On finding the "right" reference material,

or the Quality Manager's lament!

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Finding the right reference material (RM) or reference substance (RS) for a particular analytical process has never been easy, but in the last couple of years it seems to have become harder. Why? In this essay we examine the problem and in Part 2, offer some relatively painless advice and guidance on finding the RM or RS needed!

There are a number of reasons why it is not always easy to find the right RM or RS. The main ones are:

- Accreditation to ISO 17025
- The growth of the RM market
- An ever increasing financial pressure on laboratories
- The nature of RM producers

The International Standard on General Requirements for the competence of testing and calibration laboratories, better known as ISO 17025, has replaced ISO 9000 and its various versions as "the" standard to which most analytical laboratories, outside the pharmaceutical and clinical sectors, are accredited. There have been extensions to the scope of ISO 17025 by other interested parties: a good example is the UK Environment Agency's "MCERTS" Standard for the analysis of contaminated land. This is a performance standard that adds to ISO 17025 requirements by defining how a lab shall be organised and the analytical performances it must achieve. It also specifies how a lab must validate each method used by number of replicate samples and matrices.

In ISO 17025 paragraph 5.6.3 of the 2005 edition makes specific reference to RM use, the use of RMs can be found in a number of other paragraphs, including 5.4.4 on non-standard methods and 5.9 on assuring the quality of test and calibration results.

The growth of the RM marketplace has made finding the right material more difficult. Fifteen years ago, RMs were mostly supplied either by the producer or by specialist distributors with a broad knowledge of RM producers: they could advise on who made what, how to buy and from whom. Most of the businesses were run by analysts with understanding of the customers needs: they worked on small margins, made possible by low overheads and little expenditure on glossy catalogues and expensive marketing.

As the demand for RMs and RS grew in the late 1990s the market evolved: a number of the specialist distributors became prominent, followed by mergers and then acquisitions. The sourcing and supply of RMs became a part of the mainstream laboratory supply business. This was, for most consumers, a positive development with more choice of RM from a greater range of producers. But there was a downside: the knowledgeable specialists who had underpinned the small businesses became detached from the day to day customer interface. The junior staff who replaced them did not have the knowledge, gained over many years, of their predecessors and in some areas service suffered.

The increasing financial burden faced by RM users has also played a part: RM producers have always insisted that their products are inexpensive: possibly so, based on the amount of analytical effort and administrative work that goes into RM production. But when contrasted with the prices paid to commercial laboratories for a particular test, the RM or RS can seem costly. Recently one lab manager, from a commercial laboratory working for both the food and pharmaceutical sectors, commented that £80.00 for a RS doesn't seem much, but when the RS is consumed entirely in calibrating a procedure that is charged out at £125.00 per test, the economics get quite challenging. Fine when there is a run of 200 samples, but when they have only five samples to do… .

The structure of the RM "industry" compounds the problem: it is difficult to imagine any other "industry", whose products are of such crucial importance to so many areas being built up from a myriad of small specialist organisations, many of them quasi academic and with little or no real marketing or international distribution skills. A recent look at the COMAR Database identified 200 producers in 27 countries, yet this is only the tip of the iceberg. A report by the Jenks Partnership for the DTI in 2004 identified almost 100 UK producers of matrix and organic RMs, so on that basis alone there might be 1500 RM and RS producers world wide!

The result of this focus on RMs, coupled with in increasing diligence by accreditation service auditors on the RM aspect of ISO 17025 conformity has started to place an increasing burden on the Quality Manager (QM) or Operations Manager, to sort the "wheat from the chaff" and identify sources of RMs that relate to his labs area of excellence.

In part 2 we look at information resources that can help the hard pressed QM!