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**Hong Kong Accreditation Service**

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***Hong Kong Experience in the  
coordination of 3 APLAC workshops as part  
of the establishment of APLAC MRA on  
accreditation of RM producer***

# APLAC RM MRA

- Signed in Kuala Lumpur in December 2007
- Inaugural signatories:
  - A2LA
  - NATA
  - CNAS
  - IAJapan

# APLAC RM MRA



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# APLAC MRA Council Reference Material WG

- Formally established in Nov 2002 with the following ToR
  1. *Review RMP requirements and propose rec to APLAC for policy formulation*
  2. *Review and propose amendments to APLAC MR-001 and -002 to cover RM accreditation*
  3. *To advise MRA Council on RM MRA*

# APLAC MRA Council Reference Material WG

- *Matters needed to be considered by the WG included:*
  - *Mechanism and policy for inclusion in the MRA of the accreditation of RM activities*
  - *Acceptable criteria for accreditation*
  - *Timeframe for implementation*
  - *Evaluator resource issues*

# Principles for Accreditation of RMPs in 2003

- *Two initial tasks*
- *Agree on the fundamental principles*
- *Survey to see where we are*

# Principles for Accreditation of RMPs in 2003

- *Use ISO G34:2000*
- *Replace ISO/IEC Guide 25 by ISO/IEC17025*
- *Generally require labs accredited to ISO/IEC17025 when practical*
- *Use ISO/IEC17011 as requirements for ABs*

## Principles for Accreditation of RMPs in 2003 (cont'd)

- *Require signatories to be signatories to testing, calibration and/or inspection*
- *Use APLAC MR001 as the procedure for evaluation after suitable modifications*
- *Amend APLAC MR002 to include RM MRA*
- *Use experts in RM production in evaluation*

# First RM Workshop

- *APLAC MRA RES. 14.21*

*That the MRA Council support the request for funding of USD9,000 to support the RM producer workshop planned for Hong Kong, China in March 2005*

# First RM Workshop

- *APLAC MRA RES. 14.20*

*That the timeline for the work of the RM Producer MRA Working Group only be finalised after the outcome of the RM Producer Workshop is reviewed at the April 2005 MRA Council meeting*

## **Timeline proposed in 2004**

***April 05 – APLAC Secretariat seek notification of interest***

***July 05 – interested ABs indicate their intention***

***October 05 – accept application for joining RM MRA***

***January 06 – start first round evaluation***

***End of 06 or mid-2007 - RM MRA signed??***

## MILESTONE!!!

- *APLAC GA RES. 10.13*

*That the General Assembly commits to proceeding with an extension of the APLAC MRA to include accreditation of RM producers, unless the March 2005 workshop recommends otherwise.*

# Expected Deliveries

*APLAC MRA RES. 14.20 –*

*That the following are expected deliverables from the March 2005 RM  
Producer workshop:*

- **Technical issues relevant to accreditation of RM producers**
- **Exploration of the extent of interest in an extended APLAC MRA to cover accredited RM producers**
- **Possible mechanics for implementing a potential extension of the APLAC MRA to include accreditation of RM producers**
- **Draft advice on practices in the accreditation of RM producers.**

# First RM Workshop

**Date** – *11 and 12 March 2005*

**Place** – *Hong Kong*

**Number of Participants** – *20*

**Number of ABs** – *14 (APLAC) + 1 (IAAC)*

**Number of economies** – *11 (APLAC) + 1 (IAAC)*



# First RM Workshop

**Programme: *four sessions***

**Session 1 – *ISO/IEC 17025 issues***

**Session 2 – *ISO Guide 34 (& other related guides) issues***

**Session 3 – *MRA issues***

**Session 4 – *Summary and conclusion***

## First RM Workshop

*Dr Ed de Leer*, Chair of IAGRM and  
Director of Science, NMI Van Swinden  
Laboratorium, Dutch National  
Measurement Standards Institute

*Dr Robert Watters*, Chief, Analytical  
Measurement Division, NIST

*Mr Alan Squirrell*, ILAC Secretary

# First RM Workshop Outcome

- 1. To proceed with the extension of the current APLAC MRA to cover accreditation of RMPs*
- 2. To initial actions identified at the workshop. A timeframe of now to 2 years from now has been suggested for extension of MRA*
- 3. ISO/REMCO informed of the suggested amendments to ISO Guides 31, 34 and 35*

# First RM Workshop Outcome

4. *5 modes of operation of RMPs identified. A matrix showing application of 17025 and G34 should be developed*
5. *Variations in the description of scopes of accreditation were identified. Harmonisation suggested*
6. *A global workshop on 17025, G34, etc., suggested.*
7. *Training of RMP technical assessors and evaluator needed. Technical experts from other regions may need to be enlisted in the evaluation process. A worldwide list of technical experts is helpful.*

## First RM Workshop Outcome

8. *Relevant bodies such as ILAC, ISO/REMCO, IAGRM, etc., kept informed of development in APLAC and requested to consider the outcomes of the workshop.*
9. *Amend APLAC MR-001*  
*Suggested amendments presented to MRA Council meeting in Dec 04.*
10. *IAJapan will provide their G34 and 17025 gap analysis to the WG*

APLAC RM  
Workshop report

APLAC MRA Council (for consideration at  
the April 2005 meeting)

ISO/REMCO

ILAC

CIPM

Regional Cooperation Bodies

ILAC AIC

IAGRM

**ILAC AIC INFORMED OF THE OUTCOMES OF THE WORKSHOP  
AND REQUESTED TO CONSIDER THEM IN THEIR WORK ON  
RELATED ISSUES**

## **First RM Workshop Recommendations**

***The workshop recommends to proceed  
with the extension of the MRA to  
include accreditation of RM***

***According to GA RES. 10.13, APLAC will  
proceed with the extension.***

# First RM Workshop

*Workshop – now to 2 years from now*

*How ready are we?*

*Survey results*

*Still some actions to be completed – work in parallel*

*How soon do we want to have the MRA?*

*Too long = more divergent or more consistent?*

*Problems always exist*

*Laboratories need a means to source reliable RMs*

*Question of impact on ILAC MRA – At its meeting in Mar 05, the ILAC ARC decided to put forward a proposal to extend MLMRA to include RMPs at the next GA in Sep 05, subject to ILAC Executive endorsement at June's meeting*

## **First RM Workshop**

**May 05** – **APLAC Secretariat seek notification of interest**

**August 05** – **interested ABs indicate their intention**

**February 06** – **accept applications to join RM MRA**

**May 06** – **start first round evaluation**

**Mid- or end of - 2007 - RM MRA signed??**

**Council's endorsement on the above timeline sought**

# First RM Workshop Action Plan

- 1. Proposed amendments to MR-001 were presented to the December 2004 MRA Council meeting. These proposed amendments are generally consistent with the outcomes of the workshop. Further amendments will be made taking into consideration suggestions of the workshop. Draft to be ready at the MRA Council meeting in Nov 05. Endorsement will be sought at the meeting.***

## **First RM Workshop Action Plan**

- 2. Amendments to MR002 and MR003 to be drafted and presented to the next MRA Council meeting for endorsement in Nov 05.***
- 3. Training of evaluators – to be organised after MR001 amended and adopted, 1<sup>st</sup> quarter of 06.***

***Revised MR001, 002 and 003 to be adopted and published by Jan 06***

# Reference Material Accreditation Survey in Jan 05

- *31 copies sent out*
- *Covered all full members and 1 associate member*
- *18 completed questionnaires returned*
- *Return rate: 58%*
- *No. of ABs accrediting RMPs: 6 (33%)*

# Reference Material Accreditation Survey in Jan 05

## Number of accredited RM producers

- *14 (as calibration labs)*
- *8*
- *2 (RMPs being assessed)*
- *2 (one other assessed)*
- *2*
- *0*

# Reference Material Accreditation Survey in Jan 05

## Operation in substantial compliance with ISO/IEC 17011

*6 out of 6 say yes*

*Comments: However, the following interpretative comments needs to be included in ISO/IEC 17011*

- In general, a RMP should be referred to as a facility rather than a laboratory.*
- SCOPE: To include the term “production of reference materials” in para 3 under this section.*
- Cl. 7.9.5: To include the requirements for a RMP certificate.*
- To include a NOTE under cl. 7.15: To relate the requirements for the accredited RMP and its collaborators to participate in relevant proficiency testing.*

# Reference Material Accreditation Survey in Jan 05

ISO G34 and ISO17025 as criteria

4 “yes” and 2 “no”

*Reasons for “no”:*

- *We do not require 17025 accreditation for the labs supporting the RMP although our past and current RMPs have chosen to have their labs accredited to 17025*
- *17025 only*

# Reference Material Accreditation Survey in Jan 05

*Both ABs with “no” response said they will  
change criteria:*

- *If said criteria become APLAC MRA requirements*
- *In 2007 RMPs currently accredited as cal labs will be transferred to G34 once dedicated programme is launched*

# Reference Material Accreditation Survey in Jan 05

*All 6 ABs currently have RM programme are interested in joining RM MRA*

*ABs with no RM programme currently,*

- *8 intend to develop this programme*
- *7 of these are interested in joining RM MRA*

*4 ABs no intention to develop RM programme*

*Overall: 13 ABs intend to join RM MRA (72%)*

# Reference Material Accreditation Survey in Jan 05

Time ready for evaluation

*For the 6 with RM programme -*

*As soon as available: 3*

*2006: 2*

*2011: 1*

*For others -*

*2006: 1*

*2008: 1*

*2009: 3*

*2010: 2*

# Reference Material Accreditation Survey in Jan 05

*Of the 12 ABs currently with no RM programme,  
10 say that there are RM producers  
interested in seeking accreditation*

## First RM Workshop

- **The workshop recommends to proceed with the extension of the MRA to include accreditation of RM**
- **The Workshop report was presented to the 15<sup>th</sup> MRA Council meeting in April 2005 in Narita. All recommendations of the workshop were accepted.**

# First RM Workshop

*MRA RES. 15.21 –*

*That APLAC MR 003 be revised to include accreditation of RM producers and that call for applications to join the extended APLAC MRA be sent to all current APLAC MRA signatories on 1 January 2006, with applications closing on 30 June 2006. Of the 12 ABs currently with no RM programme, 10 say that there are RM producers interested in seeking accreditation*

# First RM Workshop

*MRA RES. 15.22 –*

*That the inaugural signing of the extended  
APLAC MRA take place once 4 accreditation  
bodies have been evaluated and have met all  
the conditions for the extension of their  
scopes of recognition to include RM  
producers.*

# First RM Workshop

*MRA RES. 15.24 –*

*That the APLAC Technical Committee develop a matrix to cover the 5 different modes of operation of RMPs (proposal 4), working closely with the RM Producer Working Group.*

# First RM Workshop

*MRA RES. 15.25 –*

*That the APLAC Technical Committee work closely with the RM Producer Working Group on the harmonisation of the scopes of accreditation of RM producers (proposal 5).*

# First RM Workshop

*MRA RES. 15.26 –*

*That the RM Producer MRA Working Group  
propose to ILAC that a global workshop on  
RM accreditation issues be held in  
conjunction with either ILAC 2005 or ILAC  
2006*

# First RM Workshop

*MRA RES. 15.27 –*

*That the RM Producer Working Group discuss  
the need for an APLAC training course for  
RM producer assessors with the Chair of the  
APLAC Training Committee*

# First RM Workshop

*MRA RES. 15.28 –*

*That the report from the RM workshop be sent to ILAC and the regions, with a general summary for the APLAC MRA Council's resolutions in relation to the workshop's proposals; that these also be posted on the public area of the APLAC website (proposal 8).*

# First RM Workshop

*MRA RES. 16.16 (in Dec 2005, Chiang Mai) –*

*Proposed revision of MR-001 for inclusion of  
RMP in the MRA approved.*

# First RM Workshop

## *APLAC Accreditation requirements for RMP*

### *APLAC MR-001 Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Amongst Accreditation Bodies*

#### *Part 3 CRITERIA*

##### *Clause 3.1 Standards*

*Sub-clause 3.1.2 An applicant body shall ensure its accredited organisations fulfil the following criteria:*

- For RMPs, ISO Guide 34 and ISO/IEC 17025 in combination*

# First RM Workshop

*MRA RES. 18.14 (in Sep 2006, Taipei) –*

*That, within the context of the APLAC MRA for accreditation of reference material producers (RMP), an accredited RMP is an organisation that assigns the property values and determines the associated uncertainties (ISO Guide 34:2000, clause 5.15), and issues the certificate (ISO Guide 34:2000, clause 5.16); that accredited RMPs shall be competent to do those tasks that cannot be outsourced to collaborators, subcontractors or other outside parties.*

# First RM Workshop Impact

- *Most important workshop*
- *Established the recommendation to have a RM MRA*
- *Interpretation of ISO Guides*

# Second RM Workshop

**Date** – *10 to 12 April 2006*

**Place** – *Beijing, China*

**Number of Participants** – *16*

**Number of economies** – *11 (APLAC) + 1 (IAAC)  
+ 1 (EA)*

# Second RM Workshop



# Second RM Workshop

**Programme: seven sessions**

**Session 1 – Extension of the APLAC MRA to include RMP**

**Session 2 – Setting up of an accreditation programme on RMP and approaches to the assessment of RMPs**

**Session 3 – Application of ISO/IEC17025 to the assessment of RMPs**

**Session 4 – ISO Guide 34 requirements**

# Second RM Workshop

**Programme: seven sessions**

**Session 5 – ISO Guides 30, 31 and 35 requirements**

**Session 6 – Planning of assessments**

**Session 7 – Discussions, experience sharing and wrap-ups**

# Second RM Workshop

*Dr Ed de Leer*, Chair of IAGRM and Director of  
Science, NMI Van Swinden Laboratorium,  
Dutch National Measurement Standards  
Institute

*Ms Roxanne Robinson*, Vice President, A2LA

*Mr W W Wong*, Convenor, APLAC MRA Council  
WG on RM MRA

## Second RM Workshop Outcome

*Extension of the APLAC MRA to include RMPs*

**If RMP is doing testing/calibration or measurement then the RMP must meet ILAC P9; an accredited collaborator would also have to meet ILAC P9 and a non-accredited collaborator would need to demonstrate competence through PT or other equivalent means**

# Second RM Workshop Outcome

*Application of ISO/IEC 17025 to the assessment  
of RMPs*

**A candidate organisation can only be  
accredited as an RMP if they are the party  
responsible for the assignment of RM  
values and issuance of the certificate.**

# Second RM Workshop Outcome

## *ISO G34 requirements*

**The rigor of RMP's processes for analytical method development and validation must be much stronger, an assessor should include a careful look at traceability and measurement uncertainty estimation, in line with the scrutiny given to a calibration laboratory.**

# Second RM Workshop Outcome

## *ISO G34 requirements*

If the testing collaborator is accredited to the specific test and the degree of contract review done between the lab and the RMP client is appropriate and looks at measurement uncertainty, traceability and PT (where suitable and applicable) and there is attention by the testing lab to performing the work with technical rigour, site assessment is not normally needed. It should be noted that the responsibility for meeting the requirements of ISO G35 and the design of the measurement programme rests with the RMP, which is always responsible for assigning values. This measurement programme, including a reference to the ISO G35 requirements, should be provided by the RMP as part of the contract review.

# Second RM Workshop Outcome

## *ISO G34 requirements*

**When the testing collaborator is not accredited, the same issues must be addressed, but an on site assessment/surveillance may be needed.**

# Second RM Workshop Outcome

## *ISO G34 requirements*

**If the testing lab is properly assessed for its testing capabilities and related in-house calibrations, accreditation for the in-house calibrations is not necessary.**

# Second RM Workshop Outcome

## *ISO G34 requirements*

**The clause 4.1.4 in ISO/IEC 17025 that looks at conflict of interest should be applied when assessing the in-house testing function and its relationship with the production department.**

# Second RM Workshop Outcome

*ISO G34 requirements*

**ISO/IEC 17025 was not applicable for the  
production task (except if testing is  
involved)**

# Second RM Workshop Outcome

*ISO Guides 30, 31 and 35 requirements*

**ISO G34 requires certificates to meet all of the requirements of ISO G31, noting that ISO G31 has many “should” statements that are not requirements; however, these “should” may be considered on a case by case basis as additional requirements where they are fundamental to the technical validity of the RM production.**

## Second RM Workshop Outcome

*ISO Guides 30, 31 and 35 requirements*

**An AB should also investigate available global technical standards that might be included as application ISO G34 for discipline specific RM programmes to underpin the technical rigour of the programme.**

# Second RM Workshop Outcome

## *ISO Guides 30, 31 and 35 requirements*

**RMPs are not labs and should not be required to meet the ISO/IEC 17025 requirements for the RM certificate content; RM certificates must meet ISO G31 requirements. So an AB should not include Section 5.10 of ISO/IEC 17025 in an assessment of an RMP to ISO G34 in combination with ISO/IEC 17025.**

# Second RM Workshop Outcome

*ISO Guides 30, 31 and 35 requirements*

**ISO G32 does not prohibit the RMP from including a brand name on the certificate and label; however RM must meet all of the other requirements of Section 5.4, 5.5 and 5.6 of ISO G31.**

# Second RM Workshop Outcome

## *Planning of assessments*

**An RMP doing the minimal number of tasks (only assignment of values and issuance of the certificate) would at least have to meeting the requirements of ISO/IEC 17025, Sections 5.4.1, 5.4.2, and 5.4.6.**

# Second RM Workshop Outcome

## *Planning of assessments*

**The scope of accreditation and the certificate of accreditation for all RMPs should include a statement such as “meets the requirements of ISO G34 and the relevant sections of ISO/IEC17025.**

# Second RM Workshop Outcome

## *Planning of assessments*

**Scopes should include measurement uncertainty, range, where relevant. If the arrangements with any of the RMP's collaborators change during the accreditation period, the AB should properly investigate the new collaborator arrangements.**

## Second RM Workshop Impact

- *Highlighted the difficulties in using ISO Guide 34 and ISO/IEC17025 in combination*
- *Recognised the difficulties in using the varies ISO REMCO Guides as the accreditation criteria*
- *Recognised the difficulties in the assessment and accreditation of RMPs*

# Third RM Workshop

**Date** – *30 May to 1 June 2007*

**Place** – *Tsukuba, Japan*

**Number of Participants** – *17*

**Number of ABs** – *13 (APLAC) + 1 (IAAC)*

**Number of economies** – *9 (APLAC) + 1 (IAAC)*

# Third RM Workshop Objectives

- **Application of ISO/IEC 17025 to RMP tasks**
- **Review of APLAC TC008 to identify those guidelines which are considered to be essential for achieving a consistent approach to the accreditation of RMPs using ISO G34 and ISO/IEC17025 in combination as criteria.**
- **Training on the newly published SIO G35.**
- *Sharing of experience.*

# Third RM Workshop

**Programme: *eight sessions***

**Session 1 – *Application of ISO/IEC17025 to RMP tasks***

**Session 2 – *Production procedure for CRMs***

**Session 3 – *Sharing of experiences of assessment of RMPs using ISO G34 and ISO/IEC17025 in combination***

**Session 4 – *Overall view of ISO REMCO Guides and examples of CRMs production***

# Third RM Workshop

**Programme: *eight sessions***

**Session 5 – *APLAC TC 008 RMP guidance document***

**Session 6 – *International dimension of CRMs and RMs***

**Session 7 – *ISO G35***

**Session 8 – *Wrap up***

# Third RM Workshop

*Dr Martina Hedrich, BAM, Germany*

*Ms Roxanne Robinson, Vice President, A2LA*

*Mr W W Wong, Convenor, APLAC MRA Council WG on RM MRA*

*Mr Alan Squirrell, ILAC Secretariat*

*Dr Kazutoshi Kakita, Japan Society for Analytical Chemistry*

*Dr Hidetaka Imai, IAJapan/NITE, NMIJ/AIST*

*Dr Tsutomu Miura, NMIJ*

# Third RM Workshop

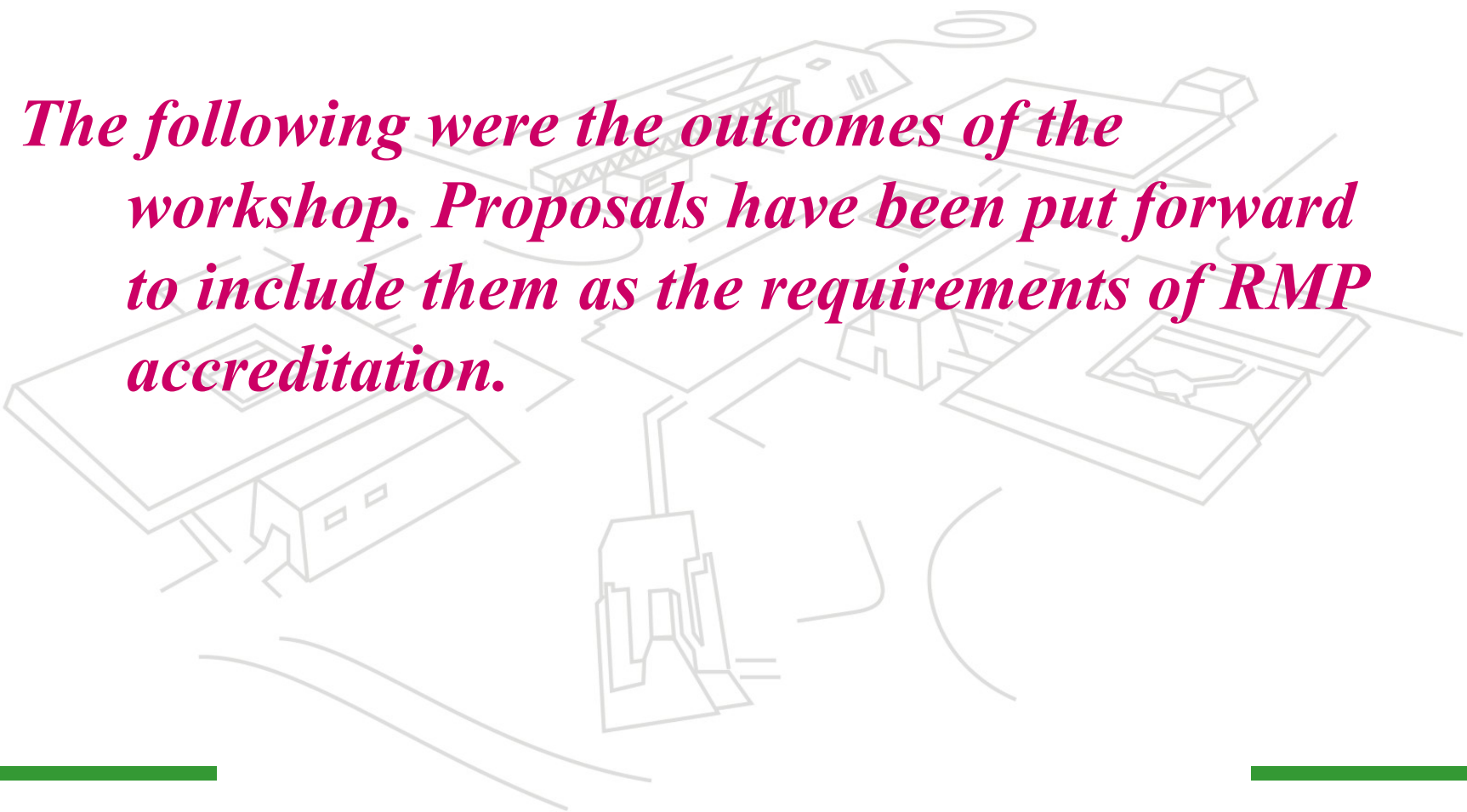


# Third RM Workshop



## Third RM Workshop

*The following were the outcomes of the workshop. Proposals have been put forward to include them as the requirements of RMP accreditation.*



## Third RM Workshop

*With respect to the ILAC resolution 8.12, the core criteria document is ISO G34, noting that ISO/IEC17025 is a normative reference in ISO G34.*

# Third RM Workshop

*ISO G34 is applicable to all activities of RMP  
including testing, calibration and  
measurement.*



## Third RM Workshop

*The relevance of a requirement should be assessed in the context of activities performed rather than the organisation structure of the RMP facility. In other words, “the laboratory” in ISO/IEC17025 means testing, calibration and measurements and related activities, and not restricted to the part of the organisation that is called “laboratory”.*

# Third RM Workshop

*A RMP facility may be considered as an organisation whose business is for production (and certification) of (C)RMs where testing, calibration and measurement activities are undertaken. Even if all performance of testing, calibration and measurement may be carried out by outside parties, the RMP facility is still performing some activities related to measurements such as “review of requests, tenders and contracts”, “subcontracting of tests and calibrations”, “Selection of methods”, “Estimation of uncertainty of measurement”, “Control of data”, “Sampling”, “Handling of test and calibration items”, etc.*

## Third RM Workshop

*Depending on the actual situation of the RM and the RMs they produced, general guidelines or principles for application of ISO/IEC17025 that are relevant to the activities of RMP tasks are more useful than specific guidelines. Specific guidelines may lead to rigidity and hamper the exercise of professional judgment. This might undermine competence assessment. Examples of application are useful.*

# Third RM Workshop

*All requirements of IOS/IEC17025 may be applicable to testing, calibration and measurement activities of RMPs.*



## Third RM Workshop

*Testing, calibration and measurement activities include not just performance of tests, calibrations, measurements and sampling, but also other related activities such as review of requests, tenders, and contracts, subcontracting of tests and calibrations, selection of methods, validation of methods, measurement traceability, assuring the quality of test and calibration results, etc.*

# Third RM Workshop

*The requirements of ISO/IEC17025 are not applicable to activities of the RMP other than testing, calibrations and measurement and other related activities.*



## Third RM Workshop

*For those requirements where they are given in both ISO G34 and ISO/IEC17025, they are both applicable to the activities related to testing, calibration and measurement. Only ISO G34 requirements are applicable to other activities (i.e. activities not related to testing, calibration and measurement) of the RMP. There should not be inconsistent requirements, but only more specific requirements given in ISO/IEC17025 for activities related to testing, calibration and measurement.*

## Third RM Workshop

*The applicability of ISO G34 and ISO/IEC17025 requirements should be considered on a case-by-case basis because they may vary from case to case and depend on the actual situation of the RMP and the RMs they produced, and they may also change as the production process changes. The assessment team needs to perform an analysis of the RMP operation and determine how the two criteria documents should be applied based on the above principles.*

# Third RM Workshop

*Some more important clauses of ISO/IEC17025  
that are related to RMP tasks are identified.  
But all requirements need to be considered  
for each of the RMP tasks.*



## Third RM Workshop Impact

*Established further how ISO G34 and ISO/IEC 17025 should be used in combination*

*Established the key elements that should be regarded as mandatory for accreditation of RMPs*

*Recognised the importance of sharing of experience in harmonising practices*

# Fourth RM Workshop

*4th quarter of this year*

*Theme : Training the trainers*

*Sharing of experience*

*In Hong Kong*

謝謝

*Thank you for your attention*

*Have a nice day*