ACTIVITY 1.4

TRAININGS OF MOLDAC PERSONNEL INVOLVED IN ACCREDITATION PROCESS INCLUDING THE ISSUE REGARDING THE REQUIREMENTS OF THE NEW VERSIONS OF THE EA, IAF, ILAC DOCUMENTS

ILAC-P10:01/2013

-Calibration-

Maria Pia TONI e Giulia SURIANI

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PREAMBLE

Metrological traceability of measurement results is a **key topic** for which a **harmonised** policy is needed if the market is to **have confidence in calibrations, testing and inspections performed by accredited laboratories and inspection bodies covered by the ILAC Arrangement**.

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JCGM 200:2012
International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

§2.41 (6.10)
metrological traceability

property of a measurement result whereby the result can be related to a reference through a documented **unbroken chain of calibrations**, **each contributing to the measurement uncertainty**

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JCGM 200:2012
International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

§2.41 (6.10)
metrological traceability

NOTE 4 For measurements with more than one input quantity in the measurement model, **each of the input quantity values should itself be metrologically traceable** and the calibration hierarchy involved may form a branched structure or a network. **The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.**

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ILAC-P10:01/2013 **ILAC Policy on Traceability of Measurements Results**

PREAMBLE

The persistent misconception that metrological traceability may be linked to a particular organization (e.g., "traceable to a specific National Metrology Institute") **fosters continued confusion with regard to its nature.**

Metrological traceability pertains to reference quantity values of measurement standards and results, **not the organization providing the results.**

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PREAMBLE

Factors that **influence the establishment of a harmonized ILAC policy on metrological traceability** of measurement results **include the following**:

(a) **The concept of metrological traceability** of measurement results in fields such as the **chemical, medical**, and **biological sciences is still under development**;

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PREAMBLE

Factors that **influence the establishment of a harmonized ILAC policy on metrological traceability** of measurement results **include the following**:

(b) **Not all economies have the complete range of national measurement standards** or calibration and measurement capabilities **needed to support the calibration and testing needs of all applicants for accreditation in their economy**;

PREAMBLE

Factors that **influence the establishment of a harmonized ILAC policy on metrological traceability** of measurement results **include the following**:

(c) **The role of reliable and traceable certified reference materials** in providing metrological traceability of measurement results **has not yet been fully established internationally.**

ILAC-P10:01/2013 **ILAC Policy on Traceability of Measurements Results**

PURPOSE

This document describes the 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**).

PURPOSE

For **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** in section 2 **is applicable**.

Internal calibrations are also known as "In-house" calibrations.

ISO/IEC 17025:2005

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

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.*

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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.

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ILAC P10:2013 ILAC Policy on the Traceability of Measurement Result

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.

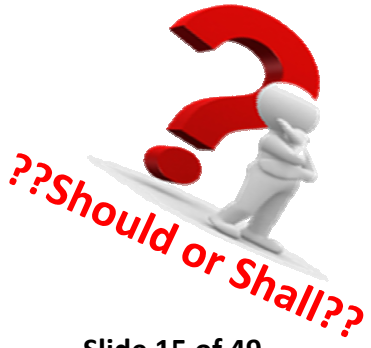
-> Let's have a look at the KCDB BIPM

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 recognized 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**.



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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.

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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**.

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

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.

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.

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ILAC P10:2013 Annex A: Guidelines for considerations when traceability is not established through the CIPM MRA and the ILAC Arrangement (Informative)

Appropriate evidence for the technical competence of the laboratory and claimed metrological traceability **is likely to include but not be restricted to the following**:- (numbers refer to clauses in ISO/IEC17025:2005):

- ❑ Records of calibration method validation (5.4.5)
- ❑ Procedures for estimation of uncertainty (5.4.6)
- ❑ Documentation for traceability of measurements (5.6)
- ❑ Documentation for assuring the quality of calibration results (5.9)
- ❑ Documentation for competence of staff (5.2)
- ❑ Documentation for accommodation and environmental conditions (5.3)
- ❑ Audits of the calibration laboratory (4.6.4 and 4.14)

ILAC P10:2013 Annex A: Guidelines for considerations when traceability is not established through the CIPM MRA and the ILAC Arrangement (Informative)

For non-accredited laboratories it should be noted that it may be **necessary to perform a practical assessment of the laboratory used**, similar to that which would be undertaken by an Accreditation Body against the standard ISO/IEC 17025, **to ensure that competent work is actually being performed.**

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.

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 within the framework of these two possibilities is to be considered of equal validity, granted the different value of the calibration uncertainties which shall be adequate for the Laboraties's needs.

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ACCREDIA Policy on the Traceability of Measurement Results in *Calibration*

There may be situations in which it is not possible to obtain metrological traceability from either one of the two cases mentioned here. **The alternatives mentioned below are only acceptable if they are supported by evidence as set out in point 6.**

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

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

ACCREDIA Policy on the Traceability of Measurement Results in *Calibration*

Case **3a** should not be chosen on the basis of purely economic or logistic reasons, but it should be considered as a final resource if cases **1** and **2** are not available.

Case **3b** shall be chosen only if type 1, 2 and 3a suppliers are not available. In such cases the **evaluation of the supplier** by the Laboratory shall take place through **second party audits** in the presence of an ACCREDIA assessment team, containing a Technical Officer. **The evaluation of the supplier by the Laboratory is itself assessed 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**.

ACCREDIA Policy on the Traceability of Measurement Results in *Calibration*

6) Laboratories using calibration services offered according to the cases 3a and 3b, uses services which have **not been subjected to peer review or accreditation**. The Laboratory shall therefore ensure that there is evidence available regarding the competence of the supplier and, in particular, regarding traceability and measurement uncertainty of the calibrations supplied. **ACCREDIA shall assess the evidence as well as the ability of the Laboratory to perform evaluations.**

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

Evidence of metrological traceability accepted by ACCREDIA is limited only to the specific procedures and to the quantities submitted to assessment, and it does not imply any assessment of competence for other measurements or other services offered by the organization (in cases **3a** and **3b**).

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ACCREDIA Policy on the Traceability of Measurement Results in *Calibration*

Adequate evidence of the technical competence of the supplier's calibration Laboratory and of the metrological traceability **is likely to include but not be restricted to the following:**

- Records of the outcomes of the participation at ILCs in the CIPM-MRA framework or organized at regional level (e.g. EURAMET);
- Records of the outcomes of the participation at ILCs with other NMIs or Designated Bodies;
- Records of the validation of the calibration methods (scientific publications, technical reports, etc.).

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ACCREDIA Policy on the Traceability of Measurement Results in *Calibration*

Adequate evidence of the technical competence of the supplier's calibration Laboratory and of the metrological traceability **is likely to include but not be restricted to the following:**

- Procedures for the uncertainty estimate and copy of the metrological capabilities;
- Documentation regarding the traceability of measurement results;
- Documentation regarding the quality assurance of the calibration results;
- Evidence of the competence of the personnel performing the calibrations;

ACCREDIA Policy on the Traceability of Measurement Results in *Calibration*

Adequate evidence of the technical competence of the supplier's calibration Laboratory and of the metrological traceability **is likely to include but not be restricted to the following:**

- Documentation regarding the Laboratory's premises and the environmental conditions of the calibrations;
- Records of internal audits;
- Records of second party audits.

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§4 ILAC POLICY TRACEABILITY PROVIDED THROUGH REFERENCE MATERIALS (RMS) AND CERTIFIED REFERENCE MATERILAS (CRMS)

ISO/IEC 17025:2005 traceability requirements in relation to reference materials include:

5.6.3.2 Reference materials

Reference materials shall, where possible, ***be traceable to SI units of measurement, or to certified reference materials****.*

Note 1: Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.

§4 ILAC POLICY TRACEABILITY PROVIDED THROUGH REFERENCE MATERIALS (RMS) AND CERTIFIED REFERENCE MATERILAS (CRMS)

ISO/IEC 17025:2005 traceability requirements in relation to reference materials include:

5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.

Note 2: **At present, the ILAC Arrangement does not cover the accreditation of reference material producers (RMPs).** At the regional level, APLAC operates an MRA for RMPs and a number of countries operate systems for the accreditation of RMPs, and the number of accredited RMPs is therefore increasing.

EA-4/14 INF:2003 The Selection and Use of Reference Materials

§1 – TYPES OF REFERENCE MATERIALS

RMs are used to **support measurements** concerned with chemical composition, biological, clinical, physical, engineering properties and miscellaneous areas such as taste and odour.

For example RMs are used for:

- Calibration
- Method Validation
- Measurement verification
- Evaluating Measurement Uncertainty
- Training purposes

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EA-4/14 INF:2003 The Selection and Use of Reference Materials

§1 – TYPES OF REFERENCE MATERIALS

RMs are used to **support measurements** concerned with chemical composition, biological, clinical, physical, engineering properties and miscellaneous areas such as taste and odour.

They may be characterised for:

- **'identity'** (e.g. chemical structure, fibre type, microbiological species etc.)

  → intended use in examination of nominal properties

- **'property values'** (e.g. amount of specified chemical entity, hardness etc.).

  → intended use in measurements

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EA-4/14 INF:2003 The Selection and Use of Reference Materials

§1 – TYPES OF REFERENCE MATERIALS

Some commonly encountered types of **reference materials** are as follows:

1. **Pure substances** characterised for chemical purity and/or trace impurities.
For example: 95% pure sodium chloride *(CITAC/Eurachem Guide §20.3)*

2. **Standard solutions and gas mixtures**, often prepared gravimetrically from pure substances and used for calibration purposes.

For example: an aqueous solution containing 1% (w/v) copper (II) sulphate and 2% (w/v) magnesium chloride *(CITAC/Eurachem Guide §20.3)*

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EA-4/14 INF:2003 The Selection and Use of Reference Materials

§1 – TYPES OF REFERENCE MATERIALS

Some commonly encountered types of reference materials are as follows:
[..]
3. **Matrix reference materials**, characterised for the composition of specified major, minor or trace chemical constituents. Such materials may be prepared from matrices containing the components of interest, or by preparing synthetic mixtures.

For example: *soil, drinking water, metal alloys, blood (ISO Guide 30:2015 §2.1.4);* a powdered polymer with a particular weight and distribution range *(CITAC/Eurachem Guide §20.3);*

A chemical substance dissolved in a pure solvent is it a matrix material?

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EA-4/14 INF:2003 The Selection and Use of Reference Materials

§1 – TYPES OF REFERENCE MATERIALS

4. **Physico-chemical reference materials** characterised for properties such as melting point, viscosity, and optical density.

For example: a crystalline solid melting in the range 150-151 °C *(CITAC/Eurachem Guide §20.3)*

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EA-4/14 INF:2003 The Selection and Use of Reference Materials

§1 – TYPES OF REFERENCE MATERIALS

5. **Reference objects or artefacts** characterised for functional properties such as taste, odour, octane number, flash point and hardness. This type also includes microscopy specimens characterised for properties ranging from fibre type to microbiological specimens.

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EA-4/14 INF:2003 The Selection and Use of Reference Materials

§ 2 – CLASSIFICATION OF REFERENCE MATERIALS

Two classes of materials are recognized by ISO, namely 'certified reference materials' (CRMs) and 'reference materials' (RMs)

1. **CRMs:** must by definition be traceable to an accurate realization of the unit in which the property values are expressed. Each property value must be accompanied by an uncertainty at a stated level of confidence.

2. **RMs:** materials whose property values are sufficiently homogeneous and stable and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

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TERMINOLOGY (1/)

REFERENCE MATERIAL (RM): material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for purpose for its intended use in a measurement process ***(ISO Guide 30:2015).***

Note 1 : RM is a generic term.

Note 2: Property can be quantitative or qualitative, e.g. identity of substances or species.

Note 3: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4: ISO/IEC Guide 99:2007 has an analogous definition (5.13), but restricts the term “measurement” to apply to quantitative values. However, Note 3 of ISO/IEC Guide 99:2007, 5.13 (VIM), specifically includes qualitative properties, called “nominal properties”.

TERMINOLOGY (2/)

CERTIFIED REFERENCE MATERIAL (CRM): reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. ***(ISO Guide 30:2015).***

Note 1 : The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence

Note 2 : Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guides 34 and 35.

Note 3 : ISO Guide 31 gives guidance on the contents of RM certificates.

Note 4 : ISO/IEC Guide 99:2007 has an analogous definition (5.14).

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ISO Guide 30: 2015

Foreword

"This third edition of ISO Guide 30 cancels and replaces ISO Guide 30:1992. It was revised principally for introducing new definitions for RMs and CRMs as well as to update other terms and definitions.

The definitions for RM and CRM were developed by REMCO to incorporate the concepts of both quantitative and qualitative analysis. There exist different definitions for these terms in other sources, notably ISO/IEC Guide 99:2007 and JCGM 200:2008. It remains as a future goal to harmonize these definitions in subsequent editions of these terminology guides. The terms included in this version are limited to those required to support the principles and concepts set forth in other REMCO Guides. Existing definitions in referenced publications are used wherever possible. In other cases, some definitions are specifically tailored to enhance the understanding of RMs and their uses."

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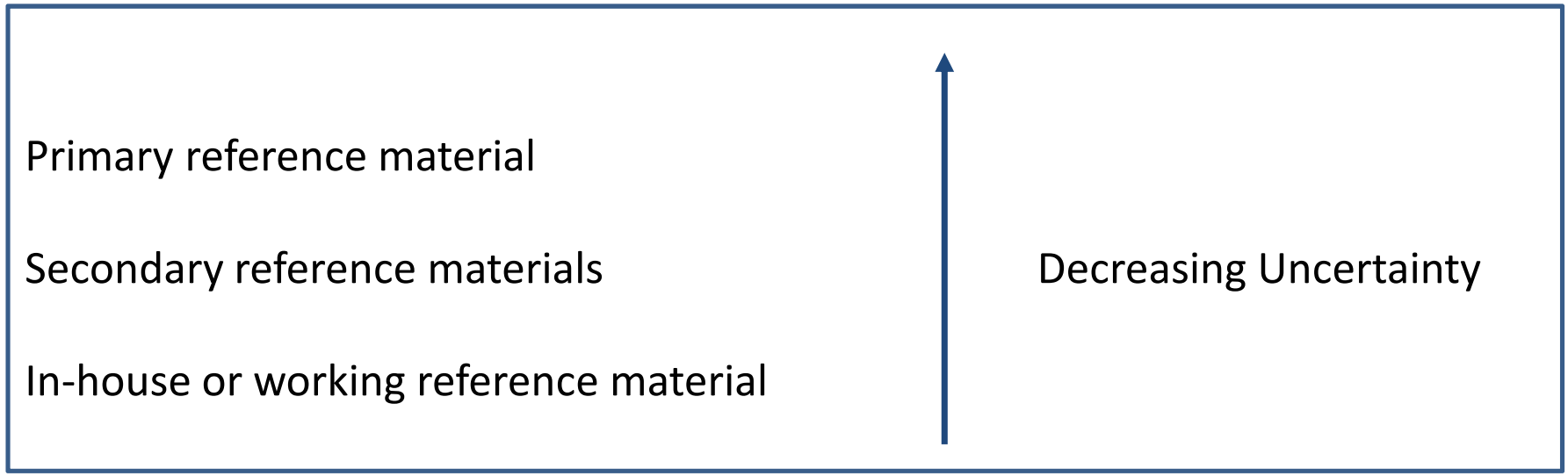
EA-4/14 INF:2003 The Selection and Use of Reference Materials

§ 2 – CLASSIFICATION OF REFERENCE MATERIALS

The following classes of reference materials are also encountered:



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§3 – TRACEABILITY OF REFERENCE MATERIALS

Reference materials are important tools for the transfer of measurement accuracy between laboratories and their property values should, where feasible, be traceable to SI. Traceability is, however, a relatively new concept in the field of chemical measurement and as a consequence very few chemical reference materials are explicitly traceable to SI.

A hierarchy of methods is, however, used for assigning property values to materials and even if not stated, their traceability can be described as follows

Measurement Method	Traceability
Primary method	SI
Method of known bias	SI/International standard
Independent method(s)	Results of specified methods
Interlaboratory comparison	Results of specified methods

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CITAC/EURACHEM Ed.2002 - Guide To Quality Analytical in Chemistry

§15 – METROLOGICAL TRACEABILITY

"property of a **measurement result** whereby the result can be related to a reference through a documented unbroken chain of **calibrations**, each contributing to the **measurement uncertainty** " (ISO/IEC Guide 99:2007)

- Traceability concerns the requirement to relate the results of measurements to the values of standards or references, the preferred reference points being the internationally recognised system of units, the SI.
- This is achieved through the use of primary standards (or other high level standards) which are used to establish secondary standards that can be used to calibrate working level standards and related measuring systems.
- Traceability is established at a stated level of measurement uncertainty, where every step in the traceability chain adds further uncertainty.
- Traceability is important because it provides the linkage that ensures that measurements made in different laboratories or at different times are comparable

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§15 – METROLOGICAL TRACEABILITY

§15.2 Chemical measurements are invariably made by calculating the value from a
measurement equation that involves the measured values of other quantities, such as mass, volume, concentration of chemical standards etc.
For the measurement of interest to be traceable, all the measurements associated with the values used in the measurement equation used to calculate the result must also be traceable. **Other quantities not present in the measurement equation**, such as pH, temperature etc **may also significantly affect the result**.
Where this is the case, the traceability of measurements used to control these quantities also need to be traceable to appropriate measurement standards.

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§4 ILAC POLICY TRACEABILITY PROVIDED THROUGH REFERENCE MATERIALS (RMS) AND CERTIFIED REFERENCE MATERILAS (CRMS)

The ILAC policy in regard to traceability provided by RMPs is:

7) The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34:2009, are considered to have established valid traceability (see ILAC General Assembly resolution ILAC 8.12).

Example: INRIM'S CMCs for CHEMISTRY
Example: SIAD's CMCs for CHEMISTRY - Amount of substance, Gases

§4 ILAC POLICY TRACEABILITY PROVIDED THROUGH REFERENCE MATERIALS (RMS) AND CERTIFIED REFERENCE MATERILAS (CRMS)

The ILAC policy in regard to traceability provided by RMPs is:

8) The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.
JCTLM database

9) The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and **the laboratory shall demonstrate that each RM or CRM is suitable for its intended** use as required by clause 4.6.2 in ISO/IEC 17025:2005 or ISO 15189:2007.

ACCREDIA Policy on the Traceability Provided Through RMS and CRMS – *Calibration Department*

5 – In certain cases the metrological traceability shall be obtained by means of certified reference materials (CRMs).
In this case it is necessary to use materials produced by bodies responding to the characteristics of the preceding points or produced by accredited producers of reference materials.
The standard UNI CEI EN ISO/IEC 17025 provides that, apart from these, it's possible to use materials produced by "competent" producers, also applying ISO Guides 34 and 35, other applicable standards and applicable ILAC, EA and ACCREDIA documents.

ACCREDIA Policy on the Traceability Provided Through RMS and CRMS –

Calibration Department

CASE

STUDIES

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