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Accreditation to ISO 17025: 2005

The consequences for reference material and proficiency testing users

Peter J. Jenks
the Jenks Partnership, Newhaven House, Junction Road, Alderbury, Salisbury, Wiltshire SP5 3AZ, UK.

In the UK, the United Kingdom Accreditation Service (UKAS) is starting to use the new ISO 17025:2005 Standard as the basis for its assessment visits to testing and calibration laboratories. There are no significant changes between the old 1999 version and the 2005 version of ISO 17025: the majority are to bring the revisions in ISO 9000:2000 into ISO 17025.

This short article is intended to highlight what the new version of ISO 17025 means to users of reference materials, but, first, it is worth looking at the main changes that together alter the underlying ethos of the standard. This is important as it is certain that UKAS Chemistry Assessors will take onboard these changes and it will be reflected in the way they approach their assessment visits to accredited laboratories.

Perhaps the most significant change is that the words "quality system", so familiar to users of ISO 9000 and previous editions of ISO 17025, are replaced with management system and I'm lead to understand that this should be considered to include the quality, administrative and technical systems that govern the operations of a laboratory; in addition, the word client is replaced by customer; together these changes would seem to impose a much more "business like" approach to the way the Standard is applied.

The new version goes on to highlight the way that management, at all levels, is not just responsible for quality, but must take proactive steps to ensure that there is almost a mission to improve quality. After reviewing the 1999 and 2005 versions of ISO 17025, this author is left with the strong impression that quality managers and lab managers who feel that their quality systems are good enough and only need to be monitored may find that this is insufficient: it would seem to be implicit in the new version that there must be improvement. Nowhere is this expressed more clearly than in the new Clause 5.9.2, which states that:

"Quality Control data shall be analysed and where they are found to be outside predefined criteria planned action shall be taken to correct the problem and prevent incorrect results from being reported."

This means, I believe, that labs will have to show that they have a plausible action plan that can be put into effect in case of QC data is outside limits and that they will be expected to demonstrate how action is to be taken. Although out of limit QC data has always required corrective actions, this new clause will mean that if QC data is out of limits, Assessors will pay much more attention to the problem, so there is more reason to include a more rigorous process QC regime than was required before. This change can be expected to have a profound impact on the use of reference materials and proficiency testing services to ensure that QC data does remain within limits. It will be necessary to use more regular within-batch and between-batch QC reference materials.

The proper use of reference materials has always been an important part of ISO 17025, clause 5.6 covers them specifically, but their proper use is implicit within clauses 5.8 and 5.9 which are concerned with the handling of test and calibration items and assuring the quality of test and calibration results. Given that the proper use of reference materials is fundamental to method validation, instrument calibration and routine quality control, it is reasonable to expect that an indirect consequence of the introduction of Clause 5.9.2 will be that UKAS Assessors will pay more attention to a laboratory's proper use of reference materials and will want to be certain the laboratory appreciates the difference between a reference material, a QC reference material and a certified reference material and that they are used appropriately.

In May 2004, UKAS released Edition 1 of Technical Policy Statement 47– "TPS 47" (www.ukas.com/information_centre/publications.asp) which clearly states UKAS policy on participation in Proficiency Testing. In essence the policy statement says that laboratories shall participate in PT schemes where they are available and appropriate. Although not explicitly stated, the wording of the TPS suggests that externally organised PT schemes are preferable to the use of in-house arrangements, such as the analysis of duplicate or replicate samples and CRMs.

As with reference materials, Assessors can be expected to pay more attention to this area than before as the proper use of PT programmes is a key strategy to ensuring routine QC data is not found to be outside predefined criteria.