Into the future (Part 2): changes to ISO 17025 and ISO Guide 34

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In Vol. 26 No. 5 (2014),[1] in the appropriately titled "Into the future: changes to ISO 17025 and ISO Guide 34", Peter Jenks and I discussed the status of these two important ISO documents, and considered the way forward.

We finished the article with a significant phrase, namely:

Part 1: *"John and I will continue to report on developments as they are revealed!"*

Given that ISO 17034:2016 was published on 1 November 2016, and the revision of ISO/IEC 17025 is approaching completion, and thereby publication, this article looks back at some of statements made in 2014, and reviews the outcome, and again the way forward.

However, before moving forward to this comparative review, there are significant changes to the 17xxx series of Standards in both the new ISO 17034 and revised ISO/IEC 17025, and these need to be explained first.

ISO 17xxx series Standards

This restructuring is based on the common structure adopted by other International Standards on conformity assessment (e.g. ISO/IEC 17020 Requirements for the operation of various types of bodies performing inspection) developed by the ISO Technical Committee on conformity assessment (ISO/CASCO), and in a significant change, includes the option to use ISO 9001 to meet the management requirements.

In addition, there is the requirement to include the obligatory and recommended requirements detailed in ISO/CASCO procedure QS-CAS-PROC 33:

- Impartiality
- Confidentiality
- Complaints and appeals
- Management system

The most significant change is in the structure of the Standard(s), which are completely revised, now distinguishing "resource" from "process" and acknowledging the possible role of an ISO 9001 based management system. So now, unlike the previous structural template, where "Section 4—Management requirements" preceded "Section 5—Technical requirements", these Standards sequentially follow and re-define the requirements in this order: "General"; "Structural"; "Resource"; "Process"; and "Management", effectively reversing the sequence.

There are two options available to fulfil the Management requirement, Option A and Option B.

Option A will require the laboratory to address the requirements of:

- Management system documentation;
- Control of management system documents;
- Control of records;
- Actions to address risks and opportunities;
- Improvement;
- Corrective action;
- Internal audits;
- Management reviews.

Alternatively, Option B allows a laboratory that has established and maintains a management system in accordance with ISO 9001 (which can support and demonstrate the consistent fulfilment of the "General", "Structural", "Resource" and "Process" requirements) to be recognised as fulfilling the intent of the management system requirements as outlined in Option A.

Also, clearly stated in the introduction to these Standards (for the first time) is the following clarification with respect to the terms used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

ISO Guide 34 / ISO 17034

Part 1: *"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 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."*

ISO/CASCO Joint Working Group (WG) 43 was duly formed, with significant membership from ISO/REMCO and convenorship of the group, and the resultant Standard ISO 17034 was published on 1 November 2016, after a series of discussion and review meetings held at ISO headquarters in Geneva, Switzerland.

This first edition of ISO 17034 cancels and replaces ISO Guide 34:2009, which has been technically revised, and incorporates the following major changes:

- inclusion of requirements for production of all types of reference materials, and additional specified requirements for certified reference materials;
- harmonisation with the revisions of ISO Guide 31 and ISO Guide 35;
- inclusion of more details on required reference material documentation;
- inclusion of risks and opportunities;
- restructuring based on the common structure adopted by other International Standards on conformity assessment developed by CASCO;
- incorporation of modifications based on ISO/CASCO PROC 33.

It outlines the general requirements for the producers of RMs, including certified reference materials (CRMs). It supersedes ISO Guide 34:2009 and is aligned with the relevant requirements of ISO/IEC 17025. Further guidance (e.g. concerning the content of certificates and the design of characterisation, homogeneity and stability studies) is provided in ISO Guide 31 and ISO Guide 35. While the approaches outlined in ISO Guide 31 and ISO Guide 35 meet the relevant requirements of ISO 17034, there might be alternative ways to achieve compliance to this International Standard.

RMPs that comply with this International Standard will also operate generally in accordance with the principles of ISO 9001. For tests performed in the medical field, ISO 15189 can be used as the reference instead of ISO/IEC 17025.

Part 1: *"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."*

At the time of drafting Part 1, and as shown in the document, once the decision to convert ISO Guide 34 into ISO 17034 had been taken, the discussion was now centred on the associated ISO/REMCO Guides, and whether these supporting documents should be considered as normative references to ISO 17034. ISO Guide 35, which deals with the characterisation, and associated stability, homogeneity and uncertainty budget considerations was central to this debate, as it was also scheduled for review and update.

However, as required by any Standard development process, a clear and unambiguous statement is required, and therefore the agreed resolution is very clearly stated in the introduction to ISO 17034:

"This International Standard outlines the general requirements for the producers of RMs, including certified reference materials (CRMs). It supersedes ISO Guide 34:2009 and is aligned with the relevant requirements of ISO/IEC 17025. Further guidance (e.g. concerning the content of certificates and the design of characterization, homogeneity and stability studies) is provided in ISO Guide 31 and ISO Guide 35. While the approaches outlined in ISO Guide 31 and ISO Guide 35 meet the relevant requirements of this International Standard, there might be alternative ways to achieve compliance to this International Standard."

Implicit in the above statement, and clearly stated in Section 2, the only normative reference to ISO 17034 which is "indispensable for its application" is ISO/IEC 17025.

It is also significant that this reference is undated, because for dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies, and therefore ISO 17034 will require compliance with the new version of ISO/IEC 17025 once this becomes available—see below.

Therefore, "the wheel has turned full circle", and the ISO/REMCO Guides now essentially fulfil the purpose for which they were originally intended as stated in Part 1.

Part 1: *"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) which were produced purely as guidance documents, aimed to provide non-mandatory, technical assistance to reference material users, and producers."*

However, now there is the appropriate ISO 17034 Standard in place, and the significance of these documents in providing the essential, additional guidance to Reference Material producers in the required areas should not be under estimated. For this reason, they continue to be revised and developed further, as you will see when the recent ISO/REMCO meeting is discussed in a later article.

ISO/IEC 17025

Part 1: *"It is normal for ISO Standards to be reviewed every five years: on the last occasion (2010) 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 background to this decision is detailed in Part 1, but indeed ISO/CASCO did respond to the International Laboratory Accreditation Cooperation (ILAC) request, as this was formally submitted as a New Work Item Proposal (NWIP) jointly with the South African Bureau of Standards. Thereby, in October 2014 CASCO/WG 44 was formed and tasked with the three-year process to update and revise ISO/IEC 17025, due for completion in October 2017.

On publication, the mandated implementation period by the national accreditation bodies, is three years. If one considers, for example that there are approximately 1600 Calibration and Testing Laboratories accredited to ISO/IEC 17025 by the United Kingdom Accreditation Service (UKAS) in the UK, then the logistics of this process could surely be described as "challenging"?

ISO/REMCO

The recent 40th meeting of the Reference Material Committee of ISO, ISO/REMCO, was hosted by BAM on behalf of the German Institute for Standardization (DIN) in Berlin, Germany, from 26 to 29 June 2017, and in relation to this article one of the key topic discussed was the revision and publication of ISO Guide 35:2017. Other topics discussed will form the content of another article in the series.

Why revised ISO Guide 35:2006?

In addition to the mandatory review process, the developments in RM production approaches, and the growing range of classes of RMs with advances in technology increased the need for more widely applicable technical guidance in RM production. In addition, increasing use of ISO/IEC 17025 and ISO 15189 by laboratories led to greater demand for clear statements of metrological traceability.

ISO Guide 35:2017 provides detailed guidance on a larger range of homogeneity study designs, and describes a wider range of stability management strategies than ISO Guide 35:2006. It also contains specific provisions concerning the establishment of metrological traceability in RM production.

The document explains concepts and provides approaches to the following aspects of the production of reference materials:

- the assessment of homogeneity;
- the assessment of stability and the management of the risks associated with possible stability issues related to the properties of interest;
- the characterisation and value assignment of properties of a reference material;
- the evaluation of uncertainty for certified values;
- the establishment of the metrological traceability of certified property values.

The guidance given supports the implementation of ISO 17034. As previously stated, other approaches may also be used if the requirements of the Standard are fulfilled.

Brief guidance on the need for commutability assessment is given in the document, but no technical details are provided. A brief introduction for the characterisation of qualitative properties (9.6 to 9.10) is provided together with brief guidance on sampling such materials for homogeneity tests (Clause 7). However, statistical methods for the assessment of the homogeneity and stability of reference materials for qualitative properties are not covered. The document is also not applicable to multivariate quantities, such as spectral data.

So, in summary, in 2017.

For reference material producers (RMPs), there is now an International Standard, (and one Normative Reference) and three ISO Guides that support the production and certification of RMs to ensure that the quality of the RMs meets the requirements of the end users;

- ISO 17034 outlines the general requirements to be met by an RMP to demonstrate competence.
- ISO/IEC 17025 provides the required Standard with relation to measurement.
- ISO Guide 35 provides more specific guidance on technical issues and explains the concepts for processes such as the assessment of homogeneity, stability and characterisation for the certification of RMs.
- ISO Guide 31 describes the contents of certificates for CRMs, and of accompanying documents for other RMs, respectively.
- ISO Guide 30 contains the terms and definitions related to reference materials.

Clarity at long last?

Once again, and with the aim of completing the trilogy, we will continue to report on developments as they are revealed!

Reference

1. P. Jenks and J. Hammond, "Into the future: changes to ISO 17025 and ISO", *Spectrosc. Europe* **26(5),** 18–20 (2014). http://bit.ly/QM26-5