RM COLUMN

Regulating analytical quality: the purpose of proficiency testing

Peter J. Jenks
the Jenks Partnership, Newhaven House, Junction Road, Alderbury, Salisbury, Wiltshire SP5 3AZ, UK.

In the last RM column I finished by saying that I'd return to Proficiency Testing (PT) in this column. Researching the role of PT in regulating analytical quality I found a paper by Rippey and Williamson,[1] which to me to sums up the spirit of PT. The authors write:

"Proficiency testing programs provide many benefits to participant laboratories, functioning as an *integral component of total quality control*, as *a vehicle for self-improvement*, as *a mechanism for continuing education*, and as a fulfilment of regulatory requirements". The key words are highlighted: they are as true today as they were when I first discovered PT back in the mid 1970s working as a Clinical Biochemist at a UK hospital. We were participants in regular PT rounds pioneered by the late Professor Tom Whitehead at the Wolfson Laboratories at the QE Medical Centre in Birmingham. His work led directly to the UK National External Quality Assessment Service.[2]

Rippey and Williamson also write: "PT should not be utilized as the sole indicator of acceptable laboratory performance; unacceptable results should serve as a trigger for further inquiry and corrective action as indicated. A proficiency testing program should be a broad-based program covering the usual spectrum of laboratory disciplines without commercial bias and it should possess continuous scientific input so as to be capable of adjusting promptly to technologic advancements as well as maintaining established participant benefits. It is important that proficiency testing programs continue to develop mechanisms of mutual interchange with accreditation bodies and regulatory agencies."

Their text distils all the important points: PT should form the cornerstone of a journey of improvement, the objective being better, more reliable data. But PT should be but one element of the quality manager's toolbox. Unfortunately, as I noted in the last RM column, in some areas PT is in danger of becoming a blunt tool, debased and ultimately pointless. My literature search also highlighted a paper by David J. Hassemer[3] who wrote: "Successful laboratory performance, as defined by the new rules, became the important issue. 'How well did we perform?' and 'What did we learn?' were replaced with 'Did we pass or fail?'"

Hassemer shares my view that as Accreditation bodies, through their monitoring of labs accredited to ISO 17025: 2005, probe ever more closely into quality systems, the demands placed by users on PT providers is changing. Accredited labs demand that their PT providers are accredited to ISO 17025 and Guide 43 so many older PT programmes developed from an educational perspective are no longer acceptable. It seems that accreditation organisations more and more require the lab to participate in PT simply to show the laboratory can "jump through a hoop".

The result is that subtle pressure from the labs means that in some areas PT providers now supply PT samples that are easy to analyse. When I started work, the laboratory staff had no idea if a sample was from a routine patient or was a PT sample. The sample, covertly introduced into the work flow, got exactly the same treatment as a sample from a patient on the ward. In the early 1990s soil samples sent out to US laboratories analysing contaminated soils were designed to be as close as possible to the type of sample the lab might receive from a superfund site. This meant that the PT sample might contain bits of grit and other debris. The lab had to dry and grind the PT sample, just as it would a real sample. The analyte levels might, or might not, be within the normal working range of the lab. Today, commercial pressure from client laboratories has caused a number of US PT providers to issue PT samples that are made up of a clean soil and a "fortification" mixture that is added to the sample immediately before analysis. The samples are carefully controlled so that there are no surprises. These samples are so easy to analyse that it is almost impossible for the lab to get the wrong result.

It seems that, in this area at least, the objectives of *self-improvement* and *continuing education* have been lost. The only objective is to be shown to be able to easily jump through a very big hoop. This raises two big questions: why is are the accreditation bodies responsible willing to put up with this and why have the labs customers not cried foul?

I wish I could answer these questions.

References

1. Rippey and Williamson, *Arch. Pathol. Lab. Med.* **112(4),** 340–342 (1988).
2. www.ukneqas.org.uk
3. the Medical Laboratory Observer (MLO) for January 2006 (PDF, 199 KB), pp. 20–21, 24–25.

Writing this column I realised that it is the 25th RM Column published in *Spectroscopy Europe*. The first appeared shortly after I talked with the publisher, Ian Michael, on September 11th, 2001. at a meeting of the British Mass Spectroscopy Society. That day has gone down in history for reasons that are too well known to need further comment: it is gratifying that there were other, more constructive developments that day.