- *The role of measurement uncertainty in deciding conformance to specified requirements.*
- *Applications of the least-squares method.*

These documents respond to as many identified needs in the task of supporting the GUM and its broad application. There are three supplements that are intended to be used in conjunction with the GUM. The others are supporting documents that address general issues in the field of evaluation of measurement data. All these documents, as well as the GUM (an electronic version is being prepared by ISO), will be also available on the Web. For a more in depth description of these documents, as well as of their motivation, see W. Bich, M.G. Cox and P.M. Harris, Evolution of the 'Guide to the expression of uncertainty in measurement, Metrologia, 43 (2006) S161–S166.

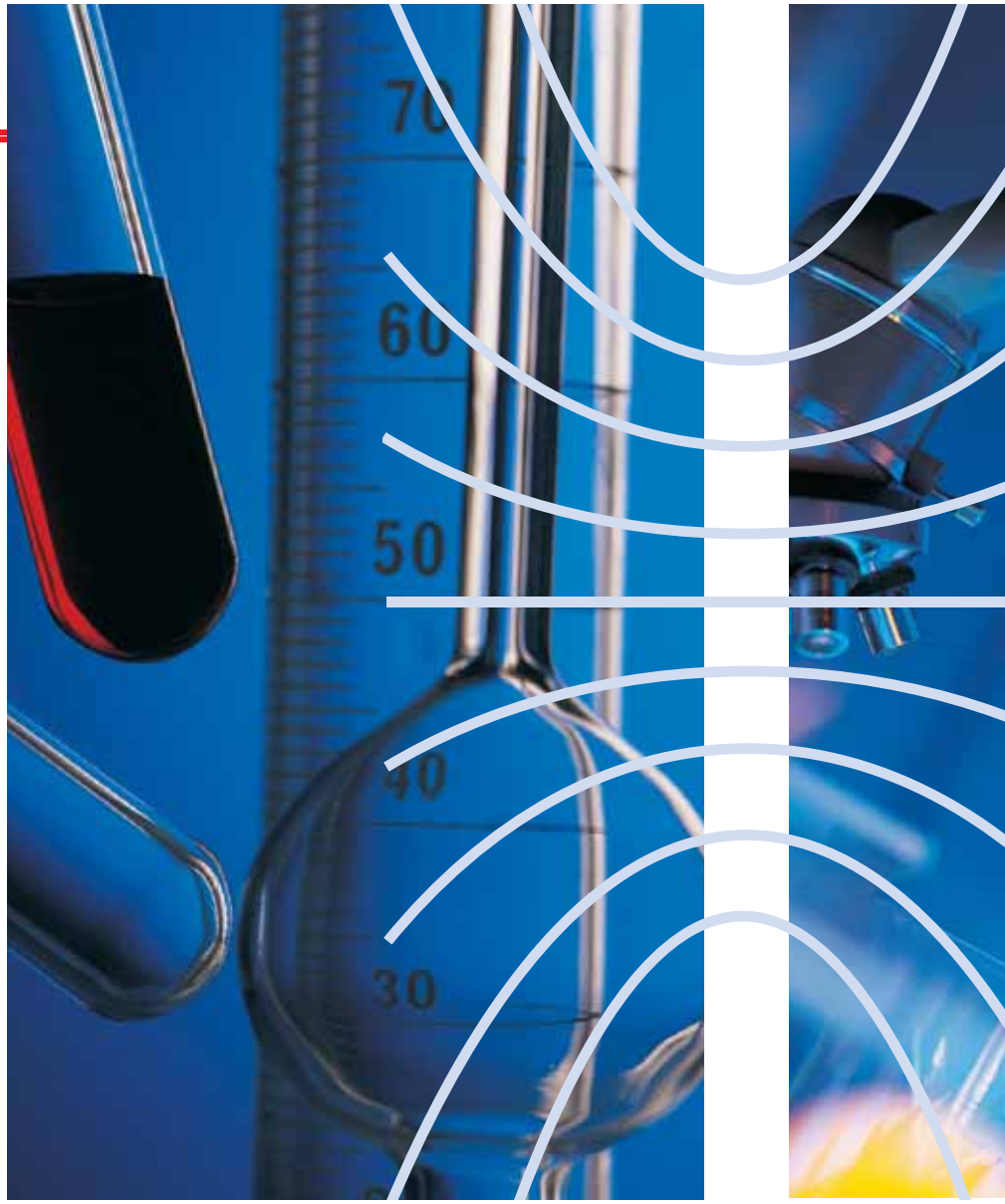
Promotion and future developments

A number of documents are being developed in this area. An introduction to the GUM and related documents will raise awareness and use. Its Web-based version will be hyperlinked to a number of relevant documents for those readers who wish to read more about concepts and methods.

Supplement 2, *Models with any number of output quantities*, will deal with the case in which several measurands are determined from a common set of input quantities. The GUM addresses this issue in an example, whereas Supplement 2 will extensively treat this case, often occurring in calibration, for example, when a set of artefact standards (such as weights or gauge blocks) are calibrated by reference to a common standard.

The remaining documents are at an earlier stage of development and will be published in the coming years.

In addition, a revision of the GUM is foreseen. Since it is widely adopted, the revision will not affect the bulk of the Guide, but address some existing internal inconsistencies. In addition, it will make it fully compliant with Supplement 1. ■



Linking metrology and standardization with laboratory accreditation

by Alan Squirrell, Secretary of the International Laboratory Accreditation Cooperation

The International Laboratory Accreditation Cooperation (ILAC) is the association for laboratory accreditation bodies around the world. There are currently a total of 113 members: 88 accreditation bodies (ABs), of which 54 are full members that are signatories to the ILAC (mutual recognition) arrangement, five regional cooperation bodies and 20 stakeholders.

One of ILAC's primary objectives is to ensure, through its arrangement, that its members are competent to deliver high-quality accreditation services. This leads, in turn, to confidence in the outputs (i.e. measurement results) from the 28 000 or so laboratories, accredited by ILAC member ABs across the world (from 78 different countries), that have been formally recognized as competent for a specific scope of measurement activity.

More than ever in our global economy, it is essential that measurements are fit for their intended use (to reduce technical barriers to trade and provide domestic and international socio-economic benefits).

To achieve this objective, it is important that ILAC members, laboratories and other stakeholders continue to give sufficient emphasis to technical issues as well as management

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systems. To assist in this, ILAC has formed a number of strategic liaisons with organizations such as ISO, Bureau International des Poids et Mesures (BIPM), Organisation Internationale de Métrologie Légale (OIML), International Electrotechnical Commission (IEC), Co-operation on International Traceability in Analytical Chemistry (CITAC) and its regional counterpart EURACHEM, United Nations Industrial Development Organization (UNIDO) and the World Anti-Doping Agency (WADA).

This article outlines recent developments with just one (due simply to space constraints for this particular article) of our liaison partners – ISO – and focus on metrology – the "science of measurement" – which consists of four main 'pillars' underpinning all measurements. These are traceability (and related measurement uncertainty), calibration, method validation and quality assurance/control (see **Figure 1** below).

The importance of standardization will also be addressed, with reference to relevant ISO (and IEC) standards and guides.

Longstanding cooperation between ILAC and ISO

ILAC has enjoyed a long and productive association with ISO and is a liaison member. This cooperation was formalized in March 2004 by a memorandum of understanding between ISO, ILAC and our sister organization, the International Accreditation Forum (IAF), which deals with the accreditation of various types of certification bodies. Basically, this provides the framework for ongoing cooperation and the exchange of information on the preparation and use of ISO standards, from both ILAC member ABs and their clients (laboratories and their customers) together with feedback on the (added) value of such standards, so that future revisions can be effective. This is achieved by regular meetings of an IAF-ILAC-ISO Joint Working Group (which consists of senior members of ISO, ILAC and IAF) and at the grass-roots level by representation by ILAC members on various ISO working groups and technical committees.

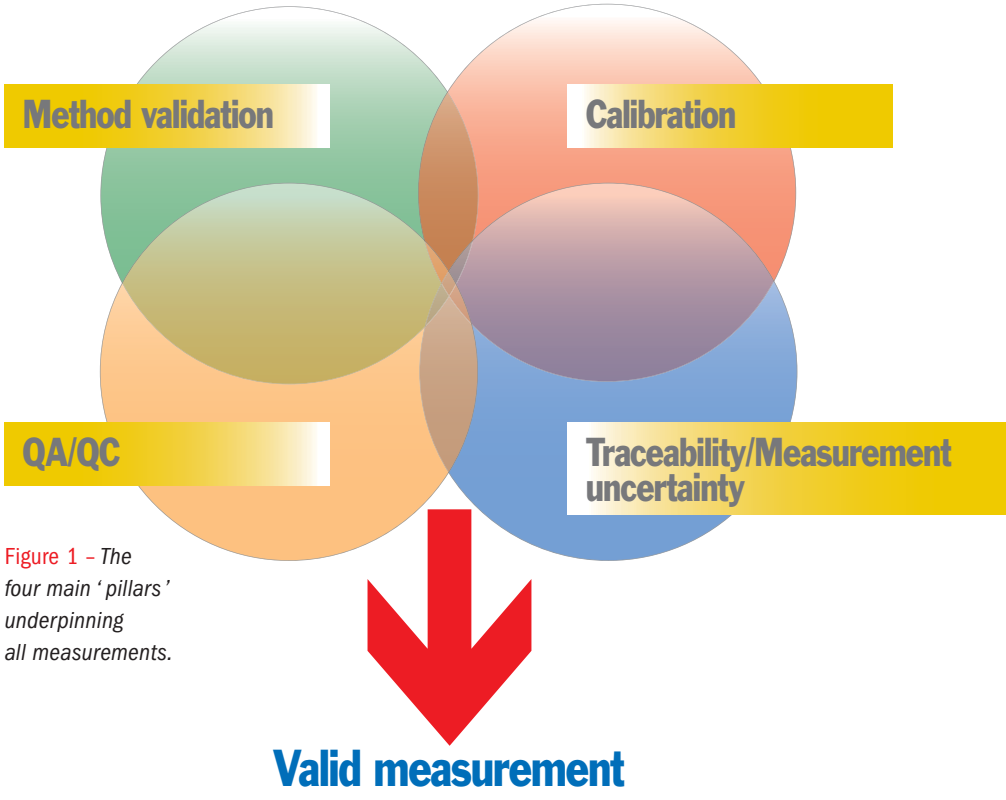

Figure 1 – *The four main 'pillars' underpinning all measurements.*

About the author

Alan Squirrell has a BSc (Hons) in applied chemistry and a post-graduate certificate of education. He joined NATA, Australia's national laboratory accreditation authority, in March 1981 and has held the position of ILAC Secretary since 1 January 2001. He has been involved in international activity associated with ILAC, its regional cooperation bodies and various other liaison organizations, particularly in relation to technical and metrological issues, for a number of years. Mr. Squirrell is also a past Chair of CITAC and the APLAC (Asia Pacific Laboratory Accreditation Cooperation) proficiency testing committee.

CASCO

CASCO is the ISO Committee which deals with conformity assessment. CASCO produces standards (ISO/IEC 17000 series) which deal with international best practice and general requirements for the competence of bodies such as laboratories (testing and calibration), inspection and certification bodies, and proficiency testing providers.

From ILAC's standpoint, one of the most important standards produced by CASCO is ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. The current version reflects a long history of involvement and input by ILAC members – indeed it was an ILAC Task Group in 1977, which started the process with ISO Guide 25. This standard was written for laboratories but is used by ABs around the world as the primary standard for the assessment of the competence of laboratories.

The metrology 'bits' (refer to **Figure 1**) are found in Clause 5 (technical requirements) and provide the basis for reliable and accurate measurements and reflect the need for sound measurement practices in both the calibration and testing areas. (Note: It is pleasing to see that ISO/IEC 17025 now emphasizes the need to address these metrological aspects associated with testing (as well as calibration) including the use of traceable reference materials for method validation, calibration and control of the measurement process.)

Whereas ISO/IEC 17025 provides a sound framework for laboratory competence with its "general requirements", accreditation is not just compliance with this standard. ISO/IEC 17025 itself (Annex B.4) recognizes that sector-specific "application documents" are often required – these (measurement and proficiency testing protocols, internal quality control procedures, etc.) elaborate on the general requirements for particular types of measurements and these are often needed if the accreditation process is to be effective. This is reflected in the "laboratory scope of accreditation" issued by the AB, which lists the specific measurement capabilities that have been assessed by trained (technical) experts, who ascertain whether the laboratory staff have the necessary technical competence, ie knowledge and skills, to perform specific tasks. Scopes can be limited (e.g. calibration of balances) or wide (e.g. large range of chemical tests on food, waters and metals).

"ILAC has enjoyed a long and productive association with ISO."

To illustrate this point, ILAC is working closely with some organizations which have statutory authority in particular measurement areas. As examples, I mention WADA and IEC, for sports drug and electrical safety testing respectively. These organizations produce, and insist on the use of, comprehensive application documents (which elaborate on the general requirements in ISO/IEC 17025 and also add their own organizational requirements). It is sensible for ILAC to work closely with organizations like WADA and IEC – indeed, joint assessments are now carried out which provide benefits to the laboratories in question by increasing harmonization and reducing duplication and costs.

So, ISO/IEC 17025 alone may often not be sufficient but this is in no way a criticism of the standard – no single standard can fully cover the plethora of (very) different measurements that are carried out globally on a daily basis. But it serves the essential purpose of providing a sound basis and the framework for assessment of laboratory competence.

Clause 4 of ISO/IEC 17025 covers the important management requirements (tailored for laboratories) which must be in place to support the consistent and long-term delivery of traceable (and thus accurate and comparable) measurement results.

Thus, ISO/IEC 17025 provides the backbone laboratory standard for best practice and the assessment of laboratory competence by ABs, which, in turn, is supported by the ILAC arrangement. (Note: I will later mention the only other standard – ISO 15189 for medical laboratories – which is specifically included in the ILAC arrangement text, but it is worth noting here that ILAC is currently discussing the possibility of including other ISO documents under its arrangement, e.g. ISO Guide 34 for reference material producers and ISO/IEC Guide 43 (future ISO/IEC 17043) for proficiency testing providers.)

ILAC members are also directly involved with many other aspects of CASCO's work. ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, is, of course, of paramount importance to ABs as it sets the general requirements for their own competent delivery of accreditation services.

ISO/IEC 17011 itself refers to the need for ABs to have access to the necessary expertise to deliver their services and this reflects the need for a national infrastructure that can deliver the necessary services in metrology, accreditation and standardization (MAS). For laboratory accreditation bodies, their close relationship to the local National Measurement Institute (NMI) and its contribution to the assessment process (e.g. provision of assessors, technical committees, proficiency testing and training and guidance on traceability and related issues) is essential.

ISO/IEC 17011 also forms the basis for a variety of ILAC procedural

(P series) documents and joint ILAC/IAF (A series) documents.

A very important activity, which also currently resides within CASCO, is proficiency testing (PT). This is an integral part of the laboratory accreditation process – arguably the only really objective way of checking laboratory performance. It is an area where many developments have taken place in the past 20 years and its important role (to complement on-site assessments and other surveillance activities) has been realized.

ISO/IEC Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons* – Part 1: *Development and operation of proficiency testing schemes* and ISO/IEC Guide 43-2:1997, *Proficiency testing by interlaboratory comparisons* – Part 2: *Selection and use of proficiency testing schemes by laboratory accreditation bodies*, was produced following a work item which emanated from the ILAC laboratory committee in the mid-1990s. It has provided a sound basis for the requirements for providers of PT programmes and is used by some ILAC member ABs for accreditation purposes for those PT providers that choose this route. Earlier this year, ILAC submitted a new work item proposal to revise this guide and to convert it into an ISO/IEC standard (17043). This proposal was approved by CASCO and the work has commenced. New initiatives and improved practices in PT will be included in the new standard and many of these have links to metrology – in particular, the use of traceable assigned (reference) value(s) for PT samples (testing) and artefacts (calibration) and the need for PT participants to input their best estimates of measurement uncertainty. (This may require new ways of assessing PT results and work has already been done in ISO/TC 69 – see below.)

The importance of proficiency testing

Whereas I would argue that successful participation in PT (even when traceable assigned values and reliable estimates of participants' measurement uncertainty are used) does not establish traceability (this should be done a priori in each individual laboratory, usually during the method validation process) it certainly provides a useful check that things are 'in good order' – i.e. sound traceability paths are in place together with reliable estimates of measurement uncertainty. Such metrological developments are welcomed and are supported by BIPM, who already use such practices in their own PT programmes (key comparisons), which underpins the Comité International des Poids et Mesures (CIPM) mutual recognition agreements for national metrology institutes.

Another group within CASCO is the Conformity Assessment and Promotion and Support (CAPS) Group. ILAC has been involved here in promoting the cooperation between CASCO and various ISO technical committees (see below), particularly those which are involved in standards dealing with requirements for (sector-specific) laboratories.

A recent proposal from ILAC, which will be discussed later this year, is to seek some amendments to the ISO/IEC Directives so that, firstly, ISO/IEC 17025 is always normatively referenced in other ISO (and IEC) standards which relate directly to laboratory requirements and, secondly, the metrological principles covered in ISO/IEC 17025 are taken into account when requirements for measurements (test and calibration) are included in other ISO (and IEC) standards – and of course, there are many of these, as measurements across various disciplines play such an important role in our daily lives and a consistent approach (through metrology and standardization) is beneficial to us all.

REMCO

This is the ISO Committee which currently produces guides relating to reference materials (RMs). The (traceable) values carried by RMs are often used (by chemical and biological laboratories, in particular) to establish their traceability chains and link them to values of "higher order" metrological standards, normally in SI units.

Hence, the competence of RM producers (i.e. the organizations which take responsibility for the values assigned to a particular reference material) is paramount if we are to achieve the necessary confidence in the measurements results provided by laboratories, and this is clearly stated in ISO/IEC 17025.

It is pleasing to note the recent publication of the revised ISO Guide 35:2006, *Reference Materials – General and statistical principles for certification*, and also the agreement to commence a review of ISO Guide 34:2000, *General requirements for the competence of reference material producers*, a document currently used both by RM producers and laboratories and also by some ILAC member ABs who currently accredit those RM producers who choose accreditation.

So, in summary, the suite of CASCO/REMCO standards and guides relating to laboratories and related organizations dealing with services to laboratories (particularly ISO/IEC 17025, ISO/IEC Guide 43 and ISO Guide 34), provides a sound basis for reliable laboratory measurements across the globe, with due attention to essential metrological principles and practices. Perhaps in the future, we will see all of these documents included in the ISO/IEC 17000 series, which would produce an integrated and harmonized set of "general requirements standards" relating to laboratories and the measurements they perform, which I think would benefit the community at large.

ISO technical committees

In addition to CASCO and REMCO, ILAC liaison officers contribute to the work of various ISO technical committees (TCs). I will briefly mention some of these:

ISO/TC 69, *Applications of statistical methods*

I have already mentioned this TC in relation to proficiency testing. Its work impacts on a number of other general technical and metrological issues (e.g. quality control and measurement uncertainty).

ISO/TC 34, *Food products*

The testing of food products is a large area and this TC writes standards relating to measurement and related activities.

ISO/TC 147, *Water quality*

This is another large sector, with standards on measurement and related activities, including proficiency testing.

ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*

This TC covers perhaps the biggest laboratory sector of all, and produces standards relating to laboratory requirements and measurements in the medical area. One of its standards, ISO 15189:2003, *Medical Laboratories – Particular requirements for quality and competence* (currently under revision to further align it with ISO/IEC 17025), is also used by ABs and cited in the ILAC arrangement (for the accreditation of medical laboratories only).

A number of other ISO/TC 212 standards are also of interest to ILAC and to the Joint Committee on Traceability in Laboratory Medicine (JCTLM). This is one of many important initiatives instigated by BIPM and here a tripartite group, consisting of the International Federation of Clinical Chemists, BIPM and ILAC, strives to provide the framework for the improvement of medical measurements by putting sound metrological procedures in place. The formation of this joint group followed the publication of an European Community In Vitro Diagnostic Directive which states that "the traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order."

"It is essential that measurements are fit for their intended use to reduce technical barriers to trade and provide domestic and international socio-economic benefits."

Having mentioned JCTLM here, it would be remiss of me not to at least briefly mention some of the other important initiatives under the BIPM umbrella, an organization which, as one would expect, leads on metrology issues. These include the Consultative Committee for Amount Substance (CCQM) – for metrology in chemistry; Joint Committee for Guides on Metrology (JCGM) – for revision of the International Vocabulary on Metrology (VIM) and the Guide to the Uncertainty of Measurement (GUM) and the Joint Committee on Coordination of Technical Assistance to Developing Countries in Metrology, Accreditation and Standardisation (JCDCMAS).

ILAC also has direct liaison with BIPM itself and has regular meetings to address issues which link accreditation to metrology, including the dissemination of traceability and measurement capabilities from national metrology institutes to "field" laboratories.

Strengthening links for the future

At a time when there is still confusion in the marketplace between 'accreditation' and 'certification' (despite many public attempts by ILAC, ISO, IAF and others to clarify the difference), it is important that the community appreciate that the extra technical focus provided by laboratory accreditation is essential if users are to get the required confidence in the measurement results produced by accredited laboratories and achieve the "tested once, accepted everywhere" objective.

Although there are no 'guarantees' in this business, the laboratory accreditation model, which includes the effective use of (good quality) proficiency testing samples and reference materials, is a cost-effective and efficient way of providing confidence in the technical competence of the accredited laboratories which provide measurement results in specific areas. These measurements must be backed up by sound metrological principles and practices, which are, and must continue to be, an integral part of the accreditation process.

Hopefully this article also provides insight into the importance of a holistic approach to metrology, accreditation and standardization, particularly in developing economies (so that they are provided with the assistance needed). This can only be achieved by ongoing communication and cooperation between ILAC and its regional cooperation bodies with relevant (expert) organizations that are active in these areas. It is important that these links continue to be strengthened in the future so that laboratory accreditation provides the added value that laboratories and their customers are seeking.

Note: The "Library" section of the ILAC Web site contains a number of guidance documents specifically relating to metrological issues, which have been produced by ILAC's stakeholder (Laboratory Association) members e.g. CITAC and EURACHEM.