

## Calibration CRMs: why are they so difficult to produce?

**Peter J. Jenks**

the Jenks Partnership, Newhaven House, Junction Road, Alderbury, Salisbury, Wiltshire SP5 3AZ, UK.  
E-mail: editor@rmreport.com

Without the effective calibration of an analytical system through the proper use of reliable calibration RMs and CRMs, analytical data cannot be relied on. For many working in routine laboratories getting hold of reliable and affordable calibration RMs, both in pure and solution form, has long been a difficulty, especially for many organic analytes that have to be measured in environmental, food, public health and diagnostic laboratories. The adoption of ISO 17025 as a Quality Standard by the majority of analytical laboratories and ISO 15189 in clinical laboratories has only exacerbated the problem as producers of calibration RMs are now required to work to appropriate quality standards to ensure that their products meet the traceability requirements inherent in an ISO environment.

Europe has never been self sufficient as a producer of organic calibration RMs, especially environmental, food analysis and clinical/public health, where a significant part of demand is met from imported US sources.

Based on publicly-available information, Europe is well populated with organisations that have, or had at some stage, the capacity or potential to produce calibration RMs. Information developed in 2003 by the Jenks Partnership (TJP) for the UK Reference Materials Working Group and BSI suggest that there are a substantial number of such organisations in the UK, covering a very wide range of application areas. Across Europe there may be 100 and possibly more such organisations.

The fundamental issues that need to be resolved would seem to all stem from a single basic question:

- Why do there not seem to be enough pure calibration and solution reference materials available to meet the needs of the analytical community?

The UK Department of Trade and Industry, through the National Measure-

ment System's VAM programme has let a contract to TJP to research this crucial question. Over the remainder of this year TJP, working with IM Publications and Safety Data Services, will be undertaking a carefully-structured investigation that will look at the following issues.

### Structural issues

- Are all the organisations that appear to have the potential to produce calibration RMs currently able to do so and if they have stopped, why?
- Do they have quality systems in place that allow them to produce and maintain calibration RMs that meet current market needs?

### Organisational issues

- Are the organisations that produce calibration RMs presently meeting the needs of a wider international market or a narrow national market?
- Do the organisations have the physical resources to produce and certify the RMs themselves, or do they depend on a cooperative process?
- Are calibration RMs a core part of their business activity, or are they produced peripherally as a "service"?
- Do they have the project management skills to maintain the production of replacement lots over a prolonged period and maintain continuity of supply by replacing sold out materials?

### Regulatory issues

- Are calibration RMs mainly required to comply with national regulatory imperatives, for example the UK Environment Agencies M Certs programme?
- Have tightening health and safety regulations inhibited or stopped the production of calibration RMs in any way? In particular restrictions on the

physical handling or transport of hazardous materials RMs need to be fully understood.

- Are recent regulatory developments in the regulations that cover packaging, labelling and distribution of chemicals, especially the EU "REACH and CLEEN" projects, the Stockholm Convention on persistent organic pollutants and UN "GHS" proposals seen as a threat to calibration RM production?

### Financial issues

- How are calibration RMs marketed, sold and distributed to the end user customers?
- Does the income from sales generate a satisfactory return on capital employed?
- Are there market areas where it does not seem economically viable to produce calibration RMs, and if so, why?
- Where cooperative groups work together to produce calibration RMs, how are the members of the cooperative involved, financially?

The data developed will be compiled into a database and the key conclusions will be made available the wider analytical community through a special VAM Supplement to be included with *Spectroscopy Europe* Volume 17 Number 1, to be published in January 2005. It is expected that the database will be posted, in a searchable format on the internet, to help anyone looking for possible suppliers of calibration RMs or a partners to work on the development of a specific calibration RM.

If you would like to contribute data to the project or have any information you would like to share with the project team, please e-mail the special project address: [VAMProjectCRM@aol.com](mailto:VAMProjectCRM@aol.com)