International standards – sales value or unnecessary cost?

Jacqueline Balian, GAMBICA, jacqueline.balian@gambica.org.uk

International standards – for something that sounds so boring they are the subject of many vicious international and intercompany disputes.

In February this year the talk was all about the disintegration of US/ European Union discussions on mutual recognition of international standards. The currently highly protectionist US seems to believe that the EU is trying to muscle-in on the lucrative market for testing to US standards. Some EU negotiators think they have to find different words to disarm US suspicion, others say that semantics isn't going to sort this one out. While they leaf through their thesaurus, China is making hay at the International Standards Organisation. Thanks to a co-ordinated campaign they are managing to grab the chairs of over-arching lab committees including those on laboratory design and laboratory refrigeration products and many others.

From a UK company point of view there are risks and benefits to be had from International standards. The risk that a standard may severely impinge on UK companies' profitability or market access were raised again recently when a French company sought to amend a standard to require testing of every model of a particular type of lab equipment. Had this requirement gone through it would have cost UK manufacturers £60,000 for every model they wished to market – effectively putting small players out of business. Thankfully the risk was identified and action taken by affected companies at BSI level which ensured the effort did not succeed.

The value of getting involved in standards has been equally well demonstrated recently in the area of autoclaves. GAMBICA members who manufacture autoclaves got together to draft a standard specifically for laboratory autoclaves, as the existing ones focussed on medical autoclaves and resulted in the over-specification of lab autoclaves. Part of the motivation was to educate customers on what they should be looking for, but as there was no equivalent standard in Europe, the companies found that customers across the EU were specifying the standard which only the UK Companies had tested to. A welcome fillip for sales.

Charles Pascal

The work of manufacturers in setting out standards which help laboratories to do a significantly better job is exemplified by the work of committees which have set out how pipettes should be calibrated.

Charles Pascall, recently retired as International Business Manager of Alpha Laboratories Ltd but is still active as chair of ISO TC 48 and has been the nominated member for GAMBICA (previously BLWA) on BSI LBI 1/2 and ISO TC 48/WG4 for the last 30 years. He has overseen the complete overhaul of standards on pipette calibration.

The changes are important for lab managers, lab facilities management companies and pipette supply and servicing companies. In a recent article for GAMBICA's L@b Brief publication, Charles explained how the calibration standards have changed over time.

"Back in 1994, when I first entered the field of international standardisation, the laboratory world was very different. Most labs did not calibrate their pipettes and other Piston-Operated Volumetric Apparatus (POVA). When questioned as to how they knew the delivered volume, many said "100µl – it says so on the side"!

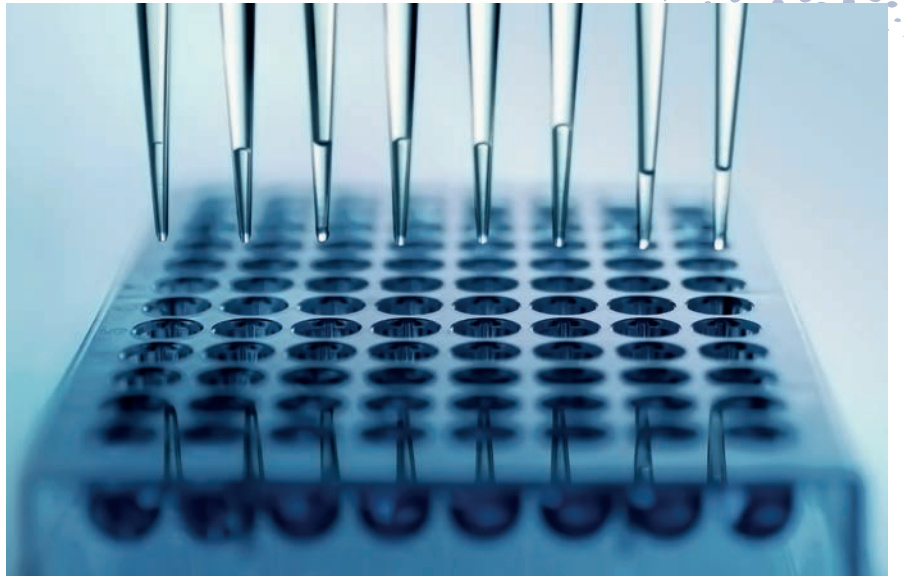
"At the time there were no international standards and calibration, as it was, was carried out using the NCCLS proposed guidelines, BS6018 and BS7532 or DIN 12 650. There was a proposal to write a new European Norm and over the next 7 years this was developed and was published in 2002 as ISO EN 8655. The standard consisted of 7 parts plus one Technical Report (TR) and the laboratory world changed significantly for the better with most laboratories considering requirements for calibration. In consequence, results are now generally repeatable and internationally transportable.

"After considerable work, an updated version of ISO 8655 started to be published in 2022. Whilst the 2002 version consisted of 7 parts with one associated Technical Report, the 2022-2024 version is considerably expanded and will be 10 parts with 2 associated TR's.

So what is new?

ISO 8655 Part	Subject	Changes include
1	Terminology	Updated to include new terminology, requirements and recommendations.
2	Pipettes	Updated maximum permissible errors and a new annex for electronic pipettes.
3	Burettes	Updated maximum permissible errors
4	Dilutors	Updated maximum permissible errors
5	Dispensers	Updated maximum permissible errors
6	Gravimetric reference measurement procedure	Updated with better defined procedure and developments in measurement.
7	Alternative procedures.	Updated and refers mainly to variations to parts 6 and 8. Now an absolute minimum of 10 repetitions for calibration and 4 for routine testing.
8	Photometric reference measurement procedure	New. A possible alternative to the established part 6.
9	Laboratory Syringes	New section for precision syringes.
10	User guidance, training and POVA/ tip suitability.	New important section to help the transfer of quality from the metrology facility to normal use in a lab.
TR 16153	Uncertainty of Photometric Method	New. Relates mainly to the new part 8.
TR 20461	Uncertainty of Gravimetric Method	Updated for the revised part 6 with the latest metrological factors.

"Possibly the greatest changes that this new version of ISO 8655 will generate are the better correlation between results obtained in advanced metrology facilities and those that can be expected in the routine laboratory. This will improve accuracy in



all fields of diagnostics, analysis and research. The confirmation that testing shall now involve preferably 10 and at minimum 4 replicates at each volume and for variable volume devices, testing at least 3 volumes will hopefully mean the end for potentially dangerous "2/2 calibrations" available on the market. These have always generated a false sense of security. (Calibrations must consist of 10 replicates and at least 3 volumes)."

Charles notes that he will not be working on the next updates and that BSI and ISO always welcome new experts in the work of standardisation, whether they be staff from manufacturers, metrology facilities or expert users of POVA. If you are interested in pursuing accuracy please do step forward and become an expert on BSI LBI 1/2 and help shape a better and more accurate future. GAMBICA nominates many industry professionals to BSI committees so as a first step you can contact me on jacqueline.balian@gambica.org.uk

In the meantime, many thanks go to Charles and his colleagues on BSI committees.