Question: Should UKAS adopt the principles of Guide 34 into ISO/EC17025 accredited laboratories?

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In a number of past editions of this column I and other guest contributors have talked about the need for producers of certified reference materials (CRMs) to be fully accredited so that users of CRMs can have confidence in their products. As recently as in the last issue of *Spectroscopy Europe* Rob Bettinson of UKAS explained why this issue was of sufficient importance for UKAS to introduce a new accreditation programme specifically for the accreditation of RM producers. Accreditation of CRM producers is but one part of the equation. In his well argued essay this month's guest columnist, Cliff Marshall, explains why there needs to be an awareness that all CRM producers are not equal and the assessors, who police ISO 17025 accredited laboratories, need to make sure that where a lab has a choice between CRMs from an accredited producer and another producer they would be advised to take the product from the accredited producer!

Peter J Jenks, RM Column Editor

Now from the start let's get this straight, this article has been written from the frustrated viewpoint of a CRM distributor who represents a reference material (RM) producer with ISO 17025 and Guide 34 status. What's Guide 34 and why am I frustrated?… read on.

Now I am sure we can agree, analysts are a "conservative" bunch who do not make changes to procedures without due cause. Improvements in technology related to instrumentation are welcomed, but materials and standard operating procedures are rarely changed. Those laboratories who have ISO/EC 17025 are deemed to apply good quality management procedures in the maintenance of their accredited status. Most laboratories have very vigorous and well-defined analytical procedures whether they hold accreditation or not.

As an accreditation body UKAS sit as judge and jury over whether you as a test and measurement laboratory satisfy their criteria to confidently state the value of a measured sample, and comply with the requirements of ISO/EC17025. Conviction in analytical data is generally expressed in confidence limits and uncertainty values which are determined through what we refer to as error budgeting.

More than ever before, people are making decisions based on chemical measurements that affect us medically, environmentally, legally and commercially. In addition measurements are required to assure compliance with international regulatory bodies.

The judge and jury scenario is rather like a mathematical formula, where criteria have been established that satisfy a statement of fact. The answer or value is made up of variables which have been measured by reference to standards, and applied to a statement. However, if we are unable to apply valid standard values to the formula, it not only puts into question the variable values, but undermines any confidence in the analytical result.

So if you are sitting as judge and jury you had better be sure you apply the rules correctly otherwise trust in the system will be undermined.

What is required of an accredited lab in its analytical methodology?

Through a national accreditation service, laboratories procedures may be assessed and recognised as achieving a standard of testing, calibrating, inspecting or certifying. The specified methods of testing are covered by the International Standard ISO/EC 17025. Laboratories that use a Total Quality Management system are able to demonstrate through recording the traceability that they have consistency and qualifiable links between results of the measured standards references, and that of the measured sample. It is the responsibility of 17025 accredited laboratories to evaluate the suppliers of critical consumables which may affect the quality of calibration and testing. A laboratory may satisfy its claim to traceability if it satisfies a combination of:

- the use of traceable standards to calibrate the measuring equipment
  "for compliance to ISO17025 it is imperative that measuring equipment used must be calibrated and offer traceability to appropriate standards whose values are traced to the SI"

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- by using or comparison to the results of a primary method
  "where applicable, traceability of the results of a primary method is achieved by direct comparison of measurement results between the primary method and test or calibration method"
- by using a pure substance RM
  "as well as their use in calibrating equipment, traceability may also be demonstrated by measurement of a sample composed of, or containing a known quantity of pure substance"
- by using a suitable matrix CRM
  "certified matrix CRM's offer traceability by comparison of the result with the certified values"
- by using an accepted closely defined procedure

What is required of the analyst?

As analysts we follow methods which should be clear and concise and which show no ambiguity as to the result, how it was derived and to what it may be traced.

This is realised by demonstrating that the values were achieved by following a precise standards operating procedure showing traceability to known standards and that the results obtained for analytical measurements may be confidently expressed and compared to those of other laboratories conducting analysis of the same sample. This may only be achieved by ensuring all laboratories are using the same validated measurement scale.

What is required of the RM producer?

The role of RMs and CRMs is evident in the analytical process. ISO Guide 34:2000 is an accreditation that deals directly with the CRM manufacturer, where the methods that manufacturer uses to certify its standards must be validated and proven to be accurate showing uncertainties which include all sources of error involved in certifying the standards to be reported on the Certificate of Analysis.

However, it is our experience that greater than 80% of laboratories do not use appropriate CRMs, and appear to have little appreciation of the importance of the content of the "Certificate of Analysis" as provided by the RM producer.

Just take a moment and examine some of the documents you have been supplied supporting recent standards purchased. If they state that it is a Certificate of Analysis, but offer only nominal values, e.g. 1000 ppm or 10,000 ppm, and a batch reference; the product has no validity as a traceable document. The document should provide absolute values achieved with confidence limits and uncertainty values. It should also indicate the methods by which these values were determined and the validation and verification of instruments used, all having traceability to standard reference materials (SRMs).

Many column inches have been dedicated to the application and acceptance of reliable RMs and CRMs by users, accredited bodies and the RM manufacturers. Without an effective method of verification of an analytical procedure through the use of such materials, the confidence in, and acceptance of analytical data must be questioned.

What is required of the accredited body?

A lead must be provided to assure confidence in the abilities and values expressed by accredited laboratories. Internationally, Mutual Recognition Agreements between accredited bodies, where producers are accredited to both ISO/EC 17025 and ISO Guide 34 are already in place with the UK being one of the exceptions.

It is clear that if UKAS does not enforce the regulations then the manufacturers will not produce CRMs to Guide 34 standards.

So now the political argument is that as there are no UK RM producers of CRMs who are able to offer standards to Guide 34. The adoption of ISO Guide 34 by CRM manufacturers offers a procedure which is transparent showing the proper traceability of their standards.

So here's the frustrating part. When we ask the question of most laboratories "Why do you use a particular chemical reference material?" the answer will fall into two categories:

- "We use it because we always have, it's compliant isn't it?"
- "We use it because it's the least expensive or is supplied by our preferred chemical supplier"

As accredited labs know, it is their responsibility to assure standards are compliant and offer appropriate traceability. Cost is a relative issue when considering the implications of the validity of your result, and would the cost of a valid reference material impose higher costs… probably not.

So where's the problem? Guide 34 should be adopted by all RM producers to assure confidence in analytical results… without question.

It is often cited that materials from the companies that hold Guide 34 status are more expensive than those who do not. In our experience this is not the case.

Does your RM producer supply CRMs with ISO17025 Guide 34? If not, why not?