which no test facilities are available and where national type evaluations and approvals are required, the OIML-CS offers a viable solution;
- b. for instrument manufacturers who are required to obtain type approval, the OIML-CS may provide evidence that their instrument type complies with the requirements of the relevant OIML Recommendations, thus avoiding duplication of type approval tests in different countries; and
- c. the OIML-CS additionally provides formal evidence to accept and utilise OIML Type Evaluation Reports validated by an OIML Certificate of Conformity.

A.4 Scope and participation

There are three categories of participants:

- a. An OIML Issuing Authority (OIML IA) is a certification body from an OIML Member State that issues OIML certificates and associated OIML type evaluation reports in accordance with Scheme A or Scheme B. The participation of OIML IAs in the OIML-CS is subject to the approval of the OIML-CS Management Committee. An OIML Member State can have more than one OIML IA in their country. Each OIML IA can designate one or more associated Test Laboratories as outlined below.
- b. A Utilizer is a national issuing authority or national responsible body from an OIML Member State that utilises and accepts OIML certificates and/or OIML type evaluation reports issued under Scheme A or Scheme B as the basis for issuing a national or regional type approval. An OIML Member State can have more than one Utilizer in their country.
- c. An Associate is the same as Utilizer with the exception that the national issuing authority or national responsible body is from an OIML Corresponding Member. An OIML Corresponding Member can have more than one Associate in their country or economy.

In addition to the three main categories of participant, each OIML IA can designate one or more associated Test Laboratories (TL). These are laboratories that perform certain or all tests on a type of measuring instrument. Participation of a TL in the OIML-CS is subject to the approval of the MC. A TL may be:

- an internal Test Laboratory of an OIML IA,
- a third-party Test Laboratory, or
- a Manufacturer Test Laboratory (MTL)

Note: TLs do not sign a Declaration as they participate in the OIML-CS under the responsibility of an OIML IA.

Those categories of measuring instruments (including families of instruments, modules, or families of modules) for which the relevant OIML Recommendation specifies the metrological and technical requirements, the test procedures, the OIML test report format, and the OIML type evaluation report format will automatically be included in the OIML-CS. A category of measuring instrument will initially be placed in Scheme B, with the intention that all categories of measuring instruments in the OIML-CS will transition to Scheme A two years after first being included in the OIML-CS.

The requirements for the participation of OIML Issuing Authorities and their associated Test Laboratories in Scheme A or Scheme B are the same, but the method of demonstrating compliance is different. OIML Issuing Authorities are required to demonstrate compliance with ISO/IEC 17065 [7] and Test Laboratories are required to demonstrate compliance with ISO/IEC 17025 [8]. For participation in Scheme B, it is sufficient to demonstrate compliance on the basis of “self-declaration” with additional supporting evidence. However, for participation in Scheme A, compliance shall be demonstrated by accreditation or peer assessment.

A.5 Structure of the OIML-CS

The structure of the OIML-CS within the OIML structure is shown in Figure 1.

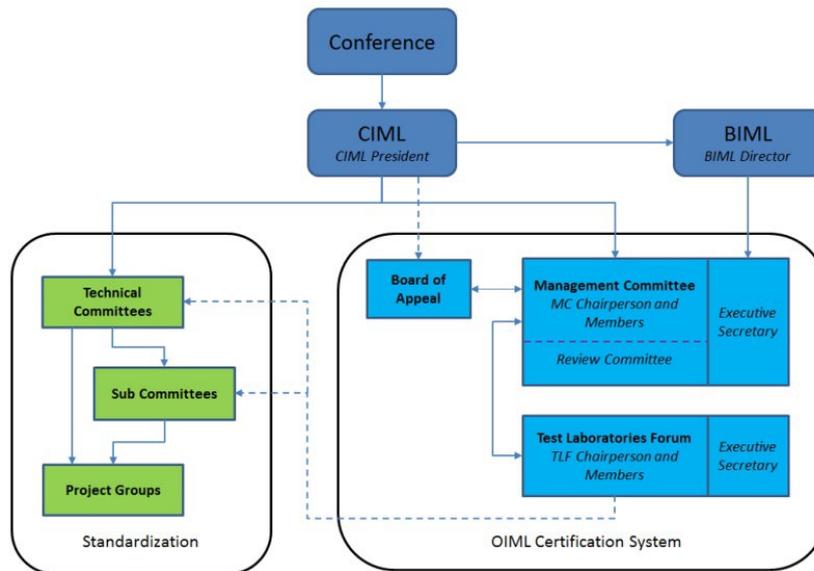


Figure 1

The Management Committee (MC) is responsible for the operation of the OIML-CS under the authority of the CIML, with an Executive Secretary from the BIML who is responsible for undertaking the day-to-day activities of the OIML-CS under the direction of the MC. The MC incorporates a Review Committee which provides recommendations to the full MC on issues such as the acceptance of new OIML Issuing Authorities and the approval of Legal Metrology Experts. The Test Laboratories Forum provides a platform for handling practical and/or technical questions pertaining to test specifications, test methods and test equipment, and to propose amendments/improvements to OIML Recommendations. A Board of Appeal is provided to address appeals against decisions of the MC and to recommend solutions to any other dispute referred to it with regard to the application of the rules of the OIML-CS.

A.6 Becoming a Utilizer or Associate

A National Issuing Authority or National Responsible Body in an OIML Member State may apply to become a Utilizer under the OIML-CS. A National Issuing Authority or National Responsible Body in an OIML Corresponding Member country may apply to become an Associate under the OIML-CS.

Utilizers and Associates will sign a Declaration which will commit them in principle to voluntarily accept and utilise OIML type evaluation and test reports, when associated with an OIML certificate issued by an OIML Issuing Authority, for type approval or recognition in their national or regional metrological controls.

Utilizers and Associates may specify Additional National Requirements. These are requirements that are not included in the relevant OIML Recommendation but that are required in order to issue a national/regional type approval. When these are specified the relevant test procedures must also be defined. OIML Issuing Authorities and their associated Test Laboratories can declare which tests they can perform.

Further detail is provided in section 10 of the OIML-UNIDO guidance document on the OIML-CS [9].

A.7 Application of the OIML-CS to type approval controls

OIML Recommendations and the OIML-CS support the implementation of new, or the development of existing type approval controls for measuring instruments used in legal applications. OIML Recommendations have been developed as model regulations and so they specify the relevant technical and metrological requirements for each category of measuring instrument.

The OIML-CS provides a ‘ready-made’ solution regarding the suitability of test results and/or certificates that could be accepted as the basis for granting a national (or regional) approval. For the Models described in this Document, it would be possible to directly accept OIML-CS certificates and/or OIML type evaluation and test reports as a basis for reducing/minimising evaluation when issuing national type approvals.

However, consideration of the following is required:

- which instrument categories to regulate,
- which edition of an OIML Recommendation to use, e.g. R 76:1992 and/or R 76:2006,
- the level of type approval control to apply – what is the national responsible body willing to ‘delegate’ to others, and
- which OIML-CS certificates and/or reports to accept:
 - Scheme A (issued on the basis of accreditation or peer assessment);
 - Scheme B (issued on the basis of self-declaration, although in some instances the OIML IA and/or TL may have accreditation or peer assessment);
 - OIML certificates and OIML type evaluation reports issued on the basis of manufacturer test results.

In all cases, if OIML-CS certificates and/or OIML type evaluation reports are to be accepted as the basis for issuing a national (or regional) type approval it is important to ensure that the OIML-CS certificate and/or report that is presented actually applies to instrument submitted. In addition, the national issuing authority will need to consider how to address modifications to instrument.

Consequently, participating in the OIML-CS as a Utilizer (OIML Member State) or Associate (Corresponding Member) allows a system of type approval controls to be established in a country or economy without the need to invest in expensive testing and type evaluation capabilities. OIML certificates and/or OIML type evaluation reports can be utilised in the knowledge that the competence of the OIML IA and TL, in accordance with international standards, has been established.