ACTIVITY 1.3 TRAINING SESSION FOLLOWING THE FINDINGS FROM PREVIOUS ACTIVITIES:

CALIBRATION
PROFICIENCY TESTING AND PROVIDERS

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REFERENCES

- **ISO/IEC 17025:2005** General Requirements for the competence of testing and calibration laboratories
- **ISO/IEC 17011:2004** Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies
- **ISO/IEC 17043:2010,** Conformity assessment – General requirements for proviciency testing
- **ILAC-P9:06/2014**, ILAC Policy for participation in Proficiency Testing activities
- **EA-4/18:2010,** Guidance on the level and frequency of proficiency testing participation
- **APLAC PT 006:09/10,** Proficiency Testing Frequency Benchmarks
- **ILAC-P13:10/2010**, Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers

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TERMINOLOGY (1/3)

PROFICIENCY TESTING (PT) : Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (*ISO/IEC 17043:2010*)

INTER-LABORATORY COMPARISON (ILC) : Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions (*ISO/IEC 17043:2010)*

PROFICIENCY TESTING PROVIDER (PTP) : organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme (ISO/IEC 17043:2010)

PARTICIPANT: laboratory, organization or individual, that receives proficiency test items and submits results for review by the proficiency testing provider NOTE In some cases the participant may be an inspection body (ISO/IEC 17043:2010)

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TERMINOLOGY (2/3)

SUB-DISCIPLINE: Area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related.
… A sub-discipline should generally not contain different technical competences, identified by the need for different qualifications, training, and use of different equipment, knowledge or experience. (EA-4/18:2010)

LEVEL OF PARTICIPATION: Number of sub-disciplines that an organisation identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation *(EA-4/18:2010)*

FREQUENCY OF PARTICIPATION: How often a laboratory determines that it needs to participate in PT for a given sub-discipline, this may vary from sub-discipline to sub-discipline within a laboratory and between laboratories with the same sub-disciplines *(EA-4/18:2010)*

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TERMINOLOGY (3/3)

PROFICIENCY TESTING ROUND: single complete sequence of distributions of proficiency test items, and the evaluation and reporting of results to the partipants (ISO/IEC 17043:2010)

PROFICIENCY TESTING SCHEME: proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection (ISO/IEC 17043:2010)

(i.e. quantitative scheme, qualitative scheme, sequential scheme, simultaneus scheme, continous scheme,….)

PROFICIENCY TEST ITEM: sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing (ISO/IEC 17043:2010)

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ISO/IEC 17025:2005 General Requirements for the competence of testing and calibration laboratories

5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

*The laboratory shall have quality control procedures for **monitoring the validity of tests and calibrations undertaken**…… This **monitoring shall be planned** and **reviewed** and may include, but not be limited to, the following:*

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

*b) **participation in interlaboratory comparison or proficiency-testing programmes**;*

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

Note The selected methods should be appropriate for the type and volume of the work.

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ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies

7.15 PROFICIENCY TESTING AND OTHER COMPARISONS FOR LABORATORIES

*"The **AB shall establish procedures** to take into account, during the assessment and the decision-making process, the **laboratory's participation and performance in proficiency testing**."*

*"The **AB** may **organize proficiency testing** or other comparisons itself, or may **involve another body** judged to be **competent**."*

*"The **AB shall ensure** that its accredited laboratories **participate in proficiency testing** or other comparison programs, where available and appropriate, and that corrective actions are carried out when necessary. The **minimum amount of proficiency testing** and the **frequency of participation** shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.*

NOTE 1 It is recognized that there are particular areas where proficiency testing is impractical."

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ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.1 - ABs … signatory to the ILAC MRA shall **demonstrate the technical competence** of their accredited calibration and testing laboratories ….

One of the elements by which accredited laboratories can demonstrate technical competence is by **satisfactory participation in PT activities** where such activities are available and appropriate.

Technical competence can also be demonstrated by successful participation in interlaboratory comparisons that have been organised for purposes other than PT in its strictest sense. For example:

- to evaluate the performance characteristics of a method;
- to characterise a reference material;
- to compare results of two or more laboratories on their own initiative;
- to support statements of equivalence of measurement of NMIs (CMC).

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ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§4.2 - The minimum PT activity according to a laboratory's scope is:

- evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;
- further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan. (The main elements of a PT participation plan are provided in 4.3 below.)

*Note: ABs should **support the use** of appropriate PT programmes which **meet the essential requirements of ISO/IEC 17043**, where applicable.*

ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.3 - ABs shall have a **policy on the use of PT activities in the assessment and accreditation process**. This policy shall include the following:

- a reference to the importance of PT as a tool to **demonstrate laboratory** and inspection body **competence** (where relevant) and to assist in **maintaining the quality** of the laboratory or inspection body performance;
- requirements regarding the **minimum level and frequency** of participation in PT by accredited laboratories, including the need for a **PT participation plan** which has been formulated by the laboratory or inspection body (where relevant) and is regularly reviewed;
- how PT participation and performance (in particular consistent poor performance), will be reviewed and utilised during the assessment and accreditation decision-making process;
- expectations regarding action by laboratories in response to poor performance in PT, and any requirements for notification of this performance to the AB…

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ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.4

ABs shall fully document their policies and procedures in relation to the use of PT in accreditation.

In particular, they must be able to evaluate, through the accreditation process, that the participation in PT activities of laboratories accredited by them is effective, and that corrective actions are carried out when necessary.

ABs shall also review the PT plans prepared by the laboratory with regard to their suitability in relation to the scope of accreditation.

Where these plans are not considered to be suitable it may be necessary for the accreditation body to provide guidance in identifying the required PT coverage

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ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.5 - ABs may **provide information that can assist laboratories** in identifying and formulating their PT participation needs and plans. Annex C of ISO/IEC 17043 provides useful information to assist ABs in this task.

Assistance may for example include:

- listings or direction to possible sources of PT, and considerations for selecting suitable programs;
- guidance on how to analyse and formulate the particular PT needs of the laboratory.

§ 4.6 - It is recognised that there are areas of testing and calibration for which suitable PT **does not exist** or **is not practical**. In such cases, the AB and the laboratory **shall discuss and agree on suitable alternative means** by which performance can be assessed and monitored. This would need to be considered as part of the planned PT and/or related activities.

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EA-4/18:2010, Guidance on the level and frequency of proficiency testing participation

§3 GENERAL ASPECTS - The following aspects should be taken into consideration by ABs when determining the suitability of a laboratory's "frequency" and "level" of participation in proficiency testing:

(1) The laboratory should define its level and frequency of participation after careful analysis of its other QA measures …

(2) The level of risk presented by the laboratory, the sector in which they operate or the methodology they are using (*number of measurements, staff turnover and competence, traceability, measurement technique, use of testing/calibration data*).

(3) Different types of PT that can be used by laboratories and should be accepted by ABs .

(4) It must be recognised that there are sectors where participation in PT may be difficult, due to the technical characteristics of the measurement, the lack of PT schemes, the low number of existing laboratories in the sector, etc. In these areas the suitability of other QA measures is paramount.

(5) Any legislative requirements for frequency of type of PT participation.

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EA-4/18:2010, Guidance on the level and frequency of proficiency testing participation

§4 LEVEL AND FREQUENCY OF PARTICIPATION

ABs should expect **laboratories to identify groups of sets of measurement techniques, properties and products** (*sub-disciplines*) on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group.

The "**level of participation**" can be deemed to have been defined once the laboratory has defined its sub-disciplines (i.e. the sub-disciplines that apply for the tests/ calibrations for which the laboratory is accredited).

When a laboratory determines that more than one measurement technique, property or product is classified under the same sub-discipline, **ABs should evaluate whether a laboratory can justify and demonstrate equivalence**.

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EA-4/18:2010, Guidance on the level and frequency of proficiency testing participation

§4 LEVEL AND FREQUENCY OF PARTICIPATION

ABs will also need to **evaluate** the suitability of a laboratories **"frequency" of participation**, based on **level of risk** and should expect a minimum frequency of participation for each sub-discipline to be set by the laboratory.

It should also be considered that according to ISO/IEC 17025:2005 (5.9.1) the laboratory should have **quality control procedures** (of which PT is one) and that these should be planned.

Therefore, once the "level" and "frequency" of participation is established, laboratories should be expected to develop a **PT strategy** that should form part of the laboratory's overall **quality control strategy**. It is **recommended** that the strategy:

- **covers, at least, one accreditation cycle** (period between full reassessments);
- is **reviewed by the laboratory** for its suitability **on an annual basis**, usually during the formal management review.

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APLAC PT 006:09/10, Proficiency Testing Frequency Benchmarks

(cited in ILAC-P9:06/2014)

APLAC document provide regional “benchmarks” for PT frequency rather than a minimum requirement as given in the EA document (EA-4/18:2010). It can be seen as a complementary concept.

The benchmark frequencies given are a result of information obtained through a survey carried out in 2005 of APLAC members on the major sub-disciplines that are required to be covered by PT.

The aim of the publication of the benchmark frequencies is to assist ABs to set their PT policies. The suggested benchmarks are not requirements and do not override each individual AB’s PT policy.

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APLAC PT 006:09/10, Proficiency Testing Frequency Benchmarks
(cited in ILAC-P9:06/2014)

Accreditation bodies may wish to consider a risk based approach to determine appropriate PT frequencies.

The AB's PT policy should focus **on more than just meeting the requirements** as stated in ILAC-P9.

This PT policy should:

- meets the ILAC-P9 requirements;
- promotes the minimum to be exceeded when cost, suitability and availability allows.

APLAC PT 006:09/10, Proficiency Testing Frequency Benchmarks

(cited in ILAC-P9:06/2014)

COMMENT

In all cases for testing and calibration the APLAC PT 006:09/10 benchmark exceeds the minimum requirements as stated in ILAC-P9. *As an example, the benchmark frequencies given for the major sub-discipline for calibration are 1/two years.*

The declared aim is that these benchmarks are tools for both the accreditation body and the evaluation teams to assess the effectiveness of a PT policy. They may be used by the accreditation body to compare its own policy with what is currently regarded as the norm.

It should be considered that "the norm" presented was estimated by monitoring for APLAC members and at the time of survey.

ILAC-P13:10/2010, Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers (PPTs)

PURPOSE

To harmonise the application of ISO/IEC 17011 for accreditation bodies in regard to **their organisation of PT** and/or **accreditation of PTP**.

CLAUSE 1

ABs offering accreditation of PTP shall do so in accordance with the requirements of ISO/IEC 17011.

CLAUSE 2

Until such time as ISO/IEC 17011 is amended to include PT Provision within its scope, the following application of the specified clauses shall apply:

2.1 *ISO/IEC 17011:2004 Clause 3.11 ……*(consultancy)

2.2 *ISO/IEC 17011:2004 Clauses 4.3.6 a) and 7.15.2 ……(impartiality and PT)*

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ILAC-P13:10/2010, Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers (PPTs)

SUB-CLAUSE 2.2 - *ISO/IEC 17011:2004 Clauses 4.3.6 a) and 7.15.2*

2.2.1

Where an AB **does not accredit PTPs** but **organizes PT or other ILC** in accordance with clause 7.15.2, this shall **not** be considered to be an activity that affects the impartiality of the AB. However the AB shall ensure that its activities in this area do not have an adverse impact on the PT services within its economy.

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SUB-CLAUSE 2.2 - *ISO/IEC 17011:2004 Clauses 4.3.6 a) and 7.15.2*

2.2.2

Where an AB **accredits PTPs** it **shall not act as a PTP** offering PT schemes as a commercial activity.

The AB **can however organize PT or other ILC activities, including measurement audits, as an integral part of its assessment process** to assist the AB in establishing competence of the laboratory in particular areas.

The AB **shall justify**, with the participation of its interested parties (as described in clause 4.3.2 of ISO/IEC 17011:2004), its role in the provision of such a scheme to ensure that its impartiality as an AB is not compromised. This justification shall be documented and should be on the basis that no alternative independent scheme or program exists or is available to the laboratories that would provide an equivalent mechanism to assist in the AB establishing competence.

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ILAC-P13:10/2010, Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers (PTPs)

CLAUSE 3 - Any PT, ILC or measurement audit activity provided by the AB should be conducted **in accordance with the relevant requirements of ISO/IEC 17043**.

CLAUSE 4 - ABs **shall declare** any PT or other comparisons they organize to any **MRA evaluation teams** so that these activities are included within the scope of the evaluation with regard to the **AB's competence and impartiality**.

CLAUSE 5 - Where an AB conducts measurement audit activities it shall consider the acceptance of alternative, **equivalent means** by which a laboratory can provide information to assist in establishing its competence, where these alternatives exist.

CLAUSE 6 - An AB, with the participation of its interested parties as described in clause 4.3.2 of ISO/IEC 17011:2004, shall **routinely review its PT/ILC and/or measurement audit activities** to ensure it is not restricting the development of the operations of alternative providers. This review shall include consideration of the availability of suitable PT schemes, as evidence of the viability of independently operated PT schemes. **This review shall be documented.**

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COMMENT

Accreditation bodies are therefore encouraged to seek (and make available to the its CABs) information on PTPs and PTs. This information could be:

1) PTP organisation accredited ISO/IEC 17043

2) Sources of relevant information on PTPs (accredited or not) and PT programs:

2.1) EPTIS (European Information System on Proficiency Testing Schemes) database (http://www.eptis.bam.de/en/index.htm).

2.2) list of PTPs drawn up by the working group «WG ILC Calibration» of EA.

3) Laboratories not accredited as PPTs but that the **AB has qualified competent** for the provision of a specific PT, such as NMIs and calibration or testing laboratories accredited. In this case, **evidence should be given** of:

3.1) an **assessment of competence** of the PTP;

3.2) a **statement of compliance** with the ISO/IEC 17043 by the PTP (or alternatively an evaluation of the AB on this specific aspect)

ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing

4.4.1.3.l The PTP shall **document a plan** before commencement of the PT scheme that shall address the following information and, where appropriate, reasons for its selection or exclusion:

f) **Selection of the measurand(s)** or characteristic(s) **of interest**, including information on what the participants are to identify, measure or test for in the specific PT round;

g) **Description of the range of values** or characteristics, or both, to be expected for the PT items

l) **Reasonable precautions** to **prevent collusion** between participants or **falsification of results**, and procedures to be employed if collusion or falsification of results is suspected

q) The origin, *metrological traceability and measurement uncertainty* of any assigned values;

r) Criteria for evaluation of performance of participants

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ISO/IEC 17043:2010, Conformity assessment – General requirements for proviciency testing

4.4.5.1 The PTP shall document the procedure for determining the assigned values for the measurands or characteristics in a particular PT scheme. This procedure shall take into account the *metrological traceability and measurement uncertainty* required to demonstrate that the **PT scheme is fit for its purpose**.

4.4.5.2 PT schemes in the area of calibration shall have assigned values with metrological traceability, including measurement uncertainty. *(i.e.* ***no consensus values in calibration PT****)*

4.4.5.3 For PT schemes in areas other than calibration, the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value shall be determined by taking into account specified requirements of participants or other interested parties, or by the design of the PT scheme.

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ISO/IEC 17043:2010, Conformity assessment – General requirements for proviciency testing

4.7.2.2 Where appropriate for the purpose of the PT scheme, the PTP shall provide expert commentary on the performance of participants with regard to the following:

a) overall performance against prior expectations taking *measurement uncertainties* into account;

4.8.2 Reports shall include the following unless it is not applicable or the PTP has valid reasons for not doing so:

– m) details of the metrological *traceability and measurement uncertainty* of any assigned value

– o) assigned values and summary statistics for methods/procedures used by each group of participants

– p) comments on participants' performance

– t) comments or recommendations, based upon the outcomes of the PT round.

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ISO/IEC 17043:2010, Conformity assessment – General requirements for proviciency testing

5.5.2 The PTPs *shall not* subcontract:

- the Planning of the PT scheme (4.4.1.2)
- the Evaluation of performance (4.7.2.1)
- the Authorization of the final reports (4.8.1)

Note: This does not preclude the PTP utilizing advice or assistance from any advisors, experts or steering group.

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ACCREDIA-DT policy on experimental assessments

CASE A.

Bilateral measurement comparison, when one or more measurement instruments or reference materials are calibrated both by the assessed Laboratory and by a reference Laboratory of suitable competence.

The reference Laboratory can be a NMI or a Laboratory accredited by ACCREDIA or by a signatory of the EA or ILAC MRA, characterised by an uncertainty which is significantly better than the one required by the audited Laboratory.

The experimental comparison can be carried out also during the on-site assessment **in the presence of an ACCREDIA technical assessor**, using instruments with known characteristics.

ACCREDIA-DT policy on experimental assessments

CASE B.

Multilateral measurement comparison, when one or more measurement instruments or reference materials are calibrated by both the Laboratory under assessment and other Laboratories able to carry out calibrations with at least a comparable uncertainty.

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ACCREDIA-DT policy on experimental assessments

CASE C.

Experimental on-site assessments, where one or more calibrations are carried out in the presence of a technical assessor appointed for verification of the correct application of technical procedures, the knowledge of the state of the art and the Laboratory's capability to apply the correct professional practice.

If possible, the calibration results are compared with the results of calibrations previously performed on the same instrument.

In the **accreditation process**, it is best **to avoid this case** of experimental assessment or **at least limit** to measurement sectors where it is not possible to proceed otherwise and where the modalities of implementation are the most important factors for the correct performance of the calibration

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ACCREDIA-DT policy on experimental assessments

The comparison may be organized by:

- ACCREDIA as part of the policy approved by the Committee of Control and Guarantee,
- PTP accredited by ACCREDIA,
- NMIs and similar foreign institute signatory to the MRA agreements of mutual recognition of the CIPM
- other Labs possessing suitable technical competences accredited by EA-MLA and ILAC-MRA signatories.

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ACCREDIA-DT policy on experimental assessments

The results obtained must enable the verification of the metrological capabilities of the Lab (CMC - Calibration and measurement capability) and they must be formalized in an experimental comparison report.
If one or more experimental assessments have a **negative result**, the Technical Officer asks the Lab to analyse the causes and to implement corrective actions and to send the evidence to the Technical Officer. If necessary, and in agreement with the technical assessor and the Lab, the Technical Officer organizes further experimental assessments.

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