

Proficiency Testing and Proficiency Testing Sub-disciplines

Background:

Consideration is requested concerning some contemplated changes in the requirements for Proficiency Testing.

According to the *A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories* (September 2005), “Proficiency testing is a process for checking actual laboratory performance (usually by means of interlaboratory data comparisons) and is a requirement for accreditation to ISO/IEC 17025:2005. Results from proficiency testing are an indication of a laboratory’s competence and are an integral part of the assessment and accreditation process. Proficiency testing programs may take many forms and standards for satisfactory performance vary depending on the field.”

“Further, if suitable and relevant to the scope of accreditation, laboratories must participate in acceptable programs in the following hierarchy:

- Programs that are available through commercial proficiency testing
- Programs that are available through well-organized inter-laboratory comparisons (ILCs);
- Internal/external round robin programs.”

It is understood that there are particular areas in which proficiency-testing programs are not relevant, available or practical. When such programs are not available or relevant to the scope of accreditation, A2LA has considered internal performance-based data in accordance with clause 5.9 of ISO/IEC 17025 as an acceptable alternative to the hierarchy mentioned above. These internal performance-based checks include (but are not limited to) the following types of activities: regular use of certified reference materials and/or internal quality control using secondary reference materials; replicate tests or calibrations using the same or different methods; retesting or re-calibration of retained items; and correlation of results for different characteristics of an item. In these instances, the laboratory is required to provide a representative sample of their yearly ‘checks’ along with their annual review submittal. Proficiency testing may not be possible for certain qualitative tests, but if the qualitative results are determined based upon comparative judgments (e.g. odor), at a minimum, quality checks per clause 5.9 shall be reviewed as proficiency testing results per this document.

ILAC, in their Accreditation Body guidance policy appears to make a bit more restrictive interpretation; according to ILAC P9:2005, Proficiency Testing is defined as “the determination of the calibration or testing performance of a laboratory...by means of *interlaboratory comparison* (ILC)”. The policy further describes “appropriate PT activities [as] include[ing] any ILC or measurement audit which monitors the laboratory’s performance, for example those conducted by national or regional accreditation bodies or co-operations, government, industry or commercial providers of formal PT schemes.” The frequency of participation is further identified as being “one activity relating to each *major sub-discipline* of a laboratory’s scope of accreditation within four years.”

It should be emphasized that the requirement for participation in relevant and available ILCs would pertain to only those areas of testing technology that have been identified by the

relevant advisory committee (LSAC) *as a sub-discipline* of the specific Field of Testing (e.g. Chemical, Biological, Environmental, etc) in the A2LA Proficiency Testing Policy document.

Thus there are two areas for consideration, the first being the issue of restricting the need to provide non ILC PT data and the second (and easiest) being whether there are additional subdisciplines which should be added to the Biological and Chemical FOTs.

Proficiency Testing Questions:

- Should LSAC hold to the more limited definition of Proficiency testing, as meaning *only* inter-laboratory comparisons?
- If Proficiency testing is defined as participation in an ILC then should A2LA require that non ILC data be submitted for review by A2LA? *Note that this would not eliminate the need for quality control and evaluation of competency however, as assessors would of course be expected to verify that laboratories continue to meet all of the requirements of section 5.9 of ISO 17025.* However is looking at two years worth of 5.9 data every two years sufficient?
- If continued submission of non-ILC results is considered necessary, then because some “checks” that are presently submitted do not have Z scores or evidence of control limits and so do not provide an indication of whether the outcomes are “satisfactory”. What should be provided by the lab as a key, (should it be the section from their procedures criteria)?
- Should qualitative tests be considered as to include categorical testing such as those dealing with identification/classification evaluations and thus not ? If yes, and the qualitative results are determined based upon comparative judgments (e.g. odor), at a minimum, how should the quality checks per clause 5.9 be reviewed?

Not mentioned but important, note that not all areas of testing or laboratory programs would be affected by this change in approach (especially in the Life Science arena) since many of our laboratories are also recognized under Specific Programs having their own particular PT requirements. As such there would be no change in the existing A2LA programs dealing with Environmental, Food, Veterinary, Animal drug (Race horses), etc., since the laboratory's participation in these programs is entirely voluntary and the extra PT burden is thus self-imposed.

Proficiency Testing Sub-disciplines

Note that with respect to Life Science laboratories, the LSAC has not as yet identified any sub-disciplines for those labs accredited under the Biological Field of Testing (FOT). Therefore, unless additional subdisciplines were identified, laboratories in this category would have only to meet the element of ISO 17025 section 5.9 pertaining to having a defined plan on monitoring QC activities. An ancillary aspect of this change would be that if the advisory committee (LSAC) felt that PT was necessary for a given testing activity then the burden would be on the committee to identify those sub-disciplines *which have available ILCs*

Listed *in italics* below are some possible disciplines for consideration that may also have commercially-run PT available to them:

Biological:

Quantitative microbiology

Qualitative microbiology

Other????

Chemical:

Wet Chemistry

Chromatography

Spectroscopy

Combustion (LECO)

Biochemistry (to include PCR and other biochemical/biomedical analyses)

Other???

Any other ideas? Have I omitted something obvious?

Note: the following suggestions were provided after the conclusion of the meeting:

Biological

Quantitative Bacteriology

Quantitative Mycology

Quantitative Virology

Qualitative Bacteriology

Qualitative Mycology

Qualitative Virology

Molecular Subtyping

Serology

ELISA

PCR

Microscopy

Chemical

Spectroscopy

- UV/Vis

- AA/CVAA/GFAA

- Fluorescence

- IR/FTIR

- ICP

- MS (MSD, MS/MS, etc)

Chromatography

-TLC

-HPLC

-GC

-IC

Combustion (LECO)

Non-instrumental Chemistry

-wet chem