QUALITY MATTERS

ISO/IEC 17025: a never-ending journey

Peter Jenks[a] and Alan Nichols[b]
[a]The Jenks Partnership, Newhaven House, Junction Road, Alderbury, Salisbury, Wiltshire SP5 3AZ, UK.
E-mail: peter@jenks.info
[b]Metrology Consultant, State College, Pennsylvania, USA. E-mail: awnichols10@gmail.com

It seems that there is no limit to the number of laboratories seeking and maintaining accreditation to ISO/IEC 17025. Why is this?

Properly described as "ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories", this standard has been around since 1999, but its origins lie in ISO Guide 25 and European Standard EN4501.

The increase in accreditation to ISO/IEC 17025 started in around 2000 and is driven by the demands of both regulatory authorities and users of laboratory testing services who each want to be certain that the data they "buy" is fit for purpose. The generally accepted means of achieving this objective is to require that laboratories demonstrate, via third party attestation, a certain level of competence and that they have in place a process that ensures that they are on a never-ending journey of improvement to the quality system. The most popular route to do this is, at least within the measurement and testing environment, accreditation to ISO/IEC 17025.

In common with other accreditation standards of the ISO 17000 series (and unlike most ISO standards for management systems), ISO/IEC 17025 requires continual improvement. Regular internal audits are intended to reveal opportunities to improve the test or calibration procedure, reducing, for example, uncertainty and increasing consistency. In addition, an accredited laboratory is expected to keep abreast of scientific and technological advances in areas relevant to the test method or procedure.

Third party auditing (assessment) of an accredited laboratory is normally carried out by the national organisation responsible for accreditation, in the UK this is UKAS, the United Kingdom Accreditation Service. Laboratories are therefore accredited under ISO/IEC 17025, rather than certified or registered as in the ISO 9000 series).

The first laboratory accreditation bodies to be established were NATA in Australia (1947) and TELARC in New Zealand (1973). Most other bodies around the world are based on the NATA/TELARC model including UKAS! In most countries, excluding the United States of America and Canada, there is a single, national Accreditation Body. In the USA there are, at the time of writing, five and in Canada, two.

In short, accreditation differs from certification by adding the concept of a third party, the accreditation body (AB) attesting to technical competence within a laboratory in addition to its adherence and operation under a documented quality system, specific to a Scope of Accreditation.

The originators of ISO/IEC 17025 had a philosophy that accreditation to this new standard should ensure that data from an accredited testing laboratory would be accepted by everyone, so to make it possible for accreditation bodies to recognise each other's accreditations, the International Laboratory Accreditation Cooperation (ILAC) worked to establish methods of evaluating accreditation bodies against another ISO/CASCO Standard, ISO/IEC 17011.

Around the world, geo-political regions such as the European Community, and Asia–Pacific, the Americas and others, established regional co-operations to manage the work needed to achieve mutual recognition. These regional bodies (all working within the ILAC umbrella) include:

- European Accreditation Cooperation (EA),
- Asia Pacific Laboratory Accreditation Cooperation (APLAC),
- Southern Africa Accreditation Cooperation (SADCA) and
- Inter-American Accreditation Cooperation (IAAC).

ISO/IEC 17025 has become the foundation for a quality management system that covers all the activity that a laboratory may want to undertake and provides the structure against which it can be accredited by the AB. Like most ISO/IEC Standards in the "17000" series it includes the following five main sections:

- Scope,
- Normative references,
- Terms and definitions,
- Management requirements and
- Technical requirements.

The two main sections in ISO/IEC 17025 are Management Requirements and Technical Requirements. Management Requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical

Requirements include factors which determines the correctness and reliability of the tests and calibrations performed in the laboratory.

As more testing laboratories achieve accreditation to ISO/IEC 17025, those that do not will find their options in the marketplace limited, hence the steady stream of laboratories seeking accreditation. To the inexperienced the pathway to accreditation can seem daunting to the laboratory: indeed, the ISO/IEC 17025 standard has many management and technical requirements that may be new to a routine analytical laboratory. A common misconception among laboratories seeking accreditation is that prior to the initial assessment they only have to write a Quality Manual and develop some procedures. This is far from the case, as the reality is that the AB's assessor will be looking for objective evidence that the laboratory meets the requirements of the standard. Therefore, the laboratory must be operating fully to the standard **prior to** the initial assessment. To be able to do so inevitably requires either the external training of an in-house project lead or the appointment of a third-party consultant.

This need for external support has led to a sophisticated industry of training and consultant support aimed at "helping" testing laboratories achieve and maintain accreditation to ISO/IEC 17025. Most such services are far from free, it is possible to spend extravagantly on preparation for accreditation to ISO/IEC 17025!

As well as demonstrating competence a lab must show that the associated paperwork and records are all correct and up to date. The main documentation areas given below.

Quality manual

The quality manual is the heart of any quality management system. Anyone assessing a lab needs to have a copy available. Needless to say, it must be fit for purpose!

Standard operating procedures

An assessor will want to verify that you have a SOP for all procedures relevant to your proposed scope of accreditation and that they are up to date and relate back to the methods listed in the scope of accreditation.

Normative documents

Any ISO or ILAC Document referenced in your QM should be available for inspection and should be the most up to date version!

Scope of accreditation

A lab's scope of accreditation is the best advertisement it can use. Make sure that it is always up to date and available for accessors as they will use it when assessing the competency of your laboratory personnel and capability.

Master document list

Your master document list references all of the documents that form your quality management system. As with your Scope, it must be up to date.

Approved subcontractors list

If you subcontract tests and(or) calibrations, you must have a list of your approved subcontractors and it must be up to date and available. Is should also include a copy of the subcontractor's scope of accreditation.

Approved suppliers list

As with the Subcontractors list, it must be up to date and available.

Complaint log

Any assessor will want to be certain that complaints are logged and documented in accordance with the quality manual.

Non-conformity reports

Assessors like to know what non-conformity events a laboratory has encountered and what corrective and(or) preventative actions, including root cause analysis, have been implemented to control them.

Corrective and preventative actions

Prepare copies of all corrective action records and make them available for your assessors to review.

Internal audits

Internal Audits are at the heart of a quality manual and assessors want to see any findings from internal audit. Again, make sure that copies are available.

Management reviews

Assessors want to see that company management is involved in the quality of laboratory operations. Therefore, it is important to evidence management reviews and their findings.

Training records and qualifications

How well laboratory staff are trained and qualified is important and assessors will ask to see their training records. They will want to know how training goals are formulated, implemented and monitored.

In this series of articles we will focus on the key Technical Requirements of ISO/IEC 17025 and look in some detail at the requirements for and the use of Traceability, Proficiency Testing and Uncertainty: the aim is to start to demystify the process and in so doing help our readers better prepare and communicate with those involved with achieving accreditation.

We will start with a topic which has engaged and engrossed the authors for more than 20 years, Reference Materials and Certified Reference Materials. Previous articles have described how a RM or CRM should be selected and the pitfalls to avoid. Here we look at the use of RMs in demonstrating Traceability within an ISO/IEC 17025 accredited laboratory.

The way a laboratory uses Reference Materials (RMs) and Certified Reference Materials (CRMs) is one of the key laboratory activities that will be assessed for accreditation. There are many different types of RM and CRM and each have specific uses: the most common forms are single and multi-component analytes in a solution form and matrix RMs and CRMs, where the analytes are present in a matrix that is similar to the type of matrix that forms the sample to be tested, for example pollutants in soil.

RMs have many uses in the analytical laboratory, including instrument qualification and calibration, method validation, within and between batch QC checks etc.

ISO/IEC 17025 requires that measurements be Traceable to the SI, a National Metrology Institute (NMI) or in some cases a recognised Authoritative organisation (e.g., the United States Pharmacopeia or the European Pharmacopoeia). Originally this meant that the laboratory must obtain its RMs and CRMs directly from an NMI, but in recent years it means that sourcing is normally from an ISO Guide 34/ISO 17034 accredited Reference Material Producer or an Authoritative organisation.

How does a laboratory choose between using a CRM or an RM? The answer is simple: check with the accreditation body! Most if not all Accreditation Bodies require the use of Certified Reference Materials (CRMs) if they are reasonably available and only when no such CRM is available can a RM be substituted.

In many industries and especially in academic research it has been traditional to use "home-made standards". This practice is generally discouraged in accredited laboratories, primarily because in-house production of RMs generally does not meet the Traceability requirement, unless the laboratory produces them in compliance with the requirements of ISO Guide 34/ISO 17034. In 2014, ISO published ISO Guide 80, that outlines the essential characteristics of reference materials for quality control (QC) purposes, and describes the processes by which they can be prepared by competent staff within the facility in which they will be used. The preparation of QCMs should involve homogeneity and stability assessments, and a limited characterisation of the material to provide an indication of its relevant property values and their variation, prior to use. It is important to understand that QCMs are not usually considered suitable for instrument qualification and calibration or method validation use.

It is common, when a laboratory is first assessed to find instances of the use of in-house RMs that do not meet the Traceability requirement. Typically, the laboratory has been preparing in-house RMs for a long time, has technically valid procedures and has difficulty understanding why this is not acceptable. It is also very unusual to find that their procedures fulfil the requirements of a CRM as defined by ISO Guide 34/ISO 17034. It is also common to find a laboratory using procured RMs that is believes to be CRMs. Unfortunately, the marketplace is confusing and not always easy to distinguish CRMs from RMs. It is also not uncommon for an ISO Guide 34/ISO 17034 accredited organisation to issue RMs that do not meet the Traceability requirements, so assumptions are not advisable.

So, what is a laboratory to do? First, be aware of the meaning of the Traceability requirement. Accreditation Bodies may have different policies on the stringency of their interpretation. Try to find CRMs for all RM needs, either from an NMI, an Accredited Reference Material Producer or an Authoritative organisation. If a suitable CRM cannot be found, be sure to document the effort in order to justify the use of RMs. Next, look at Certificates from suppliers that might supply CRMs. Look for the terms "Accredited to ISO Guide 34 or ISO 17034". You can also review their Scope of Accreditation, typically found on the website of their AB.

Things to be wary of:

- Designating a CRM without any mention of Accreditation to ISO Guide 34/ISO 17034.
- Accreditation to ISO/IEC 17025 only.
- Reference to ISO 9001 Quality System.
- Claims to traceability to NIST, without any accreditation credentials.

In conclusion, a laboratory properly using RMs and CRMs for its analytical measurements should have no problem meeting the Traceability requirement for the use of Reference Materials in their Accreditation Assessment.

References

ISO/IEC 17025 (2005). https://www.iso.org/standard/39883.html
ISO/IEC 17034 (2016). https://www.iso.org/standard/29357.html
ISO Guide 80 (2014). https://www.iso.org/standard/44313.html