Accreditation of RM producers: Who needs it?

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Accreditation of RM, CRM and PT producers: a topic that is sure to crop up whenever two or more of the community are gathered together. Since Accreditation to ISO 17025 has become "de rigueur" for analytical laboratories pressure has developed on the suppliers of the required reference materials and proficiency testing programmes to both produce more RMs and become accredited as a calibration laboratory.

So far only a small number of commercial providers have become accredited, almost exclusively to ISO 17025, but with elements of ISO Guide 34 built into the associated Quality System. One or two institutional RM producers have achieved accreditation, notably to ILAC Guide 12 and in the USA accreditation of Environmental PT Scheme providers is mostly done by NVLAP, to ISO 17025. Few European PT schemes are yet accredited in this, or any other way.

It is generally believed that satisfying the requirements of accreditation as a calibration laboratory is far more onerous than as a testing laboratory. The concerns expressed talking to RM producers at Pittcon 2003 [described in full in *RM report* 2/2] were that the cost and complexity of reaching this high standard place excessive demands on many of the smaller US companies and organisations who provide the RMs, CRMs and PT products used by many European labs, especially in the environmental, pharmaceutical and clinical areas. Outside metallurgy, Europe is far from being self sufficient in the production of RMs, with only one (BAM, Germany) of the four main European producers of metallurgical RMs accredited to ISO 17025 as a Calibration Laboratory.

Talking to more than 30 US companies and institutes about meeting future need for RMs and PT revealed three themes that recurred time and time again:

- who is going to pay for all the work associated with Accreditation?
- who is really competent to accredit us?
- will this process actually improve measurement quality?

The US companies appear to believe that European academics are responsible for the pressure to accredit, they have no regard for non-European interests or commercial reality. The so-called "4E" Group, a working group comprising members of EA, Eurolab, Eurachem and Euromet met for the 12th time in Berlin in September last year. The most important agreement at that meeting seemed to be agreement that there can only be one international working group on reference materials and the Accreditation of RM producers. They suggested that the work of 4E, ILAC, CITAC and ISO REMCO should be brought together.

Almost as important was the agreement that ISO 17025, on its own, is not sufficiently comprehensive a document against which to accredit RM producers. In some corners this is seen as part of a process which will result in ISO Guide 34 becoming ISO Standard 17034 and this will be the *de facto* standard against which RM producers will be accredited. The outcome of the next meeting, taking place in Dublin on 31 March, will be interesting.

After the numerous meetings held by the bodies mentioned above over the last six years or so we still lack any real consensus on the best document against which to accredit RM producers. The sooner that there is one standard, against which **ALL** CRM producers can be accredited, the better!

This brings us back to the real world.

The cost of achieving, and maintaining accreditation to ISO 17025 as a calibration is not as high as many believe: assuming the companies already have a good quality system in place and the required level of management then the additional cost, based on UKAS prices and UK costs, should be no more than €16K to reach the stage where final inspection can take place and €8K a year thereafter. This is not a significant burden.

Evidence from the USA shows that NVLAP charge up to €20k a year after accreditation has been achieved.

Some of the companies producing CRMs have successfully produced materials for more than 20 years, without any form of accreditation. Accreditation to ISO 17025 as a calibration laboratory requires that there is a technical assessor, as well as the administrative team. Many of the specialist CRM producers wonder where such specialist assessors can be found.

In the institutional area there have been suggestions of "peer review" to overcome this difficulty, with peer organisations advising the accreditation body, but can one realistically see, for example, a NIST staff scientist welcome as an assessor at BAM or LGC?

In the commercial world I know of one accreditation that stalled for almost a year because the only expert available to the accreditation body was a consultant also retained by a competitor! In the USA last year there was considerable anger when it was realised that the US Freedom of Information Act required NVLAP to release, if asked, information gained during assessment of one PT provider to a competitor.

When the cost of accrediting producers has been met, and the required number of impartial experts found, by how much will the standard of analysis be improved? This is where the biggest level of doubt surfaced in my many conversations.

There are no answers, yet. But the view of many is that unless the academics get a grip and involve the industrial sector in the development of a meaningful and useful "standard" the implementation of such a standard beyond ISO 17025 will do little to improve metrological quality. But it may improve the perception of quality. It also may mean that a company/organisation that has achieved accreditation as a CRM producer can better defend its data, and hence its products, in our ever more litigious society.