QUALITY MATTERS

Confidence: the key to quality

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That the quality of analytical data matters is accepted; indeed it is the name of this column! At the heart of quality data is a quality system and underpinning that system is the proper use of reference materials. So, if the appropriate reference materials are sourced and used properly to validate an analytical system then all will be well.

Unfortunately, it is not quite so simple. Despite the best efforts of the International Standards Organisation (ISO), the International Laboratory Accreditation Council (ILAC) and numerous national accreditation bodies, all reference materials are not created equal! This means that the wily quality manager must know what to look out for when selecting the right reference material to use. This means that even in a world that seems well regulated "caveat emptor", or the buyer alone is responsible for checking the quality and suitability of goods before a purchase is made, still applies.

This article has been written to help guide and inform reference material users in their selection of appropriate and suitable reference materials. It is based on several talks Alan and I have given over the years. We plan to follow up with an article on choosing the "right" reference material, and will give guidance on what to do when the right reference material simply does not exist. We will go on to introduce the concept of "commutability", which is becoming a hot topic within the reference material community.

Certified reference materials are generally thought to be of the highest metrological status (i.e., scientifically valid). They can be produced by National Metrology Institutes such as LGC, IRMM, BAM, or by "accredited producers". Whilst National Metrology Institutes do not need accreditation due to their legal status, some chose to become accredited, such as IRMM and LGC.

Any organisations that are doubly accredited to ISO/IEC 17025 and ISO Guide 34, may call themselves a reference material producer and legitimately produce and certify certified reference materials according to ISO definitions and standards. The combination of ISO 17025 and ISO Guide 34 means that the reference material producer has demonstrated that they are capable of competent measurement and have demonstrated competency in the production and distribution of reference materials.

Accreditation documents are available on the accrediting body website and usually on the reference material producer website that details the scope of their accreditation. More on this later.

However, there are no laws or requirements (outside the ISO world, which is not legally mandated) that prevent anyone from calling anything they want (even a yellow dog!) a certified reference material. So how does a Quality Manager know if a product is a legitimate certified reference material and how does a laboratory choose the best one for a particular application?

What about ISO 9001 Certification? Many producers of reference materials state they hold an ISO 9001 Certificate. Whilst this is good, it has no relevance to the production of a reference material or certified reference material. All ISO 9001 Certification does is demonstrate an organisation has a quality system. An ISO 9001 quality system has no associated published scope and it is not checked or audited by a technical expert from an accreditation body.

The current situation, as quoted from a Chinese representative from APLAC is that it is "Chaos". Why is this?

There are many different representations (and mis-representations) in the market and to make matters worse some reference material producers' certified reference materials violate or stretch the rules. For example, some accredited reference material producers have a small portfolio of certified reference materials and a large portfolio of reference materials or standards that are NOT covered by the scope of their accreditation. Often the producers marketing literature will imply that all the reference materials are certified reference materials because the producer is accredited… in these authors' opinion such behaviour is reprehensible and is verging on dishonesty.

So:

1. Just because a reference material producer is doubly accredited it does not mean that their product is a certified reference material!!
2. If a producer is not doubly accredited, their products cannot be certified reference materials!!

So, what are the "Rules" that mean a certified reference material is actually a certified reference material?

A certified reference material must be accompanied by a Certificate of Analysis that contains, at a minimum:

- Name of the material

- Producer identity and producers code for the material
- General description of the material
- Intended use
- Instructions for proper use
- Instructions for appropriate conditions of storage
- Certified property value(s), each accompanied by a statement of uncertainty
- Method(s) used to obtain property values
- Period of validity, if appropriate

Key words to look for on the Certificate supplied with a certified reference material:

- "Uncertainty Statement", this must be shown and generally appears as a Value ± another Value, e.g., 105 $\mu g mL^{-1} \pm 1.2\ \mu g mL^{-1}$
- "Traceable", this is generally interpreted as: compared to a standard from an National Metrology Institute or to another certified reference material and must be explained
- "Homogeneity", there needs to be an explanation of how the homogeneity of the certified reference material has been developed, this is normally a component of the Uncertainty Statement
- "Stability", as with Homogeneity this needs to be detailed and this is another component of the Uncertainty Statement
- Accreditation Marks on the Certificate. The name and address of the accreditation body must be shown. Normally an accredited organisation is allowed to use Accreditation Marks from their accrediting body on literature and Certificates of Analysis.
  - Note: in the US there are several Accrediting Bodies. In all other countries there is a single National Accrediting Body, for example UKAS in the UK.

It is also important to examine the reference material producer's Scope, which lists the tests/methods/technologies and type of reference materials that an organisation is accredited to produce and test. Each Accrediting Body maintains on their website a list of accredited organisations and their associated Scopes. Unfortunately, some accreditation bodies offer this information only in their national language. Most reference material producers also maintain access to their Scopes on their individual websites. In summary:

- A reference material produced and tested outside of an accredited organisation's Scope cannot be legitimately called a certified reference material.
- Accreditation marks may not legitimately appear on the associated Certificate of Analysis for out of Scope tests and reference materials.
- The ISO standards require that all tests and reference materials that are not within Scope be clearly distinguished.

It is also important to read the wording on a Certificate carefully, and particularly marketing and other commercial literature. If a product is claimed to be tested in an ISO 17025 laboratory but without any mention of ISO Guide 34 it is not a certified reference material.

Also, look out for claims that the product is tested "according to ISO 17025" and manufactured "according to ISO Guide 34", but this is not supported by any accreditation marks or evidence of accreditation on any documentation. Such a product will not be a certified reference material.

- Anybody can say this and they might actually be doing it.
- However, YOUR accrediting body will not accept this as legitimate.

In conclusion, not all certified reference materials are created equal. A certified reference material is only as good as the accompanying documentation: Certificate of Analysis (COA). There is a lot of variation amongst accredited producers. Some do a great job, some not so good.

So, to be certain you are not called out by your accreditation body auditor on their next visit you must evaluate each certified reference material based on:

- Intended use
- Completeness of documentation
- Clarity of documentation
- Company reputation