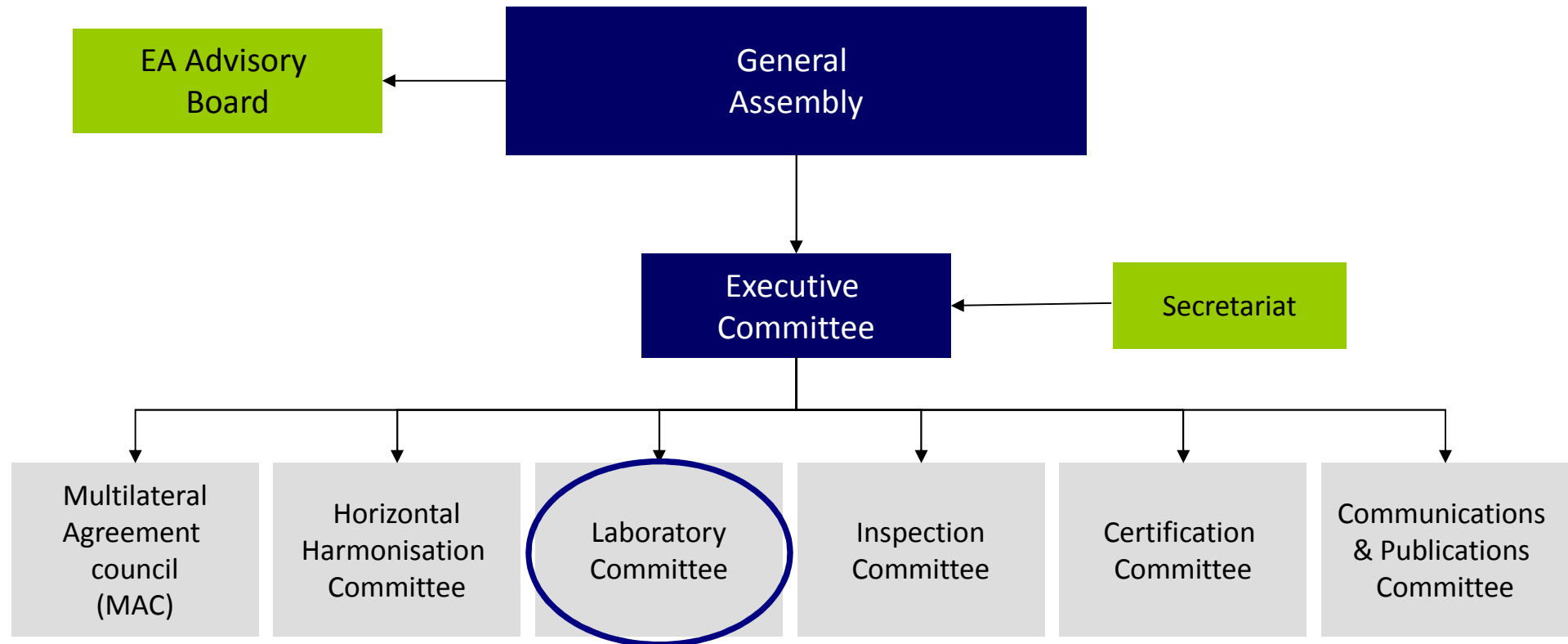


Focus on reliable test results.

Paolo Bianco – EA LC Chair

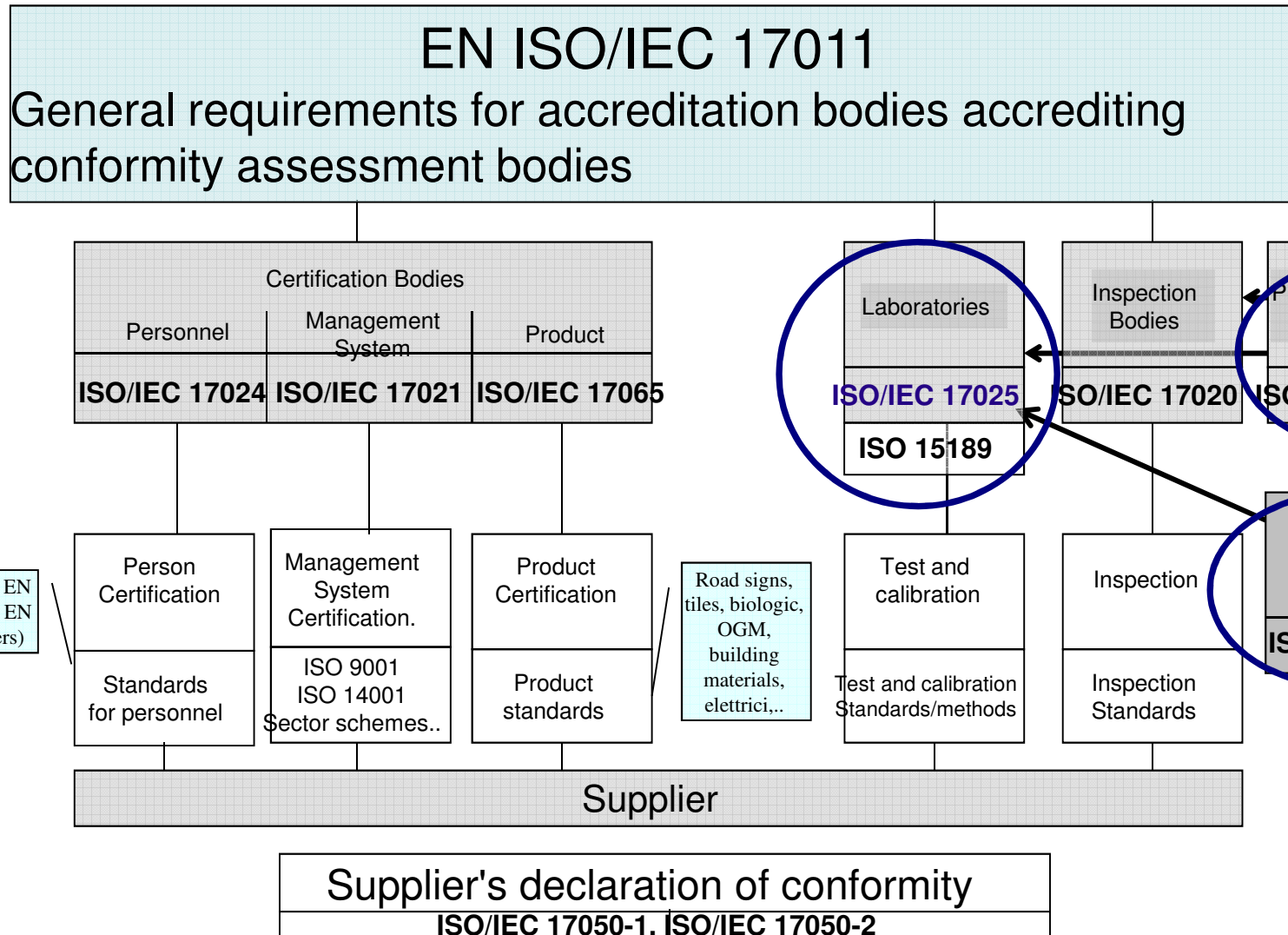
EA Organizational structure



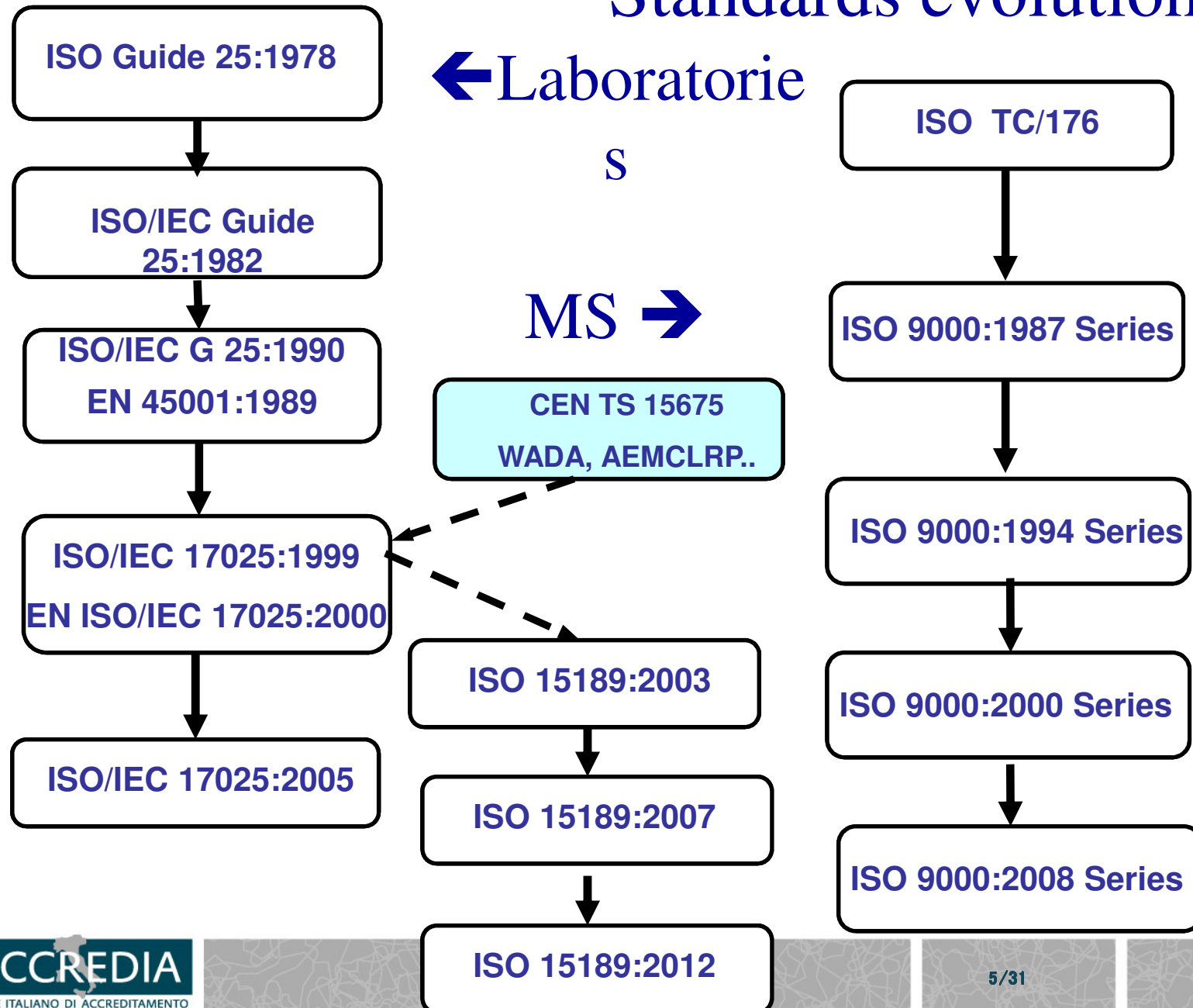
Standards for laboratories

- ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories.
- ISO 15189. Medical laboratories -- Particular requirements for quality and competence.
- ISO 22870. Point-of-care testing (POCT) -- Requirements for quality and competence.
- CEN TS 15675. Air quality. Measurement of stationary source emissions. Application of EN ISO/IEC 17025:2005 to periodic measurements.
- Other Sector standards (WADA, AEMCRLP, Bluetooth, EPA energy saving, etc.)

Conformity evaluation standards

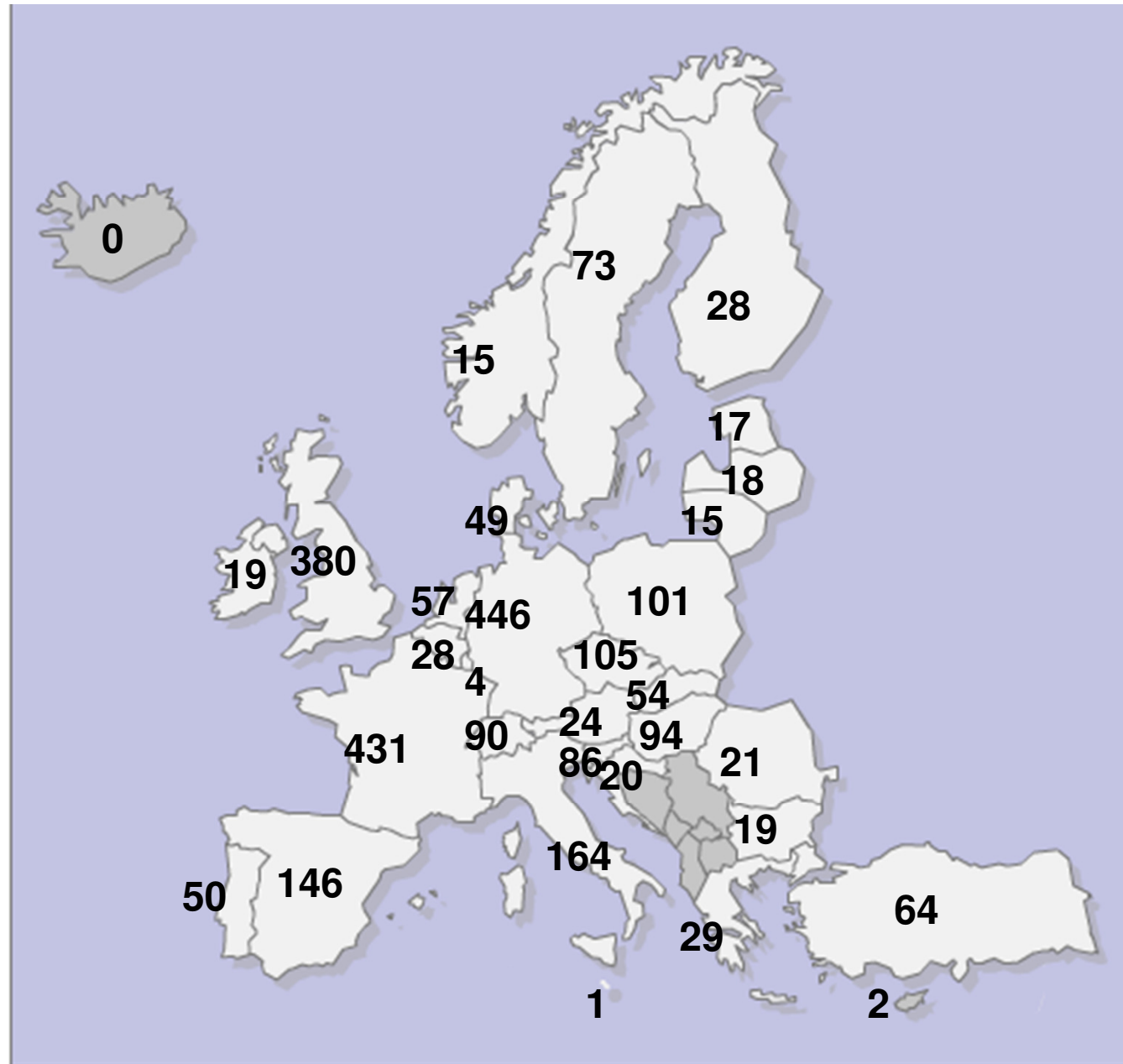


Standards evolution



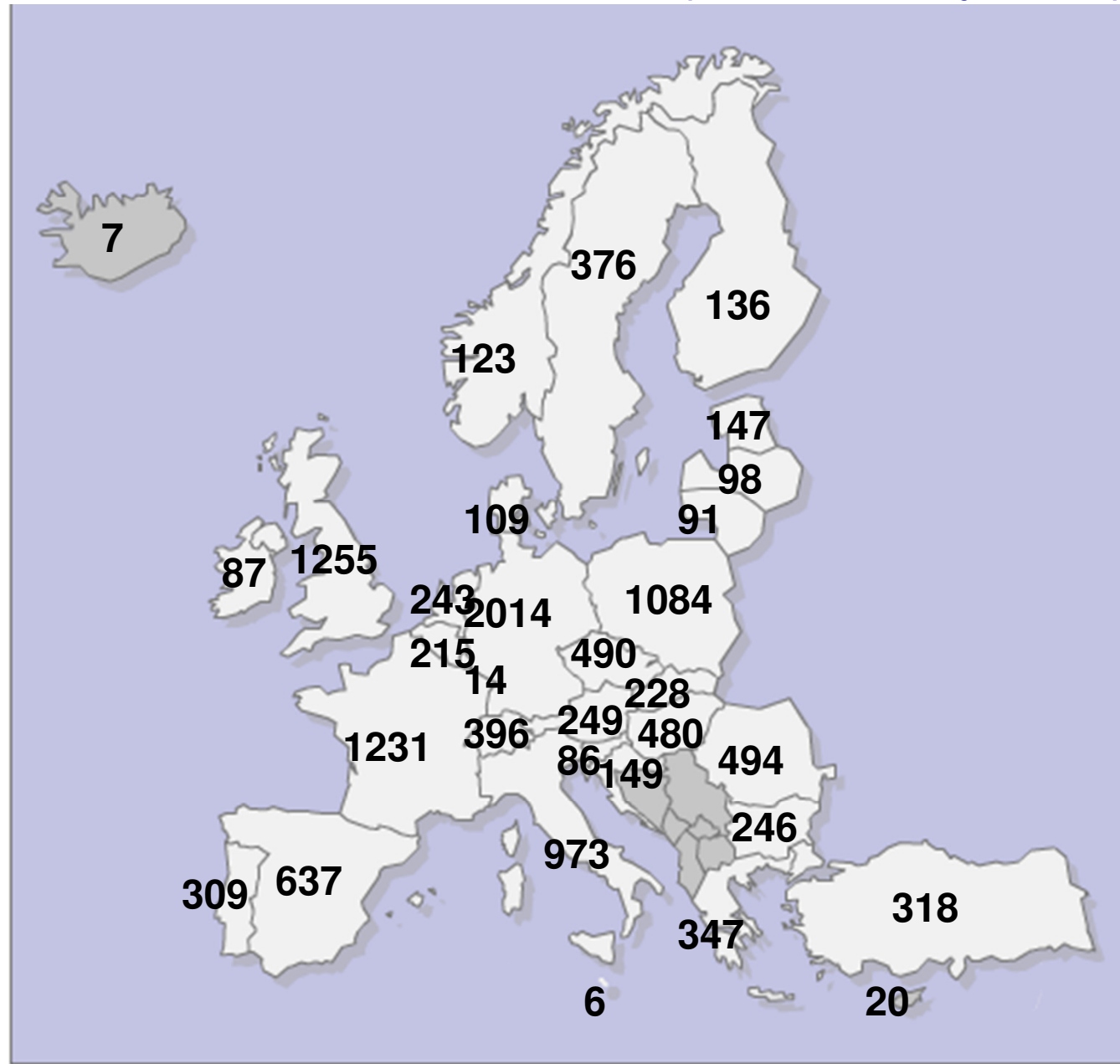
Calibration ISO/IEC 17025: total 2598

- Testing**
- Bmwfj (Austria)
 - Belac (Belgium)
 - Cgcre (Brazil)
 - Bas (Bulgaria)
 - Hkas (China)
 - Cai (Czech Republic)
 - Danak (Denmark)
 - Eak (Estonia)
 - Finas (Finland)
 - Cofrac (France)
 - Dakks (Germany)
 - Esyd (Greece)
 - Nat (Hungary)
 - Inab (Ireland)
 - Israc (Israel)
 - Accredia (Italy)
 - Latak (Latvia)
 - La (Lithuania)
 - Olas (Luxemburg)
 - Nab-malta (Malta)
 - Rva (Netherlands)
 - Ianz (New Zealand)
 - Na (Norway)
 - Pca (Poland)
 - Ipac (Portugal)
 - Haa (Republic of Croatia)
 - Renar (Romania)
 - Sac/spring (Singapore)
 - Snas (Slovakia)
 - Sa (Slovenia)
 - Sanas (South Africa)
 - Enac (Spain)
 - Swedac (Sweden)
 - Sas (Switzerland)
 - Tunac (Tunisia)
 - Turkak (Turkey)
 - Ukas (United Kingdom)



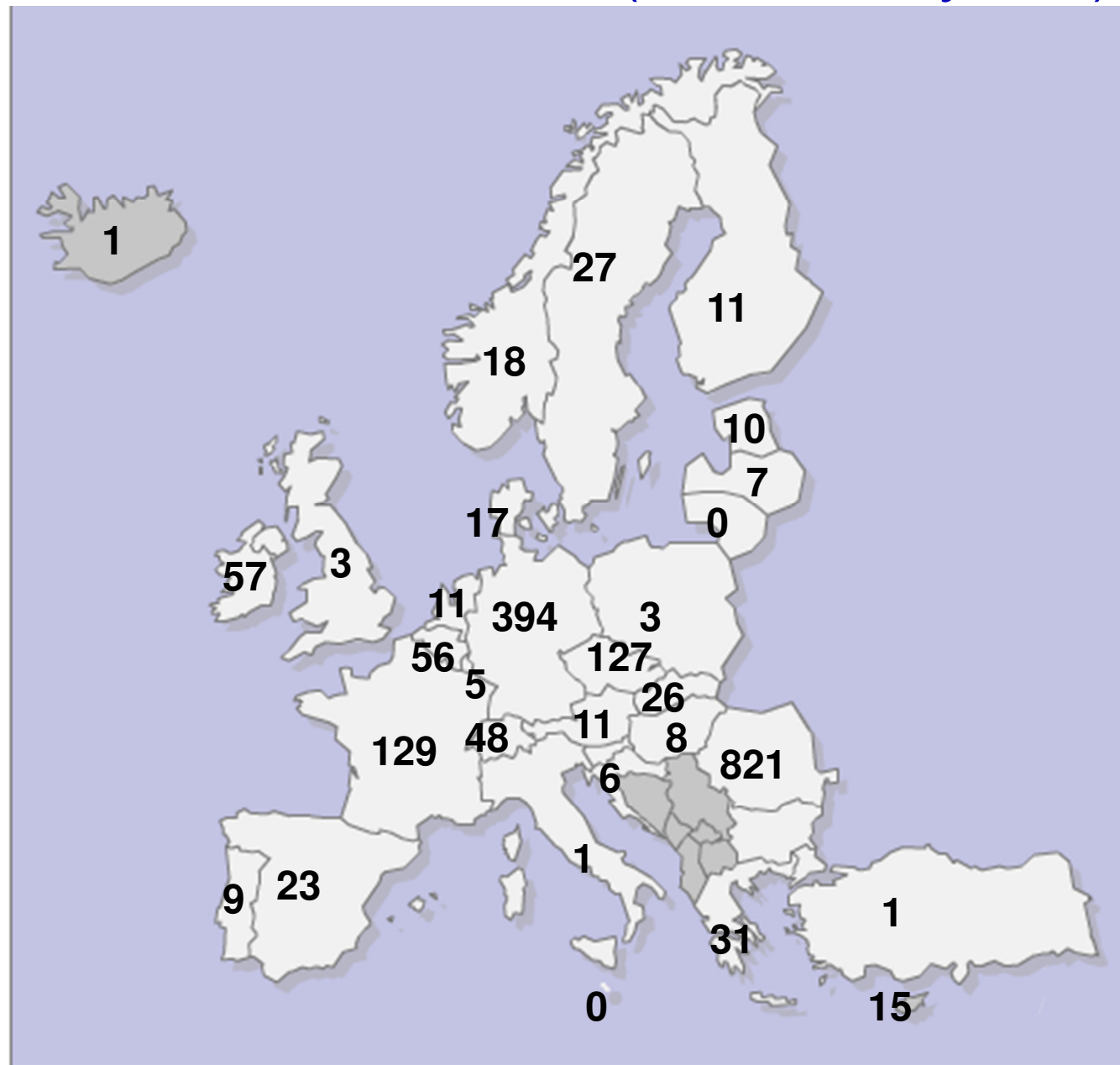
Testing ISO/IEC 17025: total 12833 (+9% in 2 years)

- Bmwfj (Austria)
- Belac (Belgium)
- Cgcre (Brazil)
- Bas (Bulgaria)
- Hkas (China)
- Cai (Czech Republic)
- Danak (Denmark)
- Eak (Estonia)
- Finas (Finland)
- Cofrac (France)
- Dakks (Germany)
- Esyd (Greece)
- Nat (Hungary)
- Inab (Ireland)
- Israc (Israel)
- Accredia (Italy)
- Latak (Latvia)
- La (Lithuania)
- Olas (Luxemburg)
- Nab-malta (Malta)
- Rva (Netherlands)
- Ianz (New Zealand)
- Na (Norway)
- Pca (Poland)
- Ipac (Portugal)
- Haa (Republic of Croatia)
- Renar (Romania)
- Sac/spring (Singapore)
- Snas (Slovakia)
- Sa (Slovenia)
- Sanas (South Africa)
- Enac (Spain)
- Swedac (Sweden)
- Sas (Switzerland)
- Tunac (Tunisia)
- Turkak (Turkey)
- Ukas (United Kingdom)



Medical ISO 15189: total 1871 (+80 % in 2 years)

- Bmwfj (Austria)
- Belac (Belgium)
- Cgcre (Brazil)
- Bas (Bulgaria)
- Hkas (China)
- Cai (Czech Republic)
- Danak (Denmark)
- Eak (Estonia)
- Finas (Finland)
- Cofrac (France)
- Dakks (Germany)
- Esyd (Greece)
- Nat (Hungary)
- Inab (Ireland)
- Israc (Israel)
- Accredia (Italy)
- Latak (Latvia)
- La (Lithuania)
- Olas (Luxemburg)
- Nab-malta (Malta)
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- Haa (Republic of Croatia)
- Renar (Romania)
- Sac/spring (Singapore)
- Snas (Slovakia)
- Sa (Slovenia)
- Sanas (South Africa)
- Enac (Spain)
- Swedac (Sweden)
- Sas (Switzerland)
- Tunac (Tunisia)
- Turkak (Turkey)
- Ukas (United Kingdom)



PTP ISO/IEC 17043 total: 116 (+90% in 3 years)

- Bmwfj (Austria)
- Belac (Belgium)
- Cgcre (Brazil)
- Bas (Bulgaria)
- Hkas (China)
- Cai (Czech Republic)
- Danak (Denmark)
- Eak (Estonia)
- Finas (Finland)
- Cofrac (France)
- Dakks (Germany)
- Esyd (Greece)
- Nat (Hungary)
- Inab (Ireland)
- Israc (Israel)
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- Latak (Latvia)
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- Nab-malta (Malta)
- Rva (Netherlands)
- Ianz (New Zealand)
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- Pca (Poland)
- Ipac (Portugal)
- Haa (Republic of Croatia)
- Renar (Romania)
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- Sa (Slovenia)
- Sanas (South Africa)
- Enac (Spain)
- Swedac (Sweden)
- Sas (Switzerland)
- Tunac (Tunisia)
- Turkak (Turkey)
- Ukas (United Kingdom)



Laboratory Committee Terms of Reference.

- a) to harmonize the implementation of the standard ISO/IEC 17011 with a view to the assessment and accreditation of laboratories against ISO/IEC 17025, ISO 15189, ISO/IEC 17043 and other relevant standards and to elaborate guidance documents where necessary
- b) to discuss and where appropriate to develop a European view on issues to be discussed in ILAC or other international organizations and to make available to LC members documents from ILAC AIC and other relevant ILAC documents

Laboratory Committee Terms of Reference.

- c) to support European Accreditation Bodies in the implementation of decisions taken by ILAC and EA and to coordinate related activities where appropriate;
- d) to cooperate with relevant working parties of related European organizations, especially as far as the implementation of the standards defining technical and organizational competence of laboratories is concerned, in particular the recognised stakeholders and, if appropriate, to approve guidance documents drafted by these organizations as EA advisory documents;

Laboratory Committee Terms of Reference.

- e) to cooperate with the other EA committees on a regular basis;
- f) to cooperate with other regional accreditation co-operations in the field of calibration and testing;
- g) to review the results of interlaboratory comparisons provided by reliable providers in designated fields (WG ILC), in order to:
 - have an overview of the comparability of calibration and test results provided by accredited laboratories;
 - draw the necessary conclusions for the further development of assessment practices;
 - have a general opinion about the efficiency of the MLA in the field of calibration and testing;

Laboratory Committee Terms of Reference.

- h) to advise the General Assembly, the Executive Committee and the other Committees in all matters related to laboratory accreditation;
- i) to perform any other task specified by the EA General Assembly;
- j) to nominate the EA/LC representatives to the PLG and to other joint Working groups with Stakeholders, such as the EEE-PT;
- k) to develop the LC knowledge database by:
 - clarifying status and use of LC results;
 - setting up, maintaining and making available a list of Frequently Asked Questions and responses.

Laboratory Committee Terms of Reference.

LC Meetings

EA/LC will meet when considered necessary by the Chairperson, by the EA General Assembly or by at least one third of its members. EA/LC will, however, meet at least once a year. Generally twice a year.

Management Group

The LC Management Group (MG) prepares the work of the LC. The MG is led by the Chairperson. Members are Vice Chair, convenors of the working groups and the technical networks. The MG meetings are arranged in conjunction with the LC meetings.

WORKING GROUPS

Working Groups are established for well-defined tasks. Terms of Reference will be defined by the LC. They will report to EA/LC at each meeting.

The convenors are nominated by EA/LC. Members of the Working Groups are representatives of Accreditation Bodies and representatives from interested parties, Recognized Stakeholders mainly laboratory organisations. They are invited by their convenors.

The Working Groups will co-ordinate their activities with the activities of Working Groups of other regional accreditation co-operations and ILAC. They will exchange results with these groups whenever possible.

WORKING GROUPS FOR INTERLABORATORY COMPARISONS IN THE FIELD OF CALIBRATION AND TESTING

The aim of Working Groups for ILCs (testing and calibration) activity is to demonstrate the comparability of the results of the accredited laboratories through the participation to international proficiency tests. The EA Members are invited to nominate accredited laboratories to participate to the relevant ILC.

The Working Groups for ILCs (testing and calibration) shall identify the needs for EA initiated comparison on a 5 year rolling plan. The ILC plans shall be presented to the LC for approval annually.

The Working Groups will discuss the outcome of Intercomparisons (ILCs).

These Intercomparisons are mainly provided by EURAMET members for calibration and provided by IRMM and other professional providers for testing.

The Working Group Health Care deals with the application of ISO 15189 and related standards (ISO 22870. Point-of-care testing) to the medical laboratories.

The main issues on the floor are the ISO 15189:2012, the multi-site accreditation and the POCT.

It is now also involved in the European Breast Cancer Project, which is managed by the JRC Ispra.

JOINT WORKING GROUPS

Joint Working Groups (groups working jointly with other organizations) will follow the same rules as Working Groups unless otherwise agreed upon by the organizations concerned. Each Joint Working Group will appoint a representative to be a member of EA/LC.

The EA representatives of EEE-PT members are nominated by the EA/LC for a period of two years. The EA representatives are requested to report about the EEE-PT activity at each LC meetings. The EEE-PT will coordinate its work with the WGs for ILCs.

TECHNICAL NETWORKS

Technical networks (TN) are established by the LC to stimulate discussion and harmonisation in selected technical fields. The TNs operate by suitable electronic means led by a convenor.

The TNs offer the EA ABs an informal platform for discussion and exchange of experience and of technical expertise and assessors.

The members of the TNs are the AB nominated persons actively engaged in the particular field of the TN

The convenor of the TN, preferably a member of the LC, is nominated by the LC for a period of two years. The convenor or co-convenor reports on the activity of the TN at each LC meetings.

The LC evaluates the need for the TN biannually. New TNs are established based on the need and interest of the LC members.

ACTIVE TECHNICAL NETWORKS

TN Calibration (traceability issues, now ILAC P10)

TN Electrical-mechanical (fire testing, material testing)

TN Environment (stack emission, sampling, water frame directive)

TN Food-feed (official control, GMO, residual analysis)

TN Forensic, cooperates with ENFSI (European Network of Forensic Science Institutes) and EWDTS (European Workplace Drug Testing Society)

TASK FORCE GROUPS

The LC, its committees and its technical networks can establish Task Force Groups for a defined task. The chairman or convenor under whose jurisdiction the TFG is established shall propose Terms of Reference for the TFG. The terms of reference shall be approved in the committee/working group. A clear time frame for the task shall be defined. The LC secretary will keep a list of the active TFGs, their tasks and composition. Stakeholder members can be nominated to the TFGs.

TASK FORCE GROUPS

TFG Opinions and Interpretation has been set up in order to harmonize the approach of the accreditation bodies in the accreditation of opinions and interpretation.

TFG accreditation of PTP and RMP in view of the expansion of the EA MLA. (see next slides)

APLAC has already included in its MLA the accreditation of RMP, IAAC is going to do the same.

These activities will be covered under the ILAC MRA in the not too distant future.

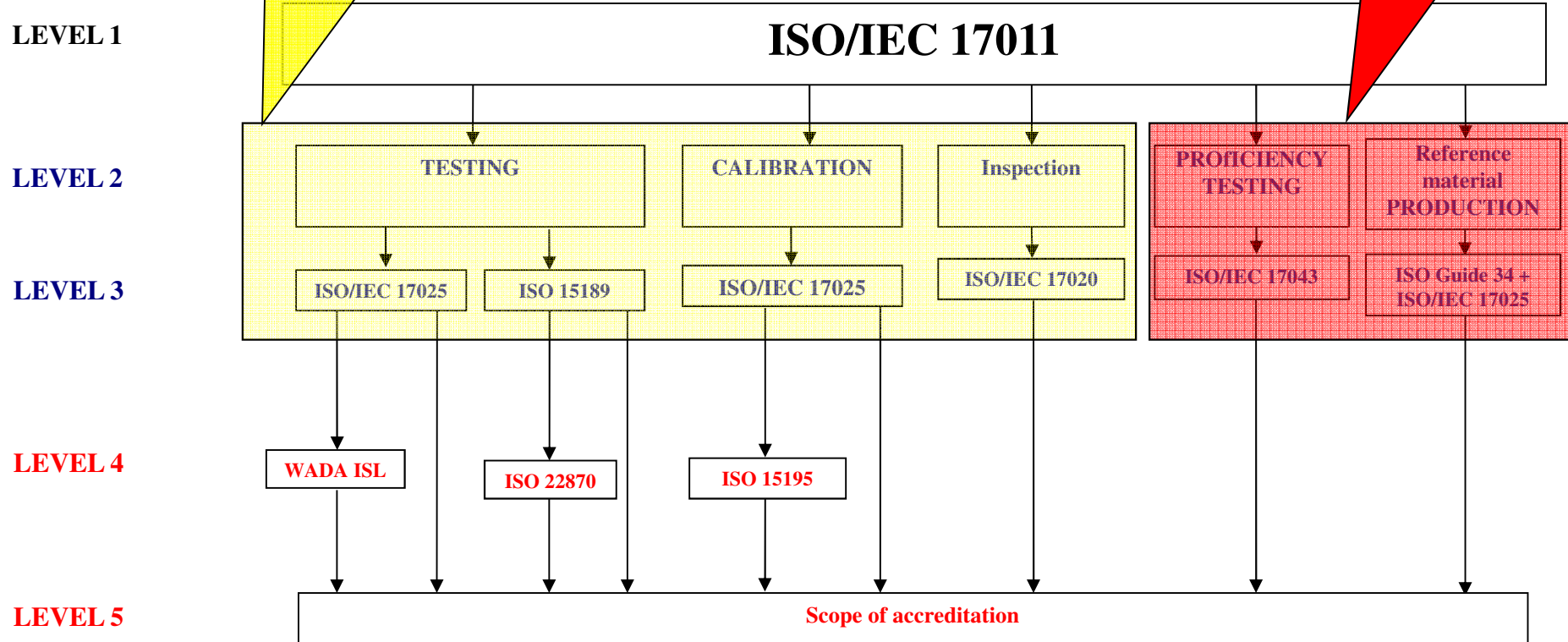
ILAC R6:07/2012 already shows that PTP and RMP accreditation activities are in the ILAC MRA structure.

ILAC R6:07/2012

Annex 1 Structure of the ILAC Arrangement

Activities today under the ILAC MRA

Future expansion of the MRA



PTP Accreditation: ISO/IEC 17043

RMP Accreditation - there are different approaches:

- Accredited as testing
- Accredited as calibration
- Accredited as product certification
- Activity outside the MLA:
 - ISO Guide 34
 - ISO Guide 34 + ISO/IEC 17025

Need for harmonization.

RMP Accreditation.

ILAC Resolution GA 16.20

As ISO Guide 34:2009 includes normative references to ISO/IEC 17025 and ISO 15189, the General Assembly resolves that accreditation of reference material producers is conducted in accordance with ISO Guide 34:2009 alone. In addition ILAC R6:07/2012 will be amended to reflect this decision.

RMP Accreditation.

APLAC has already published in 2010 the APLAC Requirements for and Guidance on Reference Material Producer Assessment and the Resulting Scope of Accreditation – APLAC TC 008.

IAAC has drafted the “IAAC Mandatory and non-mandatory application for the assessment and accreditation of reference material producers”

Possible problems:

- Impartiality: if the AB offers PTs there would be competition with the accredited body, not allowed by ISO/IEC 17011.
- The same if the AB or a related body produces CRMs.

EA LC has established a Task Force Group with the following goals:

- Revision of existing documents (e.g. EA-2/09)
- Definition of harmonized criteria for accreditation of PTP and RMP
- Seminars on ISO/IEC 17043 and ISO Guide 34
- Training of peer evaluators (MAC)

Thank you for your attention

