

Accreditation of RM producers: is the end game in sight?

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Over the two and a half years that I've been writing this Column about once every six months I have looked at the continuing debate over the accreditation of RM producers. I have considered if it is needed, what it would achieve and how it could best be done. For those keen to review the story, references are listed at the end of this column: all can be viewed and downloaded from the *Spectroscopy Europe* web site.

I'm returning to the topic again as it does look as though the end of the first stage in sight: a number of developments around the World have together pushed a consensus into being that defines the standard for accreditation. At the same time there now seems a momentum that gives hope that the formal accreditation of RM producers is going to get started within the next 12 months. There is still some uncertainty associated with the procedure and there will be a lot to learn along the way, but I think there is good reason to believe that the "End Game" is in sight.

So what has changed? A number of separate, but interrelated decisions by opinion leaders and influential committees within the RM community have taken place over the last six months that are responsible for the developing consensus. They are:

- The adoption of Guide 34 as the "golden standard" by the European Reference Materials Grouping: at their press conference at Analytica in May Dr Emons explained that for any CRM to be considered as an ERM the CRM must have been produced in full accordance with the requirements of ISO Guide 34.
- An agreement was reached earlier this year by the authoritative CCQM committee that supported the concept of the accreditation of CRM

producers to ISO Guide 34 and ISO/IEC 17025

- A Mutual Recognition Agreement (MRA) is being developed by APLAC (Asia-Pacific Laboratory Accreditation Co-operation) that ensures that CRMs produced by a producer accredited to ISO Guide 34 in one country will be recognised across the region.
- A resolution at the June 2004 ISO REMCO meeting. The resolution confirmed that producers of CRMs should apply ISO Guide 34 when developing quality management systems and demonstrating technical competence, noting that ISO Guide 34 makes normative reference to ISO 17025.
- A decision by ILAC to vote at the forthcoming Cape Town meeting on a proposal to modify the harmonised criteria for the accreditation of reference material producers be to ISO Guide 34, provided that analytical work for assigning reference values normally be conducted by laboratories accredited to ISO/IEC 17025. They go on to comment that where the producer is also a laboratory accreditation certificates should show that the organisation complies with BOTH ISO Guide 34 and ISO/IEC 17025.

The supporters of using Guide 34 have always been at something of a disadvantage because, unlike for ISO 17025, there is no MRA in place that includes ISO Guide 34. But the decision by APLAC may well become the framework for a wider international recognition, assuming the ILAC proposal is passed.

In the UK, the Accreditation Service, UKAS is starting a Pilot Project to accredit a group of UK reference material manufacturers to a combined ISO 17025 / ISO Guide 34 standard. At a recent prelimi-

nary meeting of the stakeholders there was much debate on the standard that would be most appropriate. One group supported ISO 17025 alone, mostly because UKAS has already accredited a number of UK RM producers as "Calibration Laboratories" to ISO 17025, and the international MRA is already in place. There was also support for ISO Guide 34, partly because its scope goes beyond ISO 17025 into the assignment of values, stability and storage but mainly because it allows for a CRM producer NOT to have an ISO 17025 accredited laboratory, a very important issue for those who use a cooperative approach to develop data to be used for the assignment of certified values.

Taken together, all these events do lead to a belief that within a handful of years the accreditation of CRM producers will be the norm: once a few producers have been accredited a combination of peer and market pressure will ensure that the rest will follow.

For the publicly funded and institutional producers the cost is not really an issue, once the reasons for going ahead have been justified. But for the commercial producers it is yet another burden. A spokesman for one of the leading UK commercial producers, a company that has already achieved accreditation as a calibration laboratory for the production of CRMs, commented that: "It is a logical move, but I'd be a lot more enthusiastic about the adding Guide 34 to our accreditation if UKAS was able to force analytical laboratories to use CRMs if they are available. But whilst they only recommend the use of CRMs, given the cost conscious culture in most commercial laboratories, many will continue to use the least possible number of CRMs!"

Previous RM Columns are available on the *Spectroscopy Europe* web site.