

ASEAN GUIDELINES FOR TYPE APPROVAL CONTROL SYSTEMS



one vision
one identity
one community



ASEAN Guidelines for Type Approval Control systems

The ASEAN Secretariat
Jakarta

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Table of Contents

1	Introduction	01
2	Scope	05
3	Terminology	09
4	Design of Type Approval Control systems	15
5	Operation of a Procedure A Type Approval Control systems.....	23
6	Operation of a Procedure B Type Approval Control systems	41
7	Operation of a Procedure C Type Approval Control systems	47
8	Administrative Matters	51
	Information on the OIML Certification System	57

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1 Introduction

1.1. Background

The ASEAN Consultative Committee for Standards and Quality (ACCSQ) Working Group on Legal Metrology (ACCSQ WG 3) agreed in 2016, following a workshop organized in Thailand in coordination with the ASEAN Secretariat and the Physikalisch-Technische Bundesanstalt (PTB), to work on harmonizing implementation of Type¹ Approval Control systems using the International Organization of Legal Metrology (OIML) Document 19, 1988 Edition as the basis for harmonization. All ASEAN Member States (AMS) represented at the workshop agreed that they would benefit from ASEAN guidelines on Type Approval Controls.

These Guidelines for Type Approval Control systems have evolved as a result of this work in order to provide rules and procedures for type approval control within the ASEAN Member States. They were approved and endorsed by ACCSQ during the 50th ACCSQ Meeting in June 2018.

The Guidelines are addressed primarily to two groups:

- AMS Government administrations responsible for designing and developing Type Approval Control systems, and
- Legal metrology officials within AMS governments concerned with testing, conformity assessment and type approval of measuring instruments.

The Guidelines are intended to serve as a common reference document for ASEAN Member States 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. They include advice, procedures, and influencing factors bearing on the conduct of type evaluation and on the type approval decision that follows it.

¹ Note that some earlier publications, including some of the most relevant OIML Documents, refer to "Pattern Approval" rather than "Type Approval". In the opinion of the authors the meaning is exactly the same and in order to avoid confusion throughout these Guidelines the phrase "Type Approval" is used. Similarly, "type" is used in preference to "pattern", but the two concepts are exactly the same.

At the 2016 workshop it was reported that all ASEAN Member States had either introduced Type Approval Control systems, were currently introducing a Type Approval Control system or had plan to do so. In Member States who currently operated Type Approval Controls, they were based on the OIML Recommendations for the relevant instruments and recognized certificates issued under the OIML Certificate System². The results of the workshop indicated that there are three different models existing among ASEAN Member States, and different member states continued to favor different models.

As a result, three different “Procedures” are described, but it is important to stress that, provided the Type Approval Controls adopted are based on the relevant OIML Recommendations, adopting any one of the three Procedures ought to guarantee that the same standards are being applied in ASEAN Member States and that an instrument accepted in any one of the markets will be able to be accepted in any other market within ASEAN. In that sense, the Guidelines represent a harmonized approach. Accordingly, ASEAN Member States with existing or developing Type Approval Control systems are obliged to apply or use the relevant parts of these Guidelines in order to achieve control procedures which are harmonized and in conformity with current international requirements.

1.2. Structure and Presentation of the Guidelines

The Guidelines (cf. Table of Contents) comprise of eight Sections.

Section 3 covers the terminology used in these Guidelines.

Section 4 provides guidance on the design of a Type Approval Control system based on each of the three procedures described in 2.2, including the role which can be played by OIML Recommendations and certificates issued under the OIML Certificate System.

Sections 5 describes the operational procedures which should be used when conducting Type Evaluation according to Procedure A, to assess whether a type submitted for approval conforms to the AMS requirements. These cover both the testing phase and the evaluation phase and include the arrangements for requesting type examination and for submitting supporting documents in support of

² At the time of the workshop the OIML Certificate System consisted of two schemes involving the issue of OIML Basic Certificates of Conformity and OIML MAA Certificates of Conformity respectively. Since January 2018 this has been replaced by a new OIML Certificate System (OIML-CS) with provision for existing Basic and MAA Certificates to remain valid. References in these Guidelines to the OIML Certificate System should be read as referring to the new OIML System, but including Basic or MAA Certificates that remain valid.

the application. The Section then goes on to describe the operational procedures for the formal approval or rejection stage according to Procedure A.

Section 6 describes the operational procedures which should be used when following Procedure B. This largely mirrors the approach described in Section 5 but also includes the arrangements for applying for approval and for submitting supporting documents in support of the application.

Section 7 describes the operational procedures which should be used when following Procedure C.

Section 8 is concerned with various administrative matters, including guidance on type approval certification and type approval marking.

2 Scope

2.1. Application

This document should be capable of being used for the type approval of all measuring instruments that are controlled for legal metrology purposes and may thus have wide applicability in such fields as weights and measures, environmental protection or medicine. However, it has been produced primarily for use in the type approval control of weighing and measuring instruments controlled under national regulation of an AMS, as this is the legal metrology area where harmonization is currently most advanced. Such national regulations may themselves 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.

2.2. Categories of Type Approval Control Procedures used by AMS

Three categories of procedures for type approval control are currently operated by AMS and all systems being introduced or planned are based on one of these procedures:

Procedure A: Full Evaluation and Approval

With this Procedure, the AMS operates, or has access to, testing and conformity assessment facilities which allow it to form its own judgment on whether the type submitted for approval conforms to the specifications set out in national regulation. Approval, whether on the basis of this evaluation or evaluation by a recognized third party, is a separate stage and is necessary before instruments corresponding to an approved type can be used for regulated purposes.

Procedure B: Formal Approval with Limited or No Evaluation

With this Procedure, because the AMS does not have its own evaluation facilities, the decision on whether to give approval for a type of instrument to be used for regulated purposes will usually be based on evidence of third party conformity assessment, for instance Certificates issued under the OIML Certificate System, being presented as supporting documents.

Procedure C: Based on Manufacturer/Importer Declaration (with relevant supporting documents)

With this Procedure, instruments are required to be of a type which complies with national regulations. This involves the registration of the 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 or test/evaluation report indicating compliance with relevant OIML Recommendations. The legal metrology authorities are able to act against 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 instrument before it can be used.

Sections 5, 6 and 7 deal with each of these procedures in turn but different parts of the rest of these Guidelines will be appropriate, depending on which Procedure is being used.

2.3. Relationship between Type Approval Controls and Verification

Type approval controls are different from, but complementary to, verification control such as those outlined in the *ASEAN Guidelines for the Verification of Non-Automatic Weighing Instruments*.

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.

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.

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 analyzed, 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.

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

3 Terminology

The terms in this Document are mainly taken from the 2013 edition of the International Vocabulary of Terms in Legal Metrology (VIML). Definitions of terms not found in the VIML are provided with appropriate references where applicable.

3.1. 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 17000:2004, 5.6] [VIML, A.19]

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”.

3.2. Accredited Laboratory

A testing laboratory to which accreditation has been granted.

[ISO Guide 2, «General terms and their definitions concerning standardization, certification and testing laboratory accreditation»]

3.3. Approval

Permission for a product or process to be marketed or used for stated purposes or under stated conditions.

[ISO/IEC 17000:2004, 7.1] [VIML, A.25]

3.4. Certification

Third-party attestation related to products, processes, systems or persons.

[ISO/IEC 17000:2004, 5.5] [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”.

3.5. Conformity Assessment

Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

[ISO/IEC 17000:2004, 2.1] [VIML, A.1]

3.6. Copy of a Type

An 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.

[Modified from OIML D 19:1988, 1.1.3]

3.7. Examination

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

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

3.8. Evaluation

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

Note: this is not a defined term in either ISO 17000 or VIML. This definition has been developed from the definition of Type Evaluation (see 3.25) for the purpose of these Guidelines.

3.9. Initial Verification

Verification of a measuring instrument which has not been verified previously.

[VIML, 2.12]

3.10. 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 17000:2004, 4.3] [VIML, A.11]

3.11. Jurisdiction

The 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.

[Modified from OIML D 19:1988, 1.1.7]

3.12. Laboratory Accreditation

A formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests.

Note: The generic term «accreditation» can cover the recognition of both the technical competence and the impartiality of a testing laboratory or only its technical competence. Accreditation is normally awarded following successful laboratory assessment and is followed by appropriate monitoring.

[ISO Guide 2, «General terms and their definitions concerning standardization, certification and testing laboratory accreditation»]

3.13. Legal Metrology

Practice and process of applying statutory and regulatory structure and enforcement to metrology.

[VIML, 1.01]

3.14. Legal Metrology Authority

Public authority responsible for undertaking one or more legal metrology activities, in particular type evaluation or type approval.

Note: this is not a defined term in either ISO 17000 or VIML. This definition has been produced solely for the purpose of these Guidelines.

3.15. Legal Metrology Official

Authorised employee or appointee of a legal metrology authority.

Note: this is not a defined term in either ISO 17000 or VIML. This definition has been produced solely for the purpose of these Guidelines.

3.16. Modification of a Type

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

[Modified from OIML D 19:1988, 1.1.4]

3.17. Modified Type

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

[Modified from OIML D 19:1988, 1.1.5]

3.18. Request for Type Approval

Taken together, all the documents, instruments, fees, etc. submitted to the relevant legal metrology authority when type approval is requested.

[Modified from OIML D 19:1988, 1.1.1]

3.19. Subsequent Verification

Verification of a measuring instrument after a previous verification.

[VIML, 2.13]

3.20. Testing

Determination of one or more characteristics of an object of **conformity assessment**, according to a procedure.

[ISO/IEC 17000:2004, 4.2] [VIML, A.10]

3.21. Testing Laboratory

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

[ISO Guide 2, «General terms and their definitions concerning standardization, certification and testing laboratory accreditation»]

3.22. Type

The definitive model of a measuring instrument and the class of instruments that conform to it.

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.

[Modified from OIML D 19:1988, 1.1.3]

3.23. 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]

3.24. Type Approval Process

The 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.

[Modified from OIML D 19:1988, 1.1.2]

3.25. 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]

3.26. Validity of Type Approval

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

[Modified from OIML D 19:1988, 1.1.6]

3.27. Verification

Provision of objective evidence that a given item fulfils specified requirements.

[VIM, 2.44]

4 Design of Type Approval Control systems

4.1. Introduction

Type approval, and the conformity assessment on which it is based, 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 approval, and type evaluation (itself consisting of testing and conformity assessment stages) 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, while 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 will often not be the official(s) who carried out the evaluation and these Guidelines are drafted on the assumption that these officials will be distinct.

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 or regulated 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.

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. These choices will be affected by the nature of the instrument and its application, the resources available for type evaluation and approval, and the 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 systems over the past thirty years, including changes in the balance in emphasis and effort between type approval controls and initial verification. These Guidelines cover some of the available

alternatives. There have also been changes in cooperation between legal metrology authorities 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, 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 heretofore 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.

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
- c) Which of the three Procedures discussed in 2.2 should be used.

4.2. Which Instruments should be subject to Type Approval?

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.

Control of whole categories of measuring instruments may be required by law. While this will often involve type approval controls, in some cases verification without type approval is deemed sufficient. The requirement for 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.

At the same time, certain categories of 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 instruments are automatically accepted for initial verification.

In practice, the instruments which should be a priority within ASEAN for type approval controls are those which it has been agreed should be the subject of efforts at harmonization. As noted in 2.2, these Guidelines have been prepared with weighing and measuring instruments particularly in mind.

What performance requirements should be specified?

At the workshop in April 2016, it was noted that in all cases where type approvals controls had been introduced or were planned the national regulations used by AMS were based on the relevant OIML Recommendations (e.g. R 76). There are several advantages to this. It means that instruments manufactured to international standards are able to be used without costly modifications. It ensures that obligations under the WTO's Technical Barriers to Trade Agreement are complied with. And because most of the relevant OIML Recommendations set out test methods and test report formats they make it easier to carry out the type evaluation phase.

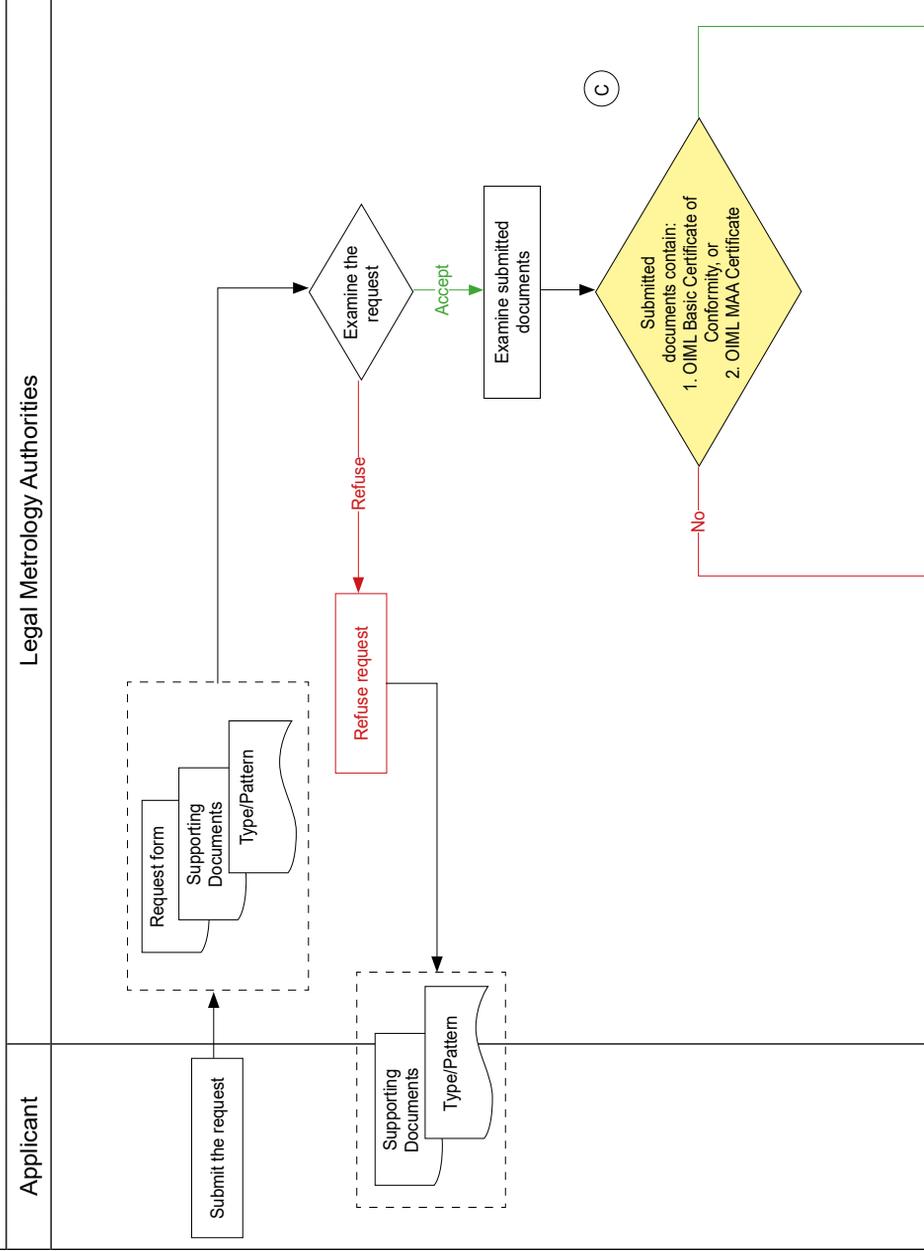
4.3. Which Type Approval Control Procedure should be used?

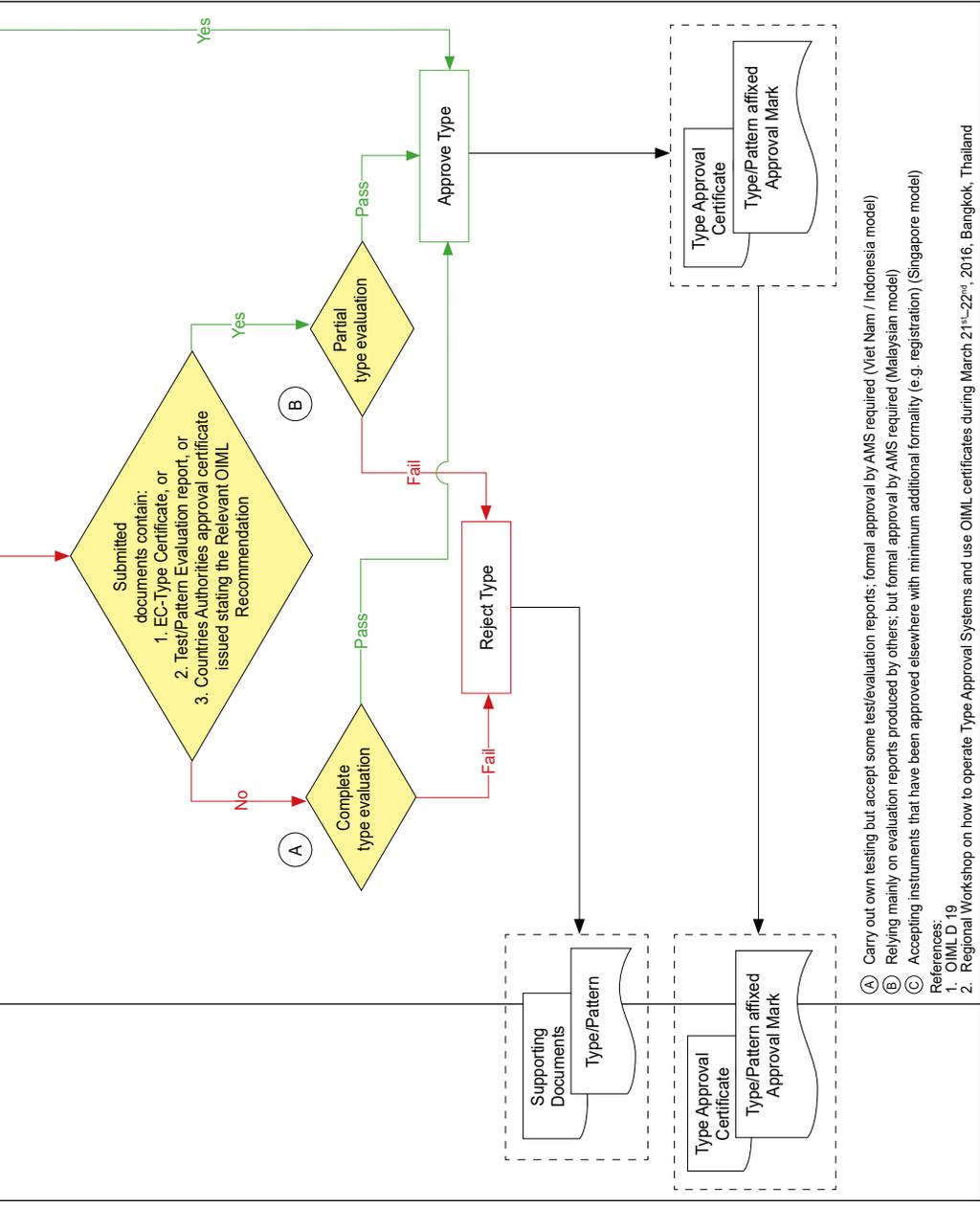
In determining which of the Procedures identified in 2.2 should be applied for a particular category instrument, there has to be regard to the fact that among ASEAN Member States, there are differences in the conditions under which legal metrology regulation takes place. Some AMS have the capability to carry out the complete type evaluation and approval process, at least for some instruments, and that means that Procedure A is a possibility. In the case of other AMS with limited resources, they will only be able to consider Procedures B or C at the present time. 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 Certificate System, there will be harmonized access for compliant instruments in all AMS together with higher standards of protection than would be the case without Type Approval Controls.

Because all three Procedures can offer the same level of protection and harmonized access, it is not the purpose of these Guidelines to put forward one Procedure as preferable to another. The choice of procedure is entirely a matter for the AMS. Moreover, even within a single jurisdiction it may be that one Procedure is applied to one set of regulated instruments (for instance Procedure A where the necessary evaluation facilities are available in the AMS) and other Procedures are applied to other categories of instruments.

The flowchart at Figure [1] illustrates how use of the three Different Procedures can be operated to achieve the required levels of protection. It incorporates elements of all 3 approaches where an AMS may choose to carry out full testing on its own where necessary (step A), conduct partial evaluation by relying on evaluation reports produced by others (step B), or choose to accept instruments that have already been approved elsewhere (step C). The letters “A”, “B”, “C” on the diagram represent the 3 procedures described in 2.2 as follows: “A” represents the Vietnam/Indonesia approach where the AMS carries out its own testing (but may accept some test/evaluation reports), formal approval by the AMS is in all cases required; “B” represents the Malaysian approach, where the AMS relies mainly on evaluation reports produced by others, but formal approval is still required; and “C” represents the Singapore approach, where authorities accept instruments that have been approved elsewhere with minimum additional formality (e.g. registration).

Figure 1. Outline Concept of ASEAN Guidelines on Type Approval Control





- (A) Carry out own testing but accept some test/evaluation reports; formal approval by AMS required (Viet Nam / Indonesia model)
- (B) Relying mainly on evaluation reports produced by others; but formal approval by AMS required (Malaysian model)
- (C) Accepting instruments that have been approved elsewhere with minimum additional formality (e.g. registration) (Singapore model)

References:
 1. OIML D 19
 2. Regional Workshop on how to operate Type Approval Systems and use OIML certificates during March 21st-22nd, 2016, Bangkok, Thailand

5 Operation of a Procedure A Type Approval Control systems

5.1. Outline of a Full Type Approval Procedure (Procedure A)

A full type approval procedure will normally consist of the following steps. The AMS 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.

5.1.1. Applications for type approval

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 pattern
- extension of application of an instrument
- 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 rejection or withdrawal of type approval, coupled with newly presented facts concerning the type, improvement of the instrument design, or a change in regulations

The requirements should also describe the documentation, the conditions of the instrument to be submitted for approval, 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

5.1.2. Initial examination of the application

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.

5.1.3. Type evaluation

The requirements should describe how and by whom the evaluation stage will be conducted. If testing of the instrument submitted and the conformity assessment judgment will be made by different individuals or organizations, this should be explained.

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 organization, 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

5.1.4. 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

5.1.5. Communicating the approval decision

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.

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

5.1.6. 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.

5.2. 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.

5.2.1. 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

5.2.2. Supporting documents

The approval 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
- 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
- reports of tests or calibrations carried out by an accredited laboratory

5.2.3. Specimen instrument

Generally one or more 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. In certain cases, definitive descriptions, such as engineering descriptions and assembly drawings, may be submitted in lieu of actual equipment.

5.2.4. Consideration of the application for type approval

The following questions should be considered before evaluation takes place:

- Is the applicant properly authorized by the manufacturer and acceptable to the approval authority³ ?
- Do regulations require type approval of the instrument, 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?

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

5.3. Type Evaluation Plan

5.3.1. Scope of evaluation plan

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

³ AMS may specify that only certain persons may apply 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 importers
- certain officials of the foreign services or consulates of other jurisdictions

The scope and nature of the Evaluation Plan should take into account:

- a) Whether the type submitted has been approved in one or more jurisdictions. Evidence of this may be an EC-Type Certificate, a Test/ Evaluation report produced by another authority, or another country's approval certificate stating the relevant OIML Recommendation has been met.
- b) Whether a certificate issued under the OIML Certification System has been presented.

Both alternatives can be effective in reducing the workload of the approving authority and helping to minimize the overall cost of the type approval process. Bilateral, regional, or international agreements between different countries may formally permit acceptance of instruments elsewhere. Even in the absence of such agreements, the authority may be authorized to accept data obtained in or conclusions drawn in the other jurisdiction. Finally, 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.

Wherever possible therefore, where there is evidence of type approval in other jurisdictions or an OIML Certificate, authorities should plan for a partial type evaluation, where they consider and decide which aspects and characteristics of the type should be tested and evaluated. Where there is no such evidence, authorities should plan to carry out a complete type evaluation, in which all aspects and characteristics of the type are tested and evaluated with regard to the relevant OIML Recommendation and the country's regulations.

5.3.2. Choice of organization to conduct evaluation

When new technologies are applied to measuring instruments or when an approval 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 testing or evaluation. In such cases it should turn for support to organizations that have

the necessary 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 organization to conduct tests at the latter's facility.

Categories of organizations that can be considered in these cases are:

- other government laboratories of the same jurisdiction
- laboratories of independent test organizations or of universities
- laboratories of manufacturer or industry associations
- government laboratories in another jurisdictions
- manufacturer facilities

5.3.3. Contents of an evaluation plan

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

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

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

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 organization.

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.

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.

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.

Complete type evaluation

In complete evaluation, all relevant aspects of the type, including metrological characteristics and technical provisions, are thoroughly evaluated to determine that it complies with applicable regulations and that copies of the type can be expected to perform properly. Typically, a complete evaluation is carried out when the type has not been previously evaluated.

Partial type evaluation

In a partial type evaluation, only a limited number of selected characteristics of a type are carefully evaluated to determine their compliance with applicable regulations. A partial evaluation may be carried out when a type has been modified such that only certain of its characteristics can be expected to have been affected by the modification (e.g., when a new indicating device has been incorporated).

Limited type evaluation

In a limited type evaluation all relevant aspects of a type are evaluated, but not as thoroughly as in a complete 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 evaluation may be carried out when the results of a previous evaluation in another jurisdiction are available and tests are carried out to quickly establish confidence in the previous results or to establish which of the characteristics of a type may have been affected by a modification.

5.4. Study of Submitted Documents

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.

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.

The conclusions of this examination should be summarized 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.

5.5. Conduct of Evaluation - Testing Phase

5.5.1. Metrological examination

The metrological examination includes the testing 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 minimize parallax
- provisions for properly or uniquely applying the measured quantity to the instrument (loading) and potential for improper loading

5.5.2. Technical examination

The relevant OIML Recommendation should cover all the important elements of the technical examination. AMS should not add requirements for technical examination not specified in the 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

5.5.3. 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 pattern, 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

5.5.4. 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

5.6. Evaluation Report

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.

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

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 were 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.

5.7. 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 should be structured in five parts, as follows:

5.7.1. 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.

5.7.2. 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

- recommendation that the type be rejected, that the applicant be adequately informed about its deficiencies, and that the pattern be accepted for a complete re-evaluation in the future, provided the applicant declares that the deficiencies have been corrected

5.7.3. 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.

5.7.4. Additional information 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 the approval authority of the manufacturer's facilities
- d) administrative requirements
- required notification of approval authority concerned or registration of instruments upon sale, purchase, installation, putting into use, recalibration, or repair of instruments
 - required notification of approval authority concerned upon changes in specified components or materials in the type of 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 instrument

5.7.5. 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

5.8. Factors Influencing Type Approval Decisions

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 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.

The data gathered during both the initial and subsequent verification of a larger number of copies of a given type will, when systematically analyzed, 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.

5.9. 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.

5.9.1. 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

5.9.2. Provisional type approval

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.

Provisional type approval, for example, may be granted after only partial or limited 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 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.

5.10. Approval on the Basis of an OIML Certificate or Other Previous Evaluation

Where an application for type approval is accompanied by either a certificate issued under the OIML Certificate System or evidence of other equivalent evaluation, the authorities may, after checking the validity of the Certificate, approve the type without requiring further evaluation.

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.

6 Operation of a Procedure B Type Approval Control systems

6.1. Outline of a Procedure B Type Approval System

A Procedure B type approval system, that is one based on evaluation carried out in another jurisdiction, will normally consist of the following steps. The AMS 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.

6.1.1. Applications for type approval

The 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 an instrument
- 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 rejection or withdrawal of type approval, coupled with newly presented facts concerning the type, improvement of the instrument design, or a change in regulations

The requirements should also describe the documentation, the conditions of the instrument to be submitted for approval, and the fees which are payable.

6.1.2. Initial examination of the application

The requirements should describe how the application will be examined prior to any approval process taking place and how incomplete or invalid applications will be dealt with. It should also make clear what forms of evaluation carried out in other jurisdictions (either OIML Certificates or approval decisions made by other authorities) are or are not acceptable for instance.

- examination and tests of instruments and/or devices
- report of evaluation, conclusions drawn, and recommendations

6.1.3. Type approval

The requirements should describe how and by whom the approval 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

6.1.4. Communicating the approval decision

The requirements should describe how a decision to grant approval will be communicated and how any accompanying certificate will be issued. It should also describe how decisions to refuse approval and requests for additional information relating to modifications will be communicated.

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

6.1.5. 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.

6.2. Initial Examination of an Application for Type Approval

The first stage in considering any application for type approval is to examine it 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.

6.2.1. 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

6.2.2. Supporting documents

The approval 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 point [6.7 of D19])
- 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
- reports of tests or calibrations carried out by an accredited laboratory

6.2.3. Specimen instrument

Generally one or more 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. In certain cases, definitive descriptions, such as engineering descriptions and assembly drawings, may be submitted in lieu of actual equipment.

6.2.4. Consideration of the application for type approval

The following questions should be considered at this initial stage:

- Is the applicant properly authorized by the manufacturer and acceptable to the approval authority⁴ ?
- Do regulations require type approval of the instrument, taking account of its intended or potential application?

⁴ AMS may specify that only certain persons may apply 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 importers
- certain officials of the foreign services or consulates of other jurisdictions

- Have all requested items of information, documents, instruments, etc, been submitted?
- Does the instrument or its description, submitted as the pattern, appear to be sufficiently definitive to serve as the pattern?

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

6.3. Factors Influencing Type Approval Decisions

Type approval judgments under Procedure B, like those under procedure A, 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 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 approval decisions so as to improve compliance with regulation or to reduce unnecessary work or expense.

The data gathered during both the initial and subsequent verification of a larger number of copies of a given type will, when systematically analyzed, 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.

6.4. 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.

6.4.1. 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

6.4.2. Provisional type approval

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.

Provisional type approval, for example, may be granted after only partial or limited evaluation when an urgent need for use of copies of the pattern exists but the approval authority is temporarily unable to carry out a complete 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.

7 Operation of a Procedure C Type Approval Control systems

7.1. Outline of a Procedure C Type Approval System

A Procedure C type approval system, based on the registration of a type or pattern following consideration of valid OIML Certificates or test/evaluation reports indicating compliance with OIML Recommendations, will normally consist of the following steps. The AMS 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.

7.1.1. Applications for registration

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

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

7.1.2. Examination of the application

The requirements should describe the main considerations for examination of the application, such as confirmation that the 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 pattern registration. They should also set out procedures for requesting and submitting additional information and explain how incomplete or invalid applications will be dealt with.

7.1.3. 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.

7.1.4. Continuing obligations on holders of type approvals

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

7.2. Examination of an Application for Pattern Registration

7.2.1. Information included in the application

Applications should be accompanied with the following:

- Company Information – name, address, etc.
- Instrument Information – manufacturer, type, capacity, etc.
- Conformity information – OIML certificate evaluation report number, name of issuing body, etc.

7.2.2. Supporting documents

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

7.2.3. Specimen instrument

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

7.2.4. 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 latest OIML Recommendations?
- Has testing/evaluation been conducted by an OIML issuing body?
- Is there a need for submission of another registration application if significant modifications are made?

7.3. Registration Certificate

Any pattern registration certificate should contain the following Information:

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

Each certificate should have a specific registration number.

7.4. Publication of Successful Registrations

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

- Instruments granted pattern registration
- Registered suppliers

7.5. Cancellation of Registrations

The Authority may consider having provisions to allow for the cancellation pattern 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 effect the cancellation/revocation of registered patterns include:

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

8 Administrative Matters

8.1. Fees

Fees will usually be payable for all applications under any of the Procedures described in Sections 5, 6 and 7. 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.

8.2. 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. These are covered below. 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.

8.2.1. 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 applications 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

8.2.2. 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.

8.2.3. 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 the type approval should include the following:

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

8.2.4. Rejection notice

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

- characteristics and the values of their parameters found to be deficient as well as the corresponding acceptable values; other conditions not fulfilled

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.

8.3. Type Approval Mark

Type approval may provide the privilege or impose an obligation to affix a type approval mark to instruments manufactured to replicate the type. 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.

Given that many instruments will already be carrying approval marks appropriate to other jurisdictions, authorities should consider carefully whether to introduce their own approval marks. Such requirements will add to the costs of manufacturers which will be passed on to those who buy and use the instruments. There are currently no plans for an ASEAN-wide approval mark.

If an AMS decides it wishes to require its own type approval marks, regulations should make clear whether marks are to be affixed by the manufacturer, importer, or verification official.

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.

8.4. Validity 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 pattern approval may lose validity is discussed below.

8.4.1. 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 may be without a limit to the period of validity.

8.4.2. 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.

8.5. Public Notices

Decisions on type approval or withdrawal should be published at the earliest possible time. The publication may be in notices in official periodicals or special bulletins or recognized web-sites. Decisions that should be announced include granting and withdrawal of type approval, extension of the scope or the validity period of an approval, and, in some instances, approval of a modification of a type. Such notices should identify the instrument covered by the 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.

8.6. Documents Conveyed to Officials Responsible for Verifications

Approval authorities or officials responsible for type approval should notify verification authorities and verification officers 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.

8.7. 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.

8.8. Confidentiality of Information

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

Information on the OIML Certification System

1. Background

At its 51st meeting in Strasbourg the CIML approved the Framework (OIML B 18) for a new OIML Certification System (OIML-CS) to replace the existing OIML Basic Certificate System and the OIML Mutual Acceptance Arrangement (MAA). The CIML approved the start date of 1 January 2018 for the OIML-CS at its 52nd meeting in Cartagena de Indias.

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 harmonize 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 or not. 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 B 18:2016 establishes these rules whereby signatories voluntarily accept and utilize OIML type evaluation and test reports, when associated with an OIML Certificate issued by an Issuing Authority, for type approval or recognition in their national or regional metrological controls.

3. Objectives and Expected Benefits

The objectives of the OIML-CS are

- a) to promote the global harmonization, 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
- 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
- c) the OIML-CS additionally provides formal evidence to accept and utilize OIML Type Evaluation Reports validated by an OIML Certificate of Conformity

4. Scope and Participation

There are three categories of participants:

- a) Issuing Authorities are participants from OIML Member States that issue OIML Type Evaluation Reports and OIML Certificates and that utilize those issued by other Issuing Authorities
- b) Utilizers are participants from OIML Member States that do not issue OIML Type Evaluation Reports or OIML Certificates, but that utilize those issued by Issuing Authorities

- c) Associates are participants from OIML Corresponding Members that are willing to utilize OIML Type Evaluation Reports or OIML Certificates. Associates do not have voting rights in the Management Committee

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, and the OIML test 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 Issuing Authorities and their associated Test Laboratories in Scheme A or Scheme B are the same, but the method of demonstrating compliance is different. Issuing Authorities are required to demonstrate compliance with ISO/IEC 17065 and Test Laboratories are required to demonstrate compliance with ISO/IEC 17025. 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 peer evaluation on the basis of *accreditation* or *peer assessment*.

5. Structure of the OIML-CS

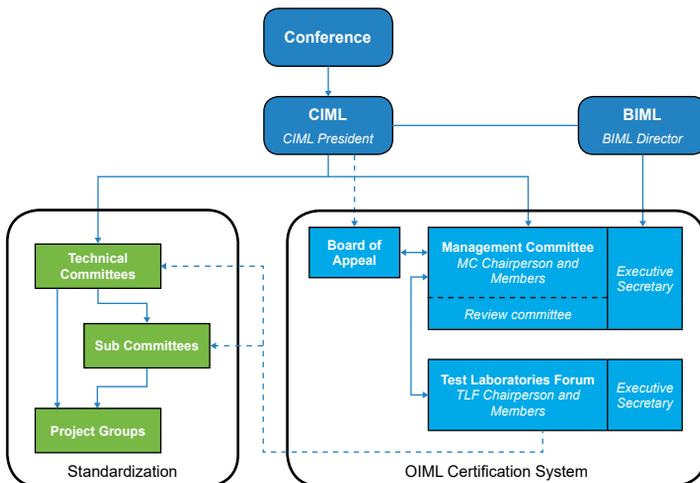
The OIML-CS comprises:

- Management Committee (MC)
- Review Committee (RC) which is a sub-committee of the MC
- Test Laboratories Forum (TLF)
- Board of Appeal (BoA)

The 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 TLF 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 BoA 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.

OIML Certification System (OIML-CS) - Structure



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 the Declaration which will commit them in principle to voluntarily accept and utilize OIML type evaluation and test reports, when associated with an OIML Certificate issued by an Issuing Authority, for type approval or recognition in their national or regional metrological controls.

7. Additional National Requirements

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.

8. Transition Arrangements

8.1. Background

The OIML-CS is due to come into operation on 1 January 2018 and will replace the existing OIML Basic Certificate System and the OIML Mutual Acceptance Arrangement (MAA). After 31 December 2017, Issuing Authorities under the Basic System and Issuing Participants under the MAA will no longer be able to issue OIML Basic Certificates and MAA Certificates respectively.

8.2. Issuing OIML Certificates from 1 January 2018

Existing Issuing Authorities and Issuing Participants will need to apply to become OIML Issuing Authorities under the OIML-CS if they wish to continue to issue OIML Certificates from 1 January 2018. Further information on becoming an OIML Issuing Authority under the OIML-CS can be found.

8.3. Validity of Existing Certificates

OIML MAA Certificates issued before 1 January 2018 will remain valid. Utilizers and Associates in the OIML-CS may establish conditions for acceptance of these certificates and/or OIML type evaluation reports.

OIML Basic Certificates issued before 1 January 2018 will also remain valid. Utilizers, Associates and Users may continue to accept these certificates and/or OIML type evaluation reports on a voluntary basis.

8.4. Revisions to Existing Certificates

Revisions to existing OIML Basic and OIML MAA Certificates will not be permitted from 1 January 2018. However, an “Annex” to the original OIML Basic Certificate or OIML MAA Certificate may be issued by the original Issuing Authority (under the Basic System) or

by the original Issuing Participant (under the MAA) respectively in the following instances:

- a) to correct an error by the applicant or the Issuing Authority/ Participant
- b) when the ownership of the Certificate is transferred to a new applicant

An “Annex” to the OIML Basic Certificate or OIML MAA Certificate will not be permitted to change the technical or metrological characteristics of the measuring instrument/module.



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