

## Standards and Accreditation

Thank you for the opportunity to comment on matters pertaining to the Research Study being conducted by the Productivity Commission.

I am a qualified industrial chemist - graduate of RMIT — and have been involved for many years in the importing and exporting of Certified Reference Materials (CRMs). I have also served on committees of both NATA and the National Standards Commission (now part of the National Standards Institute) concerned with chemical metrology and accreditation of chemical and biological laboratories.

The comments in the Commission's Circular and Issues Paper regarding standards and accreditation and the significance to Australia's national interest are highly commendable. The subject is indeed of great importance.

In perusing the Circular and the Issues Paper I can find only two references to chemical and biological testing - Table 2 on p 4, and the last para on p 5, of the Issues Paper. In both instances the references are part of sweeping statements that group chemical and biological measurements with *physical* measurements. There are particular features of chemical and biological measurements that distinguish them from physical measurements.

Chemical and biological measurements are of increasing importance in international and domestic trade, environmental control, occupational health and safety, scientific research, law enforcement etc. Not only are these measurements important domestically, it is also extremely important that chemical and biological measurements made in Sydney or Melbourne or Tokyo or Bombay or London or where ever, are comparable — that the results can be accepted with confidence and acted upon. This is more readily achieved with physical measurements, however we have difficulties in achieving this with chemical and biological measurements. CRM's and Proficiency Testing Programs are our most important tools in the pursuit of comparability.

Firstly however a word of warning — in your paper you rightly distinguish between standards that are written standards that set levels of performance etc and standards that are reference standards that are employed to calibrate measuring instruments etc. Common usage in the chemical and biological areas often uses the word 'standard' to identify what should rightfully be referred to as a Certified Reference Material (CRM).

Chemical measurements and CRM's are referred to in the National Measurement Act, so one would assume chemical and biological measurements will be considered in your study. They are now an increasingly significant part of the work being done by NATA.

Certified Reference Materials are produced by accredited laboratories — often government funded laboratories — who take a bulk quantity of material and after processing to achieve homogeneity, subject samples drawn from the bulk quantity to exhaustive analysis. This process is often extended over a length of time in order to not only determine the composition of the material but to check the stability of the material. The bulk batch is

subdivided into small units — 50 or 100 gram — or even less, depending on the circumstances — and with supporting documentation, offered for sale.

An analyst will purchase CRM's appropriate to his/her needs and employ them to calibrate analytical equipment and processing methods. Today much analysis is carried out on sophisticated computer operated analytical equipment. The availability of CRM's not only allows for ready calibration of this equipment, but also for the validation of results in the event of a dispute. Needless to say the standing of the laboratory that produced the CRM, and the body that accredited the laboratory, is of particular importance.

Consider:

- No country can ever hope to prepare a range of CRM's sufficient to satisfy the country's needs. In fact all countries combined are not able to satisfy the world's requirement for chemical and biological CRM's, yet the National Measurement Act refers to CRM's in the context of Australian National Standards. For a measurement to be accepted in an Australian court of law, the measurement must be traceable to an Australian national standard! There are few Australian national standards for chemical and biological measurements.
- The enormous range of CRM's sought by analysts all over the world means there is an ever increasing international trade in CRM's
- An analyst seeks to use a CRM that matches as closely as possible the specimen he is analyzing - the further the CRM varies in composition from the specimen being analyzed the more the analyst has to be concerned with adjustments for the variation(s). This increases further the variety of CRM's required.
- Australia, regrettably has not contributed much to the world's supply of CRM's - drugs in sports is the one area where, in recent times, Australia has contributed, otherwise our contribution has been very poor..
- Countries such as South Africa and Canada, which one could consider comparable industrially to Australia, have contributed much more and over a much longer period..
- There are basically two types of CRM's - pure substance and matrix standards.
- There is the assumption that a pure substance CRM is 'pure' and does not contain any variants within the limits specified in the accompanying documentation.
- A matrix standard contains one or more substances in a specified matrix e.g. pesticides in soil.
- Often a matrix CRM is intended to act as a measurement standard for more than one constituent - the CRM thus becomes a multi-standard.
- The method of determining each individual constituent in a mixture may not be the same - different analytical methods for different constituents - yet the results are added together.
- Analytical results are often *method dependent* - some methods give high results and some give low results. Analysts are reluctant to see 'standard analytical methods' specified as this will stifle development of new, more effective or faster methods of analysis.

- Analytical methods often require significant processing of a sample to put it in a state where particular constituent(s) can be determined.
- CRM's are produced in batches and are *consumable standards* — when a batch is depleted a new batch is prepared, but the new batch will not be identical to the initial batch — the accepted practice is to identify each individual CRM not only with its catalog number, but also the batch it came from.
- CRM's are produced not only in an enormous variety of materials and composition levels but also to varying degrees of accuracy. For one purpose a low level, low priced CRM may be quite satisfactory, whilst for another application a very high level and hence much more expensive CRM may be required.
- Not all products being analyzed chemically and more particularly biologically, are stable. In these cases CRM's are of no value and short term proficiency testing programs are the only method available.
- Results are generally expressed as ratios e.g. percentages or parts per million by weight. In some instances a result may be expressed otherwise e.g. grams of metal per tonne of ore. This is still a ratio but has been chosen for ease of comparison without the tedium of a number of decimal places.
- Because results are expressed as ratios the results are independent of the system of physical standards employed. It does not matter what system of mass measurement is employed. — yet the National Measurement Act requires traceability to Australian National Standards.
- CRM's are frequently subject to the risk of contamination once opened and sub-samples removed e.g a 100 gram of a CRM may be sufficient for a number of check analysis.
- It is not unknown for revisions to Certificates of Analysis to be issued — even the National Bureau of Standards in Washington — now the National Institute of Standards and Technology - has issued amendments to certificates of analysis, from time to time.

Perhaps I should stop listing these points of difference as I am laboring the point that there are features associated with chemical and biological measurements that require allowances not necessary with physical measurements.

Regrettably the attitude that all measurements are measurements and all must fit the one mould has resulted in these differences being overlooked by many people, including the writers of regulations and the top management of industry and commerce.

I would be delighted to co-operate with the Commission in the review of chemical and biological "standards" if that review is on the basis that chemical and biological measurements have certain characteristics not shared by physical measurements.

I don't need to emphasize the significance of chemical and biological measurements in today's world — a moments thought shows the multitude of instances where we rely on chemical and biological measurements.

Whilst the Commonwealth encourages the use of 'standards' of measurement, we as importers of CRMs, are subject to a variety of charges levied by departments such as AQIS - it costs us as much to clear a 100 gm standard of a biological material as it would a Full Container Load (FCL). We can only sell such standards to laboratories that are approved by AQIS who, understandably, want to be satisfied the effluent and discharges resulting from an analysis are properly treated. Unfortunately AQIS will not inspect laboratories more than a stipulated distance from a capital city!

We pay an annual fee for the privilege of being an AQIS approved premise and keeping records for them. We even pay a levy to the Dept of Health and the Ageing under the NICNAS program!

Statutory requirements change frequently, as do the staff applying them. Administration costs that are not significant when applied to a bulk import of a product are out of all proportion when applied to a CRM or a Proficiency Standard. The costs and the administrative burdens placed on us have to be passed on to the customer in the form of increased prices which act as a discouragement to the use of CRM's This is not to plead for no controls but to hope that administrators and policy makers can be made aware of the significance of chemical and biological measurements and the particular and unique nature of these *standards*.

There are many instances where CRMs are used to validate measurements for government bodies, including those bodies that apply controls to the import of these products.

It is interesting to note that there are laboratories in various countries - particularly government funded laboratories — who charge export customers a premium over the local price apparently on the basis that the local customer has contributed to the funding of the laboratory in the form of taxes. It may also be that it constitutes a penalty to competitor countries.

Chemical and biological measurement needs to be distinguished in your report otherwise your report will do a grave disservice to chemical and biological measurement in Australia.

I can assure you of the co-operation of myself and my staff in distinguishing chemical and biological 'standards' as worthy of consideration as a particular and unique part of the measurement system in Australia. I hope your report to the government will support this aim.

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