関連文書4

BIPM(国際度量衡局)と ILAC の連携（DRAFT 中）

概要

2001 年に２機関の間で **MOU** に署名し、最近では共同声明作りを行っている。その目的は、**NMI** と **NAB(NATIONAL ACCREDITATION BODY)**の間で必要とする共通認識をもつことであり、**CIPM MRA** と **ILAC** の **MRA** が基礎となっている。

NMI は **CIPM MRA** のもとに **RMO** 内での **INTRA-REGIONAL** と **RMO** 間での **INTER-REGIONAL** での **REVIEW** を受けた **CMC** を、**MRA** の **APPENDIX C** として、**APPENDIX B** のもとに登録する。これには、技術力とマネジメント力が必要である。

議論の内容（抜粋）

・CIPM MRA の主目的は、ILAC MRA を支援することであり、標準の供給とトレーサビリティの確保との両面からの両組織の間で共通認識の確保が重要。
・計量標準の同等性を確認するためのルートとして、KCDB の活用がある。また、認定業務に NMI 職員の技術力を活用することがあげられる。
さらに、CIPM の基幹比較と技能試験の連携を検討することも効果的。
・BMC と CMC の概念の明確化を図ることが必要。ILAC は原則的に CMC の導入を認めるが、LOGO 関連では慣習的に難しいと認識（さらなる合意が求められる）。
・CMC と NAB の認定のタイミング（認定業務と CMC 登録の時期的なずれ）に注視する必要がある。
・NMI 関連の審査員の公表の問題を検討すべきかどうか。CIPM レベルでの高度の知識と見識が求められる場合には、その分野での認知も必要。
・審査員の経費の検討、特に NMI 間での差別化の回避が必要。
・審査員教育を共通の課題とすべき。CIPM MRA の活用を含めて共通の訓練の場を検討することが有効。
・適合性評価関連業務における助言の範囲はどこまでか。「いかにするかではなく、何をすべきか」を伝えることは可能。
・校正業務における NMI と認定試験所との競合への対処に配慮すべき。政策や財政面からの国情の違いはあるが、NMI と認定試験所との衝突は回避すべき。
・NMI における認定業務の分離の課題。特に多くの途上国においては、認定と計量標準が同一の監督官庁に所属することに配慮する必要がある。(ISO/IEC 17001 と関連)
＊JCTLM(JOINT COMMITTEE ON TRACEABILITY IN LABORATORY MEDICINE) 関連の当面の課題が紹介された。［BIPM, ILAC, IFCC, WHO: OBSERVER］
・WG1：認知された高度の標準物質のリストの作成、13 の SUBGROUP 構成。
・WG2：臨床試験所に関する参照試験所のシステム開発
関連の ISO/IEC17025、ISO Guide 34 が基本であるが、関連規格として ISO 15193, 15194, 15195, 17511, 18153 を検討中。［既存規格：ISO 15189, 15190］

上記の会議議告には付録として次の二つの文書が添付されている［重要］
（いずれも JCRB で検討済の文書）
＊ＣＭＣの定義：　CIPM MRA に使われる用語としての定義（不確かさの扱いも含む）
＊校正証明書に記述する内容

· REPORT ON THE BIPM/ILAC WORKSHOP ON REGIONAL ISSUES SURROUNDING ACCREDITATION

Held on7-8, March 2005, at the BIPM, Sèvres, France

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0. Present

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Aigul Akybaeva	CAC MAS-Q
Seton Bennet	EUROMET
Ismael Castelazo	BIPM
Ana María Coro	IAAC
Orna Dreazen	ILAA
Barry Inglis	APMP
Robert Kaarls	CIPM
Rainer Köhler	BIPM
Dianne Lalla-Rodrigues	SIM
Wynand Low	SADCA
Nina Mukhamedshina	CAC MAS-Q
Mukayi Musarurwua	SADCMET
Mike Peet	ILAC
Patrick Reposeur	EA
Anthony Russel	APLAC
Alan Squirrell	ILAC
Takashi Usuda	APMP
Andrew Wallard	BIPM
Robert Watters	SIM

1. Background to this meeting

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The CIPM-ILAC collaboration activities over the last few years were reviewed. Starting with the MOU signed in 2001 both organizations have met regularly and have represented each other at various meetings. The two organizations have collaborated in a working group for the past eighteen months and have produced a draft joint statement that was distributed as a working document for this meeting. The objective of the statement is to present what both organizations believe are the best practices on how accreditors and NMIs ought to work together. The intention of the document is to present a non-prescriptive recommendation as both organizations are well aware of the national differences existing around the world. Both organizations wish to emphasize the close and essential cooperation that needs to take place between the National Metrology Institutes (NMIs) and the National Accreditation Bodies (NABs). This collaboration is underpinned by the complementing CIPM and ILAC MRAs.

However, some misunderstandings persist; for instance the different interpretations given to the terms "Best Measurement Capabilities" (BMCs) -used widely to state the scope of accredited calibration laboratories- and "Calibration and Measurement Capabilities" (CMCs) - employed in the CIPM MRA.

The process used to review and approve CMCs in the CIPM MRA was presented. They are peer-reviewed by the top experts in each area within the Regional Metrology Organizations (RMOs) and then sent for an inter-regional review. The results of key comparisons organised by the CIPM and the RMOs are one of the main sources of evidence to support the uncertainty claims of NMIs. Approved CMCs are published in Appendix C of the MRA and comparison results in Appendix B; both are publicly available in the BIPM website at **http://kcdb.bipm.org**. A prerequisite for CMC publication is the presence of a fully implemented quality system based on ISO/IEC 17025, reviewed and accepted by the local RMO. Additionally, reference materials producers need to comply with ISO Guide 34. Technical and quality issues are often reviewed by an on-site peer-review. Accredited and self-declared NMIs follow the same regional review process.

ILAC commented that they wanted to find appropriate ways of meeting the needs of NMIs who choose the accreditation route to demonstrate compliance with the CIPM MRA.

2. General discussion on the joint BIPM-ILAC statement

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The draft BIPM-ILAC statement had been distributed before the meeting and the Chairman asked for comments from attendees. Without exception, RMOs and RABs agreed on the importance of the document and that it should stimulate work at the regional level.

Attendees agreed that there are concerns on both sides of the NMI-NAB dialog and that better communication is essential. The following issues regarding closer links between the CIPM and the ILAC MRAs were identified:

2.1. NMI support for the ILAC Arrangement

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One of the major purposes of the CIPM MRA was to support the ILAC MRA through traceability to the realisation of the S.I. units. NMIs see the ILAC arrangement as a useful way to fulfil their responsibility of disseminating traceability in their countries but not as the only way. In any case, it was agreed that the metrology community benefits from the ILAC arrangement and that it is worthwhile to support it.

The CIPM would like to see the scope of accredited laboratories harmonized with those in the CIPM MRA. This would help with a common understanding of "how far the light shines" in CIPM and regional comparisons and ILCs. There is concern that some scopes are expressed in terms of very broad areas like "electrical resistance" or "calcium", in the chemical area. ILAC thinks it is possible but requested receiving a specific request from the CIPM and a clarification of the concepts of CMCs and BMCs (see below)

2.2. Confidence in the degree of equivalence obtained through the CIPM MRA

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The group discussed the possibility of treating NMIs as a special group that deserved extended periods of surveillance or a simple way to update their scope between visits. This corresponds to the type C laboratories in the accreditors' nomenclature. While some accreditors only apply this flexibility for testing laboratories the accreditors in the group considered this to be possible in the NMI world and that it would be a natural result of increased communication. It would also help reduce costs which were becoming very high at some accredited NMIs.

It was pointed out that NMIs know very well that a full implementation of ISO/IEC 17025 –not only chapter 5– is necessary to comply with the requirements of the CIPM MRA. The possibility of common training of NMI staff used by accreditors was indicated as a possible route to achieve more confidence. Some RMOs pointed out that many of their members are formally trained by their local accreditation bodies.

The concept of "degree of equivalence" has been a source of confusion in some areas. It was recommended that accreditors should look first at Appendix C of the KCDB which lists the CMCs that have been accepted by the technical review process. Only if there is an interest to verify the evidence supporting the degree of equivalence of **national standards** should they need to look at the comparison results in appendix B. It was stressed that, during the CMC assessment process, the NMI experts have looked not only at comparison results but other available evidence like scientific publications and personal knowledge of the facilities and personnel.

ILAC undertook to inform their -community about the KCDB and that it was publicly available.

Another area of collaboration mentioned by the group was the linking of CIPM key comparisons with proficiency testing exercises run by accreditors. EA, for example, has requested EUROMET to organise comparisons for them. It was pointed out that this is easier to do in some areas like chemistry whose comparisons are run in a shorter time than in others but it should be encouraged whenever possible.

The group agreed to encourage regional metrology and accreditation organizations to invite each other to relevant working group meetings such as Technical Committees or those set up to review QMS at NMIs in order to promote confidence and transparency.

2.3. CMCs v.s. BMCs

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The different interpretations of CMCs and BMCs have been a source of confusion. The attached extract from the 8th JCRB minutes (Annex 1) was circulated and welcomed by ILAC as a major clarification. The Chairman also pointed out that although some NMIs may occasionally provide calibrations based on a measurement uncertainty which was lower than that declared in their CMC, these calibration certificates were not regarded as being provided in the CIPM MRA framework and could not include the JCRB statement of acceptance (Annex 2) or the CIPM MRA logo. ILAC indicated that they will support eliminating the term BMC and using CMC for accredited laboratories. The CIPM MRA states that CMCs are sometimes referred to as best measurement capabilities. ILAC may promote the adoption of the term CMC but it is very hard to change a long tradition and ILAC can not force accreditors to use this term overnight. The recommendations in the draft statement will be forwarded to the EA laboratory committee which is meeting this week in London.

Action: ILAC to provide the recommendations on the draft statement with respect to the concepts of CMCs and BMCs to the EA laboratory committee meeting in London this week.

2.4. Timing of accreditation and CIPM MRA reviews

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There is a potential problem when an NMI seeks accreditation before undergoing an inter-regional CMC review. For a period of time an NMI might provide a traceability to the SI that is acceptable to the accreditation community but not to the other NMIs. The problem would be worse if the accreditation experts do not agree with the results of a subsequent CMC review and so may not be prepared to amend an accreditation scope in line with the reviewed CMC. The accreditors in the group felt it was necessary to document specific cases of concern and to take them to the accreditation community for discussion.

2.5. Releasing the names of laboratory assessors

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The group discussed the problems arising when NMIs request accreditors to release the names of assessors. The accreditors present in the room did not think there was a problem releasing those names if there are specific requests. In the Asia-Pacific region accreditors have agreed to have the names of assessors approved by APMP before the accreditation starts. It was reported, on the other hand, that some European accreditors are reluctant to release those names. From the point of view of the CIPM the names of assessors are important, especially for high level laboratories, because they should be people that are well know in the community. It was clarified that NMIs do not want to be able to select the assessors themselves but to be able to provide their names, in confidence, to participants in the CMC review.

On the other hand, the accreditation community would benefit from a list of qualified assessors and this could be the result of sharing the names of participants in accreditations and CIPM MRA peer reviews.

2.6. Payment of laboratory assessors

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NMIs may provide assessors on a *quid pro quo* basis in order to reduce their accreditation costs which are considerable. Accreditors should not mark up the cost of assessors used for NMIs or for other accredited laboratories above of what NMIs charge to make them available. However, each accreditor is clearly free to set up its own charging policies and ILAC can only recommend something that would be convenient for the case of NMI accreditations. Additionally, assessors used for accreditation of NMIs do not come exclusively from other NMIs. Accreditors would need to accommodate a special pricing policy for NMIs that is consistent with their need to avoid any type of discrimination.

2.7. Assessors' training

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The accreditors would like to have full confidence in the assessing skills of NMI experts. It was pointed out that most of them have this training and in some cases a pre-accreditation briefing serves as a training exercise

with the AB lead assessor. It was agreed that accreditation bodies would also benefit from receiving the NMI's feedback on traceability and how the CIPM MRA should be used. APMP and APLAC agreed to work together to organise a regional event where both communities would share their points of view. The format and contents of this event will be communicated to the members of the group after both organisations agree on them with their own constituencies. The other RMOs indicated that they will also explore the possibility of organising similar events in their regions.

Action: Regional metrology and accreditation organisations to explore the possibility of organizing joint workshops to increase awareness on the issues discussed in this meeting

2.8. Guidance for assessors who provide advice to laboratories

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It is important to define the concept of advice. It is possible to tell a lab what should be done but not how to do it. Accreditors need to look at each case separately but should stress the importance of transparency and declaration of any conflict of interest. The group con not provide a general guidance on this issue.

2.9. Competition between NMIs and accredited laboratories for calibration services

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There is a concern in the accreditation community that some NMIs have an interest in the calibration market that compromises their role as an impartial organisation. In response to this concern it was pointed out that most NMIs charge significantly higher fees than secondary laboratories and most have a policy of directing customers to secondary labs if a service is available. Accreditors, however, have observed that when NMI experts participate in accreditations they sometimes try to convince the lab to take their instruments to the NMI. This is one of the reasons why there is a wish to separate accreditation from NMIs.

NMIs have a responsibility for disseminating the national standards through accredited and other laboratories and they need to provide calibration services. In many countries NMIs would not be financially feasible if they did not obtain a good percentage of their operating budgets through services. The group agreed that there are differences in national policies as well as financial pressures on NMIs but they should make a recommendation that this type of conflicts should be avoided whenever possible.

2.10. Separation of accreditation activities from NMIs

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The concerns over the issue of impartiality come from some regulators and accreditors. The CIPM agrees with setting up safeguards to assure impartiality but does not agree with the legal separation of NMIs and

NABs. The current ISO/IEC WD PAS 17001 reflects the point of view of the CIPM but there are still some people who do not agree with this document. The fact that accreditation and metrology are part of a single bureau of standards in many developing countries needs to be taken into consideration.

ILAC thinks it is possible to set up appropriate safeguards to avoid a conflict of interest without demanding a legal separation of the two organisations. It was stated that a formal statement on this point of view would be very helpful for the metrology community.

2.11. Next steps

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It was agreed that attendees will provide comments on the draft statement by the end of May.

Action: Attendees to provide comments on the draft ILAC/CIPM statement by the end of May.

3. ILAC/CIPM Issues in relation to the JTLM

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BIPM, ILAC and IFCC signed an agreement at the end of 2003 with the support of the WHO, which can not yet sign due to legal restrictions. The main driving force is the EU directive on in-vitro diagnostics and participants include industry associations, regulators in different parts of the world, as well as standardization and quality assurance organizations.

The three signatories and the WHO as an observer have formed an Executive Committee chaired by Prof. Thijssen, with the Secretariat provided by the BIPM. Two Working Groups have been set up. WG 1, jointly chaired by Dr. May and Dr. Schimmel, is charged with drafting a list of accepted reference materials of higher order. WG 2 is chaired by Dr. Siekmann and is involved with developing a system of reference laboratories which will be the nucleus of a wider network of clinical laboratories. They are currently gathering a list of interested laboratories, discussing the organisation of comparisons and procedures and criteria for accepting the reference laboratories.

WG 1 subdivided its work into thirteen subgroups, each one looking at different categories like hormones, coagulation factors and others that are important for the clinical community. Two lines of traceability have been identified. Whenever this is possible, traceability to the SI should be established. For biological activity traceability is established to WHO international units, which are not ideal because they are not stable. Therefore, this will continue to be a matter for scientific development. The two lists have been published in the BIPM website.

JCTLM members meet regularly and a working group on quality procedures is being organised. CRM providers work on the basis of

ISO!IEC 17025 and ISO Guide 34. The use of ISO standards 15193, 15194, 15195, 17511 and 18153 is being discussed. Input from accreditors would be very desirable on these issues as well as from NMIs on the provision of traceability coordinated by the CCQM.

The accreditors have discussed the possible accreditation based on 15195 but one of the problems is its lack of references to 17025. Some ILAC members believe that 15195 should be complementary only and others consider these laboratories as belonging to the testing area, which introduces a hierarchy problem. The JCTLM would consider the use of both 17025 and 15195 and would like to liaise with ISO in discussion on 15195.

4. Next meeting

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The group will meet again next year in early March. A specific date will depend on other meetings occurring around this time and will be announced as soon as feasible by the BIPM.

5. Annex 1

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DEFINITIONS OF TERMS USED IN THE CIPM MRA
Document JCRB-8/18

Calibration and Measurement Capability (CMC)[1]

The term Calibration and Measurement Capability (CMC) as used in the CIPM MRA is defined as follows:

The CMC is the best measurement capability that is ordinarily available to customers under normal conditions,[2] for example, as published in an NMI's service list and available, in principle, at any time. It should be:

1. *performed according to a documented procedure and an established uncertainty budget under the quality system of the NMI;*
2. *performed on a regular basis; and*
3. *available to all clients.*

This is also stated in Paragraph T.7 of the CIPM MRA's Technical supplement:

"*... The calibration and measurement capabilities referred to in this paragraph are those that are ordinarily available to the customers of an institute through its calibration and measurement services; they are sometimes referred to as best measurement capabilities.*"

Uncertainty Determinations for CMCs

INCLUDED ARE uncertainty contributions inherent in the best ordinarily available customer device during its calibration or measurement at the National Metrology Institute.

The actual characteristics of the device must also be considered for individual calibration certificates issued by the NMI.

EXCLUDED ARE uncertainty contributions (including transport uncertainties) associated with a customer's device before or after its calibration or measurement at the National Metrology Institute.

These contributions are not part of the calibration or measurement performed by the NMI and are therefore outside the NMI's control. It is the client's responsibility to take these extra factors into consideration.

[1] Based on "Report of JCRB *ad hoc* Working Group on CMC Uncertainties" (Document JCRB-8/9) and "APMP Proposals on Uncertainty Calculations for CMCs" (Document JCRB-8/9(3).

[2] Note: This does *not* include the NMI's capability to measure the very best instruments.

6. Annex 2

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CALIBRATION CERTIFICATE STATEMENT
Document JCRB-8/Cal_cert_statement

This certificate is consistent with the capabilities that are included in Appendix C of the MRA drawn up by the CIPM. Under the MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in Appendix C (for details see **http://www.bipm.org)**.

Note: In making a French version it became clear that in French it is necessary to be more explicit than in English. The following is the French text that has also been agreed with L. Erard on behalf of the BNM:

Ce certificat est en accord avec les aptitudes en matière de mesures et d'étalonnages (CMCs) figurant dans l'annexe C de l'arrangement de reconnaissance mutuelle (MRA) rédigé par le Comité international des poids et mesures (CIPM). D'après les termes du MRA, tous les laboratoires participants reconnaissent réciproquement la validité des certificats d'étalonnage et de mesurage pour les grandeurs, domaines et incertitudes de mesure mentionnés dans l'annexe C (pour plus de détails, voir (**http://www.bipm.org)**.

The corresponding longer English version is the following:

This certificate is consistent with the calibration and measurement capabilities (CMCs) that are included in Appendix C of the Mutual Recognition Arrangement (MRA)drawn up by the International Committee for Weights and Measures (CIPM). Under the MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in Appendix C (for details see **http://www.bipm.org)**.

T.J.Quinn April 2002