



Support for the National Accreditation Centre MOLDAC
to successfully undergo the EA peer evaluation process

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ACTIVITY 1.3 TRAINING SESSION FOLLOWING THE FINDINGS FROM PREVIOUS ACTIVITIES:

ILAC P10 TRACEABILITY

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REFERENCE

ILAC P10:2013

ILAC Policy on the Traceability of Measurement Results

PURPOSE

ILAC policy with regard to the **metrological traceability** requirements from **ISO/IEC 17025:2005** and **ISO 15189:2007**.

This policy may also be applied to other conformity assessment activities where testing and/or calibration is involved (e.g., inspection and product certification).

For internal calibrations performed by a laboratory in order to establish metrological traceability for its own activities, and which are not a part of the laboratory's scope of accreditation, the ILAC policy for traceability in calibration is applicable.





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

MEASUREMENT TRACEABILITY

5.6.1 *All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a **significant effect on the accuracy or validity of the result** of the test, calibration or sampling **shall be calibrated** before being put into service...*

5.6.2.1.1 *For **calibration laboratories**, the **programme for calibration** of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are **traceable to the International System of Units (SI)**.... When using external calibration services, **traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability***





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

REFERENCE STANDARDS

5.6.3.1 *The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a **body that can provide traceability** as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.*





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

8.2 OBLIGATIONS OF THE ACCREDITATION BODY

8.2.2 The accreditation body shall provide the CAB with information about **suitable ways to obtain traceability** of measurement results in relation to the scope for which accreditation is provided.





ILAC P10:2013, ILAC Policy on the Traceability of Measurement Results

For equipment and reference standards that must be calibrated, the ILAC policy is that they **shall be calibrated by:**

- 1)** An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. Services covered by the CIPM MRA (CMC) can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.
- 2)** An accredited calibration laboratory whose service is suitable for the intended need and the AB is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.





ILAC P10:2013, ILAC Policy on the Traceability of Measurement Results

Laboratories that have demonstrated traceability of their measurements through the use of calibration services offered according to 1) or 2) have made use of services that have been subject to relevant peer review or accreditation.

Other routes should be applicable **only** in the situation when (1) or (2) are not possible for a particular calibration.

The laboratory must therefore **ensure** that **appropriate evidence** for claimed traceability and measurement uncertainty is available and the **AB shall assess this evidence**.





ILAC P10:2013, ILAC Policy on the Traceability of Measurement Results

For equipment and reference standards that must be calibrated, the ILAC policy is that they shall be calibrated by:

3a) An **NMI** whose service is suitable for the intended need but **not covered by the CIPM MRA**.

3b) A **calibration laboratory** whose service is suitable for the intended need but **not covered by the ILAC Arrangement** or by Regional Arrangements recognised by ILAC.

In these cases the **AB shall establish a policy** to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025:2005.





ILAC P10:2013, ILAC Policy on the Traceability of Measurement Results

4) Only in the case in which the laboratory has demonstrated that the **policy (1) to (3) cannot reasonably be met**, clause 5.6.2.1.2 of ISO/IEC 17025:2005 can be applied:

*There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing **traceability to appropriate measurement standards** such as:*

- the use of **certified reference materials** provided by a competent supplier to give a reliable physical or chemical characterization of a material;*
- the use of **specified methods and/or consensus standards** that are clearly described and agreed by all parties concerned.*

Participation in a suitable programme of inter laboratory comparisons is required where possible.

It is the responsibility of the laboratory to choose a way to satisfy 5.6.2.1.2 and to **provide the appropriate evidence**. This evidence shall be documented and the documentation **shall be assessed by the AB**.





ILAC P10:2013, ILAC Policy on the Traceability of Measurement Results

The choice of route (3a) or (3b) is unlikely to be made on purely economic grounds, and is more likely to be a **last resort if other routes are unavailable**.

When traceability is established through either (3a) or (3b) of the policy, this necessitates action:

- in the first instance, from the **AB** that **must address this situation in its policy for traceability**;
- secondly, for the **laboratories** who will then need to comply with this policy;
- and finally for peer evaluators who will assess the effectiveness of this policy during peer reviews of ABs.

Traceability covered by (3a) and (3b) ranges from NMI's performing calibrations outside the CIPM MRA, through accredited laboratories performing calibrations outside their scope of accreditation, to laboratories which are not accredited for any service (for whatever reason).





ILAC P10:2013, ILAC Policy on the Traceability of Measurement Results

In Annex A the Guidelines for considerations when traceability is not established through the CIPM MRA and the ILAC Arrangement are reported.

In particular, the **appropriate evidence** for the **technical competence** of the laboratory and **claimed metrological Traceability** are listed.





ACCREDIA Policy on the Traceability of Measurement Results in Calibration

Laboratories shall realize metrological traceability chain using equipment, instruments and measurement standards calibrated by competent bodies complying with the following characteristics:

- 1) National Metrological Institutes (NMI) and Designated Institutes (DI) whose services (CMC) are suitable and covered by the MRA CIPM and entered into the database KCDB of the BIPM.
- 2) Accredited calibration laboratories whose services are adequate and whose accreditation is granted by accreditation bodies (AB) signatory to the EA-MLA or ILAC-MRA for the purpose "calibration" in the framework and within the limits set by the CMC published by AB.

The use of calibration certificates issued under these two options is considered of equal validity, despite the different value of the uncertainties that should be adequate for the needs of the laboratory.





ACCREDIA Policy on the Traceability of Measurement Results in Calibration

The alternatives listed below are acceptable only if they are supported by evidence as described in point 6.

3a) NMI whose services are adequate but not covered by the CIPM-MRA.

The case (3a) should not be chosen on the basis of purely economic or logistic reasons, but it should be considered as a last chance if the cases 1 and 2 are not available.

3b) Calibration laboratories whose services are adequate, but not covered by agreements ILAC or regional arrangements recognized by ILAC.

The case 3b must be chosen only in case the suppliers of type 1, 2 and 3a are not available. In this case the **evaluation of supplier** of the Laboratory must be made through **second party audit** in the **presence of an assessment team of ACCREDIA**, to which he belongs a Technical Officer. **The evaluation of the provider by the laboratory is itself subject to valuation by ACCREDIA.**





ACCREDIA Policy on the Traceability of Measurement Results in Calibration

4) The point 5.6.2.1.2 of UNI CEI EN ISO / IEC 17025: 2005 shows how to operate when the calibration can not be strictly performed with reference to SI units. In these cases, it is **the responsibility of the Laboratory provide evidences** that meet the requirements of the standard. These evidences, such as the evaluations of the provider by the Laboratory, are **subject to evaluation by ACCREDIA**.

5) In some cases the metrological traceability should be obtained by certified reference materials (CRM). In this case one must use materials produced by bodies complying with characteristics of the previous points or from **producers of reference materials accredited**. Standard UNI CEI EN ISO / IEC 17025 requires that in addition to these, one can use materials produced by **producers "competent"**. The latter applies as defined in ISO Guide 34, ISO Guide 35, other standards on the subject, documents prescriptive of ILAC, EA and ACCREDIA.





ACCREDIA Policy on the Traceability of Measurement Results in Calibration

6) Laboratories that use calibration services offered according to the cases 3a and 3b, are using services that have **not been subjected to peer review and accreditation**. The Laboratory must therefore ensure that appropriate evidence is available on the competence of the supplier and particularly on traceability and on the measurement uncertainty of the calibration supplied.

ACCREDIA will assess both such evidences and the ability of the Laboratory to evaluate them in turn.

The certification of the management system of a company does not constitute attestation of competence of its laboratories.

The evidence of metrological traceability accepted by ACCREDIA is limited to the specific procedures and the quantities evaluated and **does not imply any assessment of competence for other** measures, or for other services provided by the organization (in cases 3a and 3b).





ACCREDIA Policy on the Traceability of Measurement Results in Calibration

Appropriate evidence of the technical competence of calibration laboratory of the supplier and the metrological traceability could include, but not necessarily be limited to:

- Records of the outcomes of the participation in ILC within the CIPM MRA or regionally organized (e.g. EURAMET);
- Records of the outcomes of the participation in ILC made with other NMI and / or DI;
- Records on the validation of the calibration method (scientific publications, technical reports, etc.).
- Procedures for uncertainty estimate and copy of Metrological capacity;
- Documentation on the traceability of measurement results;
- Documentation on the quality assurance of the results of calibration;
- Evidence of the competence of the personnel related to calibrations;
- Documentation on the premises used as laboratory and environmental conditions in which the calibrations were made;
- Registration of internal audits;
- Registration of Audit of the second party

