QUALITY MATTERS

Commutability or reference materials: practical implications for users

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Introduction

In the last Quality Matters Column John Hammond and I mentioned the impact caused by the need for RM producers to demonstrate the "Commutability" of their certified reference materials (CRMs), where appropriate. This has become a more pressing issue since the release of the last revision to *ISO Guide 34* where Section 4.1.3 (f) and 5.4.3 (k) require producers to assess commutability, where appropriate and Annex B provides a brief overview of the general principle. But what does this all mean to the Laboratory Quality Manager?

This short column seeks to show where it is important to check the CRM or RM you are using includes a clear statement of commutability, and when and where it can be largely ignored.

First, a definition: What does "Commutability" actually mean? The *Collins Dictionary* definition "able to be exchanged" is not that helpful in the context of laboratory quality management. There is a good, clinically driven definition in an article published back in 2007 by H.W. Vesper *et al.* in the Australian Journal, *Clinical Biochemistry Reviews*:[1] *"Commutability is defined as the equivalence of the mathematical relationships between the results of different measurement procedures for a reference material and for representative samples from healthy and diseased individual."*

Put simply it means that Commutability of reference materials is a critical property to ensure they are fit for use.

This means that the producer of the CRM is certain that the behaviour of the CRM, as a calibrator, and the test sample will be consistent between different measurement procedures or methods so that the result of one determination can reliably be used to calibrate another method. This is of paramount importance where the first measurement method is a laboratory technique not suitable for rapid, repeated methods and the second measurement is a convenient, fast method, possibly undertaken at point of sampling.

As analytical testing moves steadily towards such rapid or field tests, commutability of the CRM used to validate the rapid method is essential. CRMs produced by organisations accredited to *ISO 15194* are already familiar with the need to demonstrate Commutability. As *ISO Guide 34* moves towards becoming *ISO/IEC 17034*, probably in late 2016, the large number of existing CRM producers accredited to *ISO Guide 34* will have to adopt this way of life.

Where a commutability study has been carried out it must clearly show which measurement methods are commutable and, possibly more importantly, which are not. The statement must also explain any know factors effecting the test sample that might be expected to degrade commutability, such as interferences from metabolites or breakdown products, preservatives or stabilisers and particularly the physical form of the sample. For example, a Calibrator CRM presented in serum cannot be assumed to be suitable as a calibrator for the same material in a tissue extract.

No matter how diligently the producer may complete an assessment of commutability we all know that reference materials and CRMs made in the past are used on a daily basis and we also use CRMs and RMs for applications that the producer did not intend or expect. So who is responsible for making sure they are fit for purpose? For new CRMs and RMs it is the producer's responsibility. The certificate of analysis (CoA) should contain a clear statement whether commutability studies have been carried out, or not.

But when using CRMs for calibration or quality control it is up to the user to check that the CRM is Commutable to the intended sample and check the Commutability Assessment is applicable for the intended use.

Let us start with the areas where Commutability can largely be assumed.

- When the certified parameter has been fully structurally defined and the CRM is a simple solution. That means all elements of the periodic table and most inorganic molecules and organic molecules with a molecular weight up to a few thousand Daltons.
- When the CRM is a pure material certified for purity, however, any calibration prepared should be checked to make certain it has the same analytical behaviour as the routine sample.
- There are areas where Commutability cannot be assessed by the producer and possibly not by the user:
- When there is only one known method for the quantity intended to be measured. A good example is

where the measurand is defined by internationally recognised units, such as "WHO Units".

- Where the CRM has been produced to assist in the validation of a wide range of measurement methods that are not well matched. Such CRMs are NOT suitable for use as calibrators.

Then there are the areas where Commutability really must be assessed.

- Any CRM or RM intended for use in laboratory medicine and related procedures. For example, it is not possible to use an aqueous glucose solution to calibrate a point of care testing device: these normally have some sort of membrane extraction layer that is incompatible with samples that do not mimic whole blood.
- In environmental analysis, CRMs presented as soil matrix material are not generally commutable to direct techniques such as X-ray fluorescence.
- Any RM or CRM produced by an organisation accredited to *ISO 15194* MUST include an assessment of commutability.

To find out more about Commutability please refer to the ISO REMCO Position Paper *The Need for Assessment of Commutability of Reference Materials* published by ISO in 2014 and available in the Public area of the ISO/REMCO website.[2]

References

1. H.W. Vesper, W.G. Miller and G.L. Myers, "Reference materials and commutability", *Clin. Biochem. Rev.* **28(4),** 139–147 (2007). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2282402/
2. http://isotc.iso.org/livelink/livelink/fetch/-8854933/8854951/8854960/279217/Commutability_document_final.pdf?nodeid=16787892&vernum=-2

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ous one but the more exciting ones (not yet conceived or developed) currently do not have any application—I look forward to reading about them when they arrive!

Acknowledgements

Before I finish I want to acknowledge some people without whom this column might not have got started; it definitely would not have continued for so long. The first has to be Ian Michael because he invited me to do it and has always been very supportive and helpful. Thanks Ian, it has been fun! Next (and only just second) is Tom Fearn. Without Tom to explain things until I "got them", write lots of MATLAB™ code, gently tell me when I was writing nonsense, let me borrow his figures and ideas from "The Chemometric Space" (in *NIR news*) etc. etc. … Thanks Tom.

We all need to thank Svante Wold for coining the word, ***chemometrics***. The "folk law" is that he invented it for a funding application; I once had a very pleasant supper with him and asked him "was it true?" "Yes it was", but "Was it successful?", "Yes". I was very pleased for him.

Finally, I would like to thank contributors, readers and friends who have encouraged me. I would like to quote Douglas Adams "So Long and Thanks for all the Fish"[7] but I'm not planning on leaving the earth just yet!

Best wishes

References

1. A.M.C. Davies, "The last furlong (5). Classification and identity testing", *Spectrosc. Europe* **26(4),** 24 (2014). http://bit.ly/1°OAnef
2. S. Mitton, *New Scientist* **13 April,** 60 (1972).
3. A.M.C. Davies, H.V. Britcher, J.G. Franklin, S.M. Ring, A. Grant and W.F. McClure, "The application of Fourier-transformed NIR spectra to quantitative analysis by comparison of similarity indices (CARNAC)", *Mikrochim. Acta (Wien)* **I,** 61–64 (1988). doi: http://dx.doi.org/10.1007/BF01205839
4. A.M.C. Davies and T. Fearn, "Quantitative analysis via NIR databases: Comparison Analysis using Restructured Near infrared And Constituent data-Deux (CARNAC-D)", *J. Near Infrared Spectrosc.* **14(6),** 403 (2006). doi: http://dx.doi.org/10.1255/jnirs.712
5. D. Pérez-Marín, A. Garrido-Varo, J.E. Guerrero, T. Fearn and A.M.C. Davies, "*Advanced non-linear approaches for predicting the ingredient composition in compound feedingstuffs by near infrared reflection spectroscopy*", *Appl. Spectrosc.* **62(5),** 536 (2008). doi: http://dx.doi.org/10.1366/000370208784344389
6. T. Davies, "Strings and stripes", *Spectrosc. World* **1(1),** 30 (1989).
7. D. Adams, *So Long and Thanks for all the Fish*. Pan Books Ltd (1984).