MEASUREMENT QUALITY MATTERS: ASK TREVOR

A documented laboratory management system, ISO/IEC 17025 style

Is it an unnecessary complication and time-wasting costly overhead? Or a simple way to ensure high quality consistently valid results in your measurement work?

In this issue we shall consider the possibilities, the benefits of implementing a simple and good system and contrast the effect of that with a conflicting unwieldy inherited legacy system that does not properly fit your laboratory operation. Regrettably, the latter is all too often found.

Laboratories often start with people and sometimes documented procedures taken from other laboratories. If the people are competent then that may be a perfectly valid start point, but we must be wary of using methods or procedures developed for another laboratory. The equipment used may differ, and/or the environment may be tighter or looser to a specification and the assumed skill levels of the operatives for that given level of documentation may be inappropriate. That is sometimes the first stumbling block to getting easily and efficiently started with a new lab, and applies equally to buying an off-the-shelf procedure document from a consultant.

Let's consider the three broad principal features of modern laboratory management system standards, for example, ISO/IEC 17025:2017.

Three Essential Features

1. Technical Competence – knowing that your staff are capable of "getting the right answer" in a measurement because of their demonstrable technical skills, suitable equipment and environment
2. Management System – to ensure consistency, reliability and "once right, always right"
3. Quality Assurance Measures, interlaboratory comparisons, proficiency testing and similar activities, some of which will be external to compare your work with other laboratories. "The proof of the pudding is in the eating"

So, the best way to develop a simple and effective management system, for many labs, is to start by watching what your technically competent people actually do in practice in the laboratory. During the testing or calibration, of course, but also in defining and agreeing the work with the customer, through to issuing the results in some form of certificate or report. The aim being to document the process sufficiently for a suitably qualified and experienced person to be able to achieve comparable results. It follows, therefore, that the level of detail in the descriptions/instructions will differ according to the staff competence levels but will ensure that even the most highly qualified and experienced technician is constrained (!) to do any tasks in the same way as any other person authorised to follow the procedure. The primary aim being to ensure consistency of the work with your staff and equipment in your environment following your procedures. The best, most simple, documents are therefore usually those you have written yourselves containing what you need and only what you need.

The documentation may differ in style and structure to sort the activity. For the actual performance of test, it is usual to provide a step by step set of instructions. For things like determining the customer requirements and writing reports, the documentation might appear as a checklist to ensure all features are covered.

Some laboratories do this very well and it is often when they have developed their own procedures from scratch by observing the work of their people. A person contemplating starting a task, if he/she is already trained and authorised for the work should be able to identify any variable issues surrounding the task such as the "who, what, where, when and how" involved in getting the same valid results as the other authorised staff.

Laboratories using old legacy inherited arrangements sometimes find that they "cannot see the wood for the trees" and search in vain for where some requirement might be featured in their documentation. Not finding it, they then add another clause to their manual, often not in the right place! Over some years this can result in conflicting, unwieldy unusable documentation that does indeed constitute a heavy unnecessary overhead.

A concise, well written manual or set of procedures minimises training time, avoids disputes, errors and misunderstanding and, most importantly, prevents invalid results being given to customers.

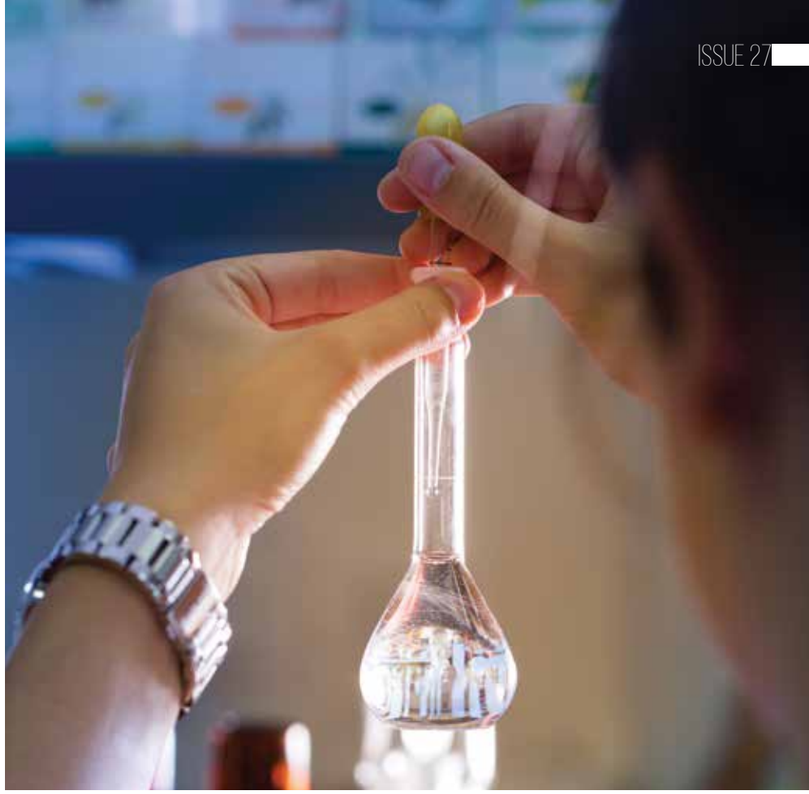
The third tenet "Quality Assurance Measures" in the chart above serves to check that your people are indeed competent, that you consistently follow sound procedures and are actually getting valid results. Staff and customers are given confidence in your work and in the comparability of the measurements made, often with SI units and sometimes internationally. In regulated sectors there are mandatory schemes, for example, in Asbestos and Water Quality, but in most industrial activity it is for the laboratory to find schemes or take part in homemade intercomparisons with other laboratories. The better schemes enable you to ascertain if your result at a particular point is within the combined measurement uncertainty of yours and of the reference laboratory. This is known as the Zeta score or En ratio.

The value of these schemes does vary as some use consensus values rather than a reference and some do not use the measurement uncertainty. There is a comprehensive database of Proficiency Testing and Interlaboratory Comparison schemes for both testing and calibration. It contains schemes in the UK, Europe and beyond. It is called the European Proficiency Testing Information Service, is operated by BAM, a large laboratory and PT provider in Berlin and is free of charge to consult. Scheme participation costs from a few tens of GB Pounds to several thousand according the nature of the scheme.

The Standard ISO 17025:2017 requires that some form of external comparison is undertaken and this drives an increasing availability of schemes. Sometimes labs, especially in niche areas of activity, make their own arrangements with other laboratories and there are several techniques for ensuring good technical comparisons whilst maintaining commercial competition.

Trevor Thompson was with the United Kingdom Accreditation Service (UKAS) for 30 years, where he assessed and managed the accreditation of many testing and calibration laboratories, mainly in the physics and electrical disciplines. He was also one of the authors of ISIO 17025:2017 being the UK representative on ISO/CASCO WG44. He is now partly retired but operates independently at www.bestmeasurement.com offering "internal" audit, mock assessments, and consultancy for laboratories.

Trevor is here to offer some expert advice in all measurement quality matters! If you have a question, please email him at questions@bestmeasurement.com and we will feature your question and answer in a future edition of the magazine.



E_N Ratio or Zeta Score

Reference value

Laboratory value

$$E_N \text{ratio} = \frac{LV - RV}{\sqrt{U_{LV}^2 + U_{RV}^2}}$$

Expanded uncertainties of the two labs

+ Establishes if the two results potentially come from the same population.
+ A lab having an E_N ratio <1 shows results within the combined uncertainties so the better the reference lab the more critical the measure.