RM COLUMN

Regulating analytical quality: are we going round in circles?

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This column was written immediately after PittCon 2006, arguably the largest and most important symposium focussed on analytical chemistry. For those who have not been there, PittCon is different. A key part of the event is the Trade Exhibition, which attracts over 1200 exhibiting companies, including almost all the US and many non-US companies that manufacture analytical standards and reference materials.

For the last 12 years I've been visiting PittCon to see what is new in the reference materials market and to talk to the exhibitors about the market and recent developments. This year there were booths from 40 businesses or organisations offering reference materials.

Talking to the RM producers two clear themes emerged: visitor numbers and accreditation.

Over the last 10 years PittCon has evolved into a place where businesses talk to businesses and in particular overseas distributors, rather than a place to meet real end-use customers. For the first time the number of people visiting PittCon fell below the psychological 20,000 barrier.

Accreditation, both of laboratories and RM and PT producers was a more heated subject. It became clear that the procedure of accreditation seems to becoming more important than improving quality and that especially in the environmental sector, the whole business was becoming politicised.

In the USA all laboratories undertaking environmental analysis are required to be accredited: there are two key players in this game, NELAC and NELAP.

Standards are set by National Environmental Laboratory Accreditation Conference (NELAC) and the National Environmental Laboratory Accreditation Program (NELAP) implements the NELAC standards. States and Federal agencies serves as Accrediting Authorities with coordination facilitated by US Environmental Protection Agency (EPA) to assure uniformity. Accreditation under NELAP may be applied to environmental laboratories performing analyses under all EPA programmes, with a few exceptions.

NELAC is a voluntary association of State and Federal agencies formed to adopt and promote mutually acceptable performance standards for the inspection and operation of environmental laboratories. NELAC is a cooperative effort of the USEPA, State and other Federal agencies.

When the Accreditation of PT producers became obligatory it was decided by the EPA that National Voluntary Laboratory Accreditation Program (NVLAP) would be the body responsible for accreditation of the PT providers. NVLAP is an organ of the US Department of Commerce and utilises staff and capabilities of NIST. As a US Government body the Freedom of Information Act applies to all data, which was a concern for some commercial providers of PT services. This, coupled with the demanding scientific component of visits resulted in some producers bringing pressure through NELAC and NELAP to allow competition into the accreditation of PT providers.

Unlike in the UK and many European other countries, in the USA there is no single, authoritative accreditation body. There are three US organisations that are full members and therefore signatures to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA), they are the American Association for Lab Accreditation (A2LA), International Accreditation Service, Inc (IAS) and NVLAP plus eight further affiliates to or stakeholders in ILAC.[1]

The result was that A2LA had become a significant provider of Accreditation for PT providers, but some US States still require that Providers are accredited by NVLAP. So in certain cases it is necessary for a provider to be accredited to the same standard by two separate bodies at considerable expense. This duplication has caused further concern as it is not yet clear who will be responsible for accrediting RM producers to ISO 17025 and ISO Guide 34.

Another issue raised was that through lobbying by Environmental labs through NELAC and NELAP PT providers have been forced to change their PT samples to make them, in the words of the head of QC at one PT provider, "so easy to analyse that they have become virtually pointless". It is well known that in the analysis of volatile organics in soil the effect of sample matrix is very significant. It is also known that the analysis of these analytes is challenging and this means that when "Real World" samples are provided as PT samples—mimicking the sort of samples a lab gets from customers—some labs will fail their PT round. So it has now been decreed that PT samples for VOA analysis must be "laboratory fortified", that is a sample of sand onto which a mix of VOAs in solvent is poured immediately before analysis. Such samples are easy to analyse, but nothing to do with measuring a laboratory's ability to measure VOAs in soil. As one Dutch scientist said "they may as well analyse the fortification mixture".

I will look further at this contentious issue in the next RM Column.

Reference

1. www.ilac.org list of members.