



BUREAU INTERNATIONAL DES POIDS ET MESURES INTERNATIONAL LABORATORY ACCREDITATION COOPERATION

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IMPROVING WORLDWIDE TRACEABILITY AND ACCEPTANCE OF MEASUREMENTS CARRIED OUT WITHIN THE CIPM MRA AND THE ILAC ARRANGEMENT

A JOINT STATEMENT BY THE CIPM AND THE ILAC ON THE ROLES AND RESPONSIBILITIES OF NATIONAL METROLOGY INSTITUTES AND NATIONAL RECOGNIZED ACCREDITATION BODIES

PRESIDENT OF THE CIPM PROF. E. GÖBEL

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Note: Acronyms used in this document are listed in Annex 2

Executive Summary

The framework for measurements traceable to the International System of Units (SI) made at a national level depends critically on two issues. Firstly, the availability of national measurement standards in National Metrology Institutes (NMIs), and secondly the national systems for accreditation of the technical competence of laboratories which need to make measurements traceable to these national standards. The first activity is governed by the NMIs and their designated institutes (DIs). The second activity is normally the responsibility of a Nationally Recognized Accreditation Body (NAB). At the highest level the BIPM works with NMIs and with ILAC to assure an unbroken traceability chain from the day-to-day measurement made by users to the SI as realized by the NMIs.

This infrastructure generally falls within the policy interests of Governments, which normally assume a significant part of the financial and other responsibility for its well being. This joint statement sets out the respective individual and joint activities which, we believe, represent best practice for NMIs and NABs, and which can be used to maximize the efficiency and effectiveness of national structures. This statement puts national activities into the context of regional and international responsibilities linked to activities under the Metre Convention and ILAC. This statement is addressed to Governments, NMIs and accreditation communities, and to international and intergovernmental bodies for which measurements are needed to implement their own missions.

1. Basis for this Joint Statement

The BIPM was created as an intergovernmental organization under a diplomatic treaty, the Convention of the Metre in 1875. Supported and financed (August 2005) by contributions from 51 Member States and subscriptions from 18 Associates of the General Conference on Weights and Measures (CGPM). The BIPM operates under the exclusive supervision of the Comité International des Poids et Mesures (CIPM) which itself comes under the authority of the Conférence Générale des Poids et Mesures (CGPM).

Resolution 11 of the 22nd CGPM (Annex 1) on the "Relationship between National Metrology Institutes, and nationally recognised accreditation bodies" called upon

"all accreditation organizations to recognize that NMIs and accredited calibration laboratories together provide an indispensable route to traceability to the SI and hence to reliability in measurements and worldwide comparability of measurement results for the whole economy and society and that they should work closely together,"

and recommended that:

• "Member Governments of the Metre Convention ensure that an appropriate relationship exists between NMIs and NABs,

• this relationship fosters collaboration on matters concerning traceability of measurement results and ensures effective and complementary actions under the CIPM MRA and the ILAC arrangement".

The Resolution provides the basis for this joint statement.

Through the activities of NMIs and NABs, BIPM and the International Laboratory Accreditation co-operation (ILAC) share responsibility for the integrity, efficiency and impartiality of the world metrology system and its end use by industry, commerce, science and the public or regulatory communities. To summarize, the world metrology system is, in essence, a combination of:

- comparable national standards, demonstrably traceable to the SI through their realization and maintenance at the NMI level, validated through the CIPM Mutual Recognition Arrangement (CIPM MRA); and
- effective national measurement systems in which measurements are traceable to those national standards, at whatever level of accuracy is appropriate to the user, generally through a network of technically competent calibration and testing laboratories accredited to ISO/IEC 17025 or other measurement standards by a NAB which is a signatory to the ILAC Arrangement.

The CIPM MRA and the ILAC MRA are complementary. Their combination helps to provide confidence in the consistency of SI-traceable measurements worldwide. This infrastructure can therefore provide the basis for equivalence and acceptance of measurements used in international trade and, specifically, its use can help reduce or eliminate Technical Barriers to Trade.

The close cooperation between CIPM and ILAC was formalized by a Memorandum of Understanding, MOU, signed in 2002, and in a joint working group set up specifically to assist progress through the MoU.

Representatives from BIPM regularly attend the annual ILAC General Assembly, and ILAC is represented at the General Conference on Weights and Measures and other meetings.

2. International Metrology

The interactions and responsibilities of the different institutions can be summarized, schematically, by the following graph:



BIPM's mission is the worldwide consistency of measurements traceable to the International System of Units (<u>SI</u>). To achieve this mission, the BIPM cooperates with NMIs, or other institutes designated by these NMIs or appropriate national authorities, as well as with a number of international and intergovernmental organizations. It also collaborates with regional metrology organizations (RMOs) which share BIPM's mission, and which are essential to its effective implementation.

2.1 The role of the BIPM

Inter alia, BIPM:

- carries out research in the development of international measurement standards;
- provides worldwide coordination at the highest metrological level through close links with NMIs;
- is a centre of excellence for world metrology bringing together experts in metrology from NMIs and other appropriate national and international or intergovernmental bodies;
- offers a limited number of calibrations to NMIs from Member States;

- works through NMIs to implement its mission and work under the Metre Convention;
- supports international so-called "key comparisons" (KCs) a set of comparisons selected by a Consultative Committee of the CIPM to test the principle techniques and methods in a particular field of metrology to underpin the equivalence of measurements made by NMIs; and
- maintains a database of the results of key comparisons and of quantitative Calibration and Measurement Capabilities of NMIs in the Key Comparison Data Base KCDB (kcdb.bipm.org).

The BIPM's formal role stops at the level of the NMIs, which then take on the role of dissemination of traceable measurements to national users in industry, commerce, the public sector, science and other fields of application. In general, traceability of these measurements to the SI, through the standards maintained at the NMI level, is through a network of laboratories accredited to international standards, notably ISO/IEC 17025. These accreditations are carried out by bodies which conform in turn to ISO/IEC 17011, the successor to ISO Guide 58.

Knowledge of the comparability of SI standards realized and maintained at the national level is an important factor in creating worldwide confidence in the abilities and capabilities of NMIs. In 1999, the International Committee of Weights and Measures (CIPM) therefore drew up a Mutual Recognition Arrangement (CIPM MRA). This provides the basis for the acceptance, by NMIs, designated institutes (DIs) and other signatories, of calibration and test certificates from other NMIs and DIs who have also signed the MRA and comply with its requirements. Representatives of more than 60 NMIs from Member States of the Metre Convention, Associates of the CGPM and two international organizations have now signed on their own behalf as well as that of another 120 DIs. The CIPM MRA provides users with transparent, comprehensive, reliable, peer reviewed, quantitative information on the capabilities of NMIs and the degree of equivalence of the SI units and quantities they maintain. It provides the technical framework for several agreements negotiated for international trade, commerce and regulatory affairs in those cases where acceptance and equivalence of the results of measurements are important.

Under the CIPM MRA, signatories initially state what they claim to be the measurement uncertainty of the services they provide. These so-called Calibration and Measurement Capabilities (CMCs) are, broadly speaking, the uncertainties they attribute to their calibration and test services. Confidence in the CMCs is underpinned firstly by the participation of the laboratories in a number of key comparisons which test the principal techniques in that field, and secondly by a detailed examination of the CMC claims by technical peers drawn from the RMOs worldwide. These claims are then finally analyzed by the JCRB (Joint Committee of the Regional Organizations and the BIPM). The results of key comparisons are published in the technical supplement of *Metrologia* and are also available on the BIPM website (<u>www.bipm.org</u>), as is a database of these results and the CMCs which have been accepted by the world community.

Signatories to the CIPM MRA are required to operate a Quality System based on the appropriate elements in ISO/IEC 17025 or other international standards relevant to the technical needs of the area. This includes ISO Guide 34 where relevant for the certification and characterization of Reference Materials delivered as a means of disseminating traceability.

The BIPM maintains a "Key Comparison Data Base", the KCDB (kcdb.bipm.org) which is the primary source of validated and objective capabilities and degrees of equivalence or comparability of the national laboratories which offer calibration services traceable to the SI. The CIPM MRA and KCDB are continually being extended and already cover physical measurements as well as some areas of chemical measurement. A separate database of measurement standards of a higher order is being developed for laboratory medicine.

2.2. Metrology at a regional and national level

All Member States of the Metre Convention support a NMI which has, in general, the role of maintaining national measurement standards, ensuring their suitability for national needs, and transferring measurement traceability, metrological expertise and knowledge to national users through high level calibration services, advice, and other assistance.

At a regional level, NMIs collaborate through Regional Metrology Organisations (RMOs), loosely based on economic groupings. These RMOs carry out a variety of tasks which include:

- promoting collaboration and the sharing of technical capabilities between members;
- organizing regional comparisons in support of the "Key Comparisons" organized internationally by the BIPM in support of the CIPM MRA;
- reviewing the technical competences and supporting quality systems of NMIs which are signatories to the CIPM MRA; and
- preparing their members who are not currently Member States of the Metre Convention or Associate of the CGPM, for such status.

RMOs collaborate with each other and with the BIPM in the Joint Committee for the BIPM and the RMOs (JCRB).

2.3. The role of the NMIs

National Metrology Institutes and, where relevant, Designated Institutes:

- maintain national realizations of the appropriate SI units and quantities at a primary or secondary level according to national needs and promote the concept of traceability to the SI;
- disseminate the national realizations of units to the accredited laboratories in industry and other users in their country;
- carry out comparisons of their national realizations of SI standards with other NMIs;
- establish traceability arrangements with other NMIs or the BIPM for those units where local realizations are at the secondary level and/or take part in RMO comparisons within the CIPM MRA framework;
- maintain a general overview of the complete national calibration/traceability hierarchy (the National Measurement System) and transfer suitable calibration services to the accredited laboratory sector;
- provide access to calibration services for industrial and other customers from inside or outside the country concerned. ;
- provide calibration services in such a way that they do not constitute an unfair competition with those services offered by accredited providers;
- maintain a QS system consistent with the requirements of the CIPM MRA and demonstrate compliance with the relevant clauses of the CIPM MRA;
- promote the CIPM MRA to Regulators, etc. at a national level and, where appropriate, within a regional economic grouping;
- are encouraged to use the JCRB statement of equivalence and CIPM MRA logo on calibration certificates produced within the framework of the CIPM MRA;
- put in place a system of checks and balances where needed to avoid conflict of interest with, for example, bodies which accredit calibration laboratories. ISO/IEC 17011 provides a guide to best practice.

3. International Laboratory Accreditation

ILAC was established in 1977 as the International Laboratory Accreditation "*Conference*" of NABs with the aim of enhancing the international acceptance of test and measurement results from accredited laboratories. It was formalized in 1996 as the International Laboratory Accreditation "*Cooperation*" when 44 national bodies

signed a formal Memorandum of Understanding. The ILAC Arrangement was signed by 37 member accreditation bodies from 28 economies in 2000. As of August 2005, there are 45 signatories to the Arrangement (covering approx. 26000 accredited laboratories worldwide). In addition to promoting mutual acceptance of measurement results and calibration or test certificates between its members, ILAC also promotes the acceptance of accredited test and calibration data by regulators and governments. A list of current Arrangement signatories can be found on the ILAC website at www.ilac.org.

The ILAC Arrangement is therefore a major cooperative effort to enhance the objective of free trade (i.e. "tested once and accepted everywhere") throughout the world.

Through the ILAC MoU and Arrangement, the work of all NABs is verified by other NABs, through peer evaluation, in order to establish and maintain mutual confidence in their technical competence and their national accreditation procedures. These elements involved in this confidence building are based on the following actions:

ILAC provides for:

- exchange of information on the development operation and guidelines for the appropriate harmonization of accreditation programs of ILAC members, associates and affiliates;
- participation in the work and decision-making of the ILAC General Assembly and ILAC committees and regional cooperations where applicable;
- participation of accredited laboratories in national and international interlaboratory comparisons and proficiency testing programs;
- participation in the work of ILAC with other scientific and technical organizations to address problems related to testing and calibration in various technical fields;
- evaluations of applicants and re-evaluations of signatories to this Arrangement conducted in accordance with ISO/IEC 17011 and other relevant ILAC and regional cooperation documents; and
- a thorough review of all technical and quality system elements within an NAB, to ensure that a similar approach to laboratory accreditation is taken by all NABs. This includes an examination of the all-important relationship between the NAB and the NMI to ensure a positive working relation.

3.1. Accreditation at a regional and national level

An integral part of the NAB assessment process is the review of performance of accredited laboratories in appropriate proficiency testing programmes, provided either by external providers, by the NAB, or even by a local RMO. Proficiency testing helps build confidence that the laboratories provide reliable traceable measurements that are

fit for their intended purpose, and that their results are comparable with those from other laboratories around the globe.

Regional Cooperation of Accreditation Bodies (RABs), all of which participate in the ILAC activities in their own right, have been created in response to specific local or regional needs, especially those which relate to regulatory or legislative requirements of free trade areas, on which many of the RABs are based.

RABs also help ensure a consistent approach, at a regional level, to ILAC's activities.

RABs should adopt the following as part of their role:

- regular liaison with RMOs;
- activities to analyze and ensure the consistency of the results from comparisons carried our between laboratories in the accredited sector and those carried out by NMIs within the CIPM MRA;
- ensure uncertainty claims are evaluated in accordance with the Guide to Uncertainty of Measurement (GUM); and
- work towards transparency and open publication of the results of comparisons between named accredited laboratories.

3.2. National Recognized Accreditation Bodies

NABs are encouraged to discharge their responsibilities fairly and transparently by:

- complying with ISO/IEC 17011 and becoming signatories to the ILAC Arrangement;
- conducting thorough assessments of laboratories, with due attention to both technical/and metrological issues as well as management system components;
- training assessors in best practice to ensure they are familiar with ISO/IEC 17025 as well as other relevant standards;
- encouraging assessors to confirm the consistency of uncertainty claims by accredited laboratories (taking into account the CMCs of NMIs as listed in the BIPM's KCDB);
- liaising with NMIs on the national measurement infrastructure; and
- promoting traceability to the SI or, if this is not yet possible, to agreed stated international references.

4. The joint activities of NMIs and NABs

The dissemination of national standards and measurement capability from the NMI to accredited laboratories is essential in order to achieve user confidence in a national measurement system.

Working together, NABs and NMIs should:

- collaborate, so as to put in place suitable arrangements through which accreditation bodies can take advantage of the expertise of NMIs and designated institutes so as to ensure a technically robust national measurement system. This may include operation of an NMI and a NAB within one organization, provided appropriate firewalls are installed to ensure impartiality as required by ISO/IEC 17011;
- arrange regular meetings of NABs NMIs and DIs to discuss matters of mutual interest and to find ways of making available the NMI advice on acceptance of certificates from other NMIs which are not signatories to the CIPM MRA;
- ensure assessors for accredited calibration laboratories are technically competent, with current knowledge of the state of the art in metrology, including uncertainty statements and are fully aware of the CIPM MRA and the KCDB database and its relevance to traceability to the SI;
- train assessors to use the KCDB so as to check that the claims of uncertainty made by an accredited laboratory are consistent with the CMCs claimed and accepted internationally by the NMI;
- promote the term CMC (rather than BMC or any other);
- promote the acceptance of the CIPM MRA and data in the KCDB by regulators and others; and
- promote the acceptance of accreditation and the role of the ILAC Arrangement.

5. Use of this Document

In this Document, CIPM and ILAC have summarized the role and responsibilities of the various players in the world measurement system through guidelines on the respective roles and responsibilities of those concerned. The two bodies commend these practices to the NMIs, and the NABs at a national level and, regionally, to RMOs and RABs.

CIPM and ILAC invite users and potential users such as Regulators to take note of, and declare their support for this Statement of the roles and responsibilities of the various bodies at the international, regional and national levels in relation to worldwide traceability and acceptance of measurements.

Annex 1: Relationship between National Metrology Institutes and Nationally Recognized Accreditation Bodies

Resolution 11

The 22nd General Conference, considering

- the key role played by National Metrology Institutes (NMIs) at the origin of accreditation of calibration and, in some countries, also of testing laboratories to meet the increasing demand for the calibration of measuring standards and instruments traceable to the International System of Units (SI),
- the essential character of a close technical cooperation between the staff of NMIs and nationally recognized accreditation bodies (NABs),
- the overriding importance to the paying customer of technical competence in the accreditation process of calibration and testing laboratories,
- recent tendencies towards the requirement for complete separation between NMI and NAB activities in the name of impartiality, independence and integrity of the latter,
- the evident danger that such a complete separation may have for the technical competence of NABs and, in consequence, for accredited calibration and testing laboratories,
- that the specification and implementation of national practices related to the national measurement and the national accreditation systems are ultimately the responsibility of national Governments,
- that the relationship between the NMI and NABs varies from country to country; the NABs may be part of the NMI, be operated by the NMI or may be completely separated from it,

emphasizing the importance of equitable and harmonized practices in respect of both large and small metrology and accreditation systems in all regions of the world,

recognizing the importance of worldwide harmonization of such practices,

welcomes the recent CIPM-ILAC Memorandum of Understanding between the International Committee for Weights and Measures and the International Laboratory Accreditation Cooperation, (ILAC),

calls upon all accreditation organizations to recognize that NMIs and accredited calibration laboratories together provide an indispensable route to traceability to the SI and hence to reliability in measurements and worldwide comparability of measurement results for the whole economy and society and that they should work closely together,

recommends that

- Member Governments of the Metre Convention ensure that an appropriate relationship exists between NMIs and NABs,
- this relationship fosters collaboration on matters concerning traceability of measurement results and ensures effective and complementary actions under the CIPM MRA and the ILAC arrangement,

and notes that calibration is not a conformity assessment activity.

Annex 2: List of Acronyms used in this document

BIPM	Bureau International des Poids et Mesures (International Bureau of Weights and Measures)
BMC	Best Measurement Capability
CGPM	General Conference on Weights and Measures (CGPM)
CIPM	Comité International des Poids et Mesures (International Committee for Weights and Measures)
CIPM MRA	CIPM Mutual Recognition Arrangement
СМС	Calibration and Measurement Capability
DI	Designated Institute
GUM	Guide to the expression of Uncertainties in Measurement
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ILAC	ILAC Mutual Recognition Arrangement
ISO	International Organization for Standardization
JCRB	Joint Committee of the Regional Organizations and the BIPM
KC	Key Comparison
KCDB	Key Comparison Data Base
MOU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement
NAB	Nationally Recognized Accreditation Body
NMI	National Metrology Institute
RAB	Regional Cooperation of Accreditation Bodies
RMO	Regional Metrology Organization
SI	Système International d'Unités

Annex 3: List of international standards relevant to this document:

- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17011: Conformity assessment General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO Guide 34: General requirements for the competence of reference material producers