UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

CERTIFICATION OF MEASURING INSTRUMENTS

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DISCLAIMER

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Guidance Document on the OIML Certification System (OIML-CS)

1. INTRODUCTION

The United Nations 2030 Agenda for Sustainable Development sets an ambitious vision for the world that we want and charts the course for how to get there. The Agenda comprises 17 interconnected and complementary Sustainable Development Goals (SDGs). Establishing an appropriate Quality Infrastructure System (QIS), including an appropriate legal metrology system, can substantially assist nations in positioning their economy to seize the many opportunities available through appropriate implementation of these SDGs. A QIS supports governmental policy objectives in areas including industrial development, trade competitiveness in global markets, the efficient use of natural and human resources, food safety, health, the environment and climate change. The QI system components assist in the verification and demonstration that products and services actually meet specified requirements.

The United Nations Industrial Development Organization (UNIDO) has an extensive and proven track record in working with governments, industry and other major stakeholders to develop and strengthen national and regional QIS. UNIDO's approach is holistic, from building awareness of the QIS to helping to initiate, develop and strengthen a fit for purpose QIS that runs efficiently and cost effectively. The approach adopted by UNIDO emphasizes the need for strong collaboration and cooperation with all stakeholders to meet shared objectives through agreed activities that lead to concrete actions.

Together with partners from the public and private sector, academia, national and international organizations in charge of standard-setting and global practices on metrology, standards and conformity assessment, UNIDO promotes good practices, capacity-building and training, and fosters global cooperation in standard-setting, measurement and compliance development along value chains. UNIDO's partners in the field of quality and standards include the International Organization of Legal Metrology (OIML).

This document has been developed by UNIDO and the OIML to provide information on the OIML Certification System (OIML-CS), including the requirements for participation, the application processes and how the OIML-CS can be used to implement a national type approval system for measuring instruments such as active electrical energy meters, taximeters, water meters, and non-automatic weighing instruments. Information is also provided on the relevant international standards and associated management system requirements, along with the supporting OIML publications that underpin the OIML-CS.

2. SCOPE

2.1 This document provides information on the structure of the OIML-Certification System (OIML-CS), and the documentation available that describes its operation. It also provides information on the requirements to become an OIML Issuing Authority (OIML IA), with one or more associated Test Laboratories (TL), and the processes that they would need to follow to apply for approval.

2.2 The different routes available for the OIML IAs and the TLs to demonstrate competence against the requirements of ISO/IEC 17065 [1] and ISO/IEC 17025 [2][3] respectively is also described. An overview of these two international standards, together with information on the use of OIML D 32 [4] and OIML D 30 [5], which provide guidance on the application of these international standards in legal metrology applications, is also provided. Type evaluation and the type approval process under the OIML-CS and the issuing of OIML Certificates is also described.

2.3 The document also provides details on how to become a Utilizer or Associate under the OIMLCS, together with important guidance on how the OIML-CS can support the implementation of a new, or expansion of an existing, national (or regional) type approval system.

3. HOW TO USE THIS GUIDE

3.1 The reader is encouraged to initially refer to sections 6 and 7 for general information on the OIML and the OIML-CS. These sections provide information on the OIML-CS framework. These sections should be read in conjunction with section 13, which explains how the OIML-CS can be used to support the implementation or expansion of a national type approval control system. It will then be possible to determine which parts of the guide are relevant for a particular organisation (for instance, the organisation wishes to become an OIML IA under Scheme A, a TL under Scheme B, or a Utilizer or Associate).

3.2 The requirements and processes described in sections 8 to 10, as applicable, can provide guidance on how to meet the particular intended outcomes. Section 11 provides an overview of the relevant management system requirements. An overview of a type evaluation and type approval process, including requirements relating to the issuing of OIML Certificates under the OIML-CS, is provided in section 12.

4. TERMINOLOGY AND ABBREVIATIONS

4.1 accreditation (from ISO/IEC 17000, 5.6 [6])

third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Note: In the OIML-CS, accreditation is equivalent to peer assessment (see 4.30).

4.2 additional national requirement

requirement that is not included in the relevant OIML Recommendation but that is required in order to issue a national/regional type approval, and that has been included in the scope of the Declaration

4.3 applicant

manufacturer and/or authorized representative who submits an application for an OIML type evaluation of a measuring instrument to an OIML Issuing Authority in order to receive an OIML type evaluation report and an OIML Certificate for that type of measuring instrument

N*ote: Upon issuance of the OIML Certificate, the applicant becomes the owner of the OIML Certificate and associated type evaluation report and test report(s).*

4.4 Associate

national issuing authority or national responsible body from an OIML Corresponding Member that has signed the Declaration indicating the terms of acceptance of OIML Certificates and/or OIML type evaluation reports

4.5 Board of Appeal

internal appeals committee of the OIML-CS

4.6 category

classification of measuring instruments for which technical and metrological requirements are laid down in an OIML Recommendation

4.7 certification body (from ISO/IEC 17065, 3.12 [1])

third-party conformity assessment body operating certification schemes

Note: A certification body can be non-governmental or governmental (with or without regulatory authority).

4.8 conformity assessment (from ISO/IEC 17000, 2.1 [6])

demonstration that specified requirements related to a product, process, system, person or body are fulfilled

4.9 conformity assessment body (from ISO/IEC 17000, 2.5 [6])

body that performs conformity assessment services

4.10 Declaration

document that is signed by OIML Issuing Authorities, Utilizers and Associates accepting to abide by the rules of the OIML-CS. The scope of certification and/or acceptance of OIML type evaluation reports issued with an OIML Certificate under Scheme A or B are detailed in separate annexes which form part of the Declaration

4.11 Executive Secretary

BIML staff member appointed by the BIML Director who is responsible for the day-to-day operation of the OIML-CS under the direction of the Management Committee (MC)

4.12 family of measuring instruments

identifiable group of measuring instruments belonging to the same manufactured type that have the same design features and metrological principles for measurement but which may differ in some metrological and technical performance characteristics, as defined in the relevant Recommendation

Note: The concept of a "family" primarily aims to reduce the testing required for OIML type evaluation. It does not preclude the possibility of listing more than one family in one OIML Certificate.

4.13 family of modules

identifiable group of modules belonging to the same manufactured type that have similar design features but which may differ in some metrological and technical performance requirements as defined in the relevant Recommendation

4.14 internal Test Laboratory

Test Laboratory that is designated by an OIML Issuing Authority, and registered in the Declaration of the OIML Issuing Authority, that is part of the same organization as the OIML Issuing Authority

4.15 Legal Metrology Expert

person, approved by the Management Committee (MC), who provides specific technical and metrological expertise with respect to the scope of an accreditation or peer assessment; is a team member who provides advice but is not considered to be an assessor unless he/she has the relevant assessor qualifications and training

4.16 Management Committee

committee established by the CIML to manage the OIML-CS

4.17 Management System Expert

person, approved by the Management Committee (MC), who has overall responsibility for leading a peer assessment

4.18 manufacturer

company or person legally responsible for producing measuring instruments and/or modules which conform to the certified type

4.19 Manufacturer's Test Laboratory (MTL)

Test Laboratory of a manufacturer that is designated by an OIML Issuing Authority, and registered in the Declaration of the OIML Issuing Authority, and performs specific tests under controlled supervision or as a third-party laboratory of an OIML Issuing Authority

Note 1: An MTL may conduct tests for the parent company and/or for other companies. The requirements for controlled supervision apply if tests are performed for the parent company. Otherwise the MTL is considered as a third-party Test Laboratory, in which case the requirements for third-

party laboratories must be satisfied.

Note 2: In the event that test data is obtained from an MTL this must be clearly indicated on the OIML type evaluation report and acceptance of that report is on a voluntary basis.

4.20 measuring instrument

device used for making measurements, alone or in conjunction with one or more supplementary devices (VIM (OIML V 2-200:2012) International vocabulary of metrology – Basic and general concepts and associated terms)

4.21 module

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

4.22 national issuing authority

certifying body or person in an OIML Member State or Corresponding Member that is responsible for national type approval and that issues national/regional Type Approval Certificates for specific categories of measuring instruments or modules on the basis of examination and testing under its own control

4.23 national responsible body

organization within an OIML Member State or Corresponding Member that does not conduct type evaluation but that is responsible for the metrological control of measuring instruments and/or modules

4.24 OIML Certificate

Type Examination Certificate, issued by an OIML Issuing Authority, attesting the conformity of a type of a measuring instrument or module with the relevant requirements of an OIML Recommendation at the time of testing and evaluation

4.25 OIML Certification System

system for issuing, registering and using OIML Certificates and associated OIML type evaluation reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements in the relevant OIML Recommendation(s)

4.26 OIML Issuing Authority

certification body from an OIML Member State issuing OIML Certificates and associated OIML type evaluation reports in accordance with Scheme A or Scheme B

Note 1: An OIML Member State having an OIML Issuing Authority for a category of measuring instrument under Scheme A shall designate at least one Utilizer for that category of measuring instrument. The Utilizer(s) may be a different organization(s) than the OIML Issuing Authority.

Note 2: The requirement to designate at least one Utilizer shall not apply when the OIML Member State does not regulate that particular category of measuring instrument in their country.

4.27 OIML test report

report issued by a test laboratory that includes the results of tests and examinations it carried out on the basis of the relevant OIML Recommendation during OIML type evaluation on identified sample(s) of a given type of measuring instrument or module

Note: Unless the OIML Recommendation states otherwise, several test reports may be issued if several test laboratories are involved in covering all of the tests and examinations specified in the relevant OIML Recommendation.

4.28 OIML type evaluation

type evaluation conducted on the basis of the relevant OIML Recommendation(s)

4.29 OIML type evaluation report

report issued by an OIML Issuing Authority participating in the OIML-CS that assesses the conformity of the type of a measuring instrument or module to the requirements in the relevant Recommendation and, if applicable, to the additional national requirements specified in the Declaration of a Utilizer or an Associate

4.30 peer assessment (from ISO/IEC 17000, 4.5 [6])

assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group

Note 1: Within the context of the OIML-CS, this is the procedure by which approved OIML experts assess, against specified requirements, the competence of OIML Issuing Authorities and Test Laboratories to participate in the OIML-CS.

Note 2: In the OIML-CS, peer assessment is equivalent to accreditation (see 4.1).

4.31 peer evaluation

process used by MC members to evaluate the compliance of OIML Issuing Authorities and Test Laboratories

4.32 Review Committee (RC)

sub-committee of the MC that provides recommendations on the approval of OIML Issuing Authorities, Legal Metrology Experts and Management System Experts

4.33 Scheme

part of the OIML-CS covering one or more categories of measuring instruments and with common requirements for participation

4.34 Scheme A

advanced level of the OIML-CS where accreditation or peer assessment is used as the basis for demonstrating compliance with the requirements of the OIML-CS

4.35 Scheme B

introductory level of the OIML-CS where “self-declaration” is used as the basis for demonstrating compliance with the requirements of the OIML-CS

4.36 Test Laboratory

laboratory performing certain or all tests on a type of measuring instrument. A Test Laboratory is designated by an OIML Issuing Authority and accepted by the MC

Note 1: A Test Laboratory may be an internal Test Laboratory of an OIML Issuing Authority, a third-party Test Laboratory or a Manufacturer’s Test Laboratory (MTL).

Note 2: The OIML Issuing Authority, and not the Test Laboratory, is responsible for issuing the OIML type evaluation report.

4.37 Test Laboratories Forum

advisory group that provides a platform for discussion on practical issues pertaining to testing. Each Test Laboratory in the OIML-CS may be represented in the TLF

4.38 third-party Test Laboratory

Test Laboratory that is designated by an OIML Issuing Authority, and registered in the Declaration, and which is independent from the OIML Issuing Authority

4.39 type (pattern) 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

Note: "Pattern" is used in legal metrology with the same meaning as "type".

4.40 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 a type approval certificate

4.41 Utilizer

national issuing authority or national responsible body from an OIML Member State that has signed the Declaration, indicating the terms of acceptance of OIML Certificates and/or OIML type evaluation reports issued under Scheme A or Scheme B

ANR	Additional National Requirement
BIML	Bureau International de Métrologie Légale / International Bureau of Legal Metrology
BoA	OIML-CS Board of Appeal
CIML	Comité Internationale de Métrologie Légale / International Committee of Legal Metrology
EMC	Electromagnetic Compatibility
IAF	International Accreditation Forum
IEC	International Electrotechnical Committee
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
ISO/CASCO	ISO Committee on Conformity Assessment
LME	Legal Metrology Expert
MAA	OIML Mutual Acceptance Arrangement
MC	OIML-CS Management Committee
MS	Management System
MSE	Management Systems Expert
MTL	Manufacturer Test Laboratory
OD	Operational Document of OIML-CS
OIML	Organisation Internationale de Métrologie Légale / International Organization of Legal Metrology
OIML-CS	OIML Certification System
OIML IA	OIML Issuing Authority
PD	Procedural Document of OIML-CS
QIS	Quality Infrastructure System
RC	Review Committee of OIML-CS
SDGs	UN Sustainable Development Goals
TER	Type Evaluation Report
TL	Test Laboratory
TLF	Test Laboratory Forum of OIML-CS
TR	Test Report
UN	United Nations
UNIDO	United Nations Industrial Development Organization

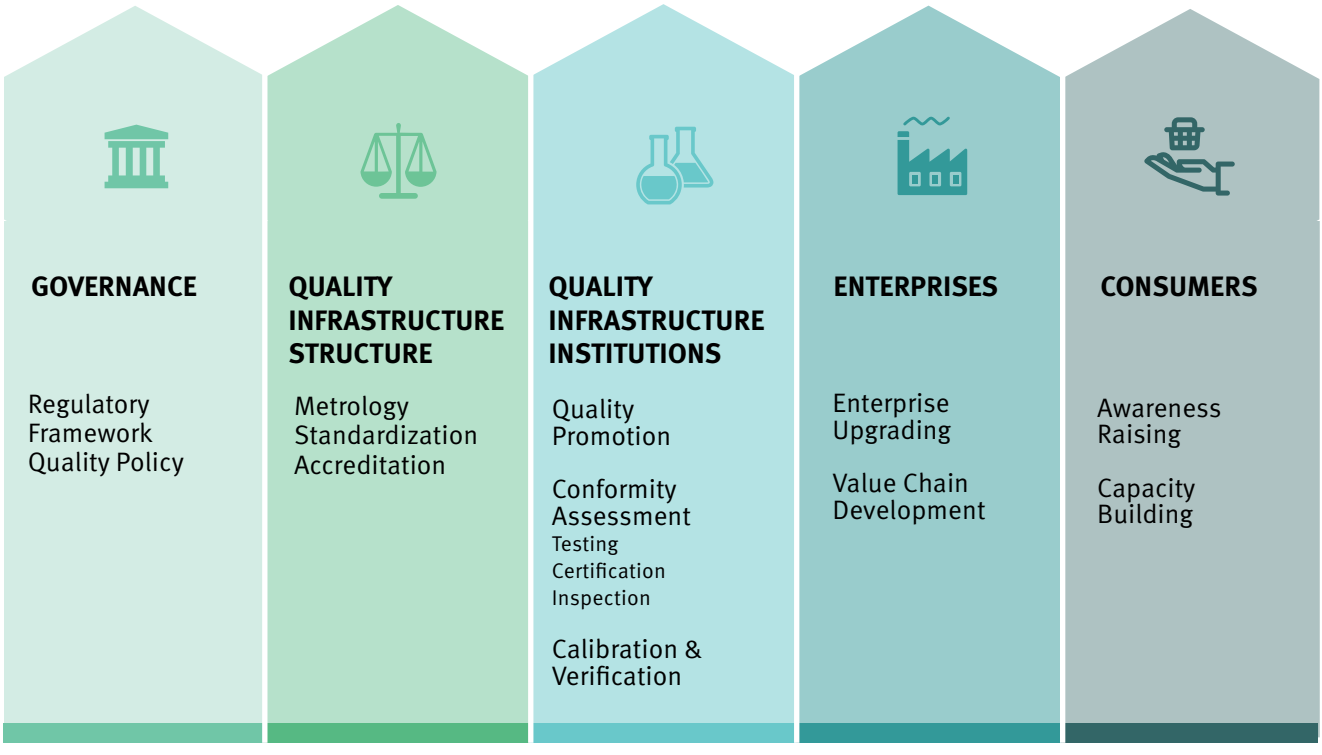
5. INTRODUCTION TO UNIDO'S QUALITY INFRASTRUCTURE DEVELOPMENT SYSTEM

The Sustainable Development Goals (SDGs) are a global call for action to protect the planet, ensure dignified lives for all people, and achieve inclusive economic growth, peace and prosperity. Adopted by the United Nations on 25 September 2015, the 2030 Agenda for Sustainable Development sets an ambitious vision for the world that we want and charts the course for how to get there. The Agenda comprises 17 interconnected and complementary Sustainable Development Goals, including a total of 169 more specific targets. The 17 goals are universal, and they take a holistic approach to development, combining its economic, social and environmental aspects.

Establishing an appropriate Quality Infrastructure System (QIS), including an appropriate legal metrology system, can substantially assist nations in positioning their economy to seize the many opportunities available through appropriate implementation of the United Nations Sustainable Development Goals (SDGs). A QIS is a combination of initiatives, institutions, organizations, activities and people. It includes a national quality policy and institutions to implement it, a regulatory framework, quality service providers, enterprises, customers and consumers (who include citizens as "consumers" of government services). It covers essential aspects such as policy, institutions, service providers, and the value-adding use of international standards and conformity assessment procedures. It supports governmental policy objectives in areas including industrial development, trade competitiveness in global markets, the efficient use of natural and human resources, food safety, health, the environment and climate change. All component parts of the QIS act synergistically with each other and provide a valuable tool for defining, developing and verifying quality requirements for products and services. The system components assist in the verification and demonstration that products and services actually meet specified requirements.

The United Nations Industrial Development Organization (UNIDO) has an extensive and proven track record in working with governments, industry and other major stakeholders to develop and strengthen national and regional QIS. UNIDO works together with them to set up an appropriate QIS. Such programs are one of the specialized services that UNIDO offers among its overall activities to promote ISID. Such an approach offers developing countries, and economies in transition, opportunities to eradicate poverty and develop sustainably. ISID also helps them to build their industrial base as a platform for social inclusiveness, economic competitiveness, environmental sustainability and integration with the global trading system. The institutions and services of QI provide businesses, policymakers and other stakeholders with a core of knowledge about ways of doing things and tools that can be operationalized to measure and assess almost any type of activity. This knowledge and tools help markets to function and governments to achieve regulatory mandates and objectives.

UNIDO's approach is holistic, from building awareness of the QIS to helping to initiate, develop and strengthen a fit for purpose QIS that runs efficiently and cost effectively. The approach adopted by UNIDO emphasizes the need for strong collaboration and cooperation with all stakeholders to meet shared objectives through agreed activities that lead to concrete actions. Together with partners from the public and private sector, academia, national and international organizations in charge of standard-setting and global practices on metrology, standards and conformity assessment, UNIDO promotes good practices, capacity-building and training, and fosters global cooperation in standard-setting, measurement and compliance development along value chains. UNIDO's partners in the field of quality and standards include the International Organization of Legal Metrology (OIML).



6. INTRODUCTION TO THE OIML

The OIML is an intergovernmental treaty organization, established in 1955, and is an "international standard-setting body" as described in the World Trade Organization's Technical Barriers to Trade Agreement.

OIML MISSION (OIML B 15:2011 [7])

The mission of the OIML is to enable economies to put in place effective legal metrology infrastructures that are mutually compatible and internationally recognized, for all areas for which governments take responsibility, such as those which facilitate trade, establish mutual confidence and harmonize the level of consumer protection worldwide.

The OIML promotes global harmonisation of legal metrology procedures through the following objectives:

- developing model regulations, standards and related documents for use by legal metrology authorities and industry,
- providing mutual recognition systems which reduce trade barriers and costs in a global market,
- representing the interests of the legal metrology community at international organizations and forums concerned with metrology, standardization, testing, certification and accreditation,
- promoting and facilitating the exchange of knowledge and competencies within the legal metrology community worldwide, and
- cooperating with other metrology bodies to raise awareness of the contribution that a sound legal metrology infrastructure can make to a modern economy.

The OIML produces OIML Recommendations to support the objective of **developing model regulations, standards and related documents for use by legal metrology authorities and industry**. These provide the metrological and technical requirements, test procedures and common reporting formats for different categories of measuring instruments.

In 1991, the OIML introduced the OIML Basic Certificate System [8] to support the objective **providing mutual recognition systems which reduce trade barriers and costs in a global market**. The OIML Mutual Acceptance Arrangement (MAA) [9] was subsequently introduced in 2005 with the aim of increasing confidence and wider acceptance of OIML Certificates and OIML type evaluation reports. A review of the operation of these certificate systems was instigated by the CIML at its meeting in 2013. In 2016 the CIML approved the Framework for the OIML Certification System (OIML-CS) [10]. The CIML took the decision in 2017 that the OIML-CS would come into operation on 1 January 2018, replacing both the OIML Basic Certificate System and the OIML MAA.

7. INTRODUCTION TO THE OIML CERTIFICATION SYSTEM (OIML-CS)

7.1 Principles

The OIML Certification System (OIML-CS) is a system for issuing, registering and using OIML Certificates and their associated OIML type evaluation and 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 OIML-CS was launched on 1 January 2018, replacing the OIML Basic Certificate System [8] and the OIML Mutual Acceptance Arrangement (MAA) [9]. The OIML-CS is intended to facilitate, accelerate and harmonize the work of national and regional bodies that are responsible for type evaluation and type 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, will benefit from the OIMLCS as it will provide evidence that their instrument type complies with the requirements of the relevant OIML Recommendation(s).

The OIML-CS is a voluntary system. OIML Member States and Corresponding Members are free to participate by signing a Declaration. Their signature commits them to abide by the rules of the OIML-CS. Document OIML B 18 [10] provides information on these rules. Signatories voluntarily accept and utilize OIML type evaluation and test reports, when associated with an OIML Certificate issued by an OIML Issuing Authority, for type approval or recognition within their national or regional legal metrology control systems.

A manufacturer or its authorized representative from any country may apply for type evaluation and for an OIML Certificate to be issued by a designated OIML Issuing Authority in any OIML Member State that participates in the OIML-CS. Likewise, any OIML Certificate and/or its associated OIML type evaluation report may be accepted and utilized by any national issuing authority or national responsible body in any country.

The OIML-CS is classified to Scheme 1a as defined in ISO/IEC 17067 [11] and requires a type evaluation of representative sample(s) of measuring instruments. . It should be noted however, that the type evaluation conducted within the OIML-CS does not include a formal evaluation to establish the representativeness of the sample as compared to the

larger group of measuring instruments that it is intended to represent.

7.2 Objectives and benefits

7.2.1 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, and

c) to establish rules and procedures for fostering mutual confidence among participating OIML Member States and Corresponding Members in the results of type evaluations that indicate conformity of measuring instruments and/or modules, under legal metrological control, to the metrological and technical requirements established in the applicable OIML Recommendation(s).

7.2.2 The intended benefits of the OIML-CS are:

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 OIMLCS offers a viable and 'ready-made' solution;

b) for instrument manufacturers who are required to obtain type approval, the OIML-CS provides evidence that their instrument type complies with the requirements of the relevant OIML

c) Recommendations, thus avoiding duplication of type approval tests in different countries; and

the OIML-CS provides the evidence required to accept and utilize OIML type evaluation reports validated by an OIML Certificate.

7.3 Participants

There are three main categories of participant in the OIML-CS. Each of these participants sign a Declaration stating that they will abide by the rules of the OIML-CS.

An ***OIML Issuing Authority (OIML IA)*** is a certification body from an OIML Member State that issues OIML Certificates and associated OIML type evaluation reports in accordance with Scheme A (Accreditation or Peer Assessment) or Scheme B (Self-Declaration). The participation of OIML IAs in the OIML-CS is subject to the approval of the OIML-CS Management Committee (MC). An OIML Member State can have more than one OIML IA in their country. Each OIML IA can designate one or more associated ***Test Laboratories*** as outlined below.

A ***Utilizer*** is a national issuing authority or national responsible body from an OIML Member State that utilizes and accepts OIML Certificates and/or OIML type evaluation reports issued under Scheme A or Scheme B as the basis for issuing a national or regional type approval. An OIML Member State can have more than one Utilizer within their country.

An ***Associate*** is the same as Utilizer with the exception that the national issuing authority or national responsible body is from an OIML Corresponding Member. An OIML Corresponding Member can have more than one Associate within their country or economy.

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

» an internal Test Laboratory of an OIML IA,

» a third-party Test Laboratory, or

» a Manufacturer Test Laboratory (MTL)

It should be noted that TLs are not required to sign a Declaration as they participate in the OIML-CS under the responsibility of an OIML IA.

7.4 Scope and transition

The categories of measuring instruments (including families of instruments, modules, or families of modules) for which the relevant OIML Recommendation specifies metrological and technical requirements, test procedures, and an OIML test report format are automatically included in the OIML-CS. Further information on OIML Recommendations can be found in paragraph 7.7.

A category of measuring instrument that fulfils the requirements specified in the previous paragraph is initially included in the OIML-CS in Scheme B, with the intention that it will automatically transition to Scheme A *two years* after first being included in the OIML-CS. However, it is possible that the transition period from Scheme B to Scheme A can be reduced or extended based on a recommendation of the OIML-CS MC. The intention is to have all categories of measuring instruments, where the OIML Recommendation fulfils the requirements specified above, in Scheme A by 1 January 2021.

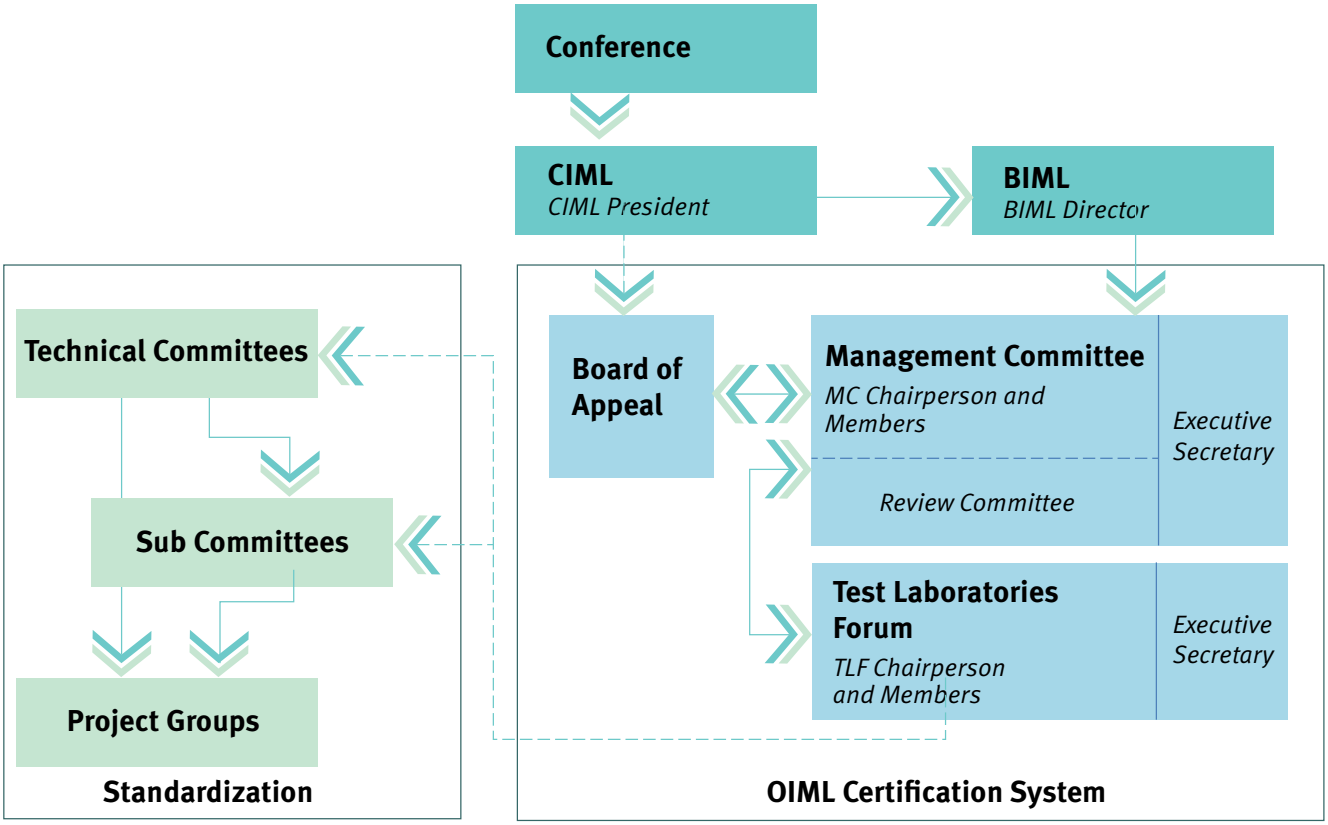
The instrument categories covered by the OIML-CS when it was launched on 1 January 2018, along with the Scheme for each category of measuring instrument and the associated OIML Recommendation is shown in Annex 1. The instrument categories included in the OIML-CS from 1 January 2019, along with the Scheme for each category of measuring instrument and the associated OIML Recommendation is shown in Annex 2. In addition, the date that each instrument category is due to transition from Scheme B to Scheme A is shown.

7.5 Structure of the OIML-CS

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

FIGURE 1

OIML-CS STRUCTURE WITHIN THE OIML STRUCTURE



7.5.1 Management Committee (MC)

The Management Committee (MC) is responsible for the operation of the OIML-CS under the authority of the CIML. The document OIML B 18, paragraph 11.1 [10], specifies the composition of the MC, with the main duties and responsibilities of the MC detailed in paragraph 11.2 [10]. Some of the key duties and responsibilities of the MC are to:

- report annually to the CIML;
- develop and make proposals to the CIML for changes in OIML-CS strategy and policy;
- promote and raise awareness of the OIML-CS and its Schemes,;
- make proposals to the CIML to extend or reduce the transition period from Scheme B to Scheme A for a measuring instrument category in the OIML-CS;
- make decisions on the participation of new OIML IAs and TLs in a Scheme;
- organize periodic reviews on the continuity of participation of OIML IAs and TLs in a Scheme;
- maintain and develop OIML-CS documentation (see OIML B 18 [10], ODs [12][13], PDs [14]-[21]);
- approve and maintain the lists of Legal Metrology Experts and Management System Experts;
- monitor the operation and effectiveness of the OIML-CS.

Detailed information on the operation of the MC is provided in the OIML operational document OD-01 [12].

7.5.2 Review Committee (RC)

The Review Committee (RC) is a subcommittee of the MC and is responsible for providing recommendations to the MC on the approval, rejection or suspension of OIML IAs and TLs. It is also responsible for providing recommendations to the MC on the acceptance or rejection of Legal Metrology Experts and Management System Experts (see 7.6). OIML B 18, paragraph 11.6.1 [10], specifies the composition of the RC, with further detail on the operation of the RC provided in OD-01 [12].

7.5.3 Test Laboratories Forum (TLF)

The Test Laboratories Forum (TLF) comprises representatives from TLs that are participating in the OIML-CS. In addition, Legal Metrology Experts may also participate in the TLF. The aim of the TLF is to promote the exchange of experience between the people who execute the testing of the measuring instruments in the TLs of the participating OIML IAs, with the objective of harmonizing the application and continuous improvement and update of the corresponding OIML recommendations. Further information on the TLF is provided in operational document OD-02 [13].

7.5.4 Board of Appeal (BoA)

The Board of Appeal (BoA) is independent of the MC. One of their key tasks is to manage appeals against decisions of the MC relating to participation in the OIML-CS. Another key task

for the BoA is to recommend solutions to any other dispute referred to it with regard to the application of the rules of the OIMLCS. Document OIML B 18, 13.1 [10] specifies the composition of the BoA, with further detail on the operation of the BoA and the handling of complaints and disputes provided in procedural document PD-01 [14].

7.6 OIML-CS Documentation

The document OIML B 18 [10] specifies the Framework for the OIML-CS. It is supported by two Operational Documents (OD-01 [12] and OD-02 [13]) which specify the operational rules of the Management Committee and the Test Laboratories Forum respectively.

These are underpinned by a set of Procedural Documents, PD-01 to PD-08 [14]-[21], which provide the detailed procedures relating to the operation of the OIML-CS, such as handling complaints and appeals, approving Experts to participate in accreditation and peer assessments, approving new OIML IAs and their associated TLs, issuing OIML Certificates and transition arrangements.

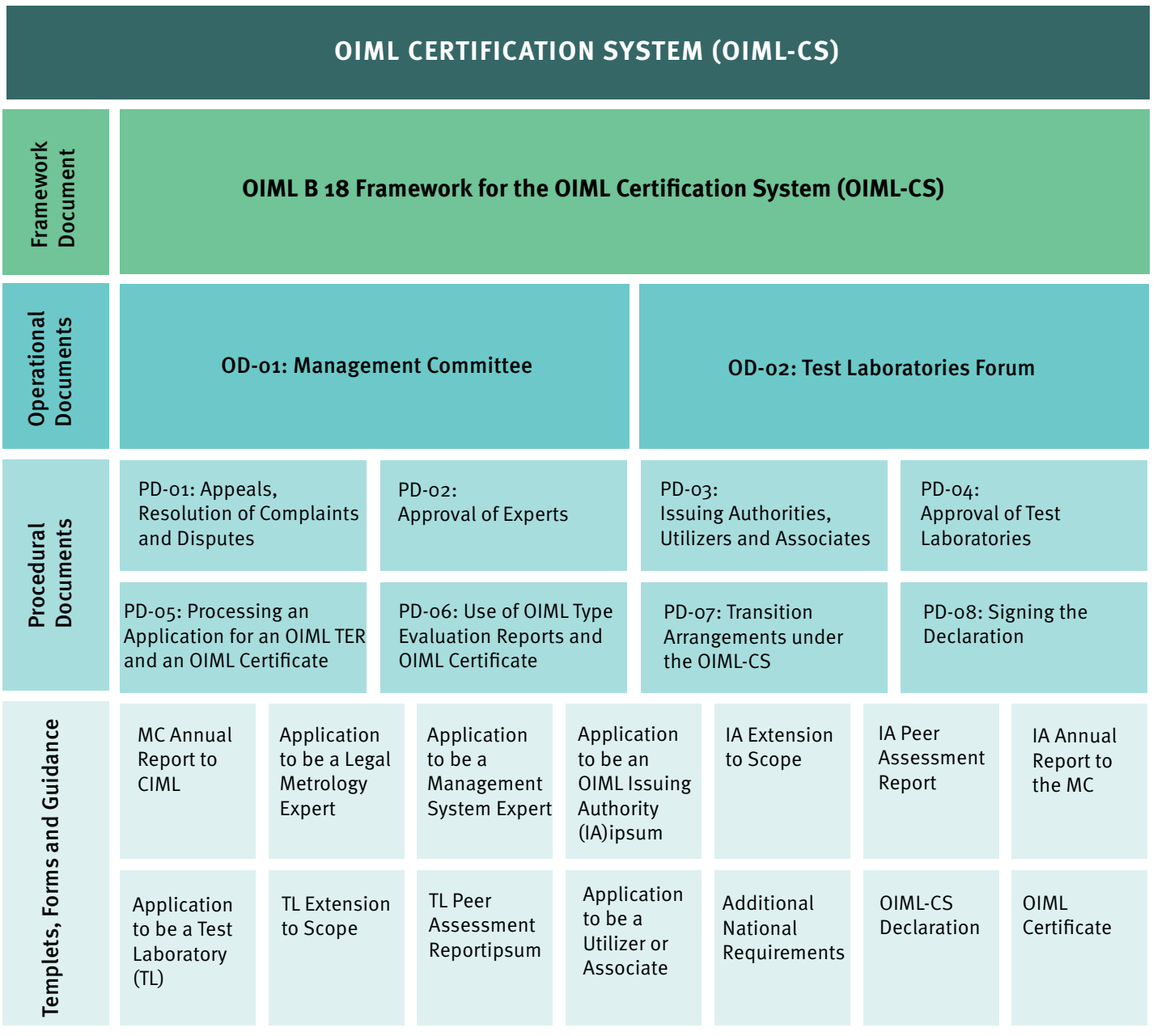
A set of templates and forms is provided to support the operation of the OIML-CS and the participants in the OIML-CS (i.e. OIML IAs, TLs, Utilizers, Associates, manufacturers).

The structure of the OIML-CS documentation is shown in Figure 2.

All of the documentation associated with the OIML-CS is publicly available and can be downloaded from the OIML website at: https://www.oiml.org/en/oiml-cs/documentation

FIGURE 2

OIML-CS DOCUMENTATION STRUCTURE



7.7 OIML Recommendations

OIML Recommendations are developed to be used as *model regulations*. They establish the metrological and technical characteristics *(specified requirements)* for categories of measuring instrument. In addition, they specify methods and equipment for assessing the conformity of measuring instruments with the specified requirements. Each recommendation applies to a category of measuring instrument, including families of instruments, modules, or families of modules. An OIML Recommendation typically comprise three component parts:

Part 1: Metrological and technical requirements
This part defines the scope of the Recommendation, terminology, metrological requirements, technical requirements, and metrological controls.

Part 2: Test methods
This part defines the test and examination procedures used to assess compliance to the requirements specified in Part 1.

Part 3: Test report format
This part defines the format and content of the OIML test report issued by the Test Laboratory and the OIML type evaluation report issued by the OIML IA.

Each of the parts include cross-references for ease of use; e.g. a test procedure in Part 2 will include a reference to the corresponding requirement in Part 1 and to the corresponding section of the test report to complete in Part 3. They may also include Mandatory or Informative Annexes.

Note 1: Some older Recommendations may combine these Parts into a single document or two Parts.

Note 2: Following a decision taken by the CIML at its meeting in 2018, OIML Recommendations that are or will be included in the OIML-CS will have separate type evaluation report and test report formats. New and revised OIML Recommendations will therefore have four parts in the future.

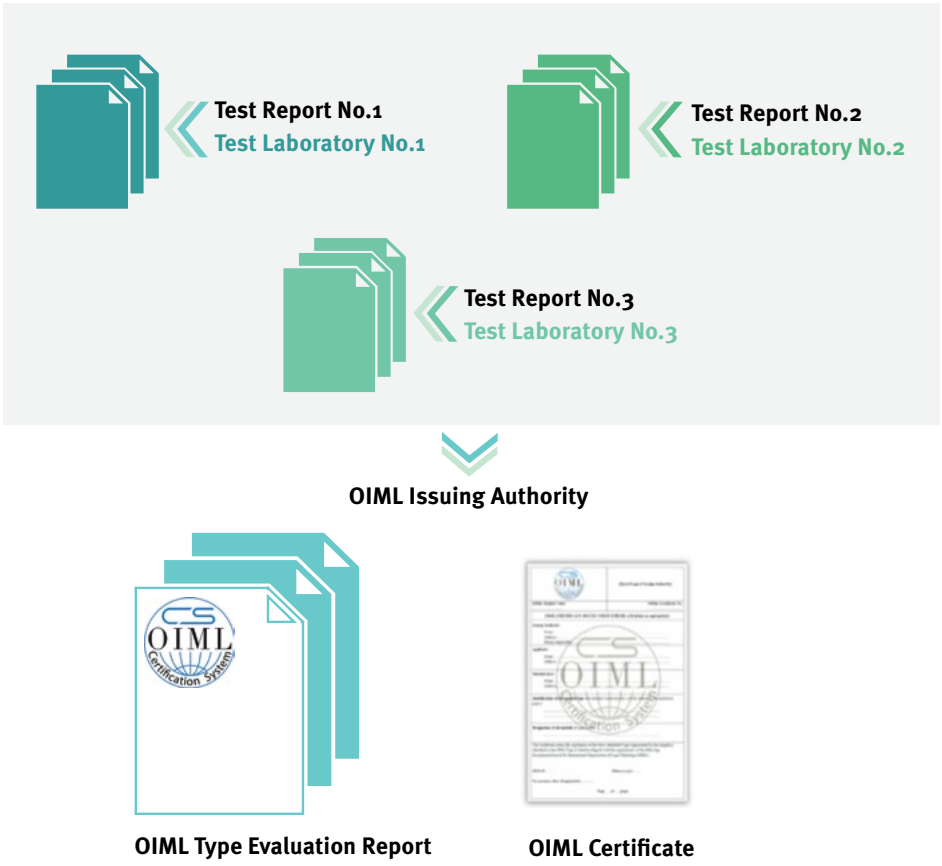
An OIML Certificate and its associated OIML type evaluation report and test report(s) are issued for a category (type) of measuring instrument (including families of measuring instruments, modules, or families of modules) based on the requirements contained in the relevant OIML Recommendation. An OIML Certificate can only be issued if conformity with all of the applicable requirements of the relevant OIML Recommendation are evaluated and have been fulfilled. OIML Recommendations are publicly available and can be downloaded from the OIML website at: https://www.oiml.org/en/publications/recommendations/publication_view?p_type=1&p_status=1

8. REQUIREMENTS TO BECOME AN OIML ISSUING AUTHORITY AND TEST LABORATORY

8.1 General

The highest level of requirements for becoming an OIML Issuing Authority (IA) and Test Laboratory (TL) under the OIML-CS are specified in OIML B 18, clause 5 [10], with further information provided in PD-03 [16] for OIML IAs and PD04 [17] for TLs respectively. The requirements for the participation of OIML IAs and their associated TLs in Scheme A or Scheme B are the same. OIML IAs are required to demonstrate compliance with the applicable requirements of ISO/IEC 17065 [1] and TLs are required to demonstrate compliance with the applicable requirements of ISO/IEC 17025 [2][3]. The method used for demonstrating compliance is however different. For participation in Scheme A compliance shall be demonstrated by accreditation (4.1) or peer assessment (4.30). For participation in Scheme B it is sufficient to demonstrate compliance on the basis of a self-declaration, with additional supporting evidence. Participation of OIML IAs and TLs in the OIML-CS (in Scheme A and Scheme B) is established through a peer evaluation process performed by members of the OIML-CS Management Committee.

The OIML has developed two Documents; OIML D 32 [4] and OIML D 30 [5]. OIML D 32 [4] that provide guidance and interpretations on the application of ISO/IEC 17065 [1] to the assessment of certification bodies in the field of legal metrology, with OIML D 30 [5] providing guidance and interpretations on the application of ISO/IEC 17025 [2][3] to the assessment of test laboratories in the field of legal metrology. These publications are intended to support Accreditation Bodies and peer assessment teams when they perform assessments of OIML IAs and TLs. OIML IAs and TLs should utilize them when developing their Management Systems to ensure that the requirements of the OIML-CS are fulfilled. In addition, a Joint International Laboratory Accreditation Cooperation (ILAC) and OIML Assessment Procedure in the field of legal metrology [22] has been published which supports the accreditation assessments of TLs. A similar Joint Assessment Procedure is under development with the International Accreditation Forum (IAF) to support the accreditation assessments of OIML IAs



8.2 Requirements for an OIML Issuing Authority

8.2.1 Self-declaration

The OIML Issuing Authority (IA) is required to declare that they comply with the requirements of ISO/IEC 17065 [1] and needs to need to provide evidence to support the declaration, e.g. an internal audit according to ISO/IEC 17065 [1] and OIML D 32 [4].

8.2.2 Accreditation

Where the accreditation option is chosen, the Accreditation Body that carries out the assessment of an OIML IA must be a full member of a mutual recognition arrangement among Accreditation Bodies (regional or international), for instance the IAF Multilateral Recognition Arrangement (MLA).

The assessment team needs to comprise of at least one Legal Metrology Expert approved by the MC. The accreditation body must ensure that the Expert(s) they use are impartial and independent and are associated with the OIML IA. It should be noted that such Legal Metrology Experts do not have to be competent for all measuring instrument categories. Further information can be found in the Joint IAF-OIML Assessment Procedure [23].

8.2.3 Peer assessment

Where the peer assessment option is chosen, it must be carried out by a team of experts that will include a Management System Expert (team leader), approved by the MC, knowledgeable in assessing quality management systems on the basis of ISO/IEC 17065 [1] and at least one Legal Metrology Expert approved by the MC. The assessment team shall include all the necessary competencies required to complete the assessment of the OIML IA.

Note 1: Where a Legal Metrology Expert does not have suitable assessment experience (according to ISO/IEC 17065) they shall operate under the supervision of the team leader or another Legal Metrology Expert that does have suitable assessment experience.

Note 2: The Legal Metrology Expert does not have to be competent for all measuring instrument categories.

Note 3: If the team leader is also a Legal Metrology Expert for one of the instrument categories then a Legal Metrology Expert is not required.

The OIML IA makes the necessary arrangements for an assessment team to be formed from the list of approved experts and informs the Executive Secretary. The team leader and Legal Metrology Expert(s) must be impartial and independent and not directly associated with the OIML IA. The team leader and Legal Metrology Expert(s) need to declare their impartiality and independence to the Executive Secretary prior to the assessment. The OIML IA is responsible for bearing the cost of such an assessment team.

8.2.4 Scope of accreditation/peer assessment

It is important that the scope of the accreditation or peer assessment covers the full scope of activities that the OIML IA is applying for. In the case of accreditation, the accreditation scope (schedule) should reference product certification under the OIML-CS and the categories of measuring instrument and/or the relevant OIML Recommendations. For both accreditation and peer assessment, any restrictions/ limitations in the capability of the OIML IA must be clearly identified.

8.3 Requirements for an OIML Test Laboratory

8.3.1 Self-declaration

The Test Laboratory (TL) is required to declare that they comply with the requirements of ISO/IEC 17025 [1]. The TL will need to provide evidence to support such a declaration, e.g. an internal audit according to ISO/IEC 17025 [2][3] and OIML D 30 [5].

8.3.2 Accreditation

Where the accreditation option is chosen, the Accreditation Body that carries out the assessment of a Test Laboratory shall participate as a full member in a mutual recognition arrangement among Accrediting Bodies (regional or international), for instance the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement).

The assessment team must include a Legal Metrology Expert, approved by the MC, for each category of measuring instrument in the intended scope of accreditation for the Test Laboratory. The accreditation body needs to ensure that the Legal Metrology Expert(s) is impartial and independent and is not directly associated with the OIML IA and TL. Further information can be found in the Joint ILAC-OIML Assessment Procedure [22].

8.3.3 Peer assessment

Where peer assessment is chosen, the peer assessment shall be carried out by a team of experts approved by the MC. The team shall comprise a Management System Expert (team leader), knowledgeable in assessing quality management systems of TLs on the basis of ISO/IEC 17025 [2][3], and one Legal Metrology Expert per category of measuring instrument. The assessment team must include all the necessary competencies required to complete the assessment of the TL.

Note 1: Where a Legal Metrology Expert does not have suitable assessment experience (according to ISO/IEC 17025) they shall operate under the supervision of the team leader or another Legal Metrology Expert that does have suitable assessment experience.

Note 2: A Legal Metrology Expert can be competent for more than one measuring instrument category.

Note 3: If the team leader is also a Legal Metrology Expert for one or more instrument categories then the team leader can act as a Legal Metrology Expert for those instrument categories.

The OIML IA is responsible for arranging for a peer assessment of the TL. The OIML IA makes all of the necessary arrangements for an assessment team to be formed from the list of approved experts and informs the Executive Secretary accordingly. The team leader and Legal Metrology Expert(s) must be impartial and independent and not directly associated with the OIML IA and TL. The team leader and Legal Metrology Expert(s) need to declare their impartiality and independence to the Executive Secretary prior to the assessment. The OIML IA or the TL is responsible for bearing the cost of such an assessment team.

8.3.4 Scope of accreditation/peer assessment

It is important to note that the scope of the accreditation or peer assessment must cover the full scope of activities that the TL is applying for. In the case of accreditation, the accreditation scope (schedule) should reference the categories of measuring instrument and the relevant OIML Recommendations. For both accreditation and peer assessment, any restrictions/limitations in the capability of the TL shall be clearly identified, e.g. the TL may be unable to perform certain tests specified in a particular OIML Recommendation.

8.4 Use of OIML Experts

Lists of approved Management System Experts (team leaders) and Legal Metrology Experts are available on the OIML website (see below). The list of Legal Metrology Experts includes information on their assessment experience according to ISO/IEC 17065 [1] and ISO/IEC 17025 [2][3].

For Management System Experts (MSEs) please see:
https://www.oiml.org/en/oiml-cs/docs/oiml-cs-list-of-management-system-experts.pdf

For Legal Metrology Experts (LMEs) please see:
https://www.oiml.org/en/oiml-cs/docs/oiml-cs-list-of-legal-metrology-experts.pdf

The Executive Secretary is able to provide contact details for these MSEs and LMEs. It is possible to use an expert(s) that has not yet been approved by the MC for both accreditation or peer assessment on the condition that the requirements of PD-02, 8.3 [15] are followed.

9. PROCESSES TO BECOME AN APPROVED OIML ISSUING AUTHORITY AND TEST LABORATORY

9.1 General

The process to become an OIML IA, with one or more associated TLs, is detailed in PD-03 [16] and PD04 [17] for the OIML IA and TL(s) respectively. ***Flowchart 1*** illustrates the process, with an explanation and information on each of the steps provided below.

9.2 Areas to consider before applying

Prior to making an application to become an OIML IA, with one or more associated TLs, there are a number of items that should be considered, as follows.

1. Which organization(s) in an OIML Member State will become an OIML IA and a TL. It is possible for there to be more than one OIML IA in an OIML Member State, with each OIML IA designating one or more TLs. The TL(s) can be an internal TL of the OIML IA, a third-party TL or a TL of a manufacturer (MTL).

   Note 1: Where an MTL is to be used the OIML IA must provide evidence of how they will implement controlled supervision of the MTL (see PD-04, Clause 7 [17] for further detail).

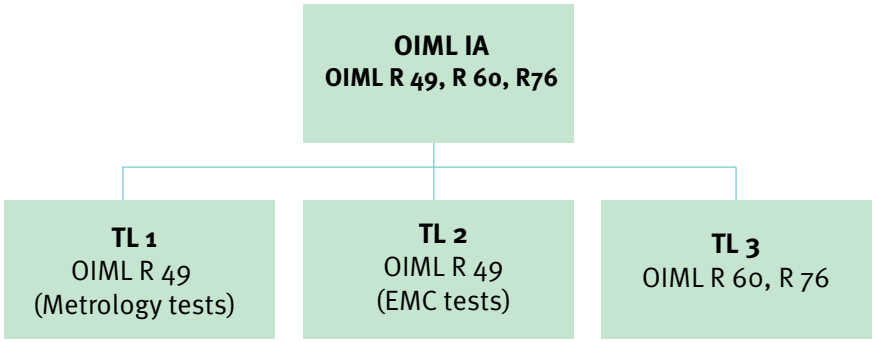
   Note 2: A TL does not need to be located in the same country as the OIML IA.

   Note 3: It is possible for an MTL to be an MTL for more than one OIML IA. In this instance, one of the OIML IAs will

be the principle OIML IA - see PD-04 [x], 7.5, Footnote 1.

2. Determine the scope of the OIML IA(s) and the TL(s). It is important to note that the scope of an OIML IA must be covered by the combined scope of its associated TL(s). This is illustrated in Figure 3.

FIGURE 3 EXAMPLE OF OIML IA AND TL SCOPES



3. For instrument categories that are in Scheme B it is necessary to gather evidence of competence in order to support the self-declaration, e.g. an internal audit according to ISO/IEC 17065 [1] and OIML D 32 [4] for the OIML IA, and ISO/IEC 17025 [2][3] and OIML D 30 [5] for the TL.
4. For instrument categories that are in Scheme A the process to demonstrate compliance with ISO/IEC 17065 [1] and OIML D 32 [4] for the OIML IA, and ISO/IEC 17025 [2][3] and OIML D 30 [5] for the TL must be selected, i.e. accreditation or peer assessment. It is possible to have a combination of accreditation and peer assessment, e.g. the OIML IA could demonstrate compliance with ISO/IEC 17065 [1] through accreditation and the TL could demonstrate compliance with ISO/IEC 17025 [2][3] through peer assessment and vice-versa. Information on the accreditation and peer assessment processes was provided in 8.2 and 8.4 for the OIML IA and TL respectively.

Note 1: For OIML IAs there is a 3-year transition period (from 1 January 2018) where self-declaration can be used for Scheme A – see the Note in PD-03, 5.2.1 [16].

Note 2: ISO and ILAC have issued a joint communiqué to re-confirm that a transition period, until 30 November 2020, will be provided for accredited laboratories to transition to the 2017 version of ISO/IEC 17025 [2][3]. Consequently, both the 2005 [2] and 2017 [3] versions of ISO/IEC 17025 can be applied during the transition period (see http://ilac.org/latest_ilac_news/joint-iso-and-ilac-170252017-transition-communique-published/). However, each TL should confirm the transition process within their jurisdiction with the relevant accreditation body.

Applications for an OIML IA shall always be supported by one or more applications for a TL and vice-versa, e.g. if a new TL is to be included for the OIML IA then the application for the new TL should be accompanied by a corresponding application for the OIML IA which will list the new TL. The only exception to this requirement is where the OIML IA intends to use an existing TL (of another OIML IA), in which case reference to the existing approval for the TL can be used instead of an application.

An OIML Member State having an OIML IA for a category of measuring instrument under Scheme A shall designate at least one Utilizer for that category of measuring instrument. The Utilizer(s) may be a different organization(s) than the OIML IA. How to become a Utilizer is detailed in 10.

Note: The requirement to designate at least one Utilizer shall not apply when the OIML Member State does not regulate that particular category of measuring instrument in their country.

9.3 Application forms

The OIML IA and TL application forms are available from the OIML website at:

https://www.oiml.org/en/oiml-cs/application-forms

Information on completing the application forms for an OIML IA is contained in Annex 3 and for a TL in Annex 4.

9.4 The Application Process

This section should be read in conjunction with Flowchart 2 at the back of the document, which shows diagrammatically the process that needs to be followed to gather the supporting documentation for an application to be an OIML IA. Flowchart 3 provides similar information regarding the gathering of supporting documentation for an application TL. Checklists 1 - 4 that are also to be found at the back of the document, are provided to assist an applicant for an OIML IA and a TL, under Scheme A or Scheme B, to check that the necessary documents have been collected. The checklists also include additional information and guidance.

Step 1: Complete and submit the application forms and supporting documentation

Once the application forms have been completed and the supporting documentation has been gathered, the applicant OIML IA should submit the forms and the necessary documentation using the email address Executive Secretary (executive.secretary@oiml.org).

Step 2: Executive Secretary review

The Executive Secretary reviews the application forms and the supporting documentation only to ensure completeness. If the Executive Secretary is satisfied that the application forms have been completed correctly and the necessary supporting documentation has been provided, they are forwarded to the Review Committee. If any errors are identified in the forms, or if documentation is missing, the applicant is contacted to rectify the issue(s).

Step 3: Review Committee stage

The Members of the Review Committee review the application forms and the supporting documentation. They are each required to make a recommendation as to whether or not to approve the OIML IA and TL(s) based on the evidence provided. If the RC members make a positive recommendation to approve the application the Executive Secretary will initiate a Management Committee vote on the approval of the application. If the RC members do not make a positive recommendation, the Executive Secretary informs the applicant of the reason(s). The applicant may then provide additional information to the Executive Secretary for forwarding to the RC for review.

Step 4: Management Committee vote

The Management Committee Member, comprising of representatives from each OIML Member State are required to vote on the approval of applications. The voting rules are specified in document OIML B 18, 11.4 [10]. If the MC approves the applications, the Executive Secretary will inform the applicant accordingly and draft a Declaration for the OIML IA based on the information provided in the application. A template for the Declaration is available on the OIML website at https://www.oiml.org/en/oiml-cs/documentation. If the MC does not approve, the applicant is informed of the reason(s). In accordance with PD-01 [14], the applicant can appeal such a decision.

Step 5: Declaration

A draft Declaration is sent to the applicant for checking. If the applicant is satisfied with the content, the responsible person in the OIML IA signs and date the Declaration and returns it to the Executive Secretary. The Executive Secretary then arranges for details regarding the OIML IA and TL, including their scopes, to be published on the OIML website. See
https://www.oiml.org/en/oiml-cs/oiml-issuing-authorities

9.5 Representation on the OIML-CS Management Committee

Once the Declaration has been signed, the CIML Member of the country concerned is able to nominate up to four representatives to participate in the OIML-CS Management Committee, although this is not mandatory. If the CIML Member choses to nominate more than one representative, one of them must be identified as the "MC Member" for the purposes of voting.

9.6 Periodic review

In accordance with PD-03, Clause 11 [16], each OIML IA and their associated TL(s) are required to demonstrate continued compliance with the requirements for participation. OIML IAs and their associated TLs are required to provide, on an annual basis, evidence to support their ongoing competence by submitting an annual summary report to the Executive Secretary. The MC reviews these annual summary reports. A template for the annual summary report is available on the OIML website at https://www.oiml.org/en/oiml-cs/documentation

Once every four years the relevant accreditation assessment and/or peer assessment reports of the OIML IAs and their TL(s) shall be submitted to the Executive Secretary. In the case of peer assessment, the OIML IA is responsible for organizing peer assessments every four years. The peer assessment team must fulfil the criteria regarding the use of OIML experts. If accreditation is the chosen route, the OIML IA is responsible for requesting their chosen accreditation body to include at least one Legal Metrology Expert approved by the MC in the assessment team. Legal Metrology Expert(s) approved by the MC for the appropriate scope shall participate in the accreditation assessment team, at least once over the accreditation renewal cycle with a maximum interval of five years.

The Review Committee reviews the reports and makes recommendations to the MC on the continued participation of the OIML IA and their associated TL(s). The MC then votes on continued participation following the same voting rules as when approving a new OIML IA and TL. The annual summary report (for both Schemes A and B) should contain:

- results of comparisons;
- changes in personnel, structure and organization;
- results of management reviews;
- results of internal audits;
- results of accreditation (surveillance) assessments, where applicable;
- complaints received; and
- number of certificates issued.

9.7 Modification/extension to scope

Modifications or extensions to scope include:

- The addition of a new category of instrument (OIML IA and TL)
- The addition of a new TL for an existing category of instrument
- A change to the capability of an existing TL, e.g. increased flow rates, new accuracy class
- Transition of a category of instrument from Scheme B to Scheme A

The same application forms previously described should be used, but only those parts that are relevant to the change that is being requested. Supporting documents should also be submitted to demonstrate competence for the modified/extended scope. The process also involves a review by Review Committee and approval by Management Committee. When an existing scope is modified/extended the Declaration is also revised to include the modified/extended scope. Information on the OIML website is also updated to reflect the modified/extended scope.

10. HOW TO BECOME A UTILIZER OR AN ASSOCIATE

10.1 General

The process to become a Utilizer or an Associate under the OIML-CS is detailed in PD-03 [16]. This section should be read in conjunction with Flowcharts 4 and 5 at the back of the document, which shows diagrammatically the application process for a Utilizer and an Associate respectively. The two processes (applying to become a Utilizer or an Associate) is fundamentally the same. The major difference is that a Utilizer is from an OIML Member State whereas an Associate is from an OIML Corresponding Member. Consequently, the CIML Member must sign (endorse) the application form for a Utilizer and the Corresponding Member Representative must sign (endorse) the form for an Associate.

The information that follows describes the process to become a Utilizer. The same information is also relevant for the process to become an Associate by substituting "Associate" for "Utilizer", "Corresponding Member Country or Economy" for "OIML Member State" and "Corresponding Member Representative" for "CIML Member" (See also Annex 5).

10.2 Areas to consider before applying

Prior to making an application to become a Utilizer there are a number of items that should be considered, as follows.

1. Which organization (national issuing authority or national responsible body) in the OIML Member State will apply to be a Utilizer.
   Note: It is possible for there to be more than one Utilizer in an OIML Member State.
2. Determine the measuring instrument categories that the Utilizer(s) will accept and utilize OIML Certificates and/or OIML type evaluation reports.
3. Determine the Scheme(s) that the Utilizer(s) will accept and utilize, e.g. Scheme A only, Scheme A and B.
4. Consider the additional national requirements that may apply for each measuring instrument category.
5. Identify any conditions on the acceptance of OIML Certificates and/or OIML type evaluation reports, e.g. OIML Certificates and/or OIML type evaluation reports issued on the basis of manufacturer test results will not be accepted.

10.3 Application forms

The Utilizer application form is available from the OIML website at:
https://www.oiml.org/en/oiml-cs/application-forms

10.4 Process

The following process should be read in conjunction with Annex 5 and Flowchart 4.

Step 1: Complete and submit the application form

Once it has been determined which organization is going to become the Utilizer, along with the scope, Additional National Requirements (ANRs) and any conditions that will be applied, an application form can be completed. The form, along with any supporting documentation relating to ANRs and/or conditions, should then be submitted to the Executive Secretary (executive.secretary@oiml.org).

Step 2: Executive Secretary review and draft Declaration

The Executive Secretary reviews the application form, and any supporting documentation. If the Executive Secretary is satisfied with the information provided a draft Declaration is produced.

Step 3: Signing the Declaration

The draft Declaration is sent to the applicant for checking. If the applicant is satisfied with the content, the responsible person in the Utilizer will sign and date the Declaration and will return it to the Executive Secretary. The Executive Secretary then arranges for the details regarding the Utilizer, including their scope, to be published on the OIML website at:
https://www.oiml.org/en/oiml-cs/utilizers-and-associates

10.5 Representation on the OIML-CS Management Committee

Once the Declaration is signed, the CIML Member of the country can nominate up to four representatives to participate in the OIML-CS Management Committee, but this is not mandatory. If the CIML Member choses to nominate more than one representative, one of them is identified as the "MC Member" for the purposes of voting. It should be noted that Associates do not have voting rights in the OIML-CS MC.

11. MANAGEMENT SYSTEMS

11.1 Introduction

The aim of this section of the Guidance Document is to provide practical guidance on the implementation and operation of a MS under Clause 8 (Option A) and general guidance on important aspects of Clauses 4 to 7. It is important to note that OIML D 32 [4] and OIML D 30 [5] provide additional guidance and interpretations to the requirements of ISO/IEC 17065 "Conformity assessment – Requirements for bodies certifying products, processes and services" [1] and ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" [2][3] respectively, and as such must be read in conjunction with these standards. A detailed description of the implementation of the requirements of ISO/IEC 17025:2005 [2] can be found in Complying with ISO 17025 A practical guidebook for meeting the requirements of laboratory accreditation schemes based on ISO 17025:2005 or equivalent national standards [28]. It must however be noted that this section focuses on the requirements of ISO/IEC 17025:2017 [3]. A TL can follow the requirements in ISO/IEC 17025:2005 [2] until the end of the transition period on 30 November 2020. However, it is recommended that organizations that are planning to become a TL under the

OIML-CS use the 2017 version [3] to avoid additional work to transition to this version when the 3-year transition period ends (see also 9.2).

Applications to become an OIML IA must include the demonstration of compliance to ISO/IEC 17065 [1], supported by the guidance and interpretations provided in OIML D 32 [4], via accreditation or peer assessment (Scheme A) or self-declaration (Scheme B). Similarly, applications to become a TL must include the demonstration of compliance to ISO/IEC 17025 [2][3], supported by the guidance and interpretations in OIML D 30 [5], whether Scheme A or Scheme B. The structure of both ISO/IEC *17065* and ISO/IEC 17025 are identical, and include the following requirements:

Clause 4	General requirements
Clause 5	Structural requirements
Clause 6	Resources requirements
Clause 7	Process requirements
Clause 8	Management system requirements

In addition to meeting the requirements of Clauses 4 to 7, the OIML IA and TL must also comply with the Management System (MS) requirements of Clause 8. The aim of the MS is to support and demonstrate the consistent, competent fulfilment of the technical requirements in the standards.

If the OIML IA or TL already operate a MS in accordance with the requirements of ISO 9001 [29], they do not have to develop a totally separate MS (Clause 8, Option B). ISO 9001 certification is not mandatory when following Option B. The OIML IA and TL are strongly advised to consider the guidance and interpretations contained in OIML D 32 [4] and OIML D 30 [5] respectively when establishing and maintaining the MS. Although examples or suggested approaches that could be adopted when implementing a Management System are provided in the sections that follow, organizations are free to also adopt other approaches to suit their particular needs.

11.2 Management System (Clause 8, Option A)

The aim of the MS is to ensure that all OIML-CS activities undertaken by the OIML IA or TL are carried out competently and consistently in accordance with the requirements in the standards and the applicable OIML publications. In practice, this means the development and maintenance of a set of controlled documents and records covering the scope of OIML-CS activities.

11.2.1 Management System documentation (Clause 8.2)

The standards do not impose any structure in terms of documentation; the OIML IA or TL can choose the structure they deem most appropriate based on the size of the organisation, scope of activities and resources required to maintain the documentation. The structure can range from a single document covering all requirements and supported by records, to a number of short documents each covering a specific set of requirements, again supported by records. In practice, the documentation would typically comprise a top-level manual, supported by procedures, work instructions, templates and records.

The manual would normally includes the policies, objectives, structure of the organisation, top management responsibilities, and references to procedures. One option to ensure all clauses are covered is to follow the structure of the standards (by aligning the manual and standard clause numbering) including text describing how each clause is met through appropriate organizational policies that reference the associated procedures and other lower level documentation as appropriate.

Procedures describe the various processes involved in the operation of an OIML IA or TL, for instance management of competencies, management of impartiality, type evaluation or testing processes. The procedures normally define the scope of the document, the responsibilities of the personnel involved in the process, the process itself (sequence of actions) and the requirements for records. References to other procedures, work instructions or records templates can be included. Procedures specifically required under the OIML-CS (in addition to any other procedures implemented to meet the requirements of the ISO/IEC standards) are listed in section 8.2.4 in OIML D 32 [4] (for the OIML IA) and OIML D 30 [5] (for the TL).

Work instructions typically describe in detail the sequence of actions followed during processes that are repeated often or by different personnel, such as certification or testing work (Clause 7 in the standards). An OIML IA or TL could decide to implement individual work instructions for the certification or testing of each instrument category.

Templates should be available to assist in the creation of the requisite documents and records in a consistent way. For instance, an OIML IA should have templates for the generation of OIML Certificates and type evaluation reports. A TL should have templates for the generation of test reports. When operating under the OIML-CS, the templates for type evaluation report and test reports need to follow the formats specified in the relevant OIML Recommendation. It is also good practice to have suitable draft templates in place for the procedures and work instructions to ensure they follow the same structure. Unique records such as certificates register (OIML IA) or calibrated equipment register (TL) obviously do not require templates.

The OIML IA and TL needs to define who is responsible for maintaining the MS documentation. Depending on the size of the organisation, this role can be fulfilled by a single person (e.g. nominated Quality Manager) or split across personnel involved in certification or testing. The OIML IA or TL must ensure that all personnel involved in certification or testing activities have access to the parts of the MS documentation and related information that are applicable to their responsibilities. In practice, this could be achieved by having all documents stored on a single server and then giving access to the relevant documents using access rights. Alternatively, when hard copies are used, the personnel made responsible for the control of MS documentation should keep a master copy of the documents with documents copied and distributed as and when required.

11.2.2 Control of Management System documents (Clause 8.3)

The OIML IA and TL shall ensure that all documents related to the Management System (MS) and its operation are controlled. In practice this means that the content and availability of each document is under the responsibility of one (or more) person. For instance, the top-level manual would be under the responsibility of the Head of OIML IA or TL, the type approval or testing procedures would be under the responsibility of the Certification or Testing Laboratory Manager. A *Control of documents* procedure can be used to

describe the process and identify responsibilities.

Internal documents must have a unique identification and must be regularly reviewed and approved before they are used. These documents would typically include the following information: document title, identification (for instance WI-xx for a work instruction), revision or issue number, date of issue, reviewed by, authorised by and date of next review. The documents must also clearly identify the successive changes between revisions, which could be in the form of a table at the end of the document, sometimes called a Revision history.

The OIML IA or TL must have a process in place to ensure that the latest version of external documents (for instance OIML-CS Documents, OIML Recommendations, OIML D 32 [4]/ OIML D 30 [5]) is available and used. In practice this means that each document is under the responsibility of one (or more) person, who will ensure by appropriate means that the documents are still relevant and that the latest version is available (for instance by checking the OIML website on a regular basis or subscribing to new updates).

It is good practice to maintain a controlled document register, listing all documents, the person responsible, the current version and other information such as the next review date. The register can be used to identify documents scheduled for review, and as a tool by personnel to ensure they work using the latest version of documents. Unintended access to obsolete versions of documents must be prevented. This can be achieved by either clearly marking such documents (using for instance “Obsolete” or “Do not use”) or storing them in an archive folder. One option is to use the documents register as the main point of access to controlled documents; links to the latest version of the documents are included in the register itself. When using hard copies, the person responsible for each document must ensure that obsolete versions are replaced at the point of use. All changes must be communicated to the relevant personnel.

Electronic documents are normally saved as Read-only to avoid unintentional or unauthorised changes. Controlled documents must be periodically reviewed at a frequency dependent on criticality and how often they are used.

11.2.3 Control of record (Clause 8.4)

The OIML IA and TL must ensure that all records related to the MS and its operation are controlled. A Control of records procedure can be used to describe the process and identify responsibilities and could be combined with the control of documents procedure described in the previous paragraph. In practice this means that all records must be clearly identified (for instance using project references, date/time, personnel), and stored in such a way that they are protected and retrievable (i.e. saved as read only or with limited access, and in a specific location defined in the relevant procedure or work instruction). The retention period must also be defined. This is normally specified in the relevant procedure (for instance the type approval or testing procedure will specify the retention period for the Type Evaluation Report (TER) or Test Report (TR) respectively). It must be noted that some records related to OIML-CS activities must be kept for as long as the certificate is registered (see PD-05 [18]).

During type approval activities OIML IAs could create a folder to store records for each type approval application. The folder may be named after the applicant’s name or product designation and contain the application reference number/ code. To facilitate the retrieval of records, sub-folders could be created to separately store the documentation submitted by the applicant, the application form and costs involved, the communication and the evaluation documents.

Similarly, during testing activities, TLs could create a folder for each application, with sub-folders to store test results, communication, test reports etc.

Access to records must be defined and restricted via access rights (electronic records) or physical means (e.g. locked cabinet for hard copies) when relevant (for instance access to personnel records is normally restricted).

11.2.4 Management review

The OIML IA and TL shall review the MS at regular intervals, normally at least once a year. The aim of the review is to identify the decisions and actions (review outputs) necessary to maintain the adequacy and effectiveness of the MS and to improve the MS, based on assessment of data (review inputs). A procedure should be available to describe the process, and specify the purpose and minimum frequency of the review, specify who is responsible for the review, the minimum items to be covered in such a meeting and a draft agenda, the requirement for records, etc.

In practice, the review process should also involve a meeting attended by top management (Head of OIML IA or TL, Certification or Testing Laboratory Manager, Quality Manager when applicable). The agenda would typically include the review of the inputs listed in the two ISO/IEC standards together with inputs relevant to the operation of the OIML-CS. It is important that the data required to inform the review is available at the time of the review. Top management should make every effort to ensure that the relevant data is collected during normal operation of the MS (for instance a process is in place to obtain customer and personnel feedback) and is suitably analysed prior to the review (for instance changes in volume or type of work since the previous review, an assessment against stated objectives etc). This aspect is important given that the management review normally focuses on trends rather than specific issues or raw data.

The management review meeting must be recorded, typically in the form of formal meeting minutes or notes, with the actions, responsibilities and the proposed completion date clearly identified. The meeting record should specify the person with assigned responsibility for each action. It is also important, especially if there are long periods between management review meetings, that progress against each of the agreed actions is monitored until completion and an evaluation is undertaken of the efficacy of the action taken in resolving the original issue. This may lead to the need for further action until the issue is satisfactorily resolved.

11.2.5 Internal audits

The OIML IA and TL must implement and operate an appropriate internal audit system, in addition to any assessments conducted for accreditation or peer assessment. The aim of internal audits is to assess if the OIML IA or TL continue to fulfil the requirements of the standards and the OIML-CS and to check if the MS is being effectively implemented and maintained. Internal audits can also be used to identify opportunities for improvement. A procedure is normally developed that describes the internal audit process, defines the responsibilities and specifies the requirements for records.

All processes must typically be audited every year against the requirements contained in the applicable standards and OIML-CS requirements. An audit programme must be in place. This could be in the form of a table listing the ISO/IEC standard clauses, OIML publication clauses or internal procedures, when the audits are scheduled, name of auditor and auditee. Depending on the size of the organisation and the complexity of the processes, the audits could be conducted in one block, or segmented through the year. Stable or rarely used processes may also be audited less often if a suitable justification is provided and recorded.

Internal audits must be conducted by competent personnel. Typically, this means the inclusion of personnel who are familiar with the requirements, including the more technical aspects, of the standards. the OIML-CS and / or with the processes in use (for instance the certification or testing manager could audit the certification or testing work conducted by the OIML IA evaluator or TL test engineer). Care should be taken in the selection of persons that are tasked to do this work noting that auditors should not be placed in a position where they audit their own work to ensure the integrity and impartiality of the audit results.

An audit report is normally produced (using a dedicated template), which includes a summary of the audit and provides a list the evidence witnessed during the audit. Evidence can include references to documents (procedures in place for a specific process) and records demonstrating that the procedure was followed and were in line with the applicable requirements.. The report must also identify any non-conformities and opportunities for improvement. Non-conformities are normally reported to the personnel in charge of the process under review. They should also identify appropriate corrective action. It is good practice to involve the auditee in the process of closing out non-conformities, given that they often have a better understanding of the cause and can then identify suitable action to remedy the situation. Non-conformities should be motivated using a specific clause of the standard or OIML publication and supported by suitable evidence.

11.2.6 Corrective actions (Clause 8.7)

The OIML IA and TL needs to identify and record the process used to address non-conformities via corrective actions. Non-conformities may be raised during internal audits or external assessments (accreditation or peer assessments), identified following customer complaints and also by personnel during their day to day activities. It is important to encourage such feedback from personnel within the organisation.

A corrective action needs to address the root cause associated with a particular non-conformity in order to minimise the possibility of its recurrence. It is important to note that addressing the cause of the non-conformity, and therefore preventing its recurrence, is often more difficult than addressing the resulting issue. Tools are freely available on the internet (such as the “5 whys”) and should be used to identify the cause (this is typically called “root cause analysis”). The effectiveness of a corrective action in addressing the issue raised should always be checked before a non-conformity is closed out.

It is common practice to have a register in place to log all non-conformities and track the status of corrective actions. Such a register should provide a description of each non-conformity, associated clause in the standard or OIML-CS requirement, cause of non-conformity, corrective action, completion date, actions taken and person responsible. The register could use colour-coding to identify outstanding or closed out actions. It can also be used in the analysis of trends that are required as inputs to the management review.

Opportunities for improvement can be treated in a similar way to non-conformities (see 11.2.9 for TL).

11.2.7 Preventive actions (ISO/IEC 17065, 8.7 [1])

The OIML IA needs to develop and maintain a process to eliminate the causes of potential non-conformities which is described in a suitable procedure. The aim of the process is to identify potential non-conformities and their causes, and to determine and implement actions to limit the risk of these non-conformities occurring. The OIML IA must also determine the impact of such potential non-conformities and then initiate appropriate remedial action that is commensurate with the potential risk. Examples of potential risks for an OIML IA include the threat to impartiality, ensuring the availability of resources to meet customer demands including the appropriate expertise.

It is important to note that the concept of preventative action has now been replaced in more recent revisions to the standards such as ISO/IEC 17025 [3] and ISO 9001 [29] by actions to address risks and opportunities. Although the principle is similar, the new categorisation also promotes a focus on opportunities for the organisation (see next section).

11.2.8 Actions to address risks and opportunities (ISO/IEC 17025, 8.5 [3])

The TL needs to develop and maintain a process to address the risks and opportunities related to its activities which is described in a suitable procedure.. The aim of the process is to identify and limit risks, enhance opportunities and achieve improvement. Examples of risks for a TL include lack of suitable resources to meet customer demands, loss of expertise through resignation or retirement or reliance on non-accredited calibration providers; examples of opportunities include extensions to scope and recruitment of appropriate staff to increase the volume and / or scope of work.

The TL must identify the risks and opportunities to determine and implement the actions necessary to mitigate the risk or contribute to the achievement of opportunities. The TL must determine the impact such risks and opportunities would have before determining the action (the action must be appropriate to the risks and opportunity).

It is good practice to develop a risk register, that categorises each risk (low to high, using the commonly adopted “impact x likelihood” approach) that could also describe the action required / taken to mitigate the risk. It must be noted that the effectiveness of the subsequent action must be checked as part of the process.

11.2.9 Improvement (ISO/IEC 17025, 8.6 [3])

The TL must identify opportunities for improvement, including those identified during internal audits, periodic review of documents, or based on customer or personnel feedback. The process to address opportunities for improvement is similar to the corrective action process (see section 11.2.6) and involves the determination of actions proportionate to

the impact and a follow-up until completion, including the effectiveness of the action.

11.3 General requirements (Clause 4)

11.3.1 General comments

The following sections provide guidance on the management of impartiality and confidentiality. OIML IAs must also refer to ISO/IEC 17065 [1] and TLs to ISO/IEC 17025 [2][3] respectively for the internationally agreed requirements and OIML D 32 [4] or OIML D 30 [5] for more specific guidance and interpretations related to legal metrology.

11.3.2 Impartiality

The OIML IA or TL needs to develop and maintain a process to ensure the impartiality of their activities which is described in a formally adopted procedure. Impartiality ensures that the OIML IA or TL does not allow commercial, financial or other pressures to compromise their activities (for instance type evaluation results and certification decision for the OIML IA, and test procedures and test results for the TL). Commitment from top management and an appropriate management structure are key to the management of impartiality. In practice, this means that top management is responsible for the development and maintenance of a procedure covering the management of impartiality, and need to review the risks to impartiality on an ongoing basis and appropriately follow up actions taken to mitigate the risks. Top management must also ensure the structure that they have in place limits the risks to impartiality from both internal or external sources.

The OIML IA, or TL, must identify the risks to impartiality and determine their actions to mitigate these risks. Examples of risks to impartiality include personnel having previously worked for an applicant, applicants representing a large portion of the volume of the work of the OIML IA or TL, and pressures from applicants to meet unrealistic deadlines. It is good practice to maintain records of the contribution of applicants in terms of volume of work (percentage of income or working hours) to determine financial impartiality. Similarly, a record of all stakeholders and relationships should be maintained. Stakeholders include applicants, contractors, owners, suppliers, regulatory bodies, accreditation bodies, manufacturers' associations etc.

11.3.3 Confidentiality

The OIML IA or TL must ensure the confidentiality of all information obtained or created during their activities. When it is a requirement to either publish (for instance OIML Certificates) or release information (for instance in case of a complaint), the applicant must be notified. These clauses are usually included in the Terms & Conditions the applicant must agree to before an application can be accepted. All personnel involved in the OIML IA or TL activities must be fully aware of the confidentiality clauses.

11.4 Structural requirements (Clause 5)

11.4.1 General comments

The following sections provide aim at providing guidance on structure and responsibilities. The OIML IA and TL should refer to ISO/IEC 17065 [1] or ISO/IEC 17025 [2][3] respectively for the complete list of requirements and OIML D 32 [4] or OIML D 30 [5] for guidance and interpretations.

11.4.2 Documentation

The OIML IA or TL must maintain documentation related to the structure, responsibilities and authorities. In practice, this usually means the development and maintenance of an organogram of the organisation showing the hierarchical structure, including job titles (and names if the cross reference between job title and job holder is not documented elsewhere). Responsibilities are either defined in the job description (for instance the OIML IA evaluator is responsible for…) or in procedures (the test report must be signed by…).

Top management and their responsibilities and authorities must also be clearly identified. Top management responsibilities include communication regarding the effectiveness of the MS, compliance to the requirements of the standards and the OIML-CS and changes to the MS. The same applies to internal or external committees if any are involved in the OIML IA or TL activities.

11.4.3 Examples of structure and responsibilities

The organograms in Annex 6 and Annex 7 provide typical examples for an OIML IA (small or large organisations, respectively) and Annex 8 and Annex 9 provide similar examples for a TL.

11.4.4 Mechanism for safeguarding impartiality (ISO/IEC 17065, 5.2 [1])

The OIML IA must have a mechanism in place for safeguarding its impartiality. Typically, this could be achieved by establishing an impartiality committee, which comprises representatives of the OIML IA (top management) and interested parties. ISO/IEC 17065, 5.2.4, Note 1 [1] gives examples of interested parties. The committee should meet at predetermined intervals and review the OIML IA policies and principles related to impartiality (for instance the impartiality procedure), assess how risks to impartiality are mitigated (analysis of financial data, risk register) and how impartiality is achieved as part of the OIML IA activities (review of recent type approval work).

11.5 Resources requirements (Clause 6)

11.5.1 Personnel

The OIML IA or TL must have a process in place to manage the competence of personnel, supported by records. In practice, this first means determining the criteria for the competence for each function in the certification or testing process, for instance the OIML IA evaluator must have knowledge of the technology and OIML Recommendation for a specific instrument category, or the TL Electromagnetic Compatibility (EMC) test engineer must have experience of EMC testing according to the ISO/IEC 61000 series, etc. This information is usually included in the appropriate job descriptions.

The OIML IA or TL must also identify the training needs, have a training programme in place and ensure delivery of the training that is required. Training could involve shadowing senior colleagues, although external training by experienced OIML IA or TL may be preferable in the case of a new OIML IA or TL. It must be noted that training could also include participation in legal metrology work at international or national level, which could be for instance providing comments when OIML Recommendations are revised. It is important to have a process in place to allow all personnel the opportunity to provide feedback on the various OIML publications (for instance, the OIML IA evaluator could suggest improvements to the type approval process in PD-05 [18], or the TL test engineer could identify an improvement to a test procedure in an OIML Recommendation).

The OIML IA or TL must have a process in place to assess the competence of personnel. In practice, this means either a review of documents produced by personnel (for instance a Type Evaluation Report (TER) produced by the OIML IA evaluator under supervision by a senior colleague) or witnessing personnel conduct a process (for instance the TL test engineer conducting testing). On-going monitoring of competence is also required, which can be done by an appropriate periodic review of documents and witnessing processes.

All personnel need to have an individual record detailing their education, experience, training, performance monitoring, authorisations and all other relevant information. It is good practice to have an additional record in place summarising the competence of all OIML IA or TL personnel, for instance a matrix identifying which OIML IA evaluator is competent for a specific instrument category, or which TL test engineer is competent for EMC testing. It must be noted that the OIML IA must ask personnel to sign a contract by which they declare they commit to comply with the rules of the OIML IA, including confidentiality, and declare any risk to impartiality or conflict of interest (ISO/IEC 17065, 6.1.3 [1]).

11.5.2 Sub-contracting

Any sub-contracted OIML-CS activities must comply with the requirements of the standards, supported by the guidance and interpretations in OIML D 32 [4] (OIML IA) or OIML D 30 [5] (TL).

11.5.3 Facilities, environmental conditions, equipment and traceability

The TL should refer to ISO/IEC 17025, 6.3 to 6.5 [1] for the detailed requirements and OIML D 30 [5] for guidance and interpretations. In addition to records for individual test equipment (for instance calibration certificates), it is good practice to develop and maintain a log that lists all equipment that needs to be controlled, use this log to monitor the expiry of calibration certificates and ensure that equipment is sent for periodic calibration as required. The TL must also ensure the combined uncertainties of measurements are determined for all test procedures and comply with the requirements in the relevant OIML Recommendations.

11.6 Process requirements (Clause 7)

The OIML IA and TL should refer to ISO/IEC 17065 [1] or ISO/IEC 17025 [2][3] respectively for the complete list of requirements and OIML D 32 [4] or OIML D 30 [5] for guidance and interpretations, as well as section 12 of this document.

11.7 Process to implement a Management System covering OIML activities

The OIML IA or TL could use the following steps to implement a Management System (MS) covering OIML activities. Compliance to the requirements of ISO/IEC 17065 [1] or ISO/IEC 17025 [2][3], supported by the guidance and interpretations in OIML D 32 [4] or OIML D 30 [5], should be checked for all stages of the process.

Determine the scope of OIML-CS activities

This involves selecting the instrument categories the OIML IA or TL wish to apply for.

Determine the structure and responsibilities

The OIML IA or TL must either create their own or use an existing structure to cover the OIML-CS activities. The structure will depend on the scope of OIML-CS activities, size of the organisation and resources available.

The OIML or TL must also determine the responsibilities for all positions and have in place suitable job descriptions. Responsibilities will depend on the structure and competence of personnel.

Review of resources

The OIML IA or TL must undertake a review of resources, in terms of personnel and their competence, as well as infrastructure when applicable (TL). Training, recruitment or equipment purchase may be necessary if gaps are identified.

Implement the MS

The OIML IA or TL must develop a set of appropriate documents and procedures related to the MS (ISO/IEC standards Clause 8 and section 11.2 of this document).

Determine and document the processes related to OIML-CS activities

This may involve writing one or more procedures for type approval or testing, as well as more operational instructions when appropriate. Procedures covering the interactions between OIML IA, TL, MC and TLF (Test Laboratory Forum) must be produced. Templates for records should also be available for the OIML-CS activities.

Initial assessment

The OIML IA or TL should conduct an internal audit of the MS and processes against the requirements of ISO/IEC 17065 [1] or ISO/IEC 17025 [2][3], supported by the guidance and interpretations in OIML D 32 [4] or OIML D 30 [5].

Identify and address areas of non-compliance

The OIML IA or TL need to appropriately address areas of non-compliance, using the corrective action process.

Final assessment

Another internal audit could then be conducted to ensure there are no further areas of non-compliance. Controlled documents can also be finalised and issued once this has been confirmed.

12. TYPE EVALUATION AND TYPE APPROVAL

12.1 Introduction

Type evaluation is the process which involves the assessment (typically tests and examinations) of a product against a set of requirements. Type approval is the decision to grant certification based on the information obtained during the type evaluation process. The product may be a prototype, from a production line test run, or from an established production line. The approved product is intended to become the "type" against which all other products are manufactured. Products subsequently manufactured in accordance to the

approved "type" can then be deemed likely to meet the same requirements as the approved type.

Commonly, type approval is the first stage of the conformity assessment processes which are needed to allow a number of identical products to be placed on the market. Under the OIML-CS, the product is a measuring instrument for which the requirements are specified in an OIML Recommendation. The outcome of the type evaluation and type approval process is the issuance of an OIML Certificate.

12.2 OIML Recommendations

See paragraph 6.7 for information relating to OIML Recommendations.

12.3 Type evaluation and type approval process

12.3.1 General information and participants

The type evaluation and type approval process is described in **Flowchart 6** and is supported by ***Checklist 5*** which can both can be found at the end of the document.

The type evaluation and type approval process includes the following participants; The applicant (the manufacturer, or an authorized representative of the manufacturer, of the type of instrument to be approved); The OIML IA (which must have the measuring instrument category and Scheme listed in its OIML-CS Declaration), manages the type evaluation and type approval process from application to completion; The Test Laboratory (which must be listed in the OIML-CS Declaration of the OIML IA for the Scheme the instrument category belongs to), conducts testing at the request of the OIML IA. In general, communication between the applicant and the Test Laboratory will be through the OIML IA. Reference can also be made to PD-05 [18] and OIML D 19 [27] for additional information.

12.3.2 Application

The applicant is required to submit an application to the OIML IA to start the process (see ***Checklist 5***, step 1). The application must include the elements listed in section 4.1.2 (Scheme B) or section 5.1.2 (Scheme A) of OIML PD05 [18]. It is common practice for an OIML IA to have a standard application form available on their website, but a formal letter or equivalent electronic document could also be accepted.

The application must be supported by documentation allowing the instrument, or family of instruments, to be unambiguously defined. In practice this means confirmation of the metrological characteristics, description of the construction (dimensional and assembly drawings) and operation (user and service manuals), identification of modules (when the instrument is made of assembled parts, which may be assessed independently, or some already certified), photos (brochure, link to manufacturer's website).

In the case of a family of instruments, differences between models must be fully identified in terms of metrological characteristics, construction, materials, operation, components, electronics and software. Existing OIML Certificates, type evaluation reports or test reports may also be provided when a similar instrument or part of the instrument (module) has already been tested and/or certified. Documentation related to the manufacturing process or Quality Management System operated by the manufacturer are not required. In practice, the complete set of documentation required in the Recommendation can be provided later during the type evaluation process, provided they are not critical at the application stage (for instance Printed Circuit Board (PCB) drawings, if the PCB is identical in all models within a family).

The application and the supporting documentation must be reviewed by the OIML IA (see ***Checklist 5***, step 2). Any decision to refuse the application, along with the reason(s) must be communicated in writing to the applicant (see ***Checklist 5***, step 3). A common reason for the refusal of an application is that the instrument is not included in the scope of the OIML IA, either in terms of instrument category or specifications. Other reasons include instruments that are submitted for approval do not fall within the scope of the Recommendation. The applicant can amend an application following a refusal, for instance by reducing the certification scope to match the OIML IA scope, or by modifying the instrument to fall within the scope of the Recommendation. If the instrument does not appear to meet the applicable requirements at this stage, the application should not be refused, but the OIML IA should inform the applicant accordingly as the instrument will likely need to be modified to be approved. In practice, it is often necessary to liaise with the applicant following submission of an application to request additional information or documentation (many applicants have no experience of the type evaluation and type approval process), to resolve issues (for instance specific test equipment to be provided), and to ensure the OIML IA has a complete understanding of the certification scope (particularly in case of unusual instruments or large families of instruments).

12.3.3 Confirmation of test samples, test programme, fees and timescales

Once an application is accepted, the OIML IA will inform an applicant in writing (see ***Checklist 5***, step 3) and provide information on the OIML-CS rules (see ***Checklist 5***, step 4). In practice, this means referring to the relevant OIML-CS documents (OIML B 18 [10] and the Procedural Documents) and the conditions of acceptance of test results, type evaluation results and certificates by Utilizers, including the right to appeal in case of non-acceptance. It is also good practice to explain the type evaluation and type approval process in case of inexperienced applicants.

The OIML IA begins the type evaluation process by determining the test samples and the test and examination programme based on the documentation submitted during the application stage. Such documentation includes existing test results which have been accepted (see ***Checklist 5***, step 5). In the case of a single instrument, it is normal to conduct the complete set of applicable tests and examinations specified in Part 2 of the recommendation, unless some of the tests can be considered as already covered by existing test results. Some Recommendations require more than one of each test samples to be provided. When this is not specified, the actual number must be mutually agreed between the OIML IA and the applicant.

In the case of a family of instruments, OIML Recommendations provide guidance for the selection of test samples. The test samples must be representative of the family of instruments and cover the complete range of specifications, constructions variants and functionalities. It is also common practice to select "worst case" configurations, or the most sensitive instrument, for performance testing. The test programme must include all applicable tests and examinations specified in Part 2 of the Recommendation, unless some of the tests are

covered by existing test results. Some tests may have to be conducted on more than one sample, if a single sample is not deemed to represent the complete family. It must be noted that the OIML IA may have to request additional equipment or documentation from the applicant, for instance when testing modules (simulators providing inputs) or unusual or large instruments (specialist or lifting equipment), or specific setup instructions. The selection of test samples and determination of the test programme requires appropriate experience (for instance knowing the effect of one particular difference in construction on the behaviour of the sample under test). In such cases the applicant's expertise in their domain can assist.

The OIML IA determines and confirms with the applicant the costs associated with the type evaluation and type approval, which could include the costs to review the application and the certificate registration fee. The cost associated with testing should be confirmed by the TL upon review of the test programme. Similarly, the OIML IA determines and confirms the approximate timescales for the process, with input from the TL (see ***Checklist 5***, steps 6 and 7). It is important to note that costs and timescales could increase as the result of failures, and that the applicant needs to accept any additional costs and associated delays before the process can resume following a failure. The applicant may decide to withdraw the application upon confirmation of initial costs and timescales or alternatively, the applicant may decide to reduce the certification scope to reduce costs and timescales, in which case the OIML IA must begin the process again.

12.3.4 Test samples

The OIML IA must confirm that the test sample(s) as received conform to the description of the type provided by the applicant. The OIML IA must also check that the test samples are not damaged and operate as intended (see ***Checklist 5***, steps 8 and 9). If a number of samples of each type was requested by the OIML IA, the OIML IA will randomly pick one sample of each type before tests and examinations are conducted (see ***Checklist 5***, step 10). The OIML IA then sets up the samples for testing and examination, using the additional equipment and documentation provided by the applicant if necessary (see ***Checklist 5***, step 11). This may involve for instance connecting simulators or calibrating the instruments. Test samples and equipment provided by the applicant must be safely stored when not used, and clearly identified, This can be achieved for instance by logging the serial numbers into a database (with a cross-reference to the applicant's name or application number) and suitably label the packaging with the application reference (see ***Checklist 5***, step 8). The test samples are then sent to the TL by the OIML IA. It is possible for the TL to perform some, or all, of the above activities under the authority of the OIML IA.

12.3.5 Test request and evaluation plan

The OIML IA produces a test request for the TL, which must include a clear identification of the test sample(s) and the tests to be conducted on each sample (see ***Checklist 5***, step 12). The test request may, as required, be accompanied by instructions or documentation from the applicant or OIML IA (for instance instructions on how to access a testing mode, or the user manual for additional equipment provided by the applicant). The test request may also specify the metrological characteristics and rated operating conditions for the test samples, references to the test procedures in Part 2 of the Recommendation, and the associated test levels.

The OIML IA also produces an evaluation plan (see ***Checklist 5***, step 13), which includes a clear identification of the samples and the examinations to be conducted on each sample. References to the documentation provided by the applicant could also be included for the evaluator.

12.3.6 Testing process

This section should be read in conjunction with **Flowchart 7** and ***Checklist 6*** that can be found at the end of the document.

Once the TL has received the test samples/equipment and test request (see ***Checklist 6***, step 1), the TL must identify and register all test samples and equipment sent by the OIML IA (see ***Checklist 6,*** step 2). The identification provided by the OIML IA could also be used for this purpose. The TL then reviews the test request (see ***Checklist 6,*** step 3) and examines the test samples to check that they conform to what is specified in the test request, they have not been damaged and operate as intended (see ***Checklist 6***, step 4). The TL will confirm in writing to the OIML IA if the test request has been accepted or rejected (see ***Checklist 6***, step 5). If the sample is rejected, the reasons must be provided. Typical reasons to reject a test request include one or more tests or the test levels are not within the scope of the TL, insufficient information has been provided (for instance the rated operating conditions have not been fully specified, the instructions to operate the instrument have not been provided or are incomplete), the test samples do not conform to the test request or do not operate as intended.

Once a test request has been accepted, the TL normally produces a test plan and allocates one or more test engineers (see ***Checklist 6***, step 6). The test engineer(s) must be authorised for the allocated tests. The test plan could include the order of the tests, test engineer and date for all tests. The test plan must take into consideration the availability of suitable test engineers and appropriate test equipment. The test request from the OIML IA may be sufficient for an experienced test engineer, who would confirm the approximate completion date and decide the order of the tests according to the availability of test equipment and other work. The TL will confirm the costs and timescales to the OIML IA. These are taken into account by the OIML IA when confirming the costs and timescales for the complete certification to the applicant (see ***Checklist 6***, step 7). In practice, the TL will only confirm the costs are correct and provide an accurate completion date to the OIML IA after the test samples have been received and the relevant test programme has been determined (see section 3).

The OIML IA will normally set up the test samples for testing, particularly when the OIML IA and TL are on the same premises. If the TL is not in the same location, the OIML IA may provide instructions for the setup as necessary (for instance how to connect the various modules and equipment) (see ***Checklist 6***, step 8). The test engineer(s) will then conduct the allocated tests in accordance with the procedures in Part 2 of the Recommendation (see ***Checklist 6***, step 9). Deviations from the procedures may be requested by the OIML IA, in which case the modified procedure should be followed. The test results could be hand-written on test result sheet templates that align with Part 3 of the relevant OIML Recommendation, with all sheets kept in a common folder bearing the project reference. The test engineer must ensure all the necessary information is recorded at the time of testing.

The TL must inform the OIML IA of any failure occurring during testing. Details of such a failure are then relayed to the applicant by the OIML IA. It must be noted that the TL and the OIML IA cannot provide a solution to address the failure, as this would be considered as providing consultancy. The TL may decide to stop testing immediately after a failure occurs, and await instructions from the OIML IA. The OIML IA may then issue a modified test request once the issue has been solved by the applicant. New test samples may also be provided. The TL would then proceed as previously described (new test plan, confirmation of additional costs and extended timescales). Even though communication with the applicant is normally through the OIML IA, it is also possible that the applicant may wish to visit the TL to witness the failure and modify the instrument under test rather than send a new sample. In such instances, the TL may wish to inform the OIML IA accordingly.

One all tests have been successfully completed the TL issues a Test Report. This involves populating a suitable template with the test data (see ***Checklist 6***, step 10). Such a templates need to be controlled documents, produced using the applicable part of Part 3 of the OIML Recommendation. A Word version can be requested from the BIML to assist the TL in this regard. A test report must be checked by another competent person (see Checklist 6, step 11) before signature by an authorised person (see ***Checklist 6***, step 12), typically the TL Manager. The test report must comply with PD-05, sections 4.4.3 to 4.4.5, and follow the format in Part 3 of the OIML Recommendation.

It is possible to issue a single test report for more than one test sample, provided that the test samples are clearly identified for each test. In the interest of clarity, it is recommended to issue one Test Report per sample when testing a large number of samples (in the case of a family of instruments). The Test Report is then sent to the OIML IA (see ***Checklist 6***, step 13). The TL will also return the test samples and equipment to the OIML IA (see ***Checklist 6***, step 14) together with a confirmation of the final costs (see ***Checklist 6***, step 15). The TL must retain a copy of the test request, applicable test results (hard copy or scanned copy) and the test report for as long as the certificate remains registered.

12.3.7 OIML IA conducts the examinations

The OIML IA evaluator conducts an examination of the selected test sample(s) in accordance with an evaluation plan (see ***Checklist 5***, step 14). This typically involves checking the applicable requirements in Part 1 of the Recommendation, using the procedures in Part 2 as applicable, and completing the Checklist from the OIML Recommendation as a record. It is good practice to add comments or references in the Remarks column of the Checklist, particularly in the case of non-compliance. It can also be helpful to request the applicant to attend specific parts of the examination, particularly in the case of complex instruments. In general, it is easier to ask an applicant to demonstrate how their instrument complies with specific requirements, rather than relying solely on the documentation provided. This stage of the process can be conducted before, in parallel with, or after the testing. In order to optimise the time needed to complete the certification process, it is recommended that the testing and examination process occur in parallel. This provides an applicant with the opportunity to appropriately address examination non-compliances, such as the modification of software, while the instrument is undergoing testing. Such an invitation needs to ensure that such software modifications does not affect the testing performance.

If one or more requirements are not met, the OIML IA must inform the applicant in writing, and provide details of the failure. The applicant must then resolve the issue, for instance by modifying the instrument or amending the documentation and resubmitting the application. The OIML IA will then review the resubmitted application and proceed as described in the applicable parts of section 12.3.2 onwards. In practice, the resubmitted application is used to support the initial application confirming the changes as compared to the initial application. If accepted, the OIML IA assesses the changes and confirms whether any additional examinations or tests are now required. Additional costs and revised estimated timescales are also then confirmed.

12.3.8 Type Evaluation Report and draft Certificate

Once the tests and examination have been performed, and if the instrument has been found to comply with the applicable requirements, the OIML IA evaluator produces a Type Evaluation Report (TER) using the Test Report(s) (TR) and Checklist provided (see ***Checklist 5***, step 15). The evaluator checks that the Test Report(s) comply with the initial test request and includes all the necessary information (see ***Checklist 5***, step 16). The TER must comply with the requirements in PD-05 section 4.5 [18] and the format in the relevant OIML Recommendation, if provided. If a TER format is not provided in the relevant OIML Recommendation, the OIML IA may use their own template on the provision it contains all relevant information. In practice, the TER will include references to the Test Report(s) issued by the TL, and not the test data itself, since test reports are issued as independent documents by the TL. The TER is intended to support the Certificate and will be used to check the validity of the certificate by Utilizers. The TER must therefore contain all the relevant information in an unambiguous manner so that it is not open to interpretation. The TER must also bear a unique identification number, for instance the application reference.

The justification for the selection of test samples within a family of instruments is an important part of the TER and must be clearly explained. In practice, this entails the listing of the tests (or including a reference to a Test Report) conducted on the selected sample and detailing the reasons why these tests allow other models within the family to also be certified. Similar justifications for the acceptance of the test results also need to be provided. Document PD-07 [20] provides more information on the acceptance of test results that have been issued under the Basic Certificate System and the OIML MAA.

The OIML IA evaluator will also draft an OIML Certificate, which must comply with the requirements in PD-05 Section 4.6 and Annex A [18], and the OIML template. An OIML approved template is available from the OIML website at: https://www.oiml.org/en/oiml-cs/documentation. It should be noted that the OIML template is indicative. Other templates may be used, provided that the information specified in the OIML template is present. It is recommended that the OIML IA evaluator forwards a copy of the draft OIML Certificate to the applicant for their review and comments before passing it to their decision maker for approval (see ***Checklist 5***, steps 17 and 18). Typically, comments would be corrections, clarification of wording, requests to add or remove information. It must be noted that OIML Certificates are published on the OIML website and as such should not contain commercially sensitive information unless an integral part of the instrument description. Such information is typically included in the TER or documentation, which is not publicly available.

The OIML Certificate that is now produced must include the information required in the OIML template, and additional pages that define the essential technical and metrological characteristics of the measuring instrument. The specific format for these additional pages are available in some of the relevant OIML Recommendations. These pages, normally called a Descriptive Annex, include a short description of the instrument type, technology and intended use, a summary of the mechanical features (material, display type, size, etc.), a list of functionalities or devices (zero-setting, price-computation, etc.), the metrological characteristics and rated operating conditions, the software identification, the sealing measures and other relevant information.

An OIML Certificate must also include a reference to the documentation file/folder. The file/folder should be based on the documentation requirements specified in the Recommendation. It is good practice to include a summary table in the TER or in the file/folder itself listing the document(s) title against the documentation requirements (see ***Checklist 5***, step 19). The OIML Certificate number must follow the format in PD-05 Section 4.6.4 [18]. It is good practice to develop and maintain a certificate number register to ensure that a number is not allocated twice (see ***Checklist 5***, step 20 which also concludes the type evaluation process).

12.3.9 Certification decision

A certification or type approval decision follows the type evaluation process and involves a review of the draft OIML Certificate, TER and Test Report(s). The evaluator may support the request for certification with an internal evaluation report summarising the project. This would provide information that is not included in the TER or OIML Certificate (for instance list of failures, modifications and resulting additional tests and examinations), including links to the various documents and a recommendation whether or not to grant certification. The granting of certification can make reference to specific conditions (see ***Checklist 5***, step 21). A decision maker must be a person who has not been involved in the evaluation process and who is competent in the category of instruments concerned. If certification is not granted following the review, the applicant should be informed in writing by the OIML IA, and the reasons explained (see ***Checklist 5***, steps 22 and 23). Reasons not to grant certification by the decision maker include: they do not consider the selection of test samples is representative of the family of instruments; the justification to accept test results is not deemed sufficient; or mistakes are evident in the Test Reports.

12.3.10 Certification granted

If certification is granted, the decision maker signs the OIML Certificate, and informs the Evaluator who in turn informs the applicant (see ***Checklist 5***, steps 22 and 23). The OIML IA issues an OIML Certificate, signed by the decision maker, to the applicant, along with the TER and Test Report(s) (see ***Checklist 5***, step 24). These documents could take different forms, e.g. printed documents or secure PDF files.

The OIML IA will also provide a copy of the final OIML Certificate, in a protected PDF format, to the BIML for registration, either directly or via its CIML Member (see ***Checklist 5***, step 25). The OIML Certificate is then published on the OIML website but the TER and TR are neither registered nor published. The applicant, OIML IA and TL must keep a copy of the documentation supplied as part of the application, the TER and Test Report(s) for as long as the OIML Certificate remains registered.

The OIML IA then confirms the final costs to the applicant, raises an invoice and arranges the return of the test samples (see ***Checklist 5***, steps 26 and 27).

12.4 OIML Certificate issued on the basis of incorrect conclusions

Information on this aspect is contained in OIML Procedure Document PD-05, clause 7 [18].

12.5 Modification of an OIML Certificate

An OIML Certificate may have to be modified for a number of reasons; the process is described in PD05, clause 8 [18]. Applicants typically request a revision to certificates in order to add new variations of the instrument (extension of product range), add modified instruments (addition of functionalities, improvements, replacing of obsolete components) or update the OIML Certificate to the latest version of the Recommendation. An OIML IA must then decide what, if any, additional tests and examinations need to be conducted.

In certain cases, the OIML IA may decide to issue a new OIML Certificate if they consider that the requested addition constitutes a new type (for instance similar operation to the approved type but different construction and components). The normal type evaluation and type approval process is then followed. The test results and OIML Certificate requirements specified in section 12.3.2 are obtained during the subsequent type evaluation and type approval processes that need to be followed before the OIML Certificate can be revised. The principles described in section 12.3.3 to determine the test samples, tests and examination also apply. The OIML IA must determine what gaps exist between the existing and requested certifications and decide what is required to close them. OIML document D 19 [27], section 2.2 and 2.3 provides some guidance on what constitutes a different or modified type. Document PD-05 section 8.3 [18] also specifies the requirements to update an OIML Certificate to the latest version of a Recommendation.

12.6 Process under Scheme A and Scheme B

Although the type evaluation and type approval process is identical under Scheme A and Scheme B, the considerations in PD-05 section 5 [18] should be taken into account when issuing a Scheme A certificate.

12.7 Use of Third-party Test Laboratory or Manufacturer Test Laboratory

The type approval process is identical when using a Third-party Test Laboratory.

The use of a Manufacturer Test Laboratory (MTL), is described in procedure PD-04, section 7.3 [17] which must be followed. The OIML IA must select the test samples, or if not practical, ensure that the MTL is not involved in the selection of test samples (for instance by asking the production department to select the samples at random). It is good practice for the OIML IA to request one or more test samples tested by the MTL and use these to repeat some of the tests to check if the results are similar. If not, the OIML IA may request all tests be repeated, either by the OIML IA's internal TL or by a Third-party TL. The TER must clearly specify when a MTL has been used. If more than one TL is involved during the type approval process, separate Test Reports must be produced.

12.8 Additional national requirements

The type evaluation and type approval process remains

unchanged when tests or examinations are conducted to assess compliance to additional national requirements. Although the tests and examination form part of the test request and evaluation plan, a separate Test Report may be issued, and a specific section created in the TER. The OIML IA must then issue a letter confirming compliance and send it to the BIML (PD-05, section 5.6.3 [22]).

13. TYPE APPROVAL CONTROL SYSTEMS

EXTRACT FROM OIML D 1 [24]

"3.6 Legal metrology

Regulations on measurements, on prepackages and on measuring instruments, as described in this Chapter, may be made in order to

- *protect the interests of individuals and enterprises,*
- *protect national interests,*
- *protect public health and safety, including in relation to the environment and medical services, and*
- *ensure fair trade and level playing fields to promote trade.*

These regulations shall, when applicable, be compatible with the OIML Recommendations and make use of their requirements. Other relevant OIML publications should also be considered.

The conformity assessment procedures required by these regulations should, when applicable, be compatible with the conformity assessment systems set up by the OIML, and, if appropriate, make use of them."

13.1 Introduction

Type evaluation and type approval are components in a system of legal metrological controls designed to provide government with the means for assuring the adequacy of measuring instruments used in legally controlled applications. Type evaluation and type approval are distinct steps in the metrological control system. Type evaluation is an objective process of determining facts concerning a type (model or range of instruments), while type approval is the decision, based on these facts and involving judgment, to approve or not to approve that type (model or range of instruments) for use in legal applications.

13.2 Type Approval Control Procedures

When considering the level of legal metrological controls to apply, consideration must be given to the categories of measuring instruments to be controlled and the applications in which they will be used. In establishing metrological controls the national responsible body can select from a number of options ranging from simply requiring a manufacturer/importer declaration all the way through to a full conformity assessment system based on type evaluation, type approval, verification and surveillance.

On the assumption that there is a need to control measuring instruments that are to be used in legal applications, the national responsible body could permit any measuring instrument which has a (type approval) certificate from a suitable issuer, or which has been approved in another jurisdiction, to be sold or used on their market without any further formalities. In this instance, consideration has to be given as to who is a suitable issuer or which (type approval) certificates from other jurisdictions will be accepted. A 'ready-made' solution in this situation would be to accept OIML Certificates that have been issued by an OIML IA under the OIML-CS, although the national responsible body will need to decide which OIML Certificates will be acceptable, e.g. Scheme A only, Scheme A and Scheme B, certificates issued on the basis of manufacturer test results, etc.

The national responsible body could alternatively require any measuring instrument to have a national type approval (issued by the national issuing authority) before it can be sold or used on their market. In this instance, there are a number of options available as detailed below.

Note: Depending upon the structure of the legal metrology system in a country or economy, the national responsible body and the national issuing authority may be the same organization or two separate organizations.

Option 1

A national issuing authority operates, or has access to, testing and evaluation capabilities that allow it to form its own judgment on whether the type submitted for approval conforms to the specifications set out in national regulation. Type approval, whether on the basis of this testing and evaluation, or testing and 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.

Option 2

In this instance, the national issuing authority does not have its own testing and evaluation capabilities, so the decision on whether to grant approval for a type of instrument to be used for regulated purposes will usually be based on evidence of third-party conformity assessment. With this approach there are three possible options that can be adopted.

Option 2.1

The national issuing authority accepts test results issued in support of a certificate from a suitable issuer, but asks for an instrument to be submitted for a limited or partial evaluation before the authority approves the instrument for use on the market.

Option 2.2

The national issuing authority accepts both the test results and the type approval judgement of a certificate issuer,

but still requires a formal approval process within their own administration, perhaps on the basis of checking the documentation.

Option 2.3
The national issuing authority accepts the type approval judgement of a certificate issuer, but still requires a formal approval process within their own administration with no documentation or further checks.

In Options 2.1 to 2.3, consideration has to be given as to which test results and/or certificates are deemed to be acceptable. Again, the OIML-CS offers a 'ready-made' solution whereby OIML Certificates and/or the associated OIML test reports/ type evaluation reports that have been issued by an OIML IA are deemed to fulfil the necessary requirements.

13.3 Application of the OIML-CS to type approval controls

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

The OIML-CS provides a 'ready-made' solution regarding the suitability of test results and/or certificates that could be accepted as the basis for granting a national (or regional) approval. For the scenarios described earlier, it would be possible to directly accept OIML-CS Certificates and/or OIML type evaluation and test reports as a basis for reducing/ minimizing evaluation when issuing national type approvals. In reaching such a decision, consideration of the following aspects is required:

- which instrument categories to regulate,
- which edition of an OIML Recommendation to use, e.g. R 76:1992 [25] and/or R 76:2006 [26],
- the level of type approval control to apply – what is the national responsible body willing to 'delegate' to others, and
- which OIML-CS Certificates and/or reports to accept:
- Scheme A (issued on the basis of accreditation or peer assessment)
- Scheme B (issued on the basis of self-declaration, although in some instances the OIML IA and/or TL may have accreditation or peer assessment)
- OIML Certificates and OIML type evaluation reports issued on the basis of manufacturer test results

If OIML-CS Certificates and/or OIML type evaluation reports are to be accepted as the basis for issuing a national (or regional) type approval it is important to ensure that the OIML-CS Certificate and/or report that is presented actually applies to instrument submitted. In addition, the national issuing authority will need to consider how to address modifications to such an instrument. Participating in the OIML-CS as a Utilizer (OIML Member State) or Associate (Corresponding Member) allows a system of type approval controls to be established in a country or economy without the need to invest in expensive testing and type evaluation capabilities. OIML Certificates and/or OIML type evaluation reports can be utilized in the knowledge that the competence of the OIML IA and TL, in accordance with international standards, has been established.

14. REFERENCES

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

[2] ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

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

[4] OIML D 32:2018 *Guide for the application of ISO/IEC 17065 to the assessment of measuring instrument certification bodies in legal metrology*

[5] OIML D 30:2008 *Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology*

[6] ISO/IEC 17000:2004 *Conformity assessment – Vocabulary and general principles*

[7] OIML B 15:2011 *OIML Strategy*

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

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

[10] OIML B 18:2018 *Framework for the OIML Certification System (OIML-CS)*

[11] ISO/IEC 17067:2013 *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*

[12] OD-01 *OIML-CS Operational Document OD-01 Management Committee*

[13] OD-02 *OIML-CS Operational Document OD-02 Test Laboratories Forum*

[14] PD-01 *OIML-CS Procedural Document PD-01: Appeals, Resolution of Complaints and Disputes*

[15] PD-02 *OIML-CS Procedural Document PD-02: Approval of Legal Metrology Experts and Management System Experts*

[16] PD-03 *OIML-CS Procedural Document PD-03: Application and approval of OIML Issuing Authorities, Utilizers and Associates*

[17] PD-04 *OIML-CS Procedural Document PD-04: Assessment of Test Laboratories*

[18] PD-05 *OIML-CS Procedural Document PD-05: Processing an application for an OIML Type Evaluation Report and OIML Certificate*

[19] PD-06 *OIML-CS Procedural Document PD-06: Use of OIML Type Evaluation Reports and OIML Certificates*

[20] PD-07 *OIML-CS Procedural Document PD-07: Transition Arrangements under the OIML-CS*

[21] PD-08 *OIML-CS Procedural Document PD-08: Signing the OIML-CS Declaration*

[22] Joint ILAC-OIML *Assessment Procedure in the field of legal metrology (February 2018)*

[23] Draft (Ver. 1.7 – 20181022) *Joint IAF-OIML Assessment Procedure in the field of legal metrology*

[24] OIML D 1:2012 *Considerations for a Law on Metrology*

[25] OIML R 76:1992 *Non-automatic weighing instruments*

[26] OIML R 76:2006 *Non-automatic weighing instruments*

[27] OIML D 19:1988 *Pattern evaluation and pattern approval*

[28] Complying with ISO 17025 *A practical guidebook for meeting the requirements of laboratory accreditation schemes based on ISO 17025:2005 or equivalent national standards*

[29] ISO 9001:2015 *Quality management systems - Requirements*

ANNEX 1 SCOPE OF OIML-CS (FROM 1 JANUARY 2018)

Measuring Instrument Category	Recommendation	Entry to OIML-CS on 1 January 2018	
		Scheme A	Scheme B
Taximeters	R 21		✓
Active Electrical Energy Meters	R 46		✓
Water Meters	R 49		✓
Continuous Totalisers	R 50		✓
Automatic Catchweighers	R 51		✓
Load cells	R 60	✓	
Automatic Gravimetric Filing Instruments	R 61		✓
Heat Meters	R 75		✓
Non-automatic Weighing Instruments	R 76	✓	
Level Gauges for Stationary Storage Tanks	R 85		✓
Vehicle Exhaust Emissions	R 99		✓
Automatic Rail-weighbridges	R 106		✓
Discontinuous Totalisers	R 107		✓
Liquids other than Water	R 117		✓
Multi-dimensional Measuring Instruments	R 129		✓
Weighing Road Vehicles in Motion	R 134		✓
Gas Meters	R 137		✓
Compressed Gaseous Fuel systems for Vehicles	R 139		✓

ANNEX 2 SCOPE OF OIML-CS (FROM 1 JANUARY 2019) AND TRANSITION DATES

Measuring Instrument Category	Scheme and Transition Date					
	1/1/18	1/1/19	1/7/19	1/1/20	1/7/20	1/1/21
R 60 Load Cells	A	A	A	A	A	A
R 76 Non-Automatic Weighing Instruments	A	A	A	A	A	A
R 49 Water Meters	B	A	A	A	A	A
R 51 Automatic catchweighers	B	B	A	A	A	A
R 117 Liquids other than water	B	B	A	A	A	A
R 46 Active electrical energy meters	B	B	B	A	A	A
R 137 Gas meters	B	B	B	A	A	A
R 61 Automatic gravimetric filling instruments	B	B	B	B	A	A
R 85 Level gauges for stationary storage tanks	B	B	B	B	A	A
R 129 Multi-dimensional measuring instruments	B	B	B	B	A	A
R 21 Taximeters	B	B	B	B	B	A
R 50 Continuous totalizers	B	B	B	B	B	A
R 75 Heat meters	B	B	B	B	B	A
R 99 Vehicle exhaust emissions	B	B	B	B	B	A
R 106 Automatic rail-weighbridges	B	B	B	B	B	A
R 107 Discontinuous totalizers	B	B	B	B	B	A
R 126 Evidential breath analyzers	B	B	B	B	B	A
R 134 Weighing road vehicles in motion	B	B	B	B	B	A
R 139 Compressed gaseous fuel systems for vehicles	B	B	B	B	B	A
R 16 Sphygmomanometer	B	B	B	B	B	A
R 35 Material Measures of Length	B	B	B	B	B	A
R 58 Sound Level Meters	B	B	B	B	B	A
R 59 Moisture meters for cereal grains and oilseeds	B	B	B	B	B	A
R 81 Cryogenic Liquids	B	B	B	B	B	A
R 88 Integrating-averaging Sound Level Meters	B	B	B	B	B	A
R 93 Focimeters	B	B	B	B	B	A
R 102 Sound Calibrators	B	B	B	B	B	A
R 104 Pure-tone Audiometers	B	B	B	B	B	A
R 110 Pressure Balances	B	B	B	B	B	A
R 122 Speech Audiometry	B	B	B	B	B	A
R 128 Ergometers for foot crank work	B	B	B	B	B	A
R 133 Liquid-in-glass thermometers	B	B	B	B	B	A
R 136 Areas of Leather	B	B	B	B	B	A
R 143 Continuous measurement of SO_2 in stationary source emissions	B	B	B	B	B	A
R 144 Continuous measurement of CO, NOx in stationary source emissions	B	B	B	B	B	A
R 145 Ophthalmic instruments - Impression and applanation tonometers	B	B	B	B	B	A
R 146 Protein measuring instruments for cereal grains and oilseeds	B	B	B	B	B	A

ANNEX 3: GUIDANCE ON COMPLETING THE OIML IA APPLICATION FORM.

Section 1 The organization (certification body) applying to be an OIML IA is located in this OIML Member State.

Section 2 This is the name of the organization (certification body) applying to be an OIML IA.

Section 3 Used to indicate whether this is an application for a new OIML IA, or whether it is a modification/extension to the scope of an existing OIML IA that has already been approved under the OIML-CS.

Section 4 The contact details of the organization (certification body) applying to be an OIML IA should be included here. The contact person will be the main point of contact for issues associated with participation in the OIML-CS.

Section 5 Used to identify the scope that the organization is applying for in terms of the instrument categories and the applicable Scheme(s). Any restrictions on the scope for each instrument category should be identified, e.g. only mechanical water meters under OIML R 49 instruments. For a modification/extension to scope only the additional or amended instrument categories need to be detailed.

Section 6 This section is used to identify how competency of the OIML IA is being demonstrated, i.e. accreditation, peer assessment or self-declaration. Information regarding the supporting evidence shall be detailed in the box provided, including references to any applicable certificate and/or report numbers.

Section 7 An application to be an OIML IA must be supported by one or more applications for a TL. Each TL should be listed in this section and a corresponding application shall be submitted. For a modification/extension to scope, only the new TL(s), or the TL(s) where the scope is changing, needs to be listed.

Section 8 This checklist should be used to identify the supporting documentation that will be provided with the application.

Section 9 The responsible person within the OIML IA should sign this section of the form. The responsible person is the person who will sign the Declaration.

Section 10 The application form must be signed by the CIML Member of the country in which the OIML IA is located.

ANNEX 4: GUIDANCE ON COMPLETING THE TL APPLICATION FORM

Section 1 The organization (TL) is located in this OIML Member State.

Section 2 This is the name of the organization (TL) applying to be an OIML IA.

Section 3 This is the name of the OIML IA that the TL application is supporting.

Section 4 Used to indicate whether this is an application for a new TL, or whether it is a modification/extension to the scope of an existing TL that has already been approved under the OIML-CS.

Section 5 The contact details of the organization (test laboratory) applying to be a TL should be included here. The contact person will be the main point of contact for issues associated with participation in the OIML-CS.

Section 6 Used to identify the scope that the organization is applying for in terms of the instrument categories and the applicable Scheme(s). Any restrictions on the scope for each instrument category should be identified, e.g. mechanical water meters under OIML R 49 instruments. For a modification/extension to scope only the additional or amended instrument categories need to be detailed.

Section 7 This section is used to identify how competency of the TL is being demonstrated, i.e. accreditation, peer assessment or self-declaration. Information regarding the supporting evidence should be detailed in the box provided, including references to any applicable certificate and/or report numbers.

Section 8 This checklist should be used to identify the supporting documentation that will be provided with the application.

Section 9 The responsible person within the TL should sign this section of the form.

Section 10 The application form must be signed by the responsible person in the OIML IA.

ANNEX 5: GUIDANCE ON COMPLETING THE UTILIZER APPLICATION FORM

Section 1 The organization (national issuing authority or national responsible body) applying to be a Utilizer is located in this OIML Member State.

Section 2 This is the name of the organization (national issuing authority or national responsible body) applying to be a Utilizer.

Section 3 Used to indicate whether this is an application for a new Utilizer, or whether it is a modification/extension to the scope of an existing Utilizer under the OIML-CS.

Section 4 The contact details of the organization (national issuing authority or national responsible body) applying to be a Utilizer should be included here. The contact person will be the main point of contact for issues associated with participation in the OIML-CS.

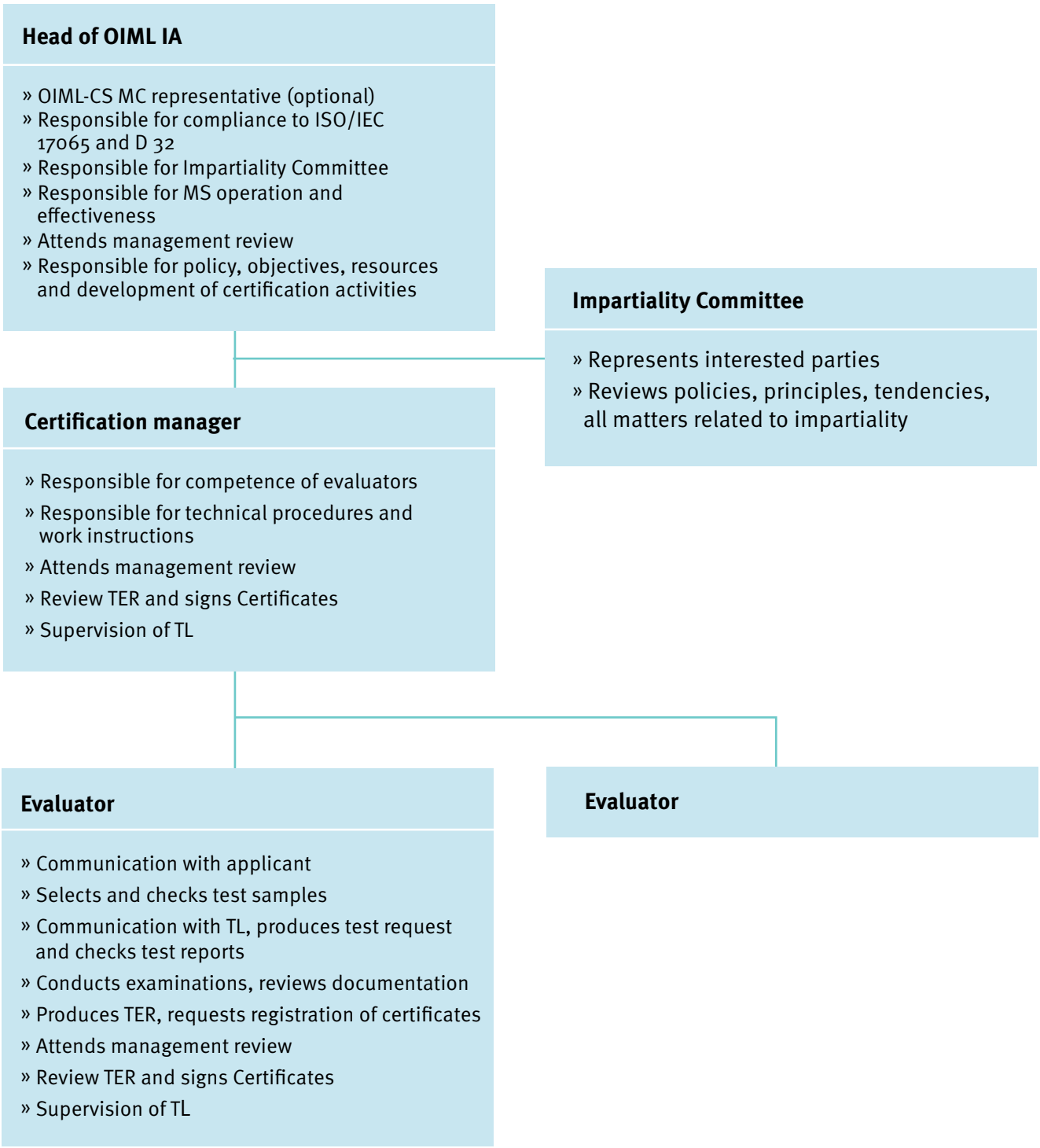
Section 5 Used to identify the scope that is applying for in terms of the measuring instrument categories and the applicable Scheme(s) that will be accepted. Options include Scheme A only, Scheme B only or Scheme A and Scheme B. An option is also included to indicate acceptance of existing MAA certificates. Any conditions on the acceptance of OIML Certificates and/or OIML type evaluation reports shall be described in this section. An example of a condition is manufacturer test results will not be accepted.

Section 6 This section is used to identify any additional national requirements (ANRs). These are requirements that are different, or in addition to the requirements in the relevant OIML Recommendation. Examples may include additional/different accuracy classes, specific marking/labelling requirements. Information regarding the ANRs should be referenced in the table and supporting documents provided.

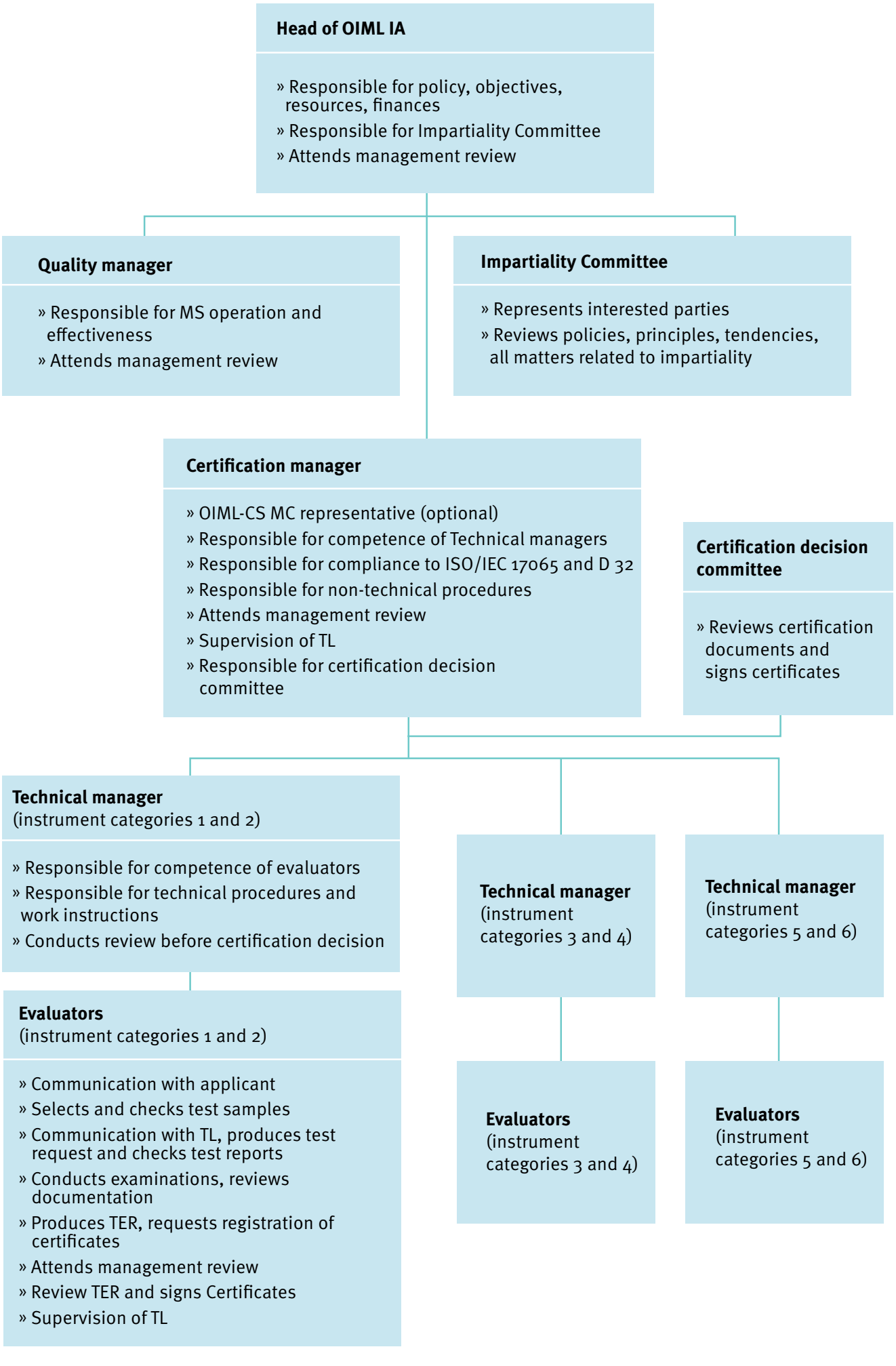
Section 7 The responsible person within the Utilizer should sign this section of the form. The responsible person is the person who will sign the Declaration.

Section 8 The application form must be signed by the CIML Member as completing the process (signing the Declaration) is committing an organization (national issuing authority or national responsible body) in the country to accept and utilize OIML Certificates and/or OIML type evaluation reports as the basis for issuing a national or regional type approval.

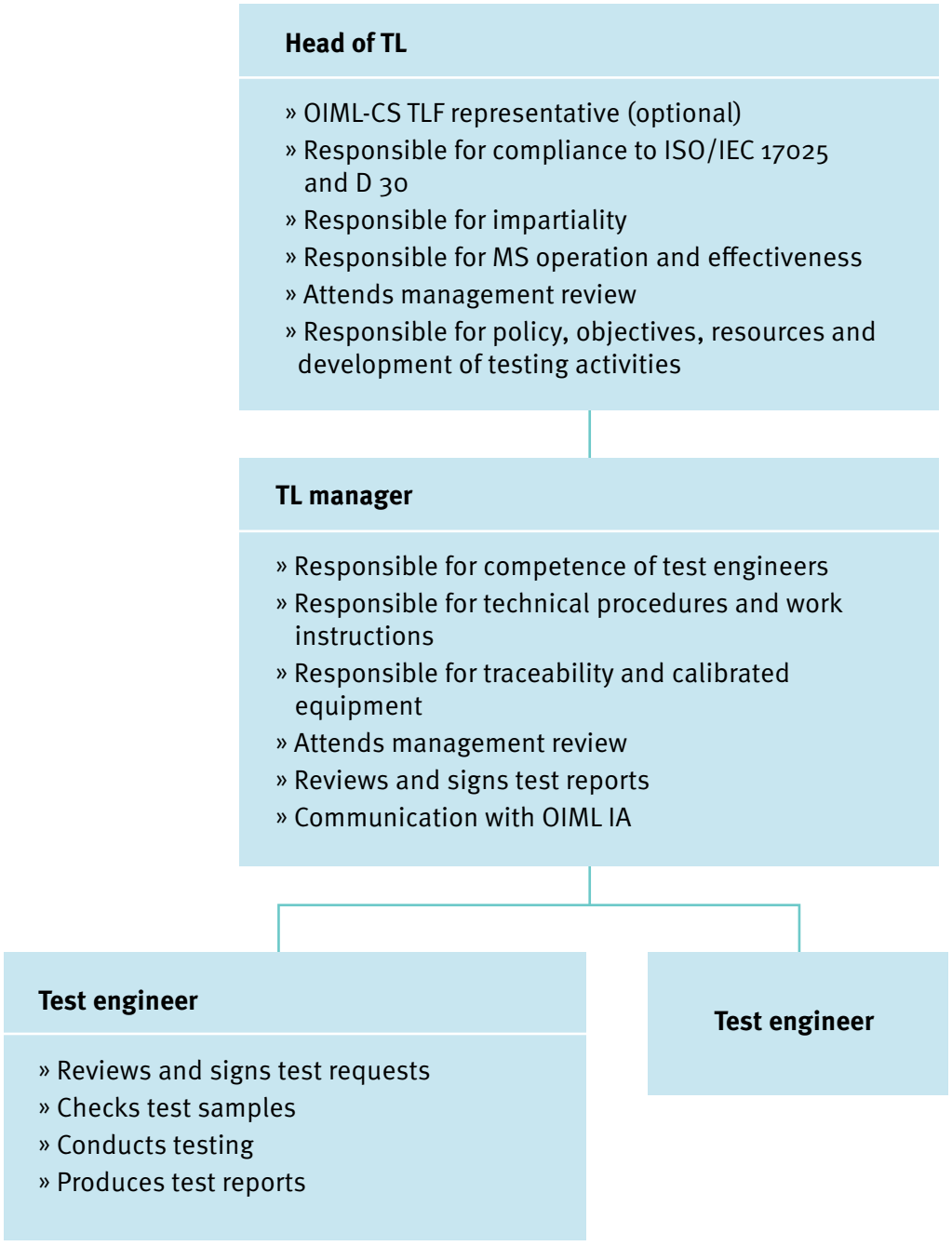
ANNEX 6: TYPICAL STRUCTURE OIML IA (SMALL ORGANISATION)



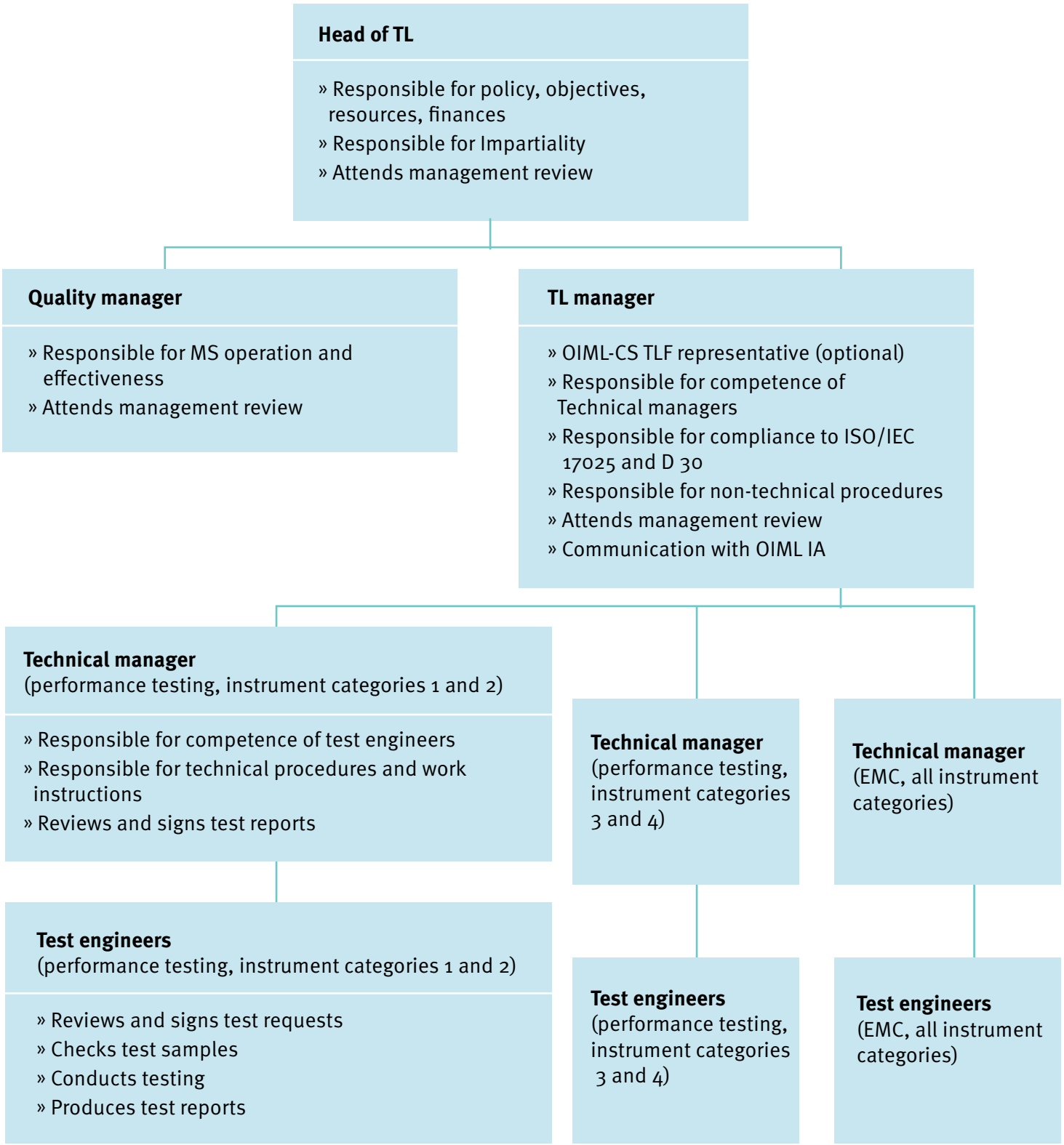
ANNEX 7: TYPICAL STRUCTURE OIML IA (LARGE ORGANISATION)



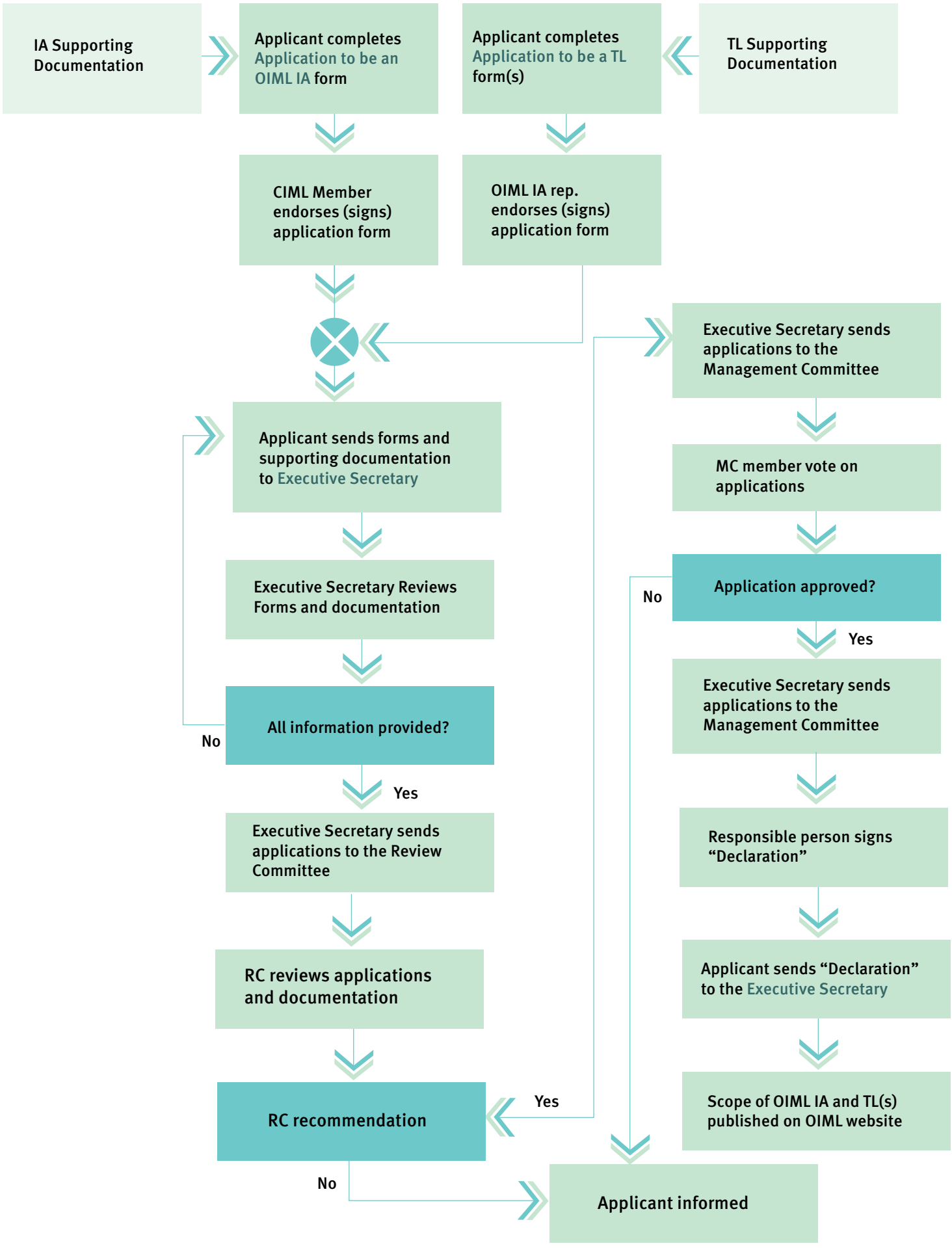
ANNEX 8: TYPICAL STRUCTURE TEST LABORATORY (SMALL ORGANISATION)



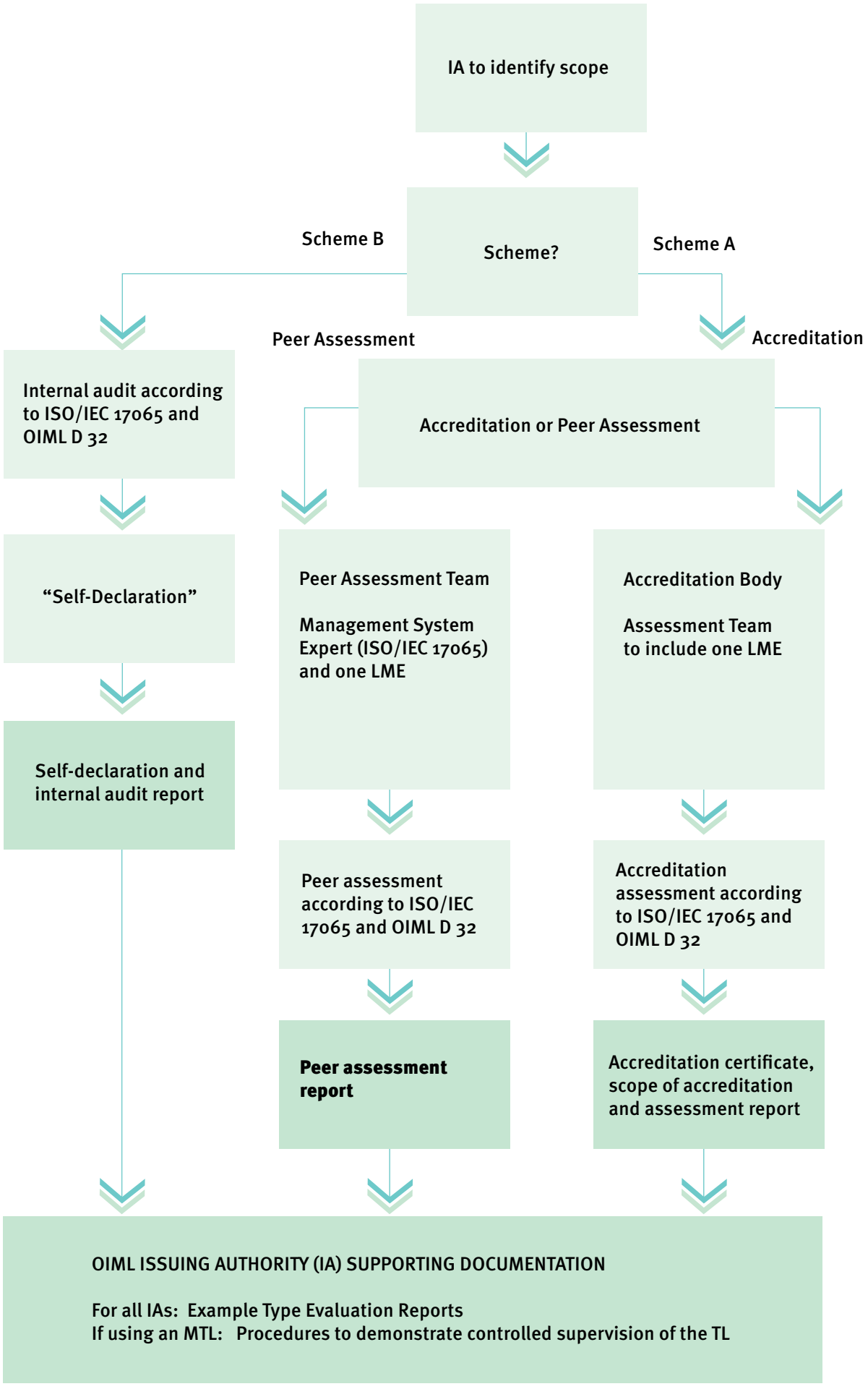
ANNEX 9: TYPICAL STRUCTURE TEST LABORATORY (LARGE ORGANISATION)



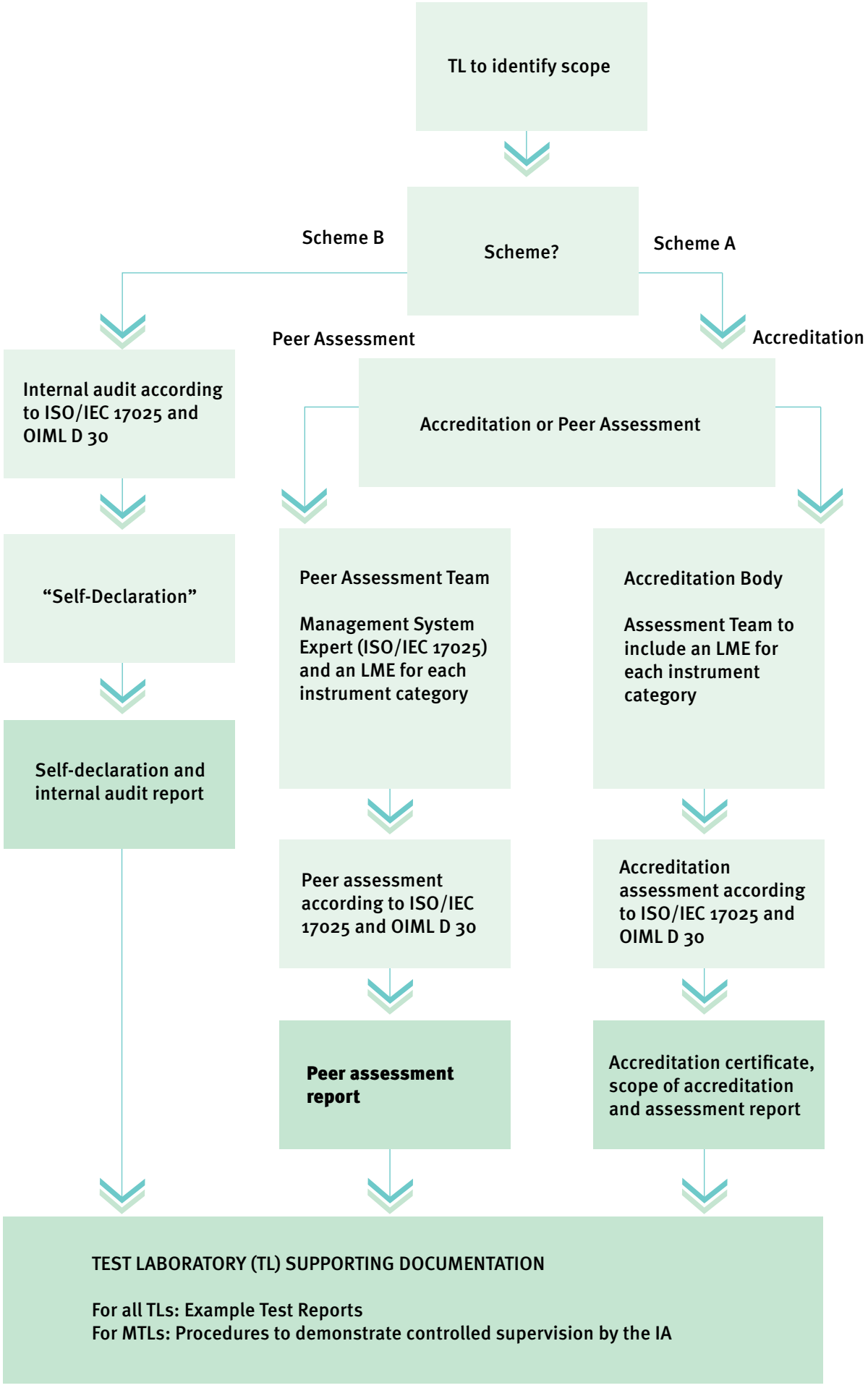
FLOWCHART 1 - PROCESS TO BECOME AN OIML ISSUING AUTHORITY AND TEST LABORATORY



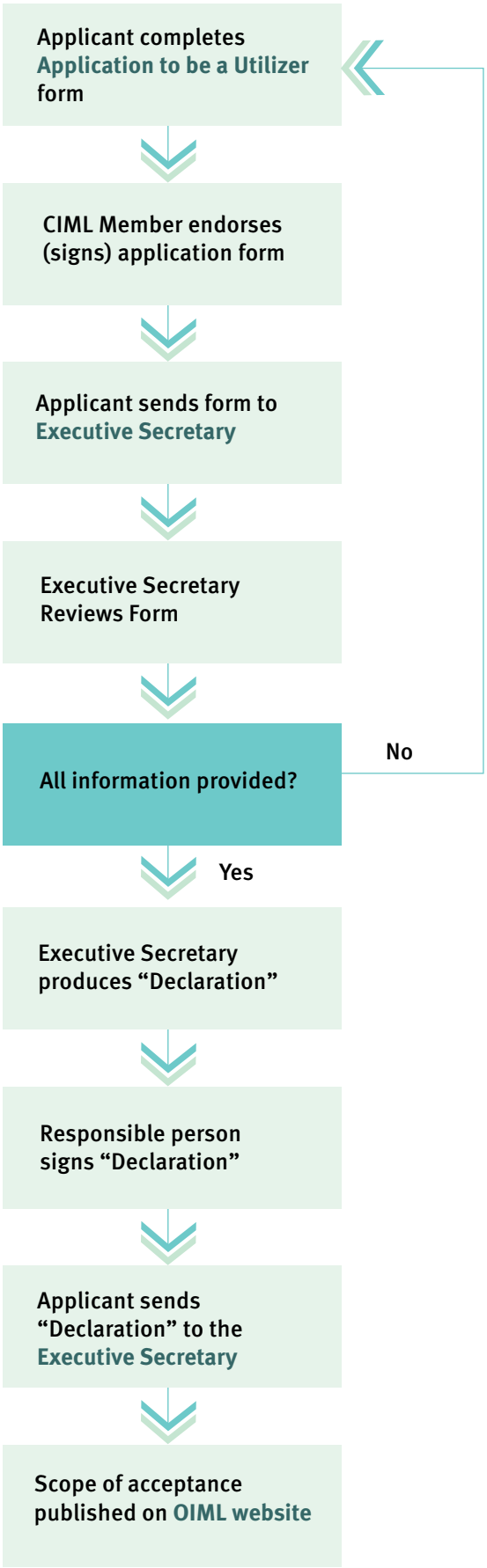
FLOWCHART 2 - OIML ISSUING AUTHORITY SUPPORTING DOCUMENTATION



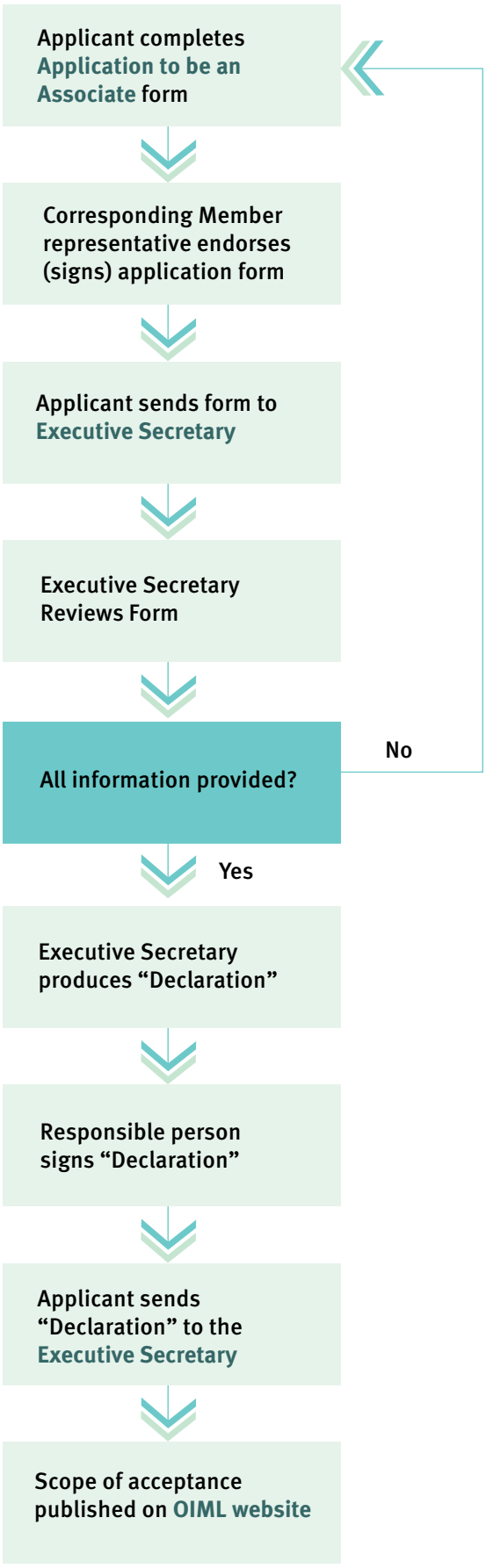
FLOWCHART 3 – TEST LABORATORY SUPPORTING DOCUMENTATION



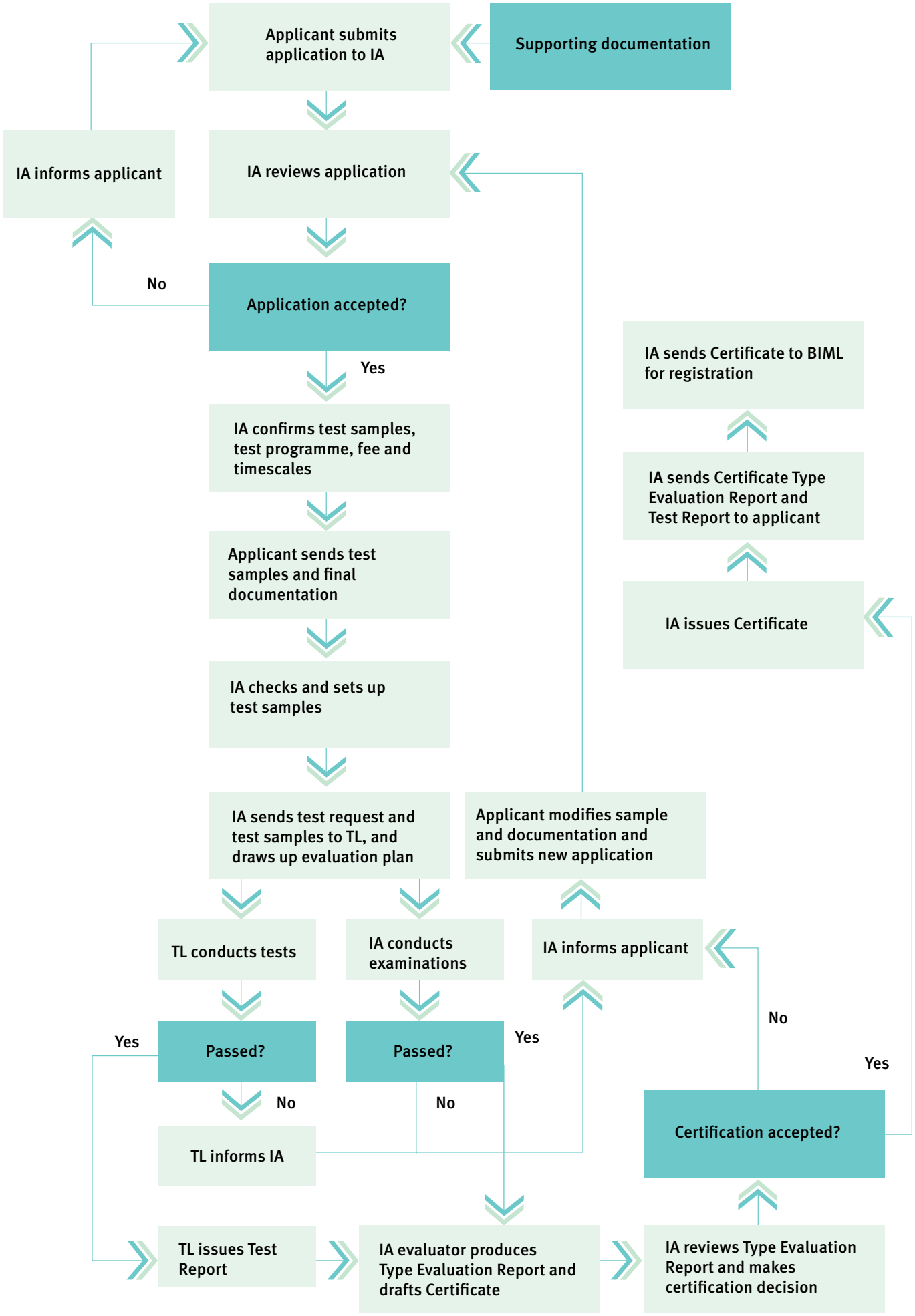
FLOWCHART 4 - PROCESS TO BECOME A UTILIZER



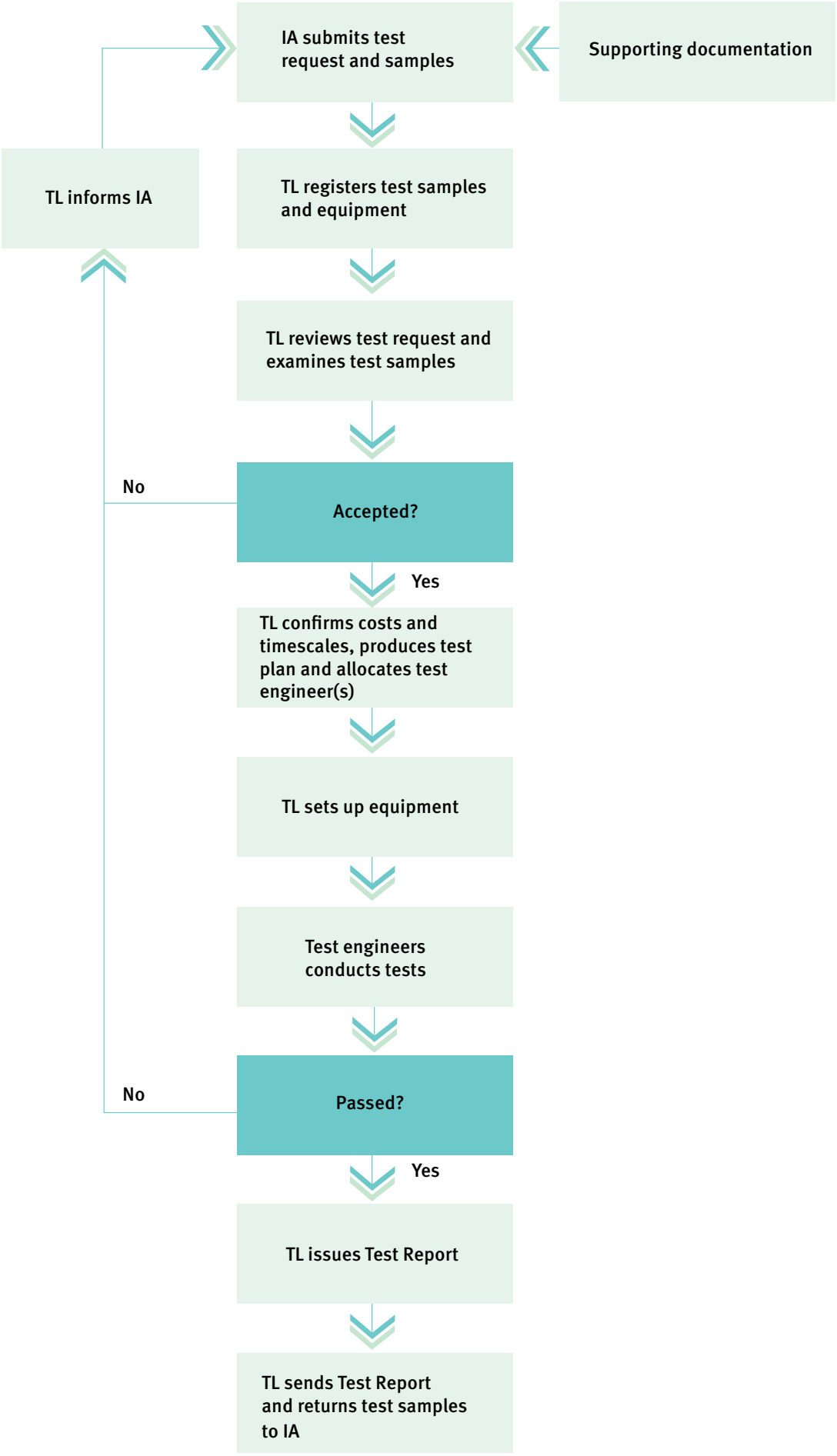
FLOWCHART 5 - PROCESS TO BECOME AN ASSOCIATE



FLOWCHART 6 - TYPE EVALUATION AND TYPE APPROVAL PROCESS



FLOWCHART 7 - TESTING PROCESS



CHECKLIST 1 - OIML ISSUING AUTHORITY SUPPORTING DOCUMENTATION (SCHEME A)

Document/Information	Yes / No / Not Applicable
Information about the assessment of competency (either accreditation or peer assessment). ***Section 6 of the TL application form.***	
Designation and contact details of the potential OIML Issuing Authority **Sections 2 and 4 of the TL application form.**	
Scope of the OIML Issuing Authority applicant, including the category(ies) of measuring instrument and the relevant OIML Recommendation(s) and the Scheme(s) ***Section 5 of the TL application form.***	
A list of all Test Laboratories indicating, for each one, which tests and examinations of the relevant OIML Recommendation(s) it performs ***Section 7 of the TL application form.***	
Where relevant, the procedures between the OIML Issuing Authority applicant and any Manufacturer Test Laboratory (MTL) to manage the controlled supervision	
In the case of accreditation, the certificate(s) of accreditation of the OIML Issuing Authority applicant and the most recent accreditation assessment report(s) which includes the relevant scope and enough information that an assessment of the legal metrology aspects of the accreditation can be determined, if accreditation applies	
In the case of peer assessment, a copy of the peer assessment report of the OIML Issuing Authority	
A copy of the most recent OIML type evaluation report issued for each of the considered categories in the event that the OIML Issuing Authority applicant is already an OIML Issuing Authority under Scheme B or they were previously an Issuing Authority or Issuing Participant under the OIML Basic or OIML MAA Certificate Systems respectively	
The most recent internal audit of the OIML Issuing Authority applicant	

CHECKLIST 2 - OIML ISSUING AUTHORITY SUPPORTING DOCUMENTATION (SCHEME B)

Document/Information	Yes / No / Not Applicable
Information about the assessment of competency (on the basis of "self-declaration") **Section 6 of the TL application form.**	
Designation and contact details of the OIML Issuing Authority applicant ***Sections 2 and 4 of the TL application form.***	
A list of all Test Laboratories indicating, for each one, which tests and examinations of the relevant OIML Recommendation and of additional national requirements included in the scope, if applicable, it performs ***Section 7 of the TL application form.***	
Evidence to support the "self-declaration", e.g. internal assessment reports	
A copy of the most recent OIML type evaluation report issued for each of the considered categories in the event that the OIML Issuing Authority applicant is already an Issuing Authority under the OIML Basic System or an Issuing Participant under OIML MAA Certificate System, or a template showing the proposed format of the OIML type evaluation format where the OIML Issuing Authority applicant was not previously an Issuing Authority under the OIML Basic System or an Issuing Participant under OIML MAA Certificate System.	

CHECKLIST 3 – TEST LABORATORY SUPPORTING DOCUMENTATION (SCHEME A)

Document/Information	Yes / No / Not Applicable
Information about the assessment of competency (either accreditation or peer assessment) ***Section 7 of the TL application form.***	
Designation and contact details of the Testing Laboratory and whether it is an internal Test Laboratory, a third-party Test Laboratory or an MTL. ***Sections 2 and 5 of the TL application form.***	
A list of the tests and examinations of the relevant OIML Recommendation it performs ***Section 6 of the TL application form.***	
Information about its type testing capabilities *Annexes to the TL application form.*	
In the case of an MTL: the procedures between the OIML Issuing Authority and the MTL to manage the controlled supervision	
In the case of accreditation, the certificate of accreditation and the scope of accreditation of the Test Laboratory and the most recent accreditation assessment report which includes the relevant scope of the OIML-CS Declaration and enough information that an assessment of the legal metrology aspects of the accreditation can be determined, if accreditation applies	
In the case of peer assessment, a copy of the peer assessment report covering the relevant scope of the Test Laboratory	
The most recent internal audit of the Test Laboratory (whether it is accredited or not) conducted on the basis of ISO/IEC 17025 and OIML D 30 for the relevant scope	
The results of intercomparisons conducted in the relevant field, if any	
A copy of the most recent OIML test report issued for each of the considered categories	

CHECKLIST 4 – TEST LABORATORY SUPPORTING DOCUMENTATION (SCHEME B)

Document/Information	Yes / No / Not Applicable
Information about the assessment of competency (on the basis of "self-declaration"). ***Section 7 of the TL application form.***	
Designation and contact details of the Test Laboratory and whether it is an internal Test Laboratory, a third-party Test Laboratory or a Manufacturer Test Laboratory (MTL). ***Sections 2 and 5 of the TL application form.***	
A definition of the capability of the Test Laboratory in terms of the tests and examinations of the relevant OIML Recommendation(s) and of additional national requirements included in the OIML-CS Declaration, if applicable, it performs. ***Section 6 of the TL application form.***	
Information about its type testing capabilities, e.g. flow range, temperature range, etc. ***Annexes to the TL application form.***	
Evidence to support the "self-declaration", e.g. internal assessment reports on the basis of ISO/IEC 17025 and OIML D 30 for the relevant scope.	

CHECKLIST 5 - TYPE EVALUATION AND TYPE APPROVAL

	Process	Date completed	Completed by
1	Application and supporting documentation received		
2	Application and supporting documentation reviewed		
3	Application accepted/refused confirmed in writing		
4	Information on the OIML-CS rules provided		
5	Test samples, test and examination programme confirmed		
6	Testing costs confirmed by the TL		
7	Overall costs and timescales confirmed in writing		
8	Test samples received, identified/registered and checked		
9	Complete documentation received and checked		
10	Test samples selected		
11	Test samples set up		
12	Test request produced and sent to the TL		
13	Evaluation plan produced		
14	Examinations conducted		
15	TER produced		
16	Test Report(s) checked		
17	Draft certificate produced and sent for comments		
18	Draft certificate agreed		
19	Documentation file/folder and summary table created		
20	Certificate number booked		
21	Evaluation report produced		
22	Certification decision made and evaluator informed		
23	Applicant informed of certification decision		
24	Test Report, TER and Certificate sent to applicant		
25	Certificate sent to the BIML for registration		
26	Final costs confirmed, invoice raised		
27	Test samples sent back to applicant		

CHECKLIST 6 - TESTING

	Process	Date completed	Completed by
1	Test samples/equipment and test request received		
2	Test samples/equipment identified and registered		
3	Test request reviewed		
4	Test samples/equipment		
5	Test request accepted/refused and confirmation in writing		
6	Test plan produced and test engineer(s) allocated		
7	Costs and timescales confirmed		
8	Test samples and equipment set up		
9	Testing completed		
10	Test Report produced		
11	Test Report checked		
12	Test Report signed		
13	Test Report sent to the OIML IA		
14	Test samples/equipment sent back to the OIML IA		
15	Final costs confirmed		

UNITED NATIONS
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