WG on the Review of the CIPM MRA:

Subgroup on Specific Issues Relating to CMCs for Chemistry and Ionizing Radiation

Report for WG meeting on 14-15 March 2016*

*With updates of October 2016

Bureau International des Poids et Mesures

Subgroup Members

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Subgroup on Specific Issues Relating to CMCs for Chemistry and Ionizing Radiation

Should new scopes and processes be developed for CMCs in chemistry? Should new areas such as biology and emerging technologies also be considered? Should the CCQM and the CCRI review and revise their CMC templates?

- **New scopes and definitions not required for Chem/Bio or IR CMCs**.
  - already have some Bio CMCs in data base
  - adequacy of templates for Chem, Bio and IR CMCs being evaluated and designed as necessary

- **CIPM MRA-based Comparison Studies should not be carried out primarily for the value-assignment of CRMs or PT samples**

Subgroup on Specific Issues Relating to CMCs for Chemistry and Ionizing Radiation *continued*

- Still need both inter-RMO CMC review and interregional review for chemistry and biology
  - There are fewer experienced NMIs in some RMOs and inconsistencies in the quality of intra-RMO review.
  - We have too much work invested in KCDB to reduce quality now.
  - Provides training in expectations regarding CMCs at both RMO and CC levels.

Changes in the CMC template for Chemistry and Biology

- **Following April 2016 meeting, CCQM President appointed CCQM ad hoc CCQM KCDB 2.0 Working Group to review and propose modifications to current templates used for proposing, reviewing, and approving chemical and biological CMCs as well as KCDB search engines and functionalities.**

- **This group has provided recommendations to CCQM President regarding changes in the CMC template for Chemistry and Biology**

  – discussion and adoption planned for next meeting of the CCQM in April 2017

Current Template for Chemistry and Biology CMCs

Country	NMI or Designated Service Provider	NMI Service Identifier	Meas. Serv. Cat. No.	Meas. Serv. Sub-Category No.	Meas. Serv. Category	Matrix	Measurand				Dissemination Range of Measurement Capability			Range of Expanded Uncertainties as Disseminated					
							Analyte Group Identifier	Analyte or Component	CAS Number	Quantity	From	To	Unit	From	To	Unit	Cov. factor	Lev. of confid.	Is the expanded uncertainty a relative one?

Range of Certified Values in Reference Materials			Range of Expanded Uncertainties for Certified Value						Mechanism(s) for Measurement Service Delivery	Source of Traceability	Measurement Technique(s) Used	Link(s) to Appendix B (Formal Comp. Name(s))	Comment(s) of Service Provider	Comments (to be published via the database)	Uncertainty Convention
From	To	Unit	From	To	Unit	Cov. factor	Lev. of confid.	Is the expanded uncertainty a relative one?							

		Additional information to assist with CMC review			
RMO Services Administration		New or Revised claim?	Exact nature of service delivered	Details of calibrants used and assessment of their purity/certification	Clear description of supporting evidence for this claim
Review Code/ Status	Review Comments				

Recommendations from the CCQM ad hoc Working Group on KCDB2.0

1. **The CMC template will be simplified by suppressing the nine columns that describe CRMs.**

   - **This information can just as well be included in the 'disseminated capability' columns (with ranges and uncertainties adjusted accordingly if necessary).**

Note 1: The 'measurement service delivery mechanism' column would include CRM names as well as calibration service identifiers which would allow the disseminated capability information to be linked to actual services.

Service identifiers for bioCMC supported services are likely to be broader than CRM and "traditional" calibration eg inclusion of value assignment for control lab PT schemes. These "higher order" metrological services, will be collated and described by the NAWG, PAWG and CAWG.

Note 2: This would meet ILAC P10 requirements, which requires use of CRMs that are listed in the BIPM KCDB

Note 3: The WG felt that in many cases the CRM columns were just a duplication of what appeared in the current 'disseminated capability columns'

Recommendations from the CCQM ad hoc Working Group on KCDB2.0 - continued

2. The current measurement service categories for the 'Amount of Substance' need to be reviewed, taking into account what these categories are being used for. This may also mean that the CMC template allows listing of a disseminated capability for a number of service categories.

Note 1: The WG agreed that the service categories are not used to search for CMCs (a keyword search function is in use), but rather for classiifying CMCs for internal reference during the review process.

Note 2: The WG noted that a capability can be used to disseminate services across a range of categories, and this will become more evident with broad claim CMCs.

Note 3: If the categories are used for review, these are carried out by experts that work in WGs. The WG field of activity is possibly a better categorization system in that case.

- *Customers are more likely to be looking for a capability service related to eg nucleic acid quantification. Maintaining and enhancing a 'Keyword' area would be supported as this would be key to searching any database with a broad claim.*
- *Term such as 'biological matrix' is not adequate as different matrices have different measurement challenges.*

Recommendations from the CCQM ad hoc Working Group on KCDB2.0 - continued

3. **The WG noted that a common request from the Bio group had been that their description of the measurand may need to be quite lengthy, and a future template/data entry field should not limit this. Expansion of the matrix field may assist in issues with entry of Bio CMC claims.**
4. **Further discussion would be needed on how broad scope CMC claims would be introduced into the KCDB. While the template did not appear in any way to limit broad scope claims being made, there were questions on what practical use broad scope claims would be for users? In bio area – broad base claims thought to be more use for customers eg NA quantification in specific range/measurement space. Studies being designed to support broader claims to better support range of measurement services being provided by NMI/DIs.**

Note 1. The WG agreed that whilst for some CMCs (e.g. those related to gas calibration standards) an equation between mole fraction and uncertainty could be agreed, in other areas this would not be feasible, and the approach of using a range of uncertainties would need to continue and be possible in KCDB2.0. *For bio CMCs the database does need to provide for uncertainties that vary with measured value. Simple relationships, including uncertainty, relative uncertainty, and range of uncertainty for stated range of measured value are important. More complex relationships could be useful for 'broad scope' CMCs in future but are not currently used*

Recommendations from the CCQM ad hoc Working Group on KCDB2.0 - continued

5. The WG agreed on the proposal to keep the field “Analyte Group” in the current template for now, as it might find use for linking the CMC claim to a HFTLS statement (e.g. stating MW and pKow for the analyte).

6. The WG supported the proposal to produce a CCQM best practice guide on preferred units to use for expressing CMCs in the KCDB, noting that the choice of units would still be driven by customer requirements, but in other cases it would be possible to harmonize (e.g. to decide whether to use g/g or kg/kg for expressing mole fractions as an example).

7. The WG supported the approach being currently investigated by the BIPM on the feasibility a web-based tool for the complete CMC submission and review giving full tracking of the CMC review process, for example as part of the KCDB 2.0; The possible web-based tool for making and tracking comments on each CMC during the intra- and/or inter-RMO review process as well as the option for uploading the QS evidences attached with a CMC submission were welcomed, as well as the ability to export CMCs, and print out or save the comments generated from the active review process (to demonstrate and track the review process). Standard reviewing web software tools could potentially be employed.

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Input regarding "Summary of Key Points from the MRA Review Meeting"

Overview – general points

The MRA should continue to maintain its high levels of quality and integrity so as not to undermine the effort invested over 15 years.

SG: Agree

The MRA should continue to be inclusive and be built on --- trust between the NMIs and between the RMOs

SG Recommendation: The MRA should continue to be inclusive and be built on "demonstrated and documented assessment of capabilities among the NMIs".

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Input regarding "Summary of Key Points from the MRA Review Meeting" – cont'd

The MRA is an arrangement between NMI Directors, it is a tool to support the NMIs in their interactions with their users.

SG recommendation: that "in their interactions with their users" be deleted and replaced with following from MRA Preamble:

"by:

- establishing the degree of equivalence of national measurement standards maintained by NMIs;
- providing for the mutual recognition of calibration and measurement certificates issued by NMIs;
- thereby providing governments and other parties with a secure technical foundations for wider agreements related to international trade, commerce and regulatory affairs."

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Input regarding "Summary of Key Points from the MRA Review Meeting" – cont'd

The total effort required to operate all aspects of the MRA should not rise above the present levels and should be reduced where possible. Steps should be taken to spread the load more widely.

Okay

The resources used in the KC/CMC processes should be tailored according to the risk and complexity of the issues being handled.

Okay

MRA processes have evolved. The JCRB and the CCs have progressively addressed short comings and many improvements have been implemented.

Okay

New, modern IT tools should be developed.

SG recommendation: add "to support the usability of the KCDB." at end of sentence.

Key Comparisons (KCs)

The planning of KCs should be strategic (eg part of the strategic plan of each CC).

Agree

As stated in the text of the MRA, key comparisons test the principal techniques and methods in the field. Not all NMI services can be directly underpinned by a KC.

Discussion:

- For Chemistry, KCs do not test "principal techniques", but rather NMI (core) capabilities. (I.e., not just the instrumental techniques, but also extraction, pretreatment, etc. as needed to provide metrologically traceable chem/bio (for CCQM) measurement services to customers

(continued on next slide)

Additional Input

TCs should review existing CMCs for need, validity and consistency, as they would have a better idea about whether CMCs are really being delivered as services or not.

SG Recommendation: better phrasing as CMCs aren't "delivered". Delete "really being …or not" and replace with "associated with actual services"

Since above Recommendations presented:

Subgroup vetted draft report with further input from CCQM and CCRI for Questions 8 & 9

Subgroup agreed that members should provide input to Questions 1-7 as well.

Subgroup provided final report to WG on CMC Review in June 2016