The Core Capability approach in support of CMCs for Inorganic Analysis: guidelines for the use of the revised approach

Introduction

Since 2009 the CCQM Inorganic Analysis Working Group (IAWG) has implemented an approach to support CMCs based upon "core capabilities" (CCs) demonstrated by participation in KCs (and selected PSs) and required in the performance of the CMC.

The IAWG has recently begun a comprehensive review of the core capability approach with the aim of reducing the number of KCs organised within the WG and simplifying the procedures for CMC submission and approval.

The revised Core Capability approach is based on a matrix table indicating how far a key comparison can support broad scope claims. The table is structured by matrix challenges and analyte groups, with most of the analyte groups based on the periodic table classification. The table also indicates the analyte content range over which a capability has been demonstrated. A table will be prepared for each KC and will become part of the key comparison report together with the traditional "how far does the light shine" statement. These tables and the NMI record of participation (see page 3) will serve as evidence when submitting broad scope CMC claims. Note that with this revised approach, there is no longer any need to submit core competency tables when reporting KC results.

This approach will allow to reduce the number of KCs organized by the IAWG using a strategic approach to the broader assessment of measurement capabilities in inorganic analysis and to set a predictable number of comparisons to cover a wide range of CMCs, in combination with the IAWG 5 year plan. Its implementation is obligatory for any KC study starting from 2018 onwards.

Summary of the process of documenting core capabilities and using demonstrated core capabilities to support new CMC claims

1) Structure of the matrix table

The matrix table is structured by:

- Matrix challenges
- Analyte groups, mostly according to periodic table classification
- Concentration levels for the analyte groups

The matrix table is attached in Annex 1.

The measurement space covered by the KCs performed in the last 5 years is given in a separate document (available on the CCQM webpage).

The completed individual CC tables are also available on the CCQM webpage.

2) Proposal of a new KC

NMIs/DIs bringing new proposals for comparisons to the IAWG should propose a CC table predicting which analytes/matrix combinations might be tested in the course of the study. NMIs/DIs should also consider how the new proposal fits within the 5 year plan (see Figure 1), avoiding unnecessary duplications of comparisons. The proposers should additionally consider whether any NMIs/DIs have plans for broad scope CMC claims in the chosen analytes/matrix combination and design their comparison to assist with such claims.

	Model 1 comparisons				Model 2
Period	**Core key comparisons** **Core Capabilities model** – KC/Sample matrix CMC cat.		**Specialised key comparisons**	**Pilot studies**	
2017	**High organics content** K139/Elements in human serum [10, 11]		K34.2016/Assay of potassium hydrogen phthalate [1]		K143 Cu calibration solutions [2]
2018	**High organics content** K145/Elements in bovine liver [10, 11]	**Difficult to dissolve metals / metal oxides** K144/Alumina powder [8, 9, 14]	K149/N in milk powder [10, 11]	P194 / Number concentration of nano-particles	
2019	**High salts content** K155/Elements in seawater [5, 10]	**Difficult to dissolve metals / metal oxides** KXXX/PGE in Autocatalyst [8, 9, 14]	K152/Assay/Purity of potassium iodate (IAWG/EAWG) [1]	PXXX Non-metallic impurities (?) [8]	
2020	**High silica content** KXXX [13]	**High organics content** KXXX / Elements and isotope ratio in grain powder [11]	Selenoprotein P and Se in serum [10]		
2021	**Water** KXXX [5]	**High volatile matrices** KXXX [12]		Solid sample analysis by LA-ICP-MS	
2022	**High organics content** KXXX [10, 11]				

Fig. 1: Example of 5 year plan (updated in April 2018)

To facilitate discussion of a proposed comparison at the IAWG, presentations must highlight analytes/matrix combinations of particular interest. These should include, for example, combinations not recently tested or those where the proposed analysis is expected to present especially difficult challenges. The proposal should contain a list of elements with similar analytical challenges for which the measurement capabilities may have been demonstrated. Final decisions on which analytes/matrix combinations to include will be made by the IAWG based on actual experience and plans of the participants. Successful planning of the IAWG KC portfolio will minimize the required number of KCs while facilitating broad CMCs.

After the completion of the KC, the table will become a specific section of the KC final report along with the HFDLS statement.

3) Use of the CC System as evidence to support broad scope CMCs

The CMC spreadsheet is completed by the NMI/DI in the usual manner. The primary basis for the details (concentration ranges, uncertainties, etc.) of the proposed CMC should come from measurement experience at the NMI/DI collected from relevant reports of analysis prepared by the NMI/DI and information provided by core capabilities demonstrated by participation in KCs which are published in the final reports of these studies.

Broad scope CMCs can be submitted by grouping multiple analytes and/or per matrices, based on the CC table approved for each KC. If there is sufficient supporting evidence, a CMC claim could even be as broad as for the combination of one of the matrix challenges and analyte groups given in the matrix table, without listing individual analytes or matrices – e.g., group I and II elements in high organics content matrices.

The CMC applicant should prepare a Record of Participation table that lists all IAWG KCs in which they have participated during the last 10 y utilizing the same instrumental methodology that is used to provide the CMC. The Record of Participation table is accompanied by a graphical representation (see Figure 2) of the performances of the Institute. One graph per instrumental methodology used is requested.

For broad scope claims, the NMI/DI should participate in at least three studies (that can support the broad CMC) over a period of 10 years.

4) Evaluation of evidences by reviewers

Reviewers of CMC claims should verify whether the claimed capabilities are underpinned by relevant supporting evidence. It should be noted that KC results constitute the most common, but not obligatory, form of supporting evidence. Assuming that KCs are part of the support provided with the CMC claim submission, the following is what the CMC reviewer has to do:

- Examine the Record of Participation provided by the NMI/DI making the submission to ensure that there is adequate support in terms of satisfactory performance in IAWG KCs
- Also consider any other supporting evidence provided
- For broad scope CMC claims
    - Ensure that the Record of Participation includes at least three KCs of the relevant analyte group/matrix challenge combination
    - Consider whether the specific analytes and matrices covered by these KCs comprise a suitable range of measurement challenges for the scope of the CMC claim and the methodology on which the claim is based (the HFTLS statements in the KC reports can be helpful)
    - Ensure that the Record of Participation graph contains no fewer than 10 points and that no less than 90 % of the points are between -1 and +1

Record of Participation in CCQM Key Comparisons/Pilot Studies

Year Time Frame:
Institute (country):
Method:

KC or Pilot ID	Year	Analyte	Matrix	Units	x_i	u_i	$\%u_i$	d_i/ U_i	Measurement technique/ Calibration approach	Analyte group	Matrix challenge

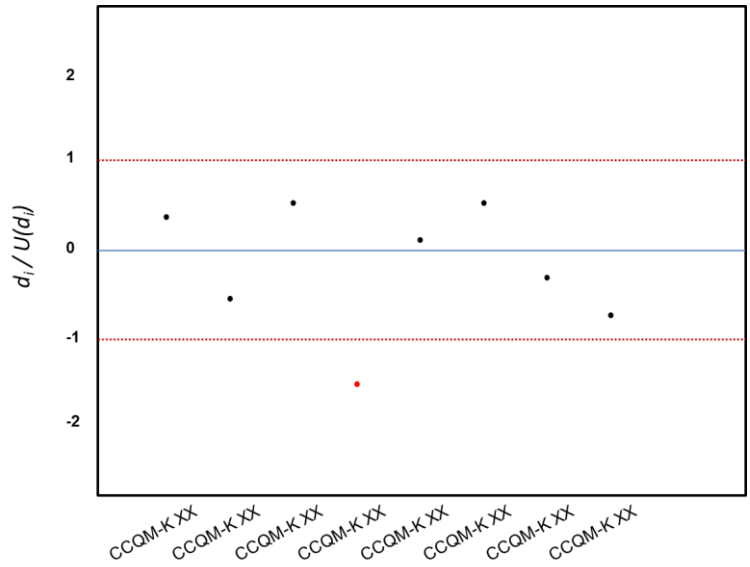

Fig. 2: Record of participation card and graphical representation of the performances

Annex 1: CCQM IAWG Core Capability table

Analyte groups	Matrix challenges						Calibration materials and solutions
	Water/aqueous	High Silica content (e.g. Soils, sediments, plants, ...)	High salts content (e.g. Seawater, urine, ...)	High organics content (e.g. high carbon) (e.g. Food, blood/serum, cosmetics, ...)	Difficult to dissolve metals (Autocatalysts, ...)	High volatile matrices (e.g. solvents, fuels, ...)	
Group I and II: Alkali and Alkaline earth (Li, Na, K, Rb, Cs, Be, Mg, Ca, Sr, Ba)							
Transition elements (Sc, Ti, V, Cr, Mn, Fe, Co, Ni, Cu, Zn, Y, Zr, Nb, Mo, Tc, Ag, Cd, Ta, W, Au, Hg, Al, Ga, In, Tl, Pb, Po)							
Platinum Group elements (Ru, Rh, Pd, Os, Ir, Pt)							
Metalloids / Semi-metals (B, Si, Ge, As, Sb, Te, Se)							
Non-metals (P, S, C, N, O)							
Halogens (F, Cl, Br, I)							
Rare Earth Elements (Lanthanides, Actinides)							
Inorganic species (elemental, anions, cations)							
Small organo-metallics							
Proteins							
Nanoparticles							

Low level (e.g. below 50 µg/kg)
High level (e.g. above 50 µg/kg)