QUALITY MATTERS

Into the future: changes to *ISO 17025* and *ISO Guide 34*

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In the almost more than 10 years since this column first appeared in *Spectroscopy Europe*, readers will have read much about *ISO/IEC 17025* and *ISO Guide 34*: together and apart the Standard and the Guide provide the framework for the development of and use of certified reference materials (CRMs) in analytical laboratories around the world.

Both the Guide and the Standard have a long history and in the last few years it has become clear that the direction taken by the reference material market has pushed the standards to the point that change is needed. In particular, accreditation of CRM producers to a guide has not met universal unquestioned acceptance: many have long felt that *ISO Guide 34* needed to be a standard. The structure of ISO means that migrating *ISO Guide 34* into a standard was not straightforward.

It is normal for ISO standards to be reviewed every five years: on the last occasion it was felt that *ISO/IEC 17025* met the needs of the users and no change was needed, so it is now ten years since the last full revision of the Standard in 2005. In 2013 it was agreed by ILAC to push for a full revision of the Standard, this process has started.

The recent 37th meeting of the Reference Material Committee of ISO, ISO/REMCO, was hosted by NIST on behalf of the American National Standards Institute (ANSI) in Boulder, Colorado, USA, from 8 to 11 July 2014. There was much discussion about the migration of *ISO Guide 34* into a standard. John Hammond reports!

Review of the status of *ISO Guide 34*

Within ISO, it has been resolved that a joint Working Group between ISO/REMCO and ISO/CASCO (the technical committee responsible for issues relating to conformity assessment) should be established, for the conversion of *ISO Guide 34*[1] into *ISO Standard 17034*. It is expected that this conversion would follow a similar route to that of the *ISO Guide 43 for Proficiency Testing* to *ISO Standard 17043*.

As a technical committee of ISO, ISO/REMCO was formed in 1975, principally to address the lack of guidance with respect to the production, use and certification of reference materials. The output from this committee, resulted in the first versions of the ISO "30 series" of guides, (*ISO Guide 30* to *ISO Guide 35*)[2–7] which were produced purely as guidance documents, aimed to provide non-mandatory technical assistance to reference material users, and producers. However, in the intervening time period, these documents have undergone version control, and have evolved to match the changes in the regulatory environment in which these reference materials are used; to the point where, as stated above, *ISO Guide 34* is effectively being used as standard by laboratory accreditation bodies, and now needs to be converted to a formal ISO standard (*ISO 17034*). This also has ramifications in respect to the normative references associated with *ISO Guide 34/ISO 17034*, in as far as these "30 series" guides, namely *ISO Guide 30*, *ISO Guide 31* and *ISO Guide 35*, will now have a mandatory aspect when considered as normative references to *ISO 17034*.

So now, with the conversion of *ISO Guide 34* into *ISO 17034*, the ISO/REMCO "guides" have diverged down two separate pathways, i.e.

1) those supporting *ISO 17034*—namely *ISO Guide 30*, *ISO Guide 31* and *ISO Guide 35* and
2. those guides which follow the original scope of ISO/REMCO to simply provide additional (non-mandatory) technical guidance for a given process involving reference materials; i.e. *ISO Guide 30*, *ISO Guide 33* and *ISO Guide 80*.

This explanation of the guide structure is explained graphically in Figure 1. As you can see, *ISO Guide 30 (Terms and Definitions)* occupies a somewhat unique position, in that its use is valid by both classifications of documents. However, as a "'vocabulary" document, this is not a surprising result, and is mirrored in other standards bodies, e.g. ASTM International Committee E13—*Molecular Spectroscopy and Separation Science* has their *E131 Standard—Standard Terminology Relating to Molecular Spectroscopy*,[8] which is also a general guidance document relating to terminology, but also defines the vocabulary used in the associated molecular spectroscopy standards produced by E13.

Review of the status of *ISO 17025*

At the International Laboratory Accreditation Cooperation (ILAC) General Assembly in October 2013

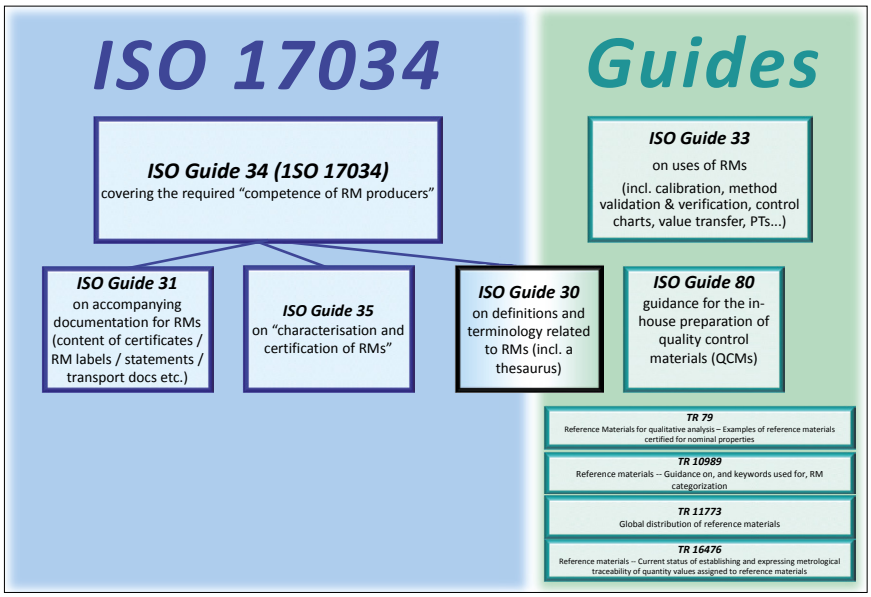

Figure 1

the Laboratory Committee (which is composed of stakeholder representatives of accredited testing and calibration laboratories) recommended that ILAC request that ISO/CASCO establish a new work item to comprehensively revise *ISO/IEC 17025:2005* as soon as practicable. Why was this done?

The current standard, issued in 2005 is nine years old and contains references to documents that no longer exist under the designation shown in the current standard, e.g. *ISO/IEC Guide 43–1* and *Guide 43–2*; *ISO/IEC Guide 58:1993* and *ISO/IEC Guide 65*, while other references are not to the most recent versions, e.g. *ISO 9001:2000*.

An ILAC Resolution was agreed by the General Assembly to allow accreditation bodies to hold a consultation process with their accredited laboratories that closed at the end of January 2014.

In the UK, the United Kingdom Accreditation Service (UKAS) carried out a basic online survey of all of its 1500 accredited laboratories. As with all surveys response rates are not large, but at its close the survey had achieved a response rate of 26%, with 68% of those in favour of bringing forward a revision, 22% against and 10% abstaining.

As mandated by the survey, the UKAS response to ILAC was clearly in support of bringing the revision forward. The UK response was no different to the majority of other ILAC members, with 84% submitting a "yes vote" and so exceeding the 75% threshold for ILAC ballot approval.

The ILAC Executive Committee has now commenced work on the preparation of a New Work Item Proposal (NWIP) to revise *ISO/IEC 17025*, for submission to ISO/CASCO. Whilst ISO/CASCO approval has to be gained, it is believed that this will happen, which means revision of *ISO/IEC 17025* will be brought forward by up to two years, with a projected publication date sometime in 2017.

What is to be done?

There is consensus amongst the IILAC AIC that areas in need of revision include:

5.4 Calibration, Measurement Uncertainty & Validation/ Verification
5.5 Equipment (possibly)
5.6 Traceability
5.7 Sampling
5.9 Quality Assurance including Proficiency Testing
5.10 Reporting Results (opinions/ interpretation)

There have been many published suggestions listing areas that should be considered in any revision, the following

are those that the authors of this article consider important, not listed in order of importance.

Terminology

The terminology used in the current standard is outdated and causes confusion, for example recent changes to VIM terminology mean that the standard is not in agreement with the VIM.

Style

ISO/IEC 17025 takes a prescriptive approach and is out of step with the modern standards approaches which are performance-based or process-based. The formatting should also be matched to newer standards such as *ISO 9001*, *ISO 15189*, *ISO/IEC 17020*, *ISO/IEC 17043*, *ISO/IEC 17021*, *ISO/IEC 17065*.

Use of sub-contractors

The use of subcontractors or outsourced suppliers is far more common than it was 10 years ago and the use of sub-contractors needs to be clarified, for example as it was handled in *ISO/IEC 17043*.

Traceability and commutability

Traceability and commutability requirements should be expanded and clarified along more informed lines.

Sampling and sample collection

In the UK, one version of MCERTS, an extended scope to *ISO 17025* used in the water industry, extends the scope right back to the point of sample collection. Sampling and sub-sampling needs to be considered with more recognition that reliable test results are directly related to sampling.

Method and system validation

There is a need to reconsider the handling of testing and calibration as separate parts of the standard. The reasons for any different approaches in the standard between these areas should be clarified and the use of "GMP like" IQ/OQ/PQ" procedures included.

Commutability

This was another important topic discussed at the Boulder meeting. Commutability describes whether a reference material behaves in the same way as the actual samples measured in the laboratory. This seemingly simple concept has, as the analysis of biological materials becomes a routine activity in laboratories accredited to *ISO/IEC 17025* and its hospital equivalent *ISO/IEC 15189*, risen up to become a topic of significant consequence. Why is this?

Commutability is always defined with respect to two methods—if a sample is a material that is commutable between two methods, it will give the same results for both methods if the two methods give on average the same result for routine methods. But what happens when the routine method has been validated using CRMs that are not the same as the samples under daily testing?

The first question that arises is "why would anyone use a CRM that is not the same matrix as the test sample?". In the past when samples were inherently stable, such as metals, minerals, soil, water and gas it was possible to produce a matrix CRM that was so close, in form and nature to the test sample that analysis of the same CRM on two different methods stood a good chance of giving the same answer and so the CRM was generally commutable.

But as the analysis of biological materials has become ever more important, so the development of stable CRMs, meeting the demanding requirements of *ISO Guide 34*, has meant that the matrix CRM is less like the matrix samples under test and does not always give the same result on all methods. This has led to method-specific CRMs used to validate analytical procedures with a result that a test sample analysed on one analytical system will not give the same result when analysed on an analyser that uses a different analytical principle.

The simplistic answer is to say that matrix CRMs used for instrument calibration must match the matrix to be analysed on that instrument. But increasingly it is impossible to produce a matrix CRM that can meet the requirements of *ISO Guide 34*.

ISO REMCO has concluded that in general all materials require commutability statements, unless the analyte is completely structurally defined, or only one method exists, or if the material is certified for purity, or if the material is intentionally produced to provide extreme challenges. More details are available on the ISO/REMCO public website (http://isotc.iso.org/livelink/livelink/fetch/-8854933/8854951/8854960/279217/Commutability_document_final.pdf?nodeid=16787892&vernum=-2).

In the revision of both *ISO/IEC 17025* and the migration of *ISO Guide 34* into a standard, dealing with commutability will be a major challenge. There is no doubt that this work will involve many, but it is vital that because of the global economic significance of accreditation to *ISO 17025* the editing of the document is done to an exemplary standard. The authors of this article would like to see the use of an external, professional editorial consultant so that the style and structural ambiguities present in the present version are minimised.

John and I will continue to report on developments as they are revealed!

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