

Matrix CRMs: the commercial “Bridge too Far”?

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In the last issue [*Spectrosc. Eur.* **14(2)**, 18 (2002)] I suggested that the commercial production of CRMs might be a growth area over the next three to five years, driven by the requirements of ISO 17025 and the increasing application of this quality standard to analytical laboratories, world wide. But I pointed out that whilst there are many companies either producing or about to produce single substance CRMs, there are very few addressing the growing need for matrix CRMs.

Two recent developments, the introduction of NTRMs in the USA and the break-up of the EU SMT office in Brussels, might give support to the view that the environment for matrix CRM production is about to change significantly and open a window of opportunity for commercial producers of matrix CRMs.

In an interview published in the *RM report*,¹ the Chief of the NIST SRM Program, John Rumble, said “NIST does not have to do everything” when talking about the need to supply SRMs for the needs of industry. He went on to say that “in areas where the required analytical and production processes are well understood and controlled, NIST will support the producers, on a fee for service basis”.

In such areas NIST appears to be willing to act as a supervisory body, ensuring that CRMs produced in the USA are traceable to NIST SRMs. This concept has been piloted in the production of gas mixture NTRMs and is expected to move into the metallurgy marketplace and single element calibration market places in the reasonably near future. But so far no company is known to be planning the production of matrix NTRMs.

Recent changes in the structure of the Commission of the European Union mean the effective end of the Community Bureau of Reference (BCR). Established in the early 1970s, this Department was given the responsibility to bring together and coordinate the many varied and diverse RM activities of both private and govern-

ment within the EU. As the BCR, the Department was responsible for the many research projects that resulted in the internationally respected range of BCR CRMs. The functions of the

BCR will be assumed by the IRMM in Geel and the various EC Directorates General that previously commissioned the BCR to carry out work on their behalf.

It is a concern that without substantial investment of experienced people at IRMM and within the DGs the support for CRM production and development may not be maintained at past high levels. Three years ago DG JRC commissioned Dr Hans Modder of PwC Consulting BV to carry out an extensive and detailed report of the role of CRMs in the European Union. The PCW report is expected to be posted on the JRC website² in the near future. It is known one of the main conclusions of the report was "facilitation of proper metrology cannot be fully left to the market, there must remain key interest at EU level".

The rest of the report is awaited with interest. This author hopes that the result of the survey will be to enthuse the DGs to make the CRMs an integral part of their legal metrology and invest strongly in the IRMM, the national RM organisations such as LGC in the UK and BAM in Germany and the private sector producers.

Why should commercial producers of matrix CRMs not rush to jump into the market? The answer is that they do not see real profit. How can this be? Matrix CRMs sell from between €100

and €250 per unit and are generally consumed. These prices are much more than most laboratory consumables. So on the surface it looks an interesting opportunity.

Consider the steps that have to be followed to produce and certify a matrix CRM. They are complex, demanding and can take a number of years. For a more detailed review of these processes refer to chapters 2 and 3 of *Reference Materials for Chemical Analysis*.³

Determination

This needs knowledge of the analytical market, forthcoming legislation and the laboratory supplies industry.

Production

This needs extensive material handling, chemical engineering, packaging and process chemistry equipment and skills. A highly skilled and ISO 17025 accredited analytical laboratory is needed, able to analyse the analytes of interest at the highest level of competence.

Evaluation

Are the analytes of interest at the right levels? Is the material stable? Are

the packed units homogeneous? The analytical work is considerable.

Analytical

This is where a mass of data is assembled for each analyte. The analytical methods used must demonstrate clear and unbroken traceability, usually to the mole. A number of different methods must be used wherever possible.

Certification

The mass of data must be examined and statistical routines undertaken, the aim is to produce a true value for each analyte with a properly constructed uncertainty assigned. An analytical report and certificate of analysis is prepared.

Commercialisation

Storage, sales, marketing and distribution cannot be ignored. The batch must be large enough to meet predicted demand for at least three and preferably five years. It also must be stable and will certainly require regular QC controls.

The resources needed are significant: capital investment in plant and equipment, skilled people, time and money. At the end there will be three to five years stock, an anathema to an accountant.

One estimate, made some years ago, was that a typical NIST SRM, if costed by a normal commercial cost accounting procedure that would be used by a laboratory supply company or pharmaceutical company, would have to be sold for more than €5000 a unit to get a satisfactory return, not €250. But the market has been educated to expect to pay €250 a unit. Which is why there are so few commercial or private sector producers of a range of matrix CRMs that begins to match the ranges offered by the Governmental Agencies.

So, from whatever way the process is examined, the commercial production of matrix CRMs does not make sound commercial sense. If we expect to have a good range of matrix CRMs available in the future and we want to use them in the way we do, then Government will have to pick up the bill.

If they do not, what do we do? The answers to these, and other questions, will appear in a future edition of *Spectroscopy Europe*.

References

1. RM report 1(2), 3 (2002).
2. <http://www.jrc.org>.
3. M. Stoeppler, W. Wolf and P.J. Jenks, *Reference Materials for Chemical Analysis*. Wiley-VCH, Weinheim (2000).