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Type evaluation and type approval

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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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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OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization’s headquarters:

Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

TYPE[1] EVALUATION and TYPE APPROVAL

1 General

1.1 Introduction

1.1.1 This OIML International Document (OIML Document) is addressed primarily to:

i. OIML Technical Committee and Subcommittee secretariats and Project Group conveners;
ii. officials in government administrations responsible for designing and developing type approval systems; and
iii. legal metrology officials concerned with conformity assessment (including testing and type approval) of measuring instruments.

Project Group conveners are responsible for the drafting of OIML International Recommendations ("OIML Recommendations) for measuring instruments subject to type evaluation and type approval. Government policy makers are responsible for designing and developing type approval systems, and 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 OIML Document has applicability across a broad range of fields such as those that facilitate trade, environmental protection, and healthcare. It includes advice, procedures, and factors which influence 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 systems for weighing and measuring instruments. This information will help industry to ensure product quality, consumer protection, and fair commercial practices.

1.1.3 This OIML Document is intended for use in the type approval of all measuring instruments subject to legal metrological control. 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.

1.1.4 Although outside of the scope of this OIML Document, information relating to a procedure based on manufacturer/importer declaration (with relevant supporting documents) is provided in Annex A.

1.1.5 Information on the OIML Certification System (OIML-CS), and how it can be used to support a type approval system, is provided in Annex B.

1.2 Relationship between type approval and verification

1.2.1 Type approval is different from, but complementary to, verification.

1.2.2 Verification is a process which is capable of being applied to every regulated measuring 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 a measuring instrument will continue to function properly over its operational lifetime.

[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.

1.2.3 Type approval, however, involves rigorous testing of a measuring instrument over a wide range of operating conditions using suitable test equipment and skilled personnel. Only a small number of measuring instruments can be tested to this degree while maintaining economic viability. A limited number are tested as exemplars of the "type" of measuring instrument for which type approval is being considered. Type approval gives greater assurance that a measuring instrument will work satisfactorily over its operating conditions. It has to be accompanied by additional checks so that legal metrology authorities can be satisfied that all measuring instruments of that type are satisfactory.

1.2.4 There are two main interactions between type approval and verification. The first is that verification can be one of the means of policing the type approval. Verification officers are in a good position to check whether a measuring 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 may, when systematically analysed, potentially 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 measuring 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 type approval.

1.2.5 Secondly, matters identified during the type evaluation and type approval stages might provide verification officers with information that is helpful for subsequent evaluations of measuring instruments of that type, e.g. appropriate reverification periods.

1.2.6 A companion OIML Document, D 20 [1], may be used to develop an appropriate balance between type evaluation and type approval, and initial verification.

2 Terms and definitions

The terms in this OIML Document are taken from the International Vocabulary of terms in Legal Metrology (VIML) [2], where appropriate. Definitions of terms not found in the VIML [2] 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, impartiality and consistent operation in performing specific conformity assessment activities
[ISO/IEC 17000 [3], 7.7] [VIML [2], A.19]

Note: ISO/IEC 17000 [3] defines "attestation" as "issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated".

2.2
application for type approval

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

2.3
approval

permission for a product, service or process to be marketed or used for stated purposes or under stated conditions
[ISO/IEC 17000 [3], 9.1] [VIML [2], A.25]

2.4
certification

third-party attestation related to an object of conformity assessment, with the exception of accreditation
[ISO/IEC 17000 [3], 7.6] [VIML [2], A.18]

Note: ISO/IEC 17000 [3] defines "attestation" as "issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated".

2.5
conformity assessment

demonstration that specified requirements are fulfilled
[ISO/IEC 17000 [3], 4.1] [VIML [2], A.1]

2.6
copy of a type

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

2.7
examination

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

Note: This is not a defined term in either ISO/IEC 17000 [3] or the VIML [2] because it is a word used in many different contexts. This definition has been produced solely for the purpose of this International Document.

2.8
initial verification

verification of a measuring instrument which has not been verified previously
[VIML [2], 2.12]

2.9
inspection

examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgment, with general requirements
[ISO/IEC 17000 [3], 6.3] [VIML [2], 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 authority of a particular country, and (4) the authority of a particular city government charged with enforcing pollution laws.

2.11
legal metrological control

the whole of legal metrology activities

Note: Legal metrological control includes:

- legal control of measuring instruments,
- metrological supervision,
- all the operations for the purpose of examining and demonstrating, e.g. to testify in a court of law, the condition of a measuring instrument and to determine its metrological properties, amongst others by reference to the relevant statutory requirements.

[VIML [2], 2.01]

2.12
legal metrology

practice and process of applying statutory and regulatory structure and enforcement to metrology
[VIML [2], 1.01]

2.13
legal metrology authority

public (government or local government) or private body authorised by law on a national level to be responsible for legal metrological supervision as a whole or in part
[Adapted from OIML D 9 [4], 2.15]

2.14
legal metrology official

authorised employee or appointee of a legal metrology authority

Note: This is not a defined term in either ISO/IEC 17000 [3] or the VIML [2]. This definition has been produced solely for the purpose of this International Document.

2.15
measuring instrument

device used for making measurements, alone or in conjunction with one or more supplementary devices

Note 1: A measuring instrument that can be used alone is a measuring system.

Note 2: A measuring instrument may be an indicating measuring instrument or a material measure.

[VIML [2], 0.10]

2.16
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

2.17
modified type

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

2.18
module

identifiable part of a measuring instrument or of a family of measuring instruments that performs a specific function or functions that can be separately evaluated according to prescribed metrological and technical performance requirements in the relevant Recommendation

Example: Typical modules of a weighing instrument are: weighing module, load cell, indicator, analogue or digital data processing device, terminal, primary display.

[VIML [2], 4.04]

2.19
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

[Adapted from OIML B 18 [5], 3.24]

2.20
subsequent verification

verification of a measuring instrument after a previous verification

[VIML [2], 2.13]

2.21
testing

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

[ISO/IEC 17000 [3], 6.2] [VIML [2], A.10]

2.22
testing laboratory

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

[ISO/IEC Guide 2 [6]]

2.23
type (of a measuring instrument or module)

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

[VIML [2], 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], 2.05]

2.25
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 application for type approval and culminating in a certificate or notice of type approval or rejection

2.26
type evaluation

conformity assessment procedure on one or more specimens of an identified type of measuring instruments which results in an evaluation report and / or an evaluation certificate
[VIML [2], 2.04]

2.27
validity of type approval

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

2.28
verification

provision of objective evidence that a given item fulfils specified requirements
[VIM [7], 2.44]

3 Design of type approval 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 of 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 of a measuring instrument or range of measuring instruments, whereas type approval is the decision, based on these facts and involving judgment, to permit or not to permit that model of a measuring instrument or range of measuring instruments to be used for regulated purposes. The official making the type approval decision (decision maker) will often not be the official(s) who carried out the type evaluation. This OIML 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 model of a measuring instrument or a range of measuring instruments and to the applicant who applies for the type approval. It conveys license to the applicant to produce and/or sell measuring 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 measuring instruments and to verification officials that the model or range of measuring instruments conforms to legal requirements. 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 Many variables, conditions, and limitations have a bearing on type evaluation. These factors should dictate the planning of the type evaluation for each particular case. The evaluation process should take into account the nature of the measuring instrument and its application, the resources available for type evaluation and approval, and applicable regulations or national practice. Additional factors may be considered as the need arises.

3.1.4 There have been important developments in type approval, including changes in the balance in emphasis and effort between type approval and initial verification. This OIML 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 type 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 measuring 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 type approval 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 a new type approval system, there are three basic decisions that need to be made:

a) Which measuring instruments should be subject to type approval;

b) What performance requirements should be specified that approved measuring instruments must conform to; and

c) How type evaluation will be conducted.

3.2 Which measuring 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, and therefore also measuring 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, 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. Examples include conventional measuring instruments of such design and construction material whose metrological qualities do not vary much with time, single measuring 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 measuring instruments not subject to type approval. There will also be requirements for verification, even if some measuring instruments are automatically accepted for initial verification.

3.3 What performance requirements should be specified

Under the OIML Convention (OIML B 1:1968 *Convention establishing an International Organisation of Legal Metrology*) there is an expectation that where a type approval system is introduced, or is 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 Convention, there are several other advantages to this approach. It means that measuring instruments manufactured to international standards are able to be used without costly modifications. It ensures compliance with the obligations under the World Trade Organisation's Technical Barriers to Trade Agreement[2]. 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 to conduct the type evaluation for a particular category of measuring instrument, variation in legal metrology regulation among OIML Member States and Corresponding Members should be considered. Some countries have the capability to carry out the complete type evaluation and approval process, at least for some measuring instruments, using their own facilities and staff. Countries with more limited resources should consider making full or partial use of evidence of third-party conformity assessment, or making use of witness testing performed by the country's staff at a third-party facility. In all cases, however, provided that the requirements are based on OIML Recommendations and provision is made for measuring instruments with appropriate certificates issued under the OIML-CS, there will be harmonised access for compliant measuring instruments in all countries, together with higher standards of protection than would be the case without type approval.

3.4.2 The three options for assessing compliance with requirements are 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 OIML 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 measuring instruments, and the full or partial use of evidence of third-party conformity assessment or witness testing is applied to other categories of measuring instruments.

[2] In application of Article 2.4 of the WTO Agreement, where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

3.5 What constitutes a different type

When two types of measuring instrument are very much alike, a decision must be made by the national issuing authority as to 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 measuring 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 measuring instrument types

Different measuring 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

Measuring instruments of a specific manufacturer which otherwise are identical in design, materials, and major components, but only 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 measuring instrument within permissible error limits.

3.5.4 Different components, materials, or manufacturing techniques

Measuring 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 measuring instruments. Similar considerations apply when the manufacturer employs different manufacturing techniques or, in electronic measuring instruments, different wiring or layouts, to produce a single type of measuring instrument. They also apply when different components are used as transducers between the measured quantity and the sensors of otherwise identical measuring instruments, e.g. 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 measuring 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 measuring instrument manufactured to replicate an approved type, three possibilities exist:

- the changed measuring 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 measuring 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 legal metrology authorities; preferably they should have the option of using either one.

3.6.1.3.1 Notification of change in measuring instrument type

The grantee of the original type approval or the manufacturer notifies the legal metrology authorities that a change has been made or is contemplated for a measuring 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 legal metrology 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 Application 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, applies for 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 measuring 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 measuring 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 system

4.1 Outline of a type approval system

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

4.1.1.2 The administrative requirements should also describe the documentation to be submitted, the conditions of the measuring instrument to be submitted for approval, the expected timescales to complete the type approval, and the fees which are payable, distinguishing between:

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

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 measuring 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 measuring 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 measuring 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 type approval stage will be conducted. It will normally be necessary to provide for the following steps:

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

4.1.5 Communicating the approval decision

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

4.1.5.2 Where there are requirements to deposit a specimen measuring 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 mark on the measuring instrument and obligations to notify the authorities of any modifications in the approved measuring instruments.

4.2 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 measuring instrument;
- documents indicating the applicant's authority to represent the manufacturer;
- category of measuring instrument and its general purpose;
- intended and other possible legal applications of the measuring 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 application
- manufacturer's designation and name for the measuring instrument;
- manufacturer's specifications of metrological characteristics of the measuring instrument that are regulated for the subject category of measuring instrument;
- inventory of measuring instruments, devices and materials, or of descriptive material, defining the type and submitted with the application.

4.2.2 Supporting documents

The national issuing authority can ask that certain documents be included with the application, 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 measuring instrument, for example, detailed specifications relating to construction, assembly, adjustment, and internal operation of the measuring instrument or to internal standards, safety devices, and self-adjusting mechanisms; also, assembly drawings, detailed drawings, layouts, and schematic diagrams;
- for measuring instruments subject to software-related requirements, the software description in the documentation includes software identification, parameters, software block diagrams, and software interfaces, etc.;
- sales literature, photographs, drawings, and documents intended for users, including instructions for installation and preparation of a measuring instrument for service, and operating, maintenance, and repair manuals;
- published papers describing the principle of operation of the measuring 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 measuring instrument

Generally, one or more sample measuring instruments or devices are submitted as part of the application for type approval; they constitute the "type". A statement should accompany submitted measuring 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 national issuing authority?[3]
- Do regulations require type approval of the measuring instrument, also taking account of its intended or potential application?
- Have all requested items of information, documents, measuring instruments, etc., been submitted?
- Does the measuring instrument or its description, submitted as the type, appear to be sufficiently definitive to serve as the type?

[3] National issuing authorities may specify that only certain persons may submit applications for type approval, such as:
- a manufacturer
- a manufacturer's sales representatives
- a distributor of the manufacturer's measuring 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

4.2.4.2 The decision to accept or refuse the application at this stage is based on a study of the documents submitted with the application for type approval. If the application is lacking in some details, the national issuing 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.

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 type 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 national issuing 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 measuring instruments elsewhere.

4.3.1.4 Even in the absence of such agreements, the national issuing authority may be authorised to accept data obtained in or conclusions drawn in the other jurisdiction. Also, the national issuing 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, national issuing 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 measuring 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, national issuing 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 measuring 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 measuring instrument type;
- the requirements of regulations concerning both the category of measuring instrument and the applications;
- the tentatively decided modes of verifications;
- the amount of information and data submitted with the application;
- information already available from prior type evaluations of related measuring 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 measuring 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 submitted by the applicant, and a testing phase which may include the testing of a prototype measuring instrument, of preliminary production measuring instruments, or of measuring 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 measuring instruments or for special applications of measuring instruments in order to determine compliance with requirements.

4.3.3.6 Of the possible steps that can be taken in the course of type evaluation, in each particular case, only some of these will be found to apply or to be necessary. Provided that the applicant consents, the type evaluation process should be stopped after one or more deficiencies of the type have been found that will result in 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, after an appropriate technical review and analysis of the modification, it is determined 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 either maintain confidence in the previous results or to determine which of the characteristics of a type may have been affected by its modification and require further review or testing.

4.5 Examination 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 measuring 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 measuring 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 refer 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 measuring instrument characteristics prescribed in the relevant OIML Recommendation. In addition to evaluation of metrological performance, the following measuring instrument features might also be examined:

- scale interval;
- scale range;
- scale marks, spacing, and numbering;
- statement of scale units and of measuring 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 measuring 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 measuring 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 measuring instrument readout for operator and customer;
- security from inadvertent disconnection of the connectors of communication lines; and
- 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 measuring 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 measuring instrument rating;
- presence and prominence of important restrictions of use and other cautions; and
- security of attachment of calibration or conversion charts to the measuring 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 a measuring instrument; and
- points located where theoretical analysis of the measuring instrument's equations indicates poles, zeroes, or exceptionally high or low sensitivities.

Any deviation from the test points shall be recorded in the test report, with a suitable justification provided for the deviation.

4.7 Evaluation report

4.7.1 The type evaluation should result in a report of the objective findings of the type examination stage and of the conclusions drawn. This will in turn lead to recommendations concerning type approval.

4.7.2 There are many reasons for writing and then maintaining the report 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 report the values of measured metrological characteristics and their uncertainties. It should identify the measuring instruments, devices and salient documents examined, as well as the personnel and laboratories that carried out the evaluation. A summary of tests carried out shall be provided, along with 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

Where the personnel carrying out the type evaluation process do not make the approval decisions, the report should describe the basis for any conclusions and recommendations given to support the type approval decision, the definition of the type, and the contents of the type approval certificate or rejection. The report might be structured in five parts, as follows.

4.8.1 Summary of the findings of type evaluation

The summary should list the characteristics, attributes, and conditions of the measuring 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

The recommendation of the personnel carrying out the type evaluation can, for example, be one of the following:

- approval;
- provisional approval;
- rejection; 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 a description of the type provided by the personnel carrying out the type evaluation, and it will include a listing of characteristics and the values of the associated parameters with their maximum permissible uncertainties. Alternatively, 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, possibly also including references to certain components of the measuring 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 measuring instrument error(s);
- maximum permissible error(s);
- required use of calibration charts, corrections, or measuring 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, verification 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 measuring instruments upon sale, purchase, installation, putting into use, recalibration, or repair of measuring instruments;
- required notification of legal metrology authority concerned upon changes in specified components or materials in the type of measuring instrument.

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 the measuring 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 verification 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 measuring instruments of the type. The type evaluation process that leads to the approval of a type is based on a very small number of measuring instruments and generates only limited data. Therefore, even the best judgment in granting type approval or setting the conditions of type approval may result in decisions that must later be rescinded. For example, inaccurate judgments about the incidence of failure, the rate of deterioration of the copies of a type, or the verification intervals and procedures might not be recognised until more data is collected through subsequent examinations. Because such judgments can in fact be too optimistic or too pessimistic, national issuing 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 measuring instrument design, manufacturing process, application of the type, or required verification procedures; in extreme cases, it might even result in withdrawal of the type approval.

4.10 Decision considerations

The person(s) who decide(s) whether to issue a type approval certificate or a rejection notice shall convey the decision to the applicant, together with other documents that may be relevant. The type approval may be a full approval, or a provisional approval, as outlined below.

4.10.1 Full type approval

In general, type approval must be regarded as full or complete despite the fact that any one type 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 type 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 national issuing authority is temporarily unable to carry out a complete type evaluation. The type 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 type approval could also be given when new technology is involved and the national issuing authority wishes to study the measuring 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 type approval mark on the type, and issue the type 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 national issuing authority and may be determined either from a fee schedule for the various categories of measuring instrument, or according to the actual work carried out by the national issuing 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 type approval certificate, or similar document reflecting the type 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 type approval certificate, it should be the subject of a separate document which must accompany the certificate. The person(s) who grant(s) the type approval 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:

- identification of the applicant, manufacturer, approving authority, person(s) responsible for granting the approval, regulations complied with, and jurisdiction(s) where approval is valid; specific measuring instruments, components, and salient documents examined;
- date of type 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.

Part of this information may, in certain instances, be conveyed by reference to more general official documents, such as regulations.

5.2.2 Extension of type approval

An extension of a type approval may be granted for a previously approved type when one or more of the original conditions of type 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 a 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 applicant, manufacturer, the national issuing authority, and the person(s) responsible for the rejection; applicable regulations; specific measuring instruments, components, and salient documents examined; and manufacturer's measuring 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 and the respective clause in the relevant OIML Recommendation; 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 person(s) responsible for the rejection, list changes in the type that would make it acceptable and, perhaps invite resubmission of the application 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 measuring instruments manufactured to replicate the type or to measuring 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 are to be affixed, 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 measuring 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 by 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, an extension of the 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 type approval; changes in regulations to take account of more stringent needs, advances in the state-of-the-art, or new technologies; unfulfilled stipulations of type approval; and failure of too many copies of the subject type of measuring 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, 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 measuring 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

National issuing authorities, or the person(s) responsible for granting the type approval, should notify verification authorities and verification officials of their type approval decisions and they should furnish the verification authorities and verification officials 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 person(s) who grant(s) the type approval 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 national issuing 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 the national issuing authority. Where more than one type approval 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 national issuing 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 national issuing authority, to properly authorised organisations or individuals, e.g., the applicant, the manufacturer and certain officials of the verification authorities.

6 References

[1] OIML D 20:1988 *Initial and subsequent verification of measuring instruments and processes*

[2] OIML V 1:2022 (E/F) *International vocabulary of terms in legal metrology (VIML)*

[3] ISO/IEC 17000:2020 *Conformity assessment — Vocabulary and general principles*

[4] OIML D 9:2004 *Principles of metrological supervision*

[5] OIML B 18:2025 *Framework for the OIML Certification System (OIML-CS)*

[6] ISO/IEC Guide 2:2004 *Standardization and related activities*

[7] OIML V 2-200:2012 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)*

[8] OIML B 3:2011 *OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments*

[9] OIML B 10:2011 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations*

[10] ISO/IEC 17065:2012 *Conformity assessment – Requirements for bodies certifying products, processes and services*

[11] ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*

[12] 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 A
(INFORMATIVE)

PROCEDURE BASED ON MANUFACTURER/IMPORTER DECLARATION

A.1 Background

With this Procedure, measuring instruments are required to be of a type which complies with national regulations. This involves the registration of the measuring instruments' type with the legal metrology authority before it is allowed to be used for regulated purposes. Registration is based on the submission of appropriate supporting documents such as an OIML certificate and/or type evaluation report indicating compliance with relevant OIML Recommendations. The legal metrology authorities are able to act against measuring instruments of that type if they are subsequently shown not to conform to regulations, for instance through verification checks or the result of enforcement activities. Such controls will usually include a registration of the type of measuring instrument before it can be used.

A.2 Outline

A system, based on the registration of a type following consideration of valid OIML certificates or test/type evaluation reports indicating compliance with OIML Recommendations, will normally consist of the following steps. The authorities 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.

A.3 Applications for registration

The administrative requirements should set out clearly the conditions under which the registration of a measuring instrument's type must be made. Typically, these may include:

- Categories of measuring instruments, and types of applications subjected to regulatory control;
- Relevant national legislation pertaining to the measuring instruments and activities subject to regulatory control;
- Clear communication of the scope/rationale for control (e.g. measuring instruments meant for trade purposes, to ensure fair weights and measures, etc.);
- Supporting documentation required;
- Fees payable.

A.4 Examination of the application

The requirements should describe the main considerations for examination of the application, such as confirmation that the measuring instrument type and its intended use fall under regulated scope, and that the OIML Recommendation it has been evaluated to is relevant to its intended use. The requirements should make clear the information required for type registration. They should also set out procedures for requesting and submitting additional information and explain how incomplete or invalid applications will be dealt with.

A.5 Communicating the decision on an application

The requirements should describe how a decision on an application for registration will be communicated, the arrangements for issuing any registration certificate, and for publishing the registration outcome in a public register.

A.6 Continuing obligations on holders of type approvals

The obligations of an applicant who has successfully registered a measuring instrument's type should be set out clearly. These will typically include the obligation to send the measuring instrument to an authorised party to be verified and to have a seal and verification mark affixed before being put into service.

A.7 Examination of an application for registration

A.7.1 Information included in the application

Applications should be accompanied with the following:

- Company information – name, address, etc.;
- Measuring instrument information – manufacturer, type, capacity, etc.; and
- Conformity information – OIML certificate, type evaluation report number, name of issuing authority, etc.

A.7.2 Supporting documents

Documents to support the application for a type registration typically include endorsed certificates and/or type evaluation reports, sealing provisions, photos, rating labels, other relevant technical documents.

A.7.3 Specimen measuring instrument

This will generally not be required, but the authorities may consider requesting a specimen measuring instrument for better understanding of the instrument's functionality, or for audit/inspection/enforcement purposes.

A.7.4 Consideration of the application for type registration

The following questions should be considered when deciding on an application for registration:

- Do the test reports and certifications provided cover the conditions and intended usage being applied for? Evaluation reports should indicate the approved ranges, maximum/ minimum capacity, reference conditions, etc.
- Is the evaluation based on the relevant edition of an OIML Recommendation?
- Has testing/evaluation been conducted by an OIML Issuing Authority?
- Is there a need for submission of another registration application if significant modifications are made?

A.7.5 Registration certificate

Any type registration certificate should contain the following information:

- model & identification of the measuring instrument;
- manufacturer details;
- test reports/certifications the registration is based on;
- the testing body; and
- the edition of the OIML Recommendation it was tested to.

Each certificate should have a specific registration number.

A.7.6 Publication of successful registrations

The most convenient way of making the public aware of which measuring instruments have been properly registered is by online registers. It will usually be desirable to have separate registers for:

- Measuring instruments granted type registration; and
- Registered suppliers.

A.7.7 Cancellation of registrations

The authority may consider having provisions to allow for the cancellation type registrations previously granted, or to impose additional conditions and amendments to the initial registration (e.g. imposing a specific validity period).

Considerations in deciding whether to cancel/revoke a registered type include:

- Findings to indicate the measuring instrument does not conform to OIML Recommendations;
- Findings to indicate that documents supporting initial type registration are invalid; and
- Reason for the authority to believe that the measuring instrument is being used in ways or applications that are not suitable for trade purposes or relevant controlled activities.

ANNEX B
(INFORMATIVE)

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

B.1 Background

The OIML-CS was launched on 1 January 2018 and replaced the previous OIML Basic Certificate System [8] and the OIML Mutual Acceptance Arrangement (MAA) [9].

B.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, measuring 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 measuring 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 [5] 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.

B.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 measuring 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 measuring instrument manufacturers who are required to obtain type approval, the OIML-CS may provide evidence that their measuring 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.

B.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 measuring 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 [10] and Test Laboratories are required to demonstrate compliance with ISO/IEC 17025 [11]. 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.

B.5 Structure of the OIML-CS

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

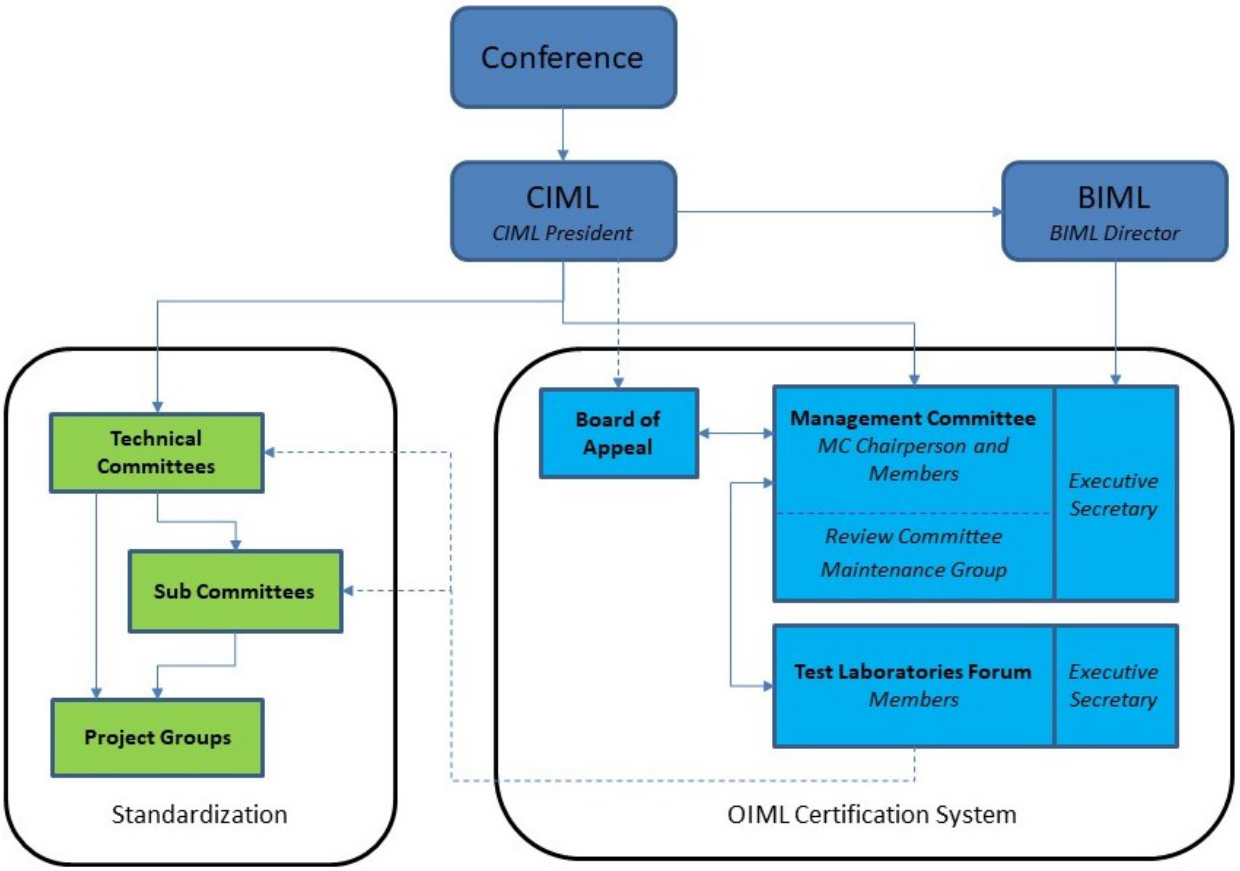


Figure 1

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.

B.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 [12].

B.7 Application of the OIML-CS to type approval

OIML Recommendations and the OIML-CS support the implementation of new, or the development of an existing type approval system 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 measuring 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 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 the measuring instrument submitted. In addition, the national issuing authority will need to consider how to address modifications to the measuring instrument.

Consequently, participating in the OIML-CS as a Utilizer (OIML Member State) or Associate (Corresponding Member) allows a type approval system 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.