QUALITY MATTERS

Change is in the air

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Just as in the political arena, the world of chemical metrology is poised on the brink of fundamental change: a new International Standard, ISO/IEC 17034, General Requirements for the Competence of Reference Material Producers was published on 1 November 2016: this means that over the next three years all existing certified reference material (CRM) producers, presently accredited to a combination of ISO REMCO Guide 34 and the International Standard ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, and together sometimes referred to as the "Gold Standard", will have to migrate their accreditations to the new standard.

In 2017, a new and fully revised version of ISO/IEC 17025 will be published. This means all labs presently accredited to ISO/IEC 17025 will, over the next couple of years, have to review their quality systems against the new version of the standard. We will look at the differences between the old and new versions in a future edition!

As regular readers of this column will know, one of the requirements of ISO/IEC 17025 is that wherever possible CRMs be used by accredited laboratories for the calibration of analytical systems, the validation of analytical methods and as a part of on-going quality assurance.

Since the early 1990s, as more and more testing laboratories sought and achieved accreditation to ISO/IEC 17025, demand for CRMs increased beyond the ability of the national metrology institutes to respond. Accordingly, commercial production of CRMs gathered pace, but at that time there was no formal route to accredit producers. It was felt that accreditation to a combination of ISO/IEC 17025 and ISO REMCO Guide 34 would at least ensure CRM production could be accredited whilst a new standard was developed.

It took far longer than expected, almost 10 years, to work out quite how to migrate an ISO REMCO Guide into an ISO/IEC Standard, but in 2014 ISO REMCO and ISO CASCO agreed a procedure that resulted in an *ad hoc* ISO CASCO Working Group AHG3 being established. The first meeting was held in Geneva in December 2014. Progress was relatively rapid and the new ISO/IEC standard was published at the end of 2016, preceeded on 26 October 2016 by the adoption of the new Standard by European Committee for Standardization (CEN, French: Comité Européen de Normalisation), thus paving the way for it to become a European Standard. Also, in late 2016 ILAC agreed to develop a global mutual recognition agreement (MRA) for reference material producers accredited to ISO/IEC 17034: this should come into effect during 2018. At the same meeting ILAC agreed with ISO that there would be a three-year transition with accreditation to ISO Guide 34 ending on 31 October 2019.

In the UK, UKAS has started a detailed gap analysis comparing the old Guide 34 with the new Standard to help prepare accredited laboratories, and also in early 2017 UKAS will start training for evaluators and peer evaluators from other accreditation bodies. This preparation phase means that accredited producers can be prepared to migrate to the new standard during 2018. Any producer that does not migrate in the second year will be informed that if they do not complete accreditation to the new standard by 31 October 2019 their accreditation will lapse.

During early 2017, UKAS will add accreditation to ISO/IEC 17034 to their ISO/IEC 17011 Scope, so that by the end of 2017 they expect to be accredited to offer accreditation to the new standard. It is worth note that the revised version of ISO 17011 includes the concept of accreditation to a flexible scope, so that all accreditation bodies can, if they wish, offer accreditation to ISO/IEC 17034 with a flexible scope. As there has been much debate within the accreditation community about the use of a flexible scope in association with accreditation to ISO Guide 34 it remains to be seen if there will be universal uptake of this aspect.

The new ISO/IEC 17034 standard contains one very significant change from the old combined accreditation, and facilitates one crucial development.

The change

It has been generally accepted that until now a CRM producer must hold the dual accreditation of ISO Guide 34 + ISO/IEC 17025: to hold an ISO 17025 accreditation required an analytical laboratory, so all CRM certification bodies had to have an accredited analytical laboratory. The new ISO/IEC 17034 standard allows the CRM certification body to use third party analytical laboratories; provided they are accredited to ISO/IEC 17025 and the scope of their accreditation is appropriate. So with the publication of the new standard, the

door is opened allowing organisations previously unable to achieve accreditation as a CRM producer to enter the market place.

Demand for CRMs is growing, rapidly. This growth, in significant double digits, is driven by the accreditation of more and more laboratories to ISO 17025 and this is, in turn, a consequence of a never ending drive to analytical quality. That new producers will be more easily able to achieve accreditation should extend the availability of CRMs, which is to the advantage of all striving to achieve good analytical data.

The development

Although accreditation to the combined "Gold Standard" is well accepted by national accreditation bodies in Europe and North America it has not been able to achieve an ILAC global MRA covering CRM production as some national accreditation bodies have not accepted that it is possible to accredit to a Guide. As mentioned above, the arrival of ISO/IEC 17034 and the accreditation of CRM producers to this standard paves the way for an ILAC MRA, facilitating the use of CRMs everywhere.

Into the future

These changes will bring an additional workload to national accreditation bodies and their clients and much will cascade down to the technical auditors, without whom accreditation would not be possible. Satisfying the technical aspect of a surveillance visit can be a daunting challenge and this is something that we would like to help you with. It gives me enormous pleasure to be able to announce that my long-time colleague, Alan Nichols, has agreed to join the "Quality Matters" team and write on the use of RMs and CRMs from the perspective of an accreditation body technical auditor.

I have known Alan since the early 1990s when he ran the Reference Materials Division of Radian Corp., a small specialist business in Austin, Texas, in the USA. Alan had graduated from the University of Texas in Austin and took his profound interest in organic synthesis to Radian. Back in the 1980s, demand for environmental reference materials was growing and Radian won a contract with the US Environmental Protection Agency (EPA) to produce reference materials and Alan was responsible for the synthesis of many compounds of environmental interest. Working in partnership with Cambridge Isotope Laboratories Inc., Alan pioneered the synthesis of many stable isotope labelled dioxins and furans. Radian went on to replicate this success developing reference materials for forensic analysis, which is when I first met him in Germany in 1994.

In the late 1990s, seeking a new challenge, Alan moved to the United States Pharmacopeia where after a spell in marketing he took over the production of USP Pharmaceutical Reference Substances.

In the late 1990s, Alan concluded that life in Washington, DC, was not everything and moved to Laramie, Wyoming, USA to join RT Corporation: at that time I was working very closely with RTC, running their European subsidiary, and with Alan and Bob Rucinski, RTC's owner, had come up with a concept to develop a range of secondary certified reference substances, traceable to the USP Primary RS and certified for purity as a CRM. This innovative programme attracted the interest of Sigma Aldrich Corp, now Merck KgAA, and in February 2011 RTC was acquired by Sigma Aldrich. So Alan and I joined Sigma Aldrich.

In 2012 Alan was asked to relocate to the Sigma Aldrich Supelco facility in Bellefonte, PA, USA, to upgrade the RM production facility to meet the requirements of ISO Guide 34 and ISO/IEC 17025 and achieve accreditation to the "Gold Standard". Achieving an accreditation is one thing, upgrading the thousand or so RMs to CRM status is another, but this was done by late 2015 and in early 2016 Alan retired. He now works as a metrology consultant and Lead Assessor for ISO/IEC 17025, ISO Guide 34 and ISO/IEC 17043.

Alan has an unmatched experience in both CRM production, accreditation and quality management: I look forward to his future contributions to this Column.