# The Basics of Measurement, Traceability and ISO/IEC 17025

Martin de Groot
Kelvin-Trainingen

Peter van de Leemput

This paper deals with accreditation of calibration laboratories, considering that for many calibration technicians the step to accreditation is a significant border to cross on the road to professional calibration. The paper consists of three parts, an introduction on conformity assessment and accreditation from an historic perspective; second we discuss the requirements of the ISO/IEC 17025; the final part of the paper is devoted to accrediting organisations and their interrelations.

*This paper is the second of a series of papers to discuss traceability, measurement techniques and measurement standards in a variety of fields. The purpose of this series is to cover as many as possible measurement fields, inviting high class metrology experts to contribute to these series about their expertise. This paper introduces ISO/IEC 17025 and experience (with possibly some European views here and there) with auditing against this standard. Later papers will deal with metrological traceability, uncertainty, and specific measurement techniques for temperature, flow, and others. We approach acknowledged senior metrologists to write these papers. The co-author of this paper is Peter van de Leemput, who was chairman of the working group that was responsible for the drafting of the ISO/IEC 17025.*

## Quality and Calibration Requirement

In the earlier times of the previous century, "calibration" was predominantly required to obey legislation. At market places the trade was based on measurements: measurement of fabric lengths and weighing of meat, vegetables and cheese (picture, right) were verified by inspections. These inspections used references such as pounds and yardsticks, or kilograms and meter rods, whichever the units were that the local law required or that consumers used. It is only in the last few decades of that century that increasing requirements for calibration arose from other than legal requirements. This trend was and still is driven from business efficiency, tolerance control, energy saving, safety and other increasing quality requirements.

Legislators are increasingly of the view that it is easier to require calibrations and a quality management system than to fix all requirements by law and to appoint a weights and measures office. In this way it is also easier to adapt the legal system to newer technology. As a recent example, the European Directive of Measuring Instruments (MID) covers ten categories of measuring instruments and abolishes the corresponding previous legislations. There is still an important role for OIML (International Organisation of Legal Metrology) in defining the requirements on measuring instruments to which the MID refers.

The basic quality requirements are set out in the ISO 9000 series of standards (first published in 1987). Several types of industry considered it necessary to develop their own

Trading based on weight in cheese markets in The Netherlands as it has been done for centuries. Cheeses being weighed in Alkmaar.

standards such as the manufacturers in Aerospace (AS9000), Pharmaceutical packaging (PS9000), Automotive (ISO/TS 16949:2002), Telecom (TL9000) and Medical (ISO13485:2003). Rumour has it that the first quality systems date back to the second world war when bombs exploded prematurely in factories. Structuring all critical work in written procedures and making workers follow these would have solved this tragedy.

The present versions of these standards require metrological traceability in more or less strict wording. ISO/TS 16949 requires that any external party doing calibrations on a critical measurement system must be accredited to ISO/IEC 17025.

In the seventies of the last century, several national metrology institutes (NMI's) started to, on request, assess calibration laboratories. It was the intention to disseminate metrological traceability to industry. The national metrology institutes were specialized in calibrations with very small associated measurement uncertainties. The NMI's calibrated the measurement standards held by industries; These industries, after being assessed and accredited by the NMi's could disseminate the traceability further to their shop floor.

Assessment was based on technical competence only, including the calculation of measurement uncertainty. In that time uncertainty calculation was done using many different techniques "as long as the calculation could be reproduced years thereafter." It was not said how this was to be guaranteed. Confidence levels (as was the old expression for coverage factors and such) could differ from one type of certificate to the other, causing big numerical differences between similar calibration results.

Some of the calibration laboratory accreditation bodies that started in this way were NKO (now RvA) in the Netherlands, BCS (now UKAS) in the United Kingdom and DKD in Germany. At the same time the accreditation bodies started to cooperate in the WECC (Western European Calibration Cooperation). After several mergers and reorganisations the activities of the WECC are now included in EA (European cooperation for Accreditation)

In the beginning of 1989 WECC decided that apart from being technically competent, accredited calibration laboratories had to set up and maintain a quality system. WECC produced its own criteria document, WECC (89)1, which was based on ISO Guide 25 (criteria for testing laboratories).

In the meantime, a European standard was developed for the accreditation of testing and calibration laboratories: EN 45001:1989. The drafting of this European standard was done on the initiative of the European Commission. The ISO Committee for Conformity Assessment, CASCO, developed in parallel ISO Guide 25. Unfortunately ISO Guide 25 and EN 45001 were not identical. ISO/IEC 17000 defines conformity assessment as demonstration that specified requirements (relating to a product process, system, person or body are fulfilled.

In 1994 ISO CASCO started with a revision of ISO Guide 25. In 1996 ISO CASCO got permission to develop international standards in addition to guides. It was immediately decided that the document under development would be published as an international standard. A great advantage to that decision is that the Vienna Agreement between ISO and CEN applies, which means that CEN will not develop a document that is contradictory to the ISO standard. Another advantage is the possibility of parallel voting on the international and European level. This has led to the publication of ISO/IEC 17025:1999, which is accepted as a European standard and in most of the ISO member states as a national standard. ISO/IEC 17025:2005 includes the criteria of ISO 9001 in laboratory language.

Recently (on 14 November 2008) ISO has again published a new version ISO 9001:2008. ISO states in its publication release that "ISO 9001:2008 contains no new requirements compared to the 2000 edition:" The revised document contains clarifications resulting from eight years of experience. There are no consequences for ISO/IEC 17025.

## Accreditation to ISO/IEC 17025 — An Assessment Visit

When we look at ISO/IEC 17025, the first three chapters are introductions and not requirements. Chapter 4 contains the management requirements and covers most of the requirements of ISO9001, while chapter 5 contains technical requirements for testing and calibration laboratories. Technical requirements are considered those elements that have an influence on the test or calibration result. As the human factor is very important, this is dealt with in chapter 5.

Usually an assessment against ISO/IEC 17025 is conducted by a team consisting of a lead assessor and one or more technical experts. The lead assessor will mainly focus on the requirements from chapter 4 while the technical assessor will mostly look at chapter 5. For the smallest calibration laboratories the accreditation body can decide to combine the roles of technical assessor and lead assessor into one person. The aim of the visit is that the laboratory demonstrates that it meets the criteria of ISO/IEC 17025.

A laboratory gets the best benefits from an assessment when it has an open attitude. Experienced assessors see when laboratory staff members try to hide aspects.

## Lead Assessor, General Requirements

The lead assessor assesses the management system. The management system (in terms of ISO/IEC 17025) is the system of (controlled) documentation that contains all that is needed to maintain and demonstrate the quality of the calibrations including the calibration and measurement uncertainties that are published on the scope or schedule

of accreditation.

The commitment of the management to have an ISO/IEC 17025 accredited laboratory can be concluded from the management review (4.15), the management system (4.2), the organisation (4.1) and the way management communicates with the personnel. In terms of ISO/IEC 17025, top management refers to those who are high enough in the organisation to decide on e.g. the financial budget and structure of the laboratory, and still have (or are supposed to have) connection with what happens in the laboratory. In short, top management is the management layer

- that has the authority to establish communication processes (4.1.6),
- that can show commitment to management system (4.2.3),
- that can decide on, judge and implement an appropriate balance between customer and company requirements (4.2.4),
- that has to maintain the integrity of the management system upon changes (4.2.7)
- that sets out or amends the quality policy of the laboratory on the basis of the management review (4.15.1, 4.10).

Essential for a laboratory are the customers. They play an important role in ISO/IEC 17025: the handling of requests (4.4), customer service including customer feedback (4.7), complaints (4.8) and the reports/certificates.

A management system has to allow for changes of the system to adapt, when needed, to customer requirements and to correct for discrepancies and nonconformities that are discovered in the system. The handling of complaints (4.8), non-conforming work (4.9), improvement (4.10), corrective actions (4.11), preventive actions (4.12) and internal audits (4.14) are representative for this constant critical look on the system.

Staff has to be appointed and qualified for the quality tasks set out in 4.1.5 with respect to the management system in general and as is detailed in 5.2 with respect to the technical competence.

The skills of personnel is the dominant factor for the laboratory's performance. The assessor will want to look at training records and observe technicians at work. Here, Jos Verbeek of the Dutch Metrology Institute, adds a mass piece on a pressure balance.

All these issues will be looked at by the lead assessor during the visits to the laboratory. Whenever applicable, the lead assessor will look at subcontracting of work (4.5) and the purchase of critical services and supplies (4.6).

The lead assessor will not only focus on the documentation, maybe even more important is whether the management system also functions, which means that it well known and understood by laboratory staff and that laboratory staff handles accordingly.

## Technical Assessor, Technical Requirements

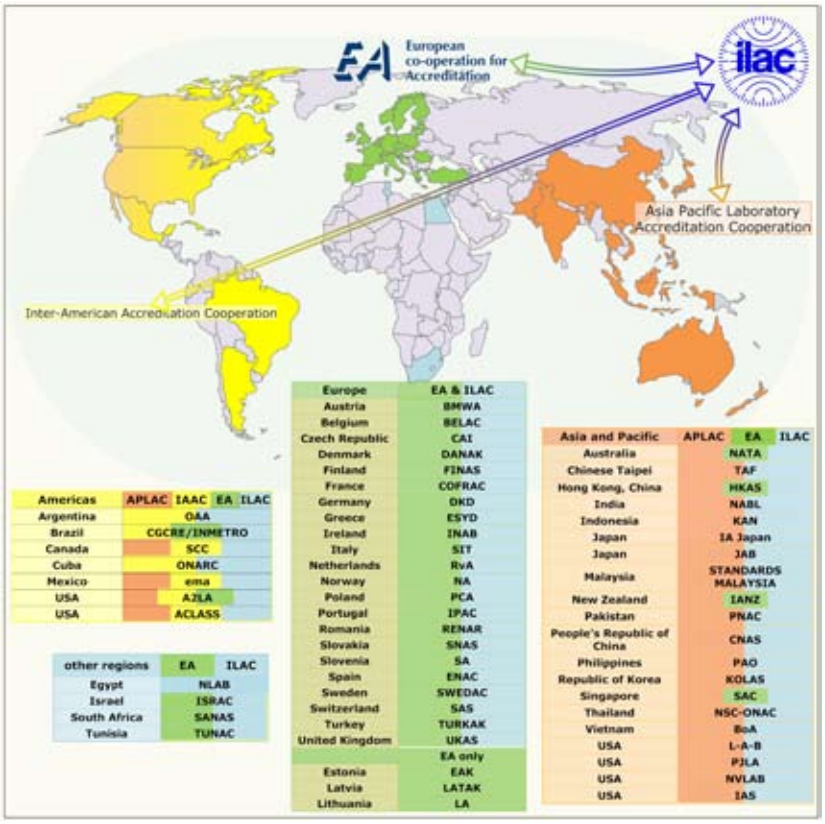
Beyond chapter 5 the technical assessor will surely look at clause 4.13 to see if all measurements are recorded or registered properly. He may also look at technical issues resulting from complaints (4.8), The technical assessor may also want to see if purchases (not only including calibration equipment) that are critical for the calibration process are properly evaluated in the system (4.6). This can apply, for example, in volume measurement

### *Clearing Non-conformities —*

***Before doing the root cause analysis it is good to know the significance of the non-conformity (4.9.1.b). This size is proportional to the effort one has to make in solving it (4.9.2). Particularly important before choosing corrective actions is to analyse the "root" cause of a non-conformity (4.11.2): Identify the real problem that the same fundamental cause does not pop up another time to result in some related shortcoming of the calibration process. Only now one can decide on the corrective action (4.11.3) and one has to be able to provide evidence of monitoring the effectiveness of the action (4.13.4 and 4.13.5). Realise that a corrective action can apply to improvement actions, complaints and non-conformities from internal and external assessments. UKAS has chosen to call any non-conformity a finding that is to be followed by an improvement action.***

to the quality of the tips of pipettes that are to be calibrated and for gas reference laboratories to supply gases that are used to generate calibration gases. In humidity measurement the cotton sleeves for psychrometers are a quality control issue. For electrical measurements (DC/LF and HF) measurement cables are critical.

The first thing for a technical assessor to look at is the calibration and measurement uncertainty (CMC) that the laboratory proposes for its accredited scope. The uncertainty is related to the measurement range or value to which that uncertainty applies. An assessor will also assess the suitability of the equipment in general and the measurement standards in particular that the laboratory uses. He can estimate if the uncertainty can be obtained with that equipment. Then the assessor will look at the competence of the laboratory staff (5.2), the uncertainty budgets (5.4.6) and the technical procedures (5.4), not necessarily in this order.




The world-wide mutual recognition of calibration certificates from accredited organisations is organised through the ILAC Mutual Recognition Arrangement (MRA). Shown are the signatories to the MRA's of ILAC and APLAC (Asia & pacific) and to the multilateral recognition arrangement (MLA) of IAAC (America's) and EA (Europe) that are accepted and peer reviewed for calibration. The background colours for each accreditation body shows the cooperations of which it has full membership: accreditation bodies can be a signatory to more then one regional cooperation body (A2LA is signatory to ILAC, APLAC and IAAC and signed a bilateral agreement with EA). EAK, LATAK and LA have not (also) signed the ILAC MRA, but signed the EA MLA. This figure and its tables are based on the information from websites of ILAC, EA, APLAC, IAAC and UKAS, acknowledging ILAC and EA for the use of their logo's.

This overview depicts accreditation of calibration organisations alone and does not contain information about national calibration laboratories where the mutual acceptance of calibration certificates is organised through the MRA of the International Committee of Weights and Measures (CIPM). Also information about associate (or other types of) members, that are working towards recognition, is not in the figure. For the actual and updated status of these MLA's and MRA's the reader is referred to the websites of the organisations involved.

The requirements for the equipment can be read from criteria in 5.5. The standards need to be traceably calibrated and checked for proper functioning (5.6). Very often a calibration laboratory chooses to control instabilities from transport of its standards to and from the calibration lab by extra check measurements before and after the external calibration. In all steps the rigidity of checks (5.9) are to be inversely proportional to the required uncertainty in the schedule and relate to the stability of the calibration system or the reference standards.

Both the lead assessor and technical expert can look at the handling of the equipment (5.8), while sampling (5.7) is generally not an issue in calibration laboratories.

Both the lead assessor and the technical expert will look in detail at certificates to see if the requirements of 5.10 are met. From a certificate a "vertical audit" can be done to see if at the time of that calibration all equipment was properly calibrated. Also the documentation is checked to show that everything was done that is required by the quality manual of the laboratory. Throughout the assessment a lab should realise that despite all critical questions that are asked by the assessment team, the aim of the assessors joins with that of the lab in assuring that the customers of the laboratory can be confident in the calibration and measurement results that are reported by the laboratory. With this in mind, generally assessments are conducted in an open atmosphere.

Finally, the proof of the pudding is in the eating: a laboratory must demonstrate that it can perform the calibration. This means it has to participate in interlaboratory comparisons for those calibrations it applies for or holds accreditation.

In the case a suitable interlaboratory comparison is not available, technical assessors may bring in an artefact for calibration and direct comparison with reference values (measurement audit). When all non-conformities have been cleared by the laboratory and if the interlaboratory comparison has provided enough confidence in the laboratory's capability, the laboratory can be accredited.

## Accreditation Bodies

Accreditation bodies themselves have to meet the requirement of ISO/IEC 17011:2004, requirements for accrediting conformity assessment bodies. Internationally there is a close collaboration between all accreditation bodies in the International laboratory Accreditation Cooperation ILAC (figure). Full members of ILAC have signed the MRA (Multilateral Recognition Arrangement). Accreditation bodies in the initial phase of being set up can register to ILAC as affiliate members. Once their system is mature enough and have demonstrated that they are operational and are committed to comply with the relevant standards of ISO, IEC and ILAC they can become associate members. When they have gone through satisfactory peer-review and have shown to meet ILAC's criteria for competence they can sign the MRA to be full members.

A peer review is an evaluation of an accreditation body by an international evaluation team led by an experienced, trained and qualified team leader. The evaluation includes an evaluation of the quality system of the accreditation body and the witnessing of actual assessments. Normally a peer review is combined with a peer review of the other activities of the accreditation body, like testing, inspection and certification. The figure shows the countries where full member calibration accreditation bodies are active.

Peer evaluations are normally conducted on the regional level. There are several recognized regional cooperations of accreditation bodies: the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the European co-operation for Accreditation (EA) and the Inter America Accreditation Cooperation (IAAC). ILAC accepts these results of the regional peer evaluations.

By this mechanism an international network of accredited calibration laboratories has been established from which the calibration certificates are accepted worldwide.

### References

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4. ISO/IEC Guide 99-12:2007, International vocabulary of Metrology, Basic and General Concepts and Associated Terms. A document which content is identical but free is JCGM 200:2008, same title, JCGM documents are downloadable from www.bipm.org under publications.
5. ISO/IEC Guide 98-3:2008 to the expression of uncertainty in measurement (content also downloadable from BIPM when referred to as JCGM 100:2008 GUM 1995 with minor corrections).
6. Evaluation of measurement data — Supplement 1 to the "Guide to the expression of uncertainty in measurement" — Propagation of distributions using a Monte Carlo method" JCGM 101:2008.

*In 1966 the US Navy issued an introductory video "Why Calibrate". The video animation shows many reasons for calibration of measurement equipment that still hold today and is available at www.youtube.com. Google for "youtube why calibrate."*

*Through www.bipm.org follow useful links to publications from metrology institutes such as NIST (from home select publications Guidelines, 1994); Or follow the links to regional metrology organisations for documented information from Euramet; Or follow the links to accreditation bodies such as ILAC, EA, APLAC and IACC for more information.*

*Photo of Jos Verbeek courtesy of VSL, formerly NMi Van Swinden laboratorium, the national metrology institute of The Netherlands. VSL has been accredited for its calibration work by RvA; on the RvA web site all details of the VSL accredited schedule can be found. VSL is also one of the signatories of the CIPM MRA (mutual recognition arrangement), and the VSL calibration and measurement capabilities authorised under the MRA can be found in the Key Comparison Database (KCDB) that can be reached from the BIPM website (www.bipm.org; kcdb.bipm.org).*

*References to organisations in this paper does not imply that these organisations approve of its contents. This paper is based on the personal professional experience of the authors and is intended as an introduction to the ISO/IEC17025 standard for staff of calibration laboratories. No legal rights can be claimed from the content of this paper. Recent, up to date information can be obtained from the websites of the referred to organisations.*

Martin de Groot, of MartinDeGroot Consultancy is consultant and teacher for Kelvin-Trainingen and external lead assessor for RvA. He has worked some eighteen years as leading scientist of the temperature and humidity section of NMi-VSL (now named VSL) in the Netherlands. He was chairman of the working Group 8 of the CCT and of the technical contact persons meeting of temperature of Euromet.

Peter van de Leemput is a senior lead assessor for RvA (Council for Accreditation) in the Netherlands. He has over 20 years of assessor experience in several accreditation schemes. He is chairman of the working group that first wrote (2000) and later revised (2005) ISO/IEC17025 for the ISO committee on Conformity Assessment (CASCO). Peter contributed to this paper on personal title.